

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

**MINUTES AND RECOMMENDATIONS
February 2025**

I. CONVENING

The DoD Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on February 5th and 6th, 2025.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of November 2024 Meeting Minutes—RDML Matthew Case, Acting Assistant Director, Health Care Administration, DHA, approved the meeting minutes from the November 2024 DoD P&T Committee meeting on January 27th, 2025.

B. Clarification of previous meeting minutes

- **November 2022**
 - **Miscellaneous Insulin Devices—Omnipod 5 Kits Formulary Status:** Omnipod 5 was reviewed for addition to the TRICARE pharmacy benefit and designated as Uniform Formulary (UF). The intent of the DoD P&T Committee was that both the pods and the kits were UF, although the meeting minutes did not specify both formulations. Therefore, both Omnipod 5 pods and kits are designated as UF and included on the TRICARE pharmacy benefit, with prior authorization and quantity limits applying.
- **November 2024**
 - **Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL-17) and IL-23 Inhibitors—Addition to the Rapid Response Program:** The IL-17 and IL-23 inhibitors will be maintained on the Rapid Response (Safety Net) program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.
 - **Weight Loss Agents—tirzepatide vials (Zepbound vials) Implementation period:** Zepbound vials were recommended for complete exclusion status, with an implementation date of 120 days. The implementation date was moved up to no later than 30 days after signing of the November, 2024 minutes, since no beneficiaries have filled prescriptions under the TRICARE pharmacy benefit for this formulation.
 - **Nonformulary Generics—Acne and Rosacea Agents:** The following updates were made: Acanya was designated as UF, and the step therapy was removed, and for Epiduo and Epiduo Forte the step therapy was also removed (also designated as UF).

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to Section 199.21(g)(5) of Title 32, Code of Federal Regulations (CFR) , and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All pharmaceutical agents selected for complete exclusion status were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All pharmaceutical agents recommended for uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and complete exclusion status considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018, permanently codified at Section 1074g(a)(10) of Title 10, United States Code (USC). Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, 10 USC 1074g(a)(9) requires beneficiaries to generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List formerly known as the Select Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

A. Sleep Disorders: Wakefulness Promoting Agents

Background—The P&T Committee evaluated the relative clinical effectiveness of the Wakefulness Promoting Agents. The subclass was previously reviewed for formulary status in August 2020. Drugs in this subclass include modafinil (Provigil, generics), armodafinil (Nuvigil, generics), sodium oxybate oral solution (Xyrem, authorized generics), sodium oxybate calcium/magnesium/potassium oral solution (Xywav), sodium oxybate extended release (ER) packets for oral suspension, (Lumryz), solriamfetol (Sunosi), and pitolisant (Wakix). The drugs in the class vary in their FDA-approved indications, which include excessive daytime sleepiness due to shift work sleep disorder, obstructive sleep apnea, narcolepsy, cataplexy associated with narcolepsy, and idiopathic hypersomnia.

Relative Clinical Effectiveness Conclusion—The current review focused on evidence from updated professional clinical practice guidelines and network meta-analyses with systematic reviews. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Clinical Practice Guidelines

- *Narcolepsy*: The 2021 American Academy of Sleep Medicine (AASM) Guideline for Treatment of Central Disorders of Hypersomnolence lists a variety of agents which may be considered for treating excessive daytime sleepiness (EDS) or

cataplexy in patients with narcolepsy. Modafinil, Wakix, sodium oxybate and Sunosi are listed as a “strong” strength of recommendation for EDS associated with narcolepsy, with Wakix and sodium oxybate listed as a “strong” strength of recommendation for cataplexy. Armodafinil and dextroamphetamines are listed as “conditional” for EDS associated with narcolepsy.

- *Obstructive Sleep Apnea (OSA)*: The 2024 French Sleep Research and Medicine Society Guideline for Assessment and Management of Residual Sleepiness in OSA recommends comprehensive medical assessment and management before consideration of pharmacotherapy. Individual drug selection should be based on clinical judgement and managed by appropriate specialists.

Efficacy

- *Narcolepsy*: A network meta-analysis and systematic review concludes that Sunosi, Xyrem, Xywav, Wakix, and modafinil result in statistically significant and clinically meaningful reductions in Epworth Sleepiness Scale (ESS) Scores compared to placebo. Additionally, Wakix and Xyrem were found to significantly reduce cataplexy rate when compared to placebo.
- *OSA*: A network meta-analysis and systematic review concludes that Sunosi, Wakix, armodafinil and modafinil treatment result in statistically significant and clinically meaningful reductions in ESS Scores versus placebo. The results were listed as “high certainty” for Sunosi, and “moderate certainty” for armodafinil, modafinil and Wakix.
- For all indications, the data is limited by the lack of head-to-head trials and low adherence to pharmacological treatments. Non-pharmacologic measures are also recommended (e.g., sleep hygiene, continuous positive air pressure for OSA). Additionally, the Wakefulness Promoting drugs only treat the disease symptoms and do not alter the underlying disease course.

Safety

- *Narcolepsy*: A network meta-analysis and systematic review demonstrated a statistically significant increase in neurologic adverse events for armodafinil and Sunosi; gastrointestinal events for armodafinil, Sunosi, and Xyrem; and psychiatric events for Sunosi, when compared to placebo. Notably, treatment withdrawal due to adverse events was significantly increased for Xyrem. None of the agents resulted in a significantly increased risk for serious adverse events compared to placebo.
- *OSA*: A network meta-analysis and systematic review demonstrated an increased risk for discontinuation due to adverse effects for armodafinil and modafinil vs. placebo (high certainty) in patients treated for excessive daytime sleepiness and OSA.

Other Factors

- *armodafinil (Nuvigil, generics) and modafinil (Provigil, generics)* are both indicated for adults with EDS due to narcolepsy, shift work disorder or OSA and are available in generic formulations. Unique safety issues include serious rashes and anaphylaxis. They are both C-IV scheduled products (low potential for abuse). Generic formulations are available.
- *pitolisant (Wakix)* does not provide compelling clinical advantages other than it is not a controlled substance. It is approved for patients as young as 6 years of age with EDS associated with narcolepsy and for adults with cataplexy. Unique safety concerns include QT interval prolongation.
- *sodium oxybate*: There are three formulations of sodium oxybate, Xyrem, Xywav, and Lumryz. All the products carry a warning for central nervous system depression, respiratory depression and risk of abuse, misuse and diversion; are subject to risk evaluation and mitigation strategies (REMS) requirements; and are controlled substances and labeled as schedule C-III drug (moderate potential for abuse). The sodium oxybate products can only be dispensed by certified pharmacies. All three products are approved for treating EDS or cataplexy associated with narcolepsy in adults and children as young as 7 years of age.
 - *sodium oxybate oral solution (Xyrem)* is the original formulation and is now available in an authorized generic formulation. Dosing is administered at bedtime, with a second dose given 2 ½ to 4 hours later.
 - *sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)* is the only drug in the subclass approved for adults with idiopathic hypersomnia; for this indication the dosing is once or twice nightly. Xywav contains less sodium than the original Xyrem formulation. There is a lack of robust data regarding this reduced sodium content, thereby limiting definitive conclusions for cardiovascular outcomes for narcolepsy patients.
 - *sodium oxybate ER packets for oral suspension (Lumryz)* is dosed once daily at bedtime.
- *solriamfetol (Sunosi)* is a C-IV scheduled product indicated for adults with EDS associated with narcolepsy or OSA. Safety concerns include hypertension and tachycardia.

Overall Conclusions

- For narcolepsy and excessive daytime sleepiness, there is a high degree of interchangeability between all the products. For narcolepsy with cataplexy, Wakix and the sodium oxybate formulations (Xyrem, Xywav, and Lumryz) have a moderate degree of therapeutic interchangeability and for sleepiness with OSA. Modafinil, armodafinil and Sunosi have a moderate degree of therapeutic interchangeability.

- In order to meet the needs of Military Health System (MHS) beneficiaries, at least one agent is required for the treatment of each clinical indication.

Relative Cost Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Sunosi was the most cost effective branded Wakefulness Promoting agent.
- BIA results showed that designating the Wakefulness Promoting Agents with the formulary status below generated significant cost avoidance for the MHS.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF generics
 - modafinil (Provigil, generics)
 - armodafinil (Nuvigil, generics)
 - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)
 - solriamfetol (Sunosi) *moves from NF to UF*
- NF
 - sodium oxybate oral solution (Xyrem) *moves from UF to NF*
 - sodium oxybate oral solution authorized generic *moves from UF to NF*
 - sodium oxybate ER packets for oral suspension (Lumryz)
 - pitolisant (Wakix)
- Complete Exclusion: none

2. COMMITTEE ACTION: MANUAL PA CRITERIA—PA criteria are not required for armodafinil or modafinil. PA criteria for the branded products have been in place since the original review and require the following: management by the appropriate specialist, confirmation of the diagnosis by objective testing, use of generic products first when clinically appropriate, and ruling out of other causes for sleep disorders. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria in new users, as outlined below. See Appendix C.

- For the indication of EDS associated with narcolepsy in adults, a trial of stimulants (e.g., methylphenidate, dextroamphetamine) and armodafinil or modafinil is required first. For children, a trial of

armodafinil or modafinil is not required, due to the limited evidence and lack of FDA-approval.

- For cataplexy associated with narcolepsy, a trial of stimulants is required, but armodafinil or modafinil is not required, due to limited evidence.
- For OSA, a trial of generic armodafinil or modafinil is required first.
- For Sunosi, an automated specialist bypass and age edit will apply. For manual PA criteria, if the patient is an adult and the provider is a neurologist, psychiatrist, sleep medicine specialist, pulmonologist, or cardiologist, then PA is not required. *Note that following the meeting it was not operationally feasible to solely have specialist criteria, therefore clinical PA criteria were added back to the PA (See Appendix C).*
- For Xywav, language now specifies that treatment for cataplexy does not require a trial of modafinil or armodafinil.
- For Xyrem, Lumryz, and Wakix, for EDS due to narcolepsy in adults, a trial of stimulants, armodafinil or modafinil, Sunosi and Xywav are required first, based on clinical and cost effectiveness. For cataplexy, the requirement for a trial of modafinil or armodafinil and Sunosi does not apply.

3. COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Lumryz, Xyrem, sodium oxybate authorized generic to Xyrem, and Wakix. See Appendix B.

4. COMMITTEE ACTION: QUANTITY LIMITS (QLs)—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for Xyrem, Xywav, Lumryz, and Wakix; new QLs were recommended for Sunosi. See Appendix D.

5. COMMITTEE ACTION: BRAND OVER AUTHORIZED GENERIC PA REQUIREMENT FOR XYREM—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) maintaining the requirement for brand Xyrem in all new users for authorized generic sodium oxybate at all points of service, based on cost effectiveness. The “brand over authorized generic” requirement will be removed administratively when it is no longer cost effective compared to AB-rated generics. The manual PA criteria for Xyrem will still apply to the authorized generic products. See Appendix C.

6. COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining all the drugs on the Specialty Drug List. Additionally, the following recommendations apply to the TRICARE Maintenance Drug List: Xyrem, Xywav, and Lumryz will continue to be excluded from the list, due to limited distribution

requirements; Sunosi will remain on the list; and Wakix will be added to the contingent list, depending on feasibility. See Appendix F for the TRICARE Maintenance Drug List details.

7. COMMITTEE ACTION: UF, PA, MN, QLs, BRAND OVER AUTHORIZED GENERIC PA, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, and IMPLEMENTATION PERIOD—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving sodium oxybate (Xyrem) and authorized generics who will be affected by the formulary status change and PA. See Appendix G.

B. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass

Background—The Narcotic Analgesics and Combinations include older generic opioids and abuse-deterrent products, along with two subclasses, the Transmucosal Immediate Release Fentanyl Products and the Buprenorphine and Combinations subclasses. The Narcotic Analgesics are routinely monitored to ensure alignment with clinical practice guidelines, emerging clinical evidence and MHS utilization trends.

Evaluation of the Narcotic Analgesics by the DoD P&T Committee revealed the following:

- Older generic opioids and abuse-deterrent formulations: New entries to the market are routinely evaluated for formulary status as part of the newly approved drugs program reviewed pursuant to 32 CFR 199.21(g)(5). Numerous clinically and cost effective opioid options are available on the formulary that do not require PA, utilization has decreased and an updated full class review of the opioid agents is not warranted.
- Transmucosal Immediate Release Fentanyl products: There are no compelling clinical advancements or updated guidelines to warrant a full review since the original subclass review in 2015.
- Buprenorphine and Combinations: Joint clinical practice guidelines from the DoD and U.S. Department of Veterans Affairs (VA) were recently updated and increasing MHS spend has been noted for the subclass. As a result, the current review focused on the Buprenorphine and Combinations Subclass. The drugs in the subclass include various formulations of buprenorphine, which are FDA-approved for managing severe and persistent pain, and combinations of buprenorphine with naloxone, which are approved for managing opioid use disorder.

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, systematic reviews, differences in FDA-labeling, and safety

profiles. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Clinical Practice Guidelines

- *Chronic Pain:* The 2022 DoD/VA guidelines for the use of opioids in the management of chronic pain assigned buprenorphine as a “weak for” recommendation, due to limitations in the available body of evidence, but superior safety profile over traditional opioids.

The 2024 updated guidance continues to recommend non-opioid medications in combination with non-pharmacologic interventions as the preferred treatment for chronic pain. Many non-opioid options are available to TRICARE beneficiaries and are regularly added to the UF through the new drug program. Buprenorphine was acknowledged to retain many of the same risks associated with use of full agonist opioids yet demonstrates less risk of respiratory depression. However, the guidelines further state when treatment with opioids is indicated, buprenorphine may be preferred over full agonist opioids due to a unique mechanism of action and safety profile.

- *Opioid Use Disorder:* The 2022 Centers for Disease Control clinical practice guideline for prescribing opioids for pain specifically mentions buprenorphine for opioid use disorder. Overall, evidence-based treatment should be used. Buprenorphine can also be considered due to reduced overdose risk compared to the risks seen with full agonist opioids.

Efficacy

- *Chronic Pain*
 - There are no head-to-head data comparing the buprenorphine formulations approved for chronic persistent pain. Based on indirect evidence, the buprenorphine patch (Butrans) and sublingual (SL) film (Belbuca) both demonstrate comparable efficacy in moderate-to-severe chronic pain.
 - A 2018 network meta-analysis and systematic review assessed the effectiveness and tolerability of buprenorphine for pain in adults and children with cancer. The conclusion was that there was insufficient evidence to designate buprenorphine as a valid first-line choice alongside standard therapies including morphine, oxycodone and fentanyl. Buprenorphine could be considered a fourth-line option.
 - Another 2023 meta-analysis and systematic review from the International Anesthesia Research Society compared the analgesic efficacy of buprenorphine to a control group for treating chronic noncancer pain. Both the transdermal and buccal administration routes produced statistically significant reductions in pain and can be considered as an alternative to traditional analgesics for non-cancer pain.
- *Opioid Use Disorder*

- When used for opioid use disorder, buprenorphine reduces withdrawal symptoms and opioid cravings.

Safety

- *Chronic Pain:* The labeling for all the buprenorphine agents carries similar safety warnings and adverse effect profiles.
 - *buprenorphine vs. other narcotic analgesics:* Buprenorphine has an analgesic ceiling effect, reducing the risk of respiratory depression and overdose. Additionally, there is a lower risk of misuse and dependence compared to full opioid agonists.
 - *buprenorphine products:* Both the Butrans patch and Belbuca buccal film have similar adverse effects and contain the same warnings seen with other opioids, including nausea, constipation, addiction, abuse, misuse, life-threatening respiratory depression, and risks with concurrent use with other central nervous system depressants.
- *Opioid Use Disorder:* For opioid use disorder, buprenorphine/naloxone combinations when compared to methadone are safer overall and safer in overdose, are more accessible, and require less frequent dosing. However, the ceiling effect may limit efficacy in some cases.

Individual Product Characteristics

- *Chronic Pain*
 - *buprenorphine transdermal system (Butrans, generics):* The patch requires once weekly application. Butrans is labeled for patients previously taking up to 80 oral morphine milligram equivalents daily. Advantages include the long duration of action. Disadvantages include the low bioavailability (15% with Butrans vs. 45% to 65% with Belbuca), risk of application-site pruritus and QTc interval prolongation at doses greater than 20 mcg/hour, which limits use in patients with unstable cardiac disease. It is contraindicated in patients with severe liver impairment.
 - *buprenorphine buccal film (Belbuca):* The buccal film has a 12-hour dosing frequency. Labeling includes patients previously taking less than 160 oral morphine milligram equivalents daily. Advantages include the high bioavailability via mucosal absorption and lower risk of QTc interval prolongation (risk is increased with doses above 900 mcg/hour). Disadvantages include adverse dental effects, including dental caries. The restriction regarding avoidance of eating, drinking and oral hygiene for 60 minutes following application may limit use.
- *Opioid Use Disorder*
 - *buprenorphine/naloxone formulations:* The combinations with naloxone include SL tablets and an oral film. Compared with the generic Suboxone SL tabs, the branded Zubsolv SL tabs are available in more dosage strengths (6 dosages vs. 5 with Suboxone), have a higher bioavailability, reported better

taste, and shorter dissolution time. For opioid use disorder, target maintenance doses can exceed 24 mg buprenorphine daily.

- *buprenorphine SL tabs (Subutex, generics)*: This generic oral buprenorphine formulation is available in 2 mg and 8 mg SL tablets.

Overall Conclusions

- In terms of efficacy and safety for chronic pain treatment, there is a moderate to high degree of therapeutic interchangeability within the buprenorphine agents indicated for pain, with differences primarily based on dosing flexibility, administration routes, adverse event profiles and formulation-specific risks.
- In order to meet the majority of needs of Military Health System (MHS) beneficiaries, multiple dosage formulations are preferred.

Relative Cost Effectiveness Analysis and Conclusion—CMA, BIA and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic Butrans was more cost effective than Belbuca, and generic buprenorphine agents for opioid use disorder were more cost effective than Zubsolv.
- BIA results found that designating Belbuca as UF resulted in increased spend, especially considering the recent price increase.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following.

- UF
 - buprenorphine transdermal patch (Butrans, generics)
 - buprenorphine buccal film (Belbuca) *moves from NF to UF*
 - buprenorphine SL tablets (Subutex, generic)
 - buprenorphine/naloxone SL tabs (Zubsolv)
 - buprenorphine/naloxone SL film (Suboxone)
 - buprenorphine/naloxone SL tabs (Suboxone tabs, generic)
- NF: none
- Complete Exclusion: none

2. COMMITTEE ACTION: MANUAL PA CRITERIA—PA criteria currently apply to the Butrans patch since it was reviewed as a new drug in August 2011 due to concerns regarding respiratory depression at high doses. The P&T Committee recommended (19 for, 0 opposed, 0

abstained, 0 absent) removing the Butrans patch PA, as the other buprenorphine formulations do not have a PA, and to maintain alignment with clinical practice guidelines for chronic pain.

3. **COMMITTEE ACTION: QLs**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for Butrans patch, based on the package insert dosing recommendations. See Appendix D.
4. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST**—The narcotic analgesics, including the buprenorphine formulations are currently not subject to the drug list requirements due to a prior P&T Committee recommended exception. See Appendix F.
5. **COMMITTEE ACTION: UF, PA removal, QL, and IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. See Appendix G.

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

Relative Clinical Effectiveness and Relative Cost Effectiveness Conclusions—The P&T Committee agreed (19 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2025 DoD P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the TRICARE Drug Maintenance List.

Addition of new medical devices to the TRICARE pharmacy benefit is also reviewed in this section. Medical devices are primarily covered by the TRICARE medical benefit, and any additions to the TRICARE pharmacy benefit are not meant to replace this pathway for procuring medical devices. See the August 2022 DoD P&T Committee meeting minutes (found at <https://www.health.mil/About-MHS/Federal-Advisory-Committees/DOD-PT-Committee/Meeting-Minutes>) for details regarding the clinical and cost effectiveness review of new medical devices. The Committee identified one medical device for review at this meeting, Omnipod 5 Intro G6/Libre 2 Plus.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:
 - UF
 - acoramidis (Attruby) – Miscellaneous Neurological Agents for transthyretin amyloidosis
 - arimoclomol (Miplyffa) – Miscellaneous Neurological Agents for Niemann-Pick disease

- crinecerfont (Crenessity) – Miscellaneous Endocrine Agents for congenital adrenal hyperplasia
- inavolisib (Itovebi) – Oncological Agents: Breast Cancer
- marstacimab-hncq (Hympavzi) – Antihemophilic Agents
- nilotinib tartrate tablets (Danziten) – Oncological Agents: Chronic Myeloid Leukemia
- olezarsen (Tryngolza) – Antilipidemics-2 for familial chylomicronemia syndrome
- Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits – Insulins: Miscellaneous Insulin Devices; this device was also added to the TRICARE Pharmacy benefit
- revumenib (Revuforj) – Oncological Agents for Acute Leukemia
- ustekinumab-auub (Wezlana) – Targeted Immunomodulatory Biologics: Interleukin-23 (IL-23) inhibitors
- vanzacaftor/tezacaftor/deutivacaftor (Alyftrek) – Cystic Fibrosis Agents
- NF
 - aripiprazole oral film (Opipza) – Antipsychotic Agents: Atypical
 - filgrastim-txid (Nypozi) – White Blood Cell Stimulants: Filgrastim
 - imatinib 80 mg/mL oral solution (Imkeldi) – Oncological Agents: Chronic Myeloid Leukemia
 - minocycline 40 mg ER capsules (Emrosi) – Antibiotics: Tetracyclines
- Complete Exclusion: none

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Emrosi, Imkeldi, Nypozi and Opipza. See Appendix B for the full criteria.

3. **COMMITTEE ACTION: PA CRITERIA**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria. See Appendix C for the full criteria.

- Applying manual PA criteria to new users of Wezlana, the biosimilar to Stelara, similar to what is required for all non-step-preferred Interleukin-23 inhibitors. A trial of adalimumab (Humira) and ixekizumab (Taltz) will be required first.
- Applying manual PA criteria and QLs to new users of Omnipod 5 Intro G6/Libre2 Plus pods and kits, similar to what is required for the Omnipod 5

G6/G7 pods and kits. Note that corresponding updates were also made to the Omnipod 5 G6/G7 PA criteria (see page 18).

- Applying manual PA criteria to Nypozi, similar to what is in place for the other non-step-preferred filgrastims. New patients receiving Nypozi or one of the other non-step-preferred filgrastims (Releuko and Neupogen) will be required to have a trial of Granix, Nivestym and Zarxio first.
- Applying manual PA criteria to new users of the oncology drugs Danziten, Imkeldi, Itovebi, and Revuforj.
- Applying manual PA criteria to new users of Alyftrek, Crenessity, Hympavzi, Opipza, and Tryngolza.
- Applying manual PA criteria to new users of Emrosi, requiring a trial of generic minocycline and other products for rosacea first, similar to what is required for other non-step-preferred minocycline products.
- Applying manual PA criteria to new users of Attruby. Accordingly, updates were made to the other drugs used for transthyretin amyloidosis (Vyndaqel, Vyndamax and Wainua); (see the utilization management section on page 17).
- Applying manual PA criteria to new users of Miplyffa; updates were also made to the Aqneursa PA, the other drug approved for Niemann-Pick disease, to allow concomitant use with Miplyffa; (see the utilization management section on page 17.)

4. **COMMITTEE ACTION: QLs**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) QLs for Alyftrek, Attruby, Crenessity, Danziten, Hympavzi, Imkeldi, Itovebi, Miplyffa, Omnipod 5, Revuforj, Tryngolza, and Wezlana. See Appendix D for the QLs.
5. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List which includes the NF medications subject to the mail requirement. Drugs recommended for addition to the Specialty Drug List are found in Appendix E.
6. **COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) adding Miplyffa, Opipza, Nypozi, Imkeldi and Wezlana to the Safety Net program as outlined in the clarification section on page one.
7. **COMMITTEE ACTION: UF, MN, PA, QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, , RAPID RESPONSE and**

IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF and NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for two recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for the newly approved drug reviews and cannot be reviewed for formulary status. Numerous cost effective formulary alternatives are available that do not require prior authorization.

- a) **Pain Agents: Topical—lidocaine 5% patch (Tridacaine XL)**—Numerous other more cost effective lidocaine 5% patches are available. Basic Core Formulary status does not apply to this specific formulation.
- b) **Narcotic Analgesics and Combinations—tramadol 75 mg tablet**—There are other tramadol formulations available, including scored tramadol 50 mg tablets, that are more cost effective than this 75 mg formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for lidocaine 5% patch (Tridacaine XL) and tramadol 75 mg tablet in new users, due to the significant cost differences compared with other available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA. See Appendix C for the full criteria.

2. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- a) **Atopy—dupilumab (Dupixent)**—The manual PA criteria were updated to allow for Dupixent use in patients with chronic obstructive pulmonary

disease (COPD) and an eosinophilic phenotype after a trial of triple therapy with traditional inhalers approved for COPD.

- b) **Oncological Agents—asciminib (Scemblix)**—The manual PA criteria were expanded to include newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Additionally, other updates were done to include the standard wording found in the other oncology PAs, including updating the National Comprehensive Cancer Network (NCCN) guidelines question and removing warnings and precautions language.
- c) **Psoriasis Agents—tapinarof 1% cream (Vtama)**—The manual PA criteria were updated to allow for treatment of atopic dermatitis in patients 2 years of age or older.
- d) **TIBs: Miscellaneous Interleukins—nemolizumab-ilto (Nemluvio)**—The manual PA criteria were updated to allow for treatment of atopic dermatitis in patients 12 years of age or older.
- e) **TIBs: IL-17s—bimekizumab-bkzx (Bimzelx)**—Bimzelx received a new indication for hidradenitis suppurativa in adults. The manual PA criteria were updated and require a trial of Humira and Cosentyx first.
- f) **Weight Loss Agents—tirzepatide (Zepbound)**—Zepbound is now indicated for moderate to severe OSA in adults with obesity. The manual PA criteria were updated. A trial of phentermine will not be required for this new indication, due to the increased risk of cardiovascular events. Patients are required to have a body mass index of at least 30 and have a documented diagnosis of sleep apnea. *Please see <https://newsroom.tricare.mil/News/TRICARE-News/Article/4266447/tricare-coverage-of-weight-loss-medications-what-to-know> for questions regarding the implementation of regulatory controls for coverage of weight loss treatments.*

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Scemblix, Vtama, Nemluvio, Bimzelx, Zepbound, and Dupixent in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

3. Updated PA and MN Criteria for Reasons other than New Indications

Updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

- a) **antidepressants and Non-Opioid Pain Syndrome Agents: Selective Serotonin Reuptake Inhibitors—vortioxetine (Trintellix)**—An automated drug lookback was added to the Trintellix PA allowing

approval if a patient has tried two formulary antidepressants in the past 720 days.

- b) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants—lisdexamfetamine capsule, chew tab (Vyvanse)**—An automated drug look back was added, allowing approval of the Vyvanse PA if a patient has had a trial of at least one amphetamine and one methylphenidate product within the past 720 days.
- c) **Atopy: Oral Janus Kinase-1 (JAK-1) Inhibitors**
- **upadacitinib (Rinvoq)**—At the November 2024 P&T meeting, ixekizumab (Taltz) was selected as the step-preferred IL-17 inhibitor. The PA criteria for Rinvoq previously required a secukinumab (Cosentyx) trial first. The PA criteria was updated to replace Cosentyx with the step-preferred IL-17 Taltz. The PA was also modified with the other TIBs standardization edits (e.g., removing the monitoring and safety questions) as previously outlined in the November 2024 DoD P&T Committee meeting minutes.
 - **abrocitinib (Cibinqo)**—The Cibinqo PA was standardized and the exception to allow for concomitant use with apremilast (Otezla) was removed, as Cibinqo and Otezla do not have overlapping indications.
- d) **Neurologic Agents: Miscellaneous drugs for Niemann-Pick disease—levacetylleucine (Aqneursa)**—The Aqneursa PA was updated to allow for concomitant use with arimoclomol (Miplyffa); (see new drug section on page 13).
- e) **Neurologic Agents: Miscellaneous drugs for transthyretin amyloidosis—tafamidis (Vyndaqel), tafamidis meglumine (Vyndamax) and eplontersen (Wainua)**—The manual PA criteria for Vyndaqel, Vyndamax and Wainua were updated due to the recent approval of acoramidis (Attruby), (see new drugs section on page 13). The PAs were updated to expand the list of other amyloidosis drugs where concomitant use is prohibited.
- f) **Oncological Agents—encorafenib (Braftovi)**—The Braftovi PA was updated as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for NCCN guideline updates. For more details on oncology PA standardization, please refer to the November 2024 meeting minutes.
- g) **Ophthalmic: Dry Eye Agents—cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose)**—The Restasis PA was updated to add an automated specialist bypass for optometrists and ophthalmologists. If the prescribing physician specialty is identified as an optometrist or ophthalmologist during adjudication, PA is not required. *Note that following the meeting it was not operationally feasible to solely have specialist criteria, therefore clinical PA criteria were added back to the PA (See Appendix C).*
- h) **TIBs: Tumor necrosis factor (TNF) inhibitors—etanercept (Enbrel)**—The Enbrel PA and MN criteria were updated to require a trial of ixekizumab (Taltz)

in addition to adalimumab (Humira) first, based on the recommendations made at the November 2024 interleukin-17 (IL-17) class review. The Taltz step therapy requirement will not apply to adult patients with rheumatoid arthritis or pediatric patients with juvenile idiopathic arthritis or juvenile psoriatic arthritis.

Other changes were made to standardize the PA, consistent with the PA criteria in place for other TIBs. Examples of these standardization edits across the TIBs class include removing monitoring and safety questions, adding a trial of NSAIDs for axial spondyloarthritis, and editing the non-biologic systemic therapy step. Additionally, the current automated PA criteria for Enbrel were removed.

i) TIBs: Miscellaneous

- **baricitinib (Olumiant)**—Similar to the Cibinqo PA, the Olumiant PA wording was standardized and the exception to allow for concomitant use with Otezla was removed. Additionally, the automated PA criteria currently in place were removed.
- **deucravacitinib (Sotyktu)**—The Sotyktu PA and MN criteria were updated to require a trial of Taltz in addition to Humira and Cosentyx before Sotyktu. Other TIBs standardization edits were also made.
- **tofacitinib (Xeljanz)**—The Xeljanz PA wording was standardized and the automated PA criteria currently in place were removed. In addition, the PA criteria that mentioned dosing requirements were removed as this is not found in other PAs within the class.

j) TIBs—ustekinumab (Stelara), guselkumab (Tremfya), risankizumab on-body injector (Skyrizi OBI), mirikizumab (Omvoh), vedolizumab (Entyvio), and infliximab (Zymfentra): Updates for Inflammatory Bowel Disease PA Criteria—Recent guideline updates for inflammatory bowel disease (IBD) prompted a review of the TIBs used for ulcerative colitis (UC) and Crohn’s Disease (CD). Similar to existing guidelines for CD, the American Gastroenterological Association’s (AGA) 2024 UC guidelines now recommend early biologic use and recommend against requiring monotherapy with non-biologic step-up therapy. Humira is listed as a lower efficacy medication for UC for both biologic therapy-naïve and biologic therapy-experienced patients. Intravenous (IV) infliximab (Remicade – available under the TRICARE Medical benefit) is listed as a highly effective medication for UC and for all special populations of CD.

Based on the AGA guideline update, the following changes were recommended for Stelara, Tremfya, Skyrizi OBI, and Omvoh: the non-biologic requirement for the UC indication was removed and a trial of IV infliximab is allowed in lieu of Humira for UC and CD. Additionally, the PA criteria for Omvoh were updated to allow for the new FDA indication for CD. The Entyvio and Zymfentra PAs were updated to add an automated specialist bypass for gastroenterologists, and to remove the requirements to

try Humira or infliximab first. As with the other IBD agents, the requirement of non-biologic therapy for UC was removed.

- k) **Miscellaneous Insulin Devices—Omnipod 5 G6/G7 pods and kits:** Updates were made to allow use for type 2 diabetics who are receiving insulin. (See the New Drugs section on page 13).

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Trintellix, Vyvanse, Rinvoq, Cibinqo, Aqneursa, Vyndaqel, Vyndamax, Wainua, Braftovi, Restasis, Enbrel, Olumiant, Sotyktu, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra in new users. See Appendix C for the full criteria.

- Implementation for Aqneursa, Vyndaqel, Vyndamax, Wainua and the Omnipod 5 G6/G7 pods and kits will be effective the first Wednesday 2 weeks after signing of the minutes, along with the PA criteria implementation for the other drugs in their respective classes.
- Implementation for Enbrel, Sotyktu, Rinvoq, Cibinqo, Olumiant, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra will be effective the first Wednesday 30 days after signing of the minutes.
- Implementation for Braftovi, Restasis, Vyvanse and Trintellix will be effective the first Wednesday 60 days after signing of the minutes.

4. Removal of PAs and return of frovatriptan to UF status

- a) **Migraine Agents: Triptans—frovatriptan (Frova, generics) and naratriptan (Amerge, generics)**—Both frovatriptan (designated as NF) and naratriptan (designated as UF) require PA. They are available as generics, have relatively low utilization and cost, and a high PA approval rate. The PAs for frovatriptan and naratriptan will be removed, and frovatriptan will move to UF status.
- b) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation: Constipation-predominant Irritable Bowel Syndrome (CIC/IBS-C)—linaclotide (Linzess) and lubiprostone (Amitiza)**—Currently, both Linzess and Amitiza are designated as UF requiring PA. They account for a high PA volume, and several commercial plans do not require a PA for these drugs. A review of the clinical and cost data supports removing the PAs for these two drugs.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA, FROVATRIPTAN RETURN TO UF STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended

(19 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for frovatriptan, naratriptan, Linzess, and Amitiza. Additionally, frovatriptan will move from NF to UF status. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Quantity Limits

- 1. Self-Monitoring Blood Glucose (SMBG) test strips**—QLs for the SMBG test strips were last updated in November 2014, limiting use to 100 test strips per 30-day supply in Retail pharmacies and 300 test strips per 90-day supply at the TMOP and MTF points of service. Clinical QL override criteria were specified at that time and updated in August 2023 to allow for situations where a larger quantity was required and appropriate, such as for gestational diabetes. Automation was added to the SMBG test strip QL override form. The QL override form is not required if the prescription is written by obstetrics and gynecology specialists (i.e., automated specialist bypass) or if the patient's medication profile shows a prescription for prenatal vitamins within the last 365 days (i.e., automated drug lookback for prenatal vitamins).
- 2. Menopausal Hormone Therapy: Vaginal Agents—estradiol acetate vaginal ring (Femring) and estradiol vaginal system (Estring)**—QLs currently do not apply to Femring or Estring. A review of MHS prescribing patterns for Femring and Estring showed higher than recommended quantities dispensed. Femring and Estring treat menopausal symptoms and are designed to release estradiol over a 3-month period in a controlled manner. Changing the ring more frequently to achieve higher estrogen levels is neither supported by the evidence nor the pharmacokinetic data. A quantity limit of 1 ring per 90 days was recommended.

COMMITTEE ACTION: SMBG TEST STRIP QL OVERRIDE FORM AUTOMATION, FEMRING AND ESTRING QLs and

IMPLEMENTATION—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updating the QL override form for the SMBG test strips and adding QLs for Femring and Estring. The update to the SMBG test strip QL override form will allow for a bypass if the order is written by a OBGYN (specialist bypass) or if the patient has had a prescription for prenatal vitamins (automated lookback). There was no change to the other clinical SMBG test strip override criteria currently in place. QL implementation will occur the first Wednesday two weeks after signing of the minutes. See Appendix D. *Note that at the November 2025 DoD P&T Committee meeting the Femring and Estring QLs were removed, and both of these products were removed from the TRICARE Maintenance Drug List.*

C. Line Extensions

The P&T Committee clarified the formulary status for two product line extensions by the original manufacturer. Line extensions have the same FDA indication(s) as the “parent” drug and retain the same formulary and copayment status as the “parent” drug.

1. Continuous Glucose Monitoring (CGM) Systems: Therapeutic CGM

Systems—designating **Freestyle Libre 2 Plus Sensor** with the same formulary status (UF) and PA as the FreeStyle Libre 2 Sensor; as a result FreeStyle Libre 2 Plus will be added to the TRICARE pharmacy benefit. The QLs will be a 30-day supply at retail pharmacies, and a 90-day supply at MTF and TMOP, consistent with the changes made to the FreeStyle Libre 3 Plus Sensor from the November 2024 meeting.

2. Diabetes Non-Insulin: DPP-4 Inhibitors—designating **sitagliptin/metformin (Zituvimet XR)** with the same formulary status (NF), non-step-preferred status, PA, and MN criteria as the parent sitagliptin/metformin (Zituvimet); a trial of sitagliptin/metformin (Janumet) is required first.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, MN, and TRICARE Maintenance Drug List for FreeStyle Libre 2 Plus Sensor and Zituvimet XR. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. ADDITION TO THE TRICARE PHARMACY BENEFIT—DEXAMETHASONE 10 mg/mL INJECTION

MTF providers requested addition of an injectable dexamethasone formulation to the TRICARE pharmacy benefit, for oral administration. Specialist feedback and clinical evidence support this addition to the TRICARE pharmacy benefit.

COMMITTEE ACTION: FORMULARY STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) addition of dexamethasone 10 mg/mL injection (GCN 27350) to the TRICARE pharmacy benefit, effective the first Wednesday 2 weeks after signing of the minutes. See Appendix G for implementation dates.

VIII. DOD P&T COMMITTEE ADMINISTRATIVE AUTHORITY

Background—The Administrative Authorities document outlines which P&T Committee functions can be performed administratively prior to the quarterly meeting, and subsequently presented to the P&T Committee for formal recommendation; those functions which require both Uniform Formulary Beneficiary Advisory Panel (UF BAP) and Director, DHA review, and those which solely require Director, DHA review and do not fall under the purview of the UF BAP panel. Prior to this meeting, the most recent update to the Administrative Authorities document occurred at the November 2023 P&T Committee meeting.

Recommendation—The P&T Committee recommended updating the document in the section for PA criteria updates to institute and/or change existing PAs, as necessary, to comply with governing federal law and policy.

Justification—The Director retains the authority to establish procedures and direct actions that are necessary to comply with governing federal law and policy and may

direct the Pharmacy Operations Division/Formulary Management Branch to take the necessary actions to ensure compliance. These actions are not part of the DoD P&T Committee process (i.e., the P&T Committee is not asked whether DoD should comply with a federal law) or subject to the UF BAP comments as they are dictated by law and cognizant higher-level authority. This update captures this inherent authority.

COMMITTEE ACTION: P&T COMMITTEE ADMINISTRATIVE

AUTHORITY UPDATE—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) to update the document as follows (changes in bold): “Implementing temporary PA requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting) and to institute and/or change existing PAs, as necessary, to comply with governing federal law and policy. See Appendix H, pages 70-74.

IX. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

- A. Pharmacy Benefit Management Clarification—Travel Vaccines:** The August 2024 DoD P&T Committee meeting minutes clarified the TRICARE pharmacy contractor may not process medical benefit pharmaceutical agents at any point of service except under limited circumstances. Prescriptions for pharmaceutical agents that are not available to the general public (e.g., not on the TRICARE uniform formulary) that are part of force health protection, may be processed by the TRICARE pharmacy contractor only at military medical treatment facility pharmacies, pursuant to Department of Defense Instruction 6490.03.

The information regarding travel vaccines was clarified with the changes in bold and strikethrough as follows: Furthermore, the TRICARE pharmacy contractor may cover travel vaccines only for active-duty family members traveling with their sponsor on permanent change of duty station orders or other official travel. For private sector care the TRICARE pharmacy contractor is responsible for verifying beneficiary category and orders prior to coverage.

The following sentence was deleted: ~~For travel vaccines dispensed by MTF pharmacies, the MTF pharmacy is responsible for verifying documentation for official travel.~~ The following sentence was added: **MTFs may administer travel vaccinations consistent with applicable law and policy.**

- B. TRICARE Pharmacy Benefit Contraception Coverage Parity**—Pursuant to Section 707 of the National Defense Authorization Act for Fiscal Year 2025, signed on December 23, 2024, the cost-share for prescription formulary contraceptives on the UF provided through a retail pharmacy or the TMOP is \$0. Non-formulary are only available at \$0 cost share only when medical necessity is submitted and approved.
- C. Over-the-Counter (OTC) drugs on the BCF**—Occasionally legend BCF agents transition to OTC status, which complicates the Pharmacy Benefits Manager (Express Scripts) maintenance of the DoD drug files. Going forward, BCF

products that are currently legend that transition solely to OTC status will be removed from the BCF.

- D. Pilocarpine 0.4% ophthalmic solution (Qlosi) is not part of the TRICARE pharmacy benefit**—Qlosi is indicated for treatment of blurred vision due to presbyopia. The product does not treat an underlying medical condition. Qlosi is not considered medically necessary, therefore it will not be part of the TRICARE pharmacy benefit, similar to the status of pilocarpine 1.25% ophthalmic solution (Vuity) from the February 2022 meeting.

X. ADJOURNMENT

The meeting adjourned at 1000 hours on February 6th. The next meeting will be in May 2025.

Appendix A—Attendance: February 2025 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary during the February 2025 DoD P&T Committee Meeting

Appendix G—Implementation Dates

Appendix H—DoD P&T Committee Administrative Authority

DECISION ON RECOMMENDATIONS

Signed/Signature on file

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

- ☒ concurs with all recommendations.
- ☐ concurs with the recommendations, with the following modifications:

- ☐ concurs with the recommendations, except for the following:

Signed/Signature on file

Bill A. Soliz
BG, USA
Acting Assistant Director
Health Care Administration
and Operations

July 20th 2026

Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
LTC Megan Donahue, MC	Army, Physician at Large
LTC Ryan Burkhardt, MC	Army, Internal Medicine Physician
COL James Masterson, MSC	Army, Pharmacy Consultant
CDR Derek Larsen, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
CAPT Peter Cole, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Maj Andrew Gaillardetz, MC	Air Force, Physician at Large
Col Soo Sohn, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
MAJ Rebecca Wetzel, MC	Army, Oncology Physician
David Nowinski, PharmD, BCOP	DHA, Oncology Pharmacist
CDR Jacklyn Finocchio, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA	TRICARE Health Plan Chief Medical Officer
COL Yang Xia, MC	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Peter Glassman, MD	Department of Veteran’s Affairs
Marsha Peterson	DHA Contracting Officer
Eugene Moore, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integration Branch
CAPT William Kelly, MSC	Defense Logistics Agency
Guests	
CAPT Tiffany Cline, MSC	DHA POD Beneficiary Advisory Panel DFO
CAPT Marisol Martinez, USPHS	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
Hazel Richardson, PharmD	CDC WTCHP
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
CDR Giao Phung, MSC	DHA POD Formulary Management Branch
Heather Johnson, PharmD, BCCP, BCCP	DHA POD Formulary Management Branch
Lt Col Pansy Uberoi, MC	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
LCDR Yasdel Ortiz Rivera	DHA POD Formulary Management Branch
Kirk Stocker, BS Pharm, MBA, MHSA	DHA POD Formulary Management Branch

Appendix A—Attendance

Michael Lee, RPh, MBM, MPharm-Econ	DHA POD Formulary Management Branch
David Folmar, RPh, MS, MBA	DHA POD Formulary Management Branch
Christopher Battey	University of Texas at Austin PharmD student
Tracy Banks	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Stephanie Erpelding	DHA Contracting
Jules Canaley	DHA Contracting
Dwight Bonham	DHA Contracting
Patricia Tyson	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity (MN) Criteria
Drug Class Reviews MN Criteria	
• pitolisant (Wakix) Sleep Disorders: Wakefulness Promoting Agents	Updates from the February 2025 meeting are in bold and strikethrough • ~~Use of three~~ All formulary agents (~~armodafinil, modafinil, and methylphenidate or amphetamine~~) have resulted in therapeutic failure Formulary Alternatives for narcolepsy and excessive daytime sleepiness: armodafinil or modafinil, methylphenidate or amphetamine, sodium oxybate calcium/magnesium/potassium oral solution (Xywav), solriamfetol (Sunosi) Formulary alternatives for narcolepsy and cataplexy: methylphenidate or amphetamine, sodium oxybate calcium/magnesium/potassium oral solution (Xywav)
• sodium oxybate (Xyrem brand) Sleep Disorders: Wakefulness Promoting Agents	Updates from the February 2025 meeting are in bold • All formulary agents resulted in therapeutic failure Formulary alternatives for narcolepsy and excessive daytime sleepiness: armodafinil or modafinil, methylphenidate or amphetamine, sodium oxybate calcium/magnesium/potassium oral solution (Xywav), solriamfetol (Sunosi) Formulary alternatives for narcolepsy and cataplexy: methylphenidate or amphetamine, sodium oxybate calcium/magnesium/potassium (Xywav)
• sodium oxybate (Xyrem authorized generics) Sleep Disorders: Wakefulness Promoting Agents	Updates from the February 2025 meeting are in bold • All formulary agents resulted in therapeutic failure Formulary alternatives for narcolepsy and excessive daytime sleepiness: armodafinil or modafinil, methylphenidate or amphetamine, sodium oxybate calcium/magnesium/potassium (Xywav), solriamfetol (Sunosi), sodium oxybate (Xyrem, brand) Formulary alternatives for narcolepsy and cataplexy: methylphenidate or amphetamine, sodium oxybate calcium/magnesium/potassium (Xywav), sodium oxybate (Xyrem, brand)
• sodium oxybate extended-release packets for oral suspension (Lumryz) Sleep Disorders: Wakefulness Promoting Agents	Updates from the February 2025 meeting are in bold and strikethrough • All formulary agents resulted in therapeutic failure Formulary alternatives for narcolepsy and excessive daytime sleepiness: armodafinil or modafinil, ~~methylphenidate or amphetamine, sodium oxybate (Xyrem),~~ sodium oxybate, calcium/magnesium/potassium (Xywav), solriamfetol (Sunosi) Formulary alternatives for narcolepsy and cataplexy: methylphenidate or amphetamine, sodium oxybate (Xywav)
New Drugs MN Criteria	
• aripiprazole oral film (Opipza) Antipsychotic Agents: Atypical	• Patient has experienced significant adverse effects from formulary agents Formulary alternatives: aripiprazole orally dissolving tablet, aripiprazole oral solution, risperidone oral solution

Appendix B—Table of Medical Necessity Criteria

filgrastim-txid (Nypozi) White Blood Cell Stimulants: Filgrastims	Patient has experienced significant adverse effects from formulary agents Formulary alternatives: tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), filgrastim-sndz (Zarxio)
imatinib 80 mg/mL oral solution (Imkeldi) Oncological Agents: Chronic Myelogenous Leukemia	Patient has experienced significant adverse effects from formulary agents Formulary alternatives: imatinib mesylate tablet (Gleevec, generics)
minocycline 40 mg ER caps (Emrosi) Antibiotics: Tetracyclines	- Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure Formulary alternatives: doxycycline capsule or tablet, minocycline capsule, topical metronidazole, and topical azelaic acid 15%
Utilization Management MN Criteria	
etanercept (Enbrel) TIBs: TNFs	Updates from February 2025 are in bold and strikethrough ~~Use of formulary agents is contraindicated~~ - Patient has experienced significant adverse effects from formulary agents - Use of formulary agents has resulted in ~~or is likely to result in~~ therapeutic failure ~~The patient previously responded to the non-formulary agent and changing to Humira would incur unacceptable risk~~ No alternative formulary agent: The patient has a diagnosis of hepatitis C infection. Formulary alternatives: ixekizumab (Taltz), ustekinumab-aauz (Otulfi), adalimumab (Humira)
deucravacitinib (Sotyktu) TIBs	Updates from February 2025 are in bold - Patient has experienced or is likely to experience significant adverse effects from formulary agents - Formulary agents result or are likely to result in therapeutic failure Formulary alternatives: apremilast (Otezla), secukinumab (Cosentyx), ixekizumab (Taltz), adalimumab (Humira)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• pitolisant (Wakix) Sleep Disorders: Wakefulness Promoting Agents	Changes from February 2025 are in bold and strikethrough Manual PA criteria apply to all new users of pitolisant (Wakix) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that PA is not required for modafinil or armodafinil. • Prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy ▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing ▪ Patient is 18 years of age or older: – The patient has history of failure, contraindication, or intolerance to all of the following: ○ modafinil or armodafinil • Treatment for cataplexy does not require trial of modafinil or armodafinil ○ stimulant-based therapy (amphetamine-based therapy or methylphenidate) ○ sodium oxybate (Xywav) ○ solriamfetol (Sunosi) • Treatment for cataplexy does not require trial of Sunosi ▪ Patient is 6 years of age or older: ▪ The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic Non-FDA approved uses are not approved Prior Authorization expires after 1 year A new PA must be submitted annually ~~Renewal PA criteria: Renewal not allowed. A new prescription will require a new PA to be submitted~~

Appendix C—Table of Prior Authorization (PA) Criteria

- sodium oxybate extended-release packets for oral suspension (Lumryz) - sodium oxybate oral solution (Xyrem brand) Sleep Disorders: Wakefulness Promoting Agents	Changes from February 2025 are in bold and strikethrough Manual PA criteria apply to all new users of sodium oxybate (Lumryz) or sodium oxybate (Xyrem, brand) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that PA is not required for modafinil or armodafinil - Prescribed by a neurologist, psychiatrist, or sleep medicine specialist - Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing - Patient is 18 years of age or older: - The patient has history of failure, contraindication, or intolerance to all of the following: modafinil or armodafinil Treatment for cataplexy does not require trial of modafinil or armodafinil. - stimulant-based therapy (amphetamine-based therapy or methylphenidate). sodium oxybate (Xywav) solriamfetol (Sunosi) Treatment for cataplexy does not require trial of Sunosi - Patient is 7 years of age or older: - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) - Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) - The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic Non-FDA approved uses are not approved Prior Authorization expires after 1 year A new PA must be submitted annually ~~Renewal PA criteria: Renewal not allowed. A new prescription will require a new PA to be submitted~~
sodium oxybate oral solution (Xyrem authorized generic) Sleep Disorders: Wakefulness Promoting Agents	Changes from February 2025 are in bold and strikethrough Manual PA criteria apply to all new users of sodium oxybate (Xyrem authorized generics) <u>Manual PA Criteria:</u> Coverage is approved if the following criteria are met: - Please provide a patient-specific justification as to why the brand Xyrem cannot be used in this patient: _____ (fill in the blank) - Acceptable reasons include a patient has had an adverse reaction not expected to occur with the generic Provider acknowledges that PA is not required for modafinil or armodafinil - Patient is 18 years of age or older - Prescribed by a neurologist, psychiatrist, or sleep medicine specialist - Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing - Patient is 18 years of age or older: - The patient has history of failure, contraindication, or intolerance to all of the following:

Appendix C—Table of Prior Authorization (PA) Criteria

	- modafinil or armodafinil - o Treatment for cataplexy does not require trial of modafinil or armodafinil - stimulant-based therapy (amphetamine-based therapy or methylphenidate) - sodium oxybate (Xywav) - solriamfetol (Sunosi) - o Treatment for cataplexy does not require trial of Sunosi • Patient is 7 years of age or older: ▪ The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic Non-FDA approved uses are not approved Prior Authorization expires after 1 year A new PA must be submitted annually ~~Renewal PA criteria: Renewal not allowed. A new prescription will require a new PA to be submitted.~~
• sodium oxybate/ calcium/ magnesium/ potassium oral solution (Xywav) Sleep Disorders: Wakefulness Promoting Agents	Updates from February 2025 are in bold and strikethrough. Manual PA criteria apply to all new users of sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) Manual PA Criteria: Coverage is approved if all criteria are met: • Provider acknowledges that PA is not required for modafinil or armodafinil • Patient is 18 years of age or older • Prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Prescribed for the treatment of idiopathic hypersomnia OR • Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy ▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing ▪ Patient is 18 years of age or older: - The patient has history of failure, contraindication, or intolerance to all of the following: - o modafinil or armodafinil • Treatment for cataplexy does not require trial of modafinil or armodafinil - o stimulant-based therapy (amphetamine-based therapy or methylphenidate) ▪ Patient is a child 7 years of age or older: - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders) • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic Non-FDA-approved uses are not approved

Appendix C—Table of Prior Authorization (PA) Criteria

	Prior authorization expires in 1 year A new PA must be submitted annually ~~Renewal PA criteria: Renewal not allowed. A new prescription will require a new PA to be submitted~~
solriamfetol (Sunosi) Sleep Disorders: Wakefulness Promoting Agents	Updates from February 2025 are in bold and strikethrough Manual PA is required for all new users of solriamfetol (Sunosi) Automated PA Criteria: When the patient is 18 years or older and when prescribed by a neurologist, psychiatrist, sleep medicine specialist, pulmonologist, or cardiologist, prior authorization is not required <u>Manual PA Criteria:</u> If automated PA criteria is not met, Sunosi is approved if all criteria are met: - Provider acknowledges that PA is not required for modafinil or armodafinil - Patient is 18 years of age or older ~~When prescribed by a neurologist, psychiatrist, sleep medicine specialist, pulmonologist, or cardiologist, prior authorization is not required~~ - Sunosi is prescribed for either: - Excessive daytime sleepiness associated with narcolepsy: - Prescribed by a neurologist, psychiatrist, or sleep medicine specialist - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing - Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea - The patient must have tried and failed, had a contraindication to, or had an inadequate response to modafinil or armodafinil - The patient must have tried and failed, had a contraindication to, or had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) - Excessive daytime sleepiness associated with obstructive sleep apnea: - Prescribed by a specialist who treats patients with obstructive sleep apnea (e.g., pulmonologist, cardiologist, sleep medicine) - Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least one month prior to initiation, and the patient demonstrated adherence to therapy during this time, and the patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of therapy - The patient must have tried and failed, had a contraindication to, or had an inadequate response to modafinil or armodafinil - The patient is not concurrently taking a central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic Non-FDA-approved uses are not approved Prior authorization expires in 1 year A new PA must be submitted annually Renewal PA criteria: No renewal allowed. A new prescription will require a new PA to be submitted.

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Newly Approved Drug PAs	
• acoramidis (Attruby) Neurological Agents Miscellaneous	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of Attruby Acoramidis (Attruby) approved if all criteria are met: • Patient is 18 years of age or older • The requested medication is being prescribed by or in consultation with a specialist who manages ~~hereditary~~ transthyretin amyloidosis (for example, cardiologist, geneticist, or neurologist) • Patient has a diagnosis of ~~wild type or hereditary~~ transthyretin-mediated amyloidosis • The patient is not receiving concurrent treatment with tafamidis (Vyndaqel, Vyndamax), inotersen (Tegsedi), patisiran (Onpattro), or vutrisiran (Amvuttra) Non-FDA-approved uses are not approved, including ATTR-polyneuropathy PA does not expire
• arimoclomol (Miplyffa) Neurological Agents Miscellaneous	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of arimoclomol (Miplyffa) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 2 to 18 years of age ~~years of age~~ or older • Prescribed by a physician who specializes in the treatment of Niemann-Pick disease type C • Patient has a genetically confirmed diagnosis of Niemann-Pick disease type C • Patient is able to walk independently or with assistance • Patient has one or more neurologic symptoms (e.g., loss of motor function, difficulty swallowing, and speech and cognitive impairment) • Patient has tried and failed or ~~had an inadequate response~~ experienced an adverse reaction or has a contraindication to levacetyleucine (Aqneursa) • Patient will use the requested medication with miglustat Non-FDA approved uses are not approved PA does not expire
• aripiprazole oral film (Opipza) Antipsychotic Agents: Atypical	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of aripiprazole oral film (Opipza) Manual PA criteria: Coverage is approved if all criteria are met: • Opipza is prescribed by a neurologist, psychiatrist, or developmental pediatrician • The provider must explain why the patient requires Opipza and cannot take the generic formulary alternatives: aripiprazole ODT and oral solution (fill-in blank) ▪ Acceptable responses include: ○ The patient has had an adverse reaction to an excipient in aripiprazole ODT and oral solution that would not be likely to occur with Opipza oral film OR ○ The patient has documented oral aversion ~~dysphagia or swallowing dysfunction (e.g., due to developmental delay, sensory aversion)~~ requiring an alternative formulation for treatment Non-FDA approved uses are not approved PA does not expire

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• crinecerfont (Crenessity) Endocrine Miscellaneous	Manual PA criteria apply to all new users of Crenessity Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 4 years of age or older • Prescribed by an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia • Patient has a diagnosis of 21-hydroxylase deficiency Congenital Adrenal Hyperplasia (CAH) • Patient will take Crenessity in combination with systemic glucocorticoids Non-FDA approved uses are not approved PA does not expire
• filgrastim-txid (Nypozi) Blood Cell Stimulants: Filgrastims	Manual PA criteria apply to all new users of filgrastim-txid (Nypozi) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) are the TRICARE preferred filgrastims and are available without a prior authorization. Please consider changing the prescription to a formulary preferred medication. Note: Granix and Nivestym are available at the generic (Tier 1) copay at the TRICARE Mail Order and Retail Pharmacies • Prescribed by or in consultation with a hematologist or oncologist • Patient experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi) • Patient experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi) • Patient experienced an inadequate treatment response or intolerance to filgrastim-sndz (Zarxio) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi) PA does not expire
• imatinib 80 mg/mL oral solution (Imkeldi) Oncological Agents: Chronic Myelogenous Leukemia	Manual PA criteria apply to all new users of imatinib oral solution (Imkeldi) Age edit: PA not required for patient 6 years of age or younger Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that generic imatinib tablets can be dissolved in water or juice and are available to TRICARE beneficiaries without requiring prior authorization • Prescribed by an oncologist • Patient has had an adverse reaction to an excipient in imatinib tablets that would not be likely to occur with Imkeldi OR • Patient has tried and failed treatment with dissolving imatinib tablets in liquid Non-FDA approved uses are not approved PA does not expire
• inavolisib (Itovebi) Oncological Agents: Breast Cancer	Manual PA criteria apply to all new users of inavolisib <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with an oncologist • Patient has locally advanced or metastatic hormone receptor (HR)-positive disease • Patient has human epidermal growth factor receptor 2 (HER2)-negative disease • Patient has PIK3CA-mutated breast cancer as detected by an FDA approved test

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	• Patient has disease recurrence on or after completing adjuvant endocrine therapy • Medication will be used in combination with Ibrance (palbociclib capsules and tablets) and fulvestrant injection • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number. _____ Other non-FDA approved uses are not approved, except as noted above PA does not expire
• marstacimab-hncq (Hypavzi) Antihemophilic Factors	Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of Hypavzi. Manual PA criteria: Hypavzi is approved if all criteria are met: • Patient is 12 years of age or older • Prescribed by or in consultation with a hematologist • Patient has moderate to severe hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors • Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding Non-FDA-approved uses are not approved PA does not expire
• minocycline 40 mg ER caps (Emrosi) Antibiotics: Tetracyclines	Updates from the current PA are in bold and strikethrough Manual PA criteria apply to all new users of Emrosi Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that minocycline immediate release (IR), metronidazole gel and cream, and azelaic acid 15% gel are available to TRICARE beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to ~~minocycline IR~~ one of these preferred agents • Patient is 18 years of age or older • Prescribed by or in consultation with a dermatologist • Patient has inflammatory lesions (papulopustular) of rosacea • ~~Please provide the clinical rationale as to why the patient requires minocycline extended release and cannot be treated with minocycline immediate release~~ • Patient has tried and failed or has a contraindication to an oral minocycline or doxycycline product • Patient has tried and failed or has a contraindication to topical ivermectin • Patient has tried and failed or has a contraindication to one of the following medications for rosacea: topical azelaic acid, topical metronidazole, isotretinoin, or topical minocycline • Prescriber will provide the name and date of trial for the three above-mentioned drugs below: ▪ Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____ ▪ Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____ ▪ Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____ Non-FDA approved uses are not approved PA does not expire

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• nilotinib tartrate tablets (Danziten) Oncological Agents	Manual PA criteria apply to all new users of Danziten <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges PA is not required for Tasigna • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist or oncologist • Patient has a diagnosis of: ▪ Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR ▪ Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib • Patient has tried Tasigna and had an adverse reaction not expected to occur with Danziten, OR • Patient cannot avoid food 2 hours before and one hour after taking Tasigna • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number. _____ Non-FDA approved uses are not approved, except as noted above PA does not expire
• olezarsen (Tryngolza) Antilipidemics-2	Manual PA criteria apply to all new users of olezarsen <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by cardiologist, an endocrinologist, or an internal medicine physician experienced in treating disorders related to severe hypertriglyceridemia • Patient has undergone genetic testing to confirm the diagnosis of familial chylomicronemia syndrome • Patient has fasting triglyceride level of 880 mg/dL or greater • Patient will adhere to a low fat-diet (less than or equal to 20 g fat per day) while receiving Tryngolza Non-FDA approved uses are not approved PA does not expire
Omnipod 5 Pods and Kits • Omnipod 5 G6/G7 • Omnipod 5 Intro G6/Libre2 Plus Insulins: Miscellaneous Insulin Device	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of Omnipod 5 Pods and Kits <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • The Omnipod 5 device is being used to monitor for diabetes mellitus • Provider acknowledges that a current approved TRICARE PA for Omnipod 3 or Omnipod 4 does not grant automatic approval for Omnipod 5. New PA is required. • Omnipod 5 is prescribed by or in consultation with an endocrinologist • Patient ~~has documented diagnosis of Type 1 diabetes mellitus~~ is receiving multiple daily injections of insulin • Patient has completed a comprehensive diabetes education program (to include teaching patient and caregiver how to administer insulin via syringe) • Patient has demonstrated willingness and ability to play an active role in diabetes self-management Non-FDA approved uses are not approved PA expires in 1 year <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met:

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	• Patient has been successful with therapy as shown by increased time in range or improved A1c • Patient has experienced a decrease in hypoglycemic episodes
• revumenib (Revuforj) Oncological Agents	Manual PA criteria apply to all new users of revumenib <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Prescribed by or in consultation with an oncologist • Patient has relapsed or refractory acute leukemia • Disease is positive for lysine methyltransferase 2A (KMT2A) gene translocation • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number. Other non-FDA approved uses are not approved, except as noted above PA does not expire
• ustekinumab-auub (Wezlana) TIBs: IL23 Inhibitors	PA criteria apply to all new users of ustekinumab-auub (Wezlana) <u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. <u>Manual PA criteria:</u> If automated PA criteria are not met, coverage is approved if all criteria are met: • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR • The patient has a contraindication to Humira • Infliximab may be used in lieu of Humira for ulcerative colitis and Crohn's disease • Coverage approved for patients 18 years of age or older with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ▪ Moderately to severely active Crohn's disease ▪ Moderately to severely active ulcerative colitis • Coverage approved for patients ages 6 to 17 years with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy • The criteria below apply to all patients unless noted: ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Crohn's Disease or ulcerative colitis) ▪ Coverage is NOT provided for concomitant use with other TIBs including, but not limited to TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA-approved uses are not approved PA does not expire

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vanzacaftor/ tezacaftor/ deutivacaftor (Alyftrek) Cystic Fibrosis Agents	Manual PA criteria apply to all new users of Alyftrek <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 6 years of age or older - Prescribed by or in consultation with a pulmonologist - Patient has diagnosis of cystic fibrosis - Patient has at least one F508del mutation or another responsive mutation to Alyftrek in the CFTR gene and if the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation Non-FDA approved uses are not approved PA does not expire
Utilization Management PAs	
lidocaine 5% patch (Tridacaine XL) Pain Agents: Topical	<i>Note that the PA was not implemented, as Tridacaine XL was determined not to be part of the TRICARE Pharmacy benefit.</i> Updates from the February 2025 meeting are in bold Manual PA criteria apply to all new and current users of lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III, Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, Tridacaine III, Tridacaine XL). <u>Manual PA criteria:</u> lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III, Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, Tridacaine III, Tridacaine XL) is approved if all criteria are met: - Provider acknowledges other formulations of lidocaine 5% patch are available without prior authorization - Provider must explain why the patient requires DermacinRx Lidocan, Lidocan II, Lidocan III, Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, or Tridacaine III, or Tridacaine XL and cannot take the cost-effective generic lidocaine 5% formulations. (blank write in) - Acceptable responses are that the patient has failed a trial of at least 3 other preferred generic lidocaine 5% patches; examples of failure include a documented allergy to an inactive ingredient or the patch not adhering to skin Non-FDA-approved uses are not approved Prior authorization does not expire
tramadol 75 mg tablet Narcotic Analgesics and Combinations	Updates from the February 2025 meeting are in bold Manual PA criteria apply to all new users of tramadol 25 and 75 mg tablet <u>Manual PA criteria:</u> tramadol 25 or 75 mg tablet is approved if ALL criteria are met: - Provider is aware and acknowledges that tramadol 50 mg is available to TRICARE beneficiaries without the need of prior authorization and providers are encouraged to change the prescription to the preferred tramadol 50 mg product - This agent has been identified to have cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives. (blank write in) - Acceptable responses are that the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg IR tablets Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• dupilumab (Dupixent) Atopy	Updates from the February 2025 meeting are in bold Note that there were no changes to the current Dupixent criteria for the other indications Chronic Obstructive Pulmonary Disease (COPD) Indication: Manual PA criteria apply to all new users of Dupixent Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by a pulmonologist • Patient has moderate to severe chronic obstructive pulmonary disease (COPD) with both chronic bronchitis and an eosinophilic phenotype (greater than 300 cells/microliter) • Patient has uncontrolled COPD symptoms despite the use of all of the following: long-acting muscarinic antagonists (e.g., Spiriva); long-acting-beta agonists (e.g., formoterol); inhaled corticosteroid (e.g., budesonide) • Medication is being requested for add-on maintenance therapy for management of COPD Non-FDA approved uses are not approved PA expires in 12 months for COPD Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• asciminib (Scemblix) Oncological Agents	Updates from the February 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Scemblix Manual PA criteria: Scemblix is approved if all criteria are met: • Patient is 18 years of age or older • Scemblix is prescribed by or in consultation with a hematologist/oncologist • The patient has Philadelphia chromosome-positive CML (Ph+ CML) in chronic phase (CP) and was previously treated with two or more tyrosine kinase inhibitors ~~• The provider will monitor for myelosuppression, pancreatitis, hypertension, hypersensitivity, and cardiovascular toxicity~~ ~~• Female patients of childbearing age are not pregnant confirmed by (-) HCG~~ ~~• Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~ ~~• Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version and page number _____. Non-FDA-approved uses are not approved except as noted above PA does not expire

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tapinarof 1% cream (Vtama) Psoriasis Agents	Updates from the February 2025 meeting are in bold. Manual PA criteria apply to all new users of tapinarof (Vtama). <u>Manual PA criteria:</u> Vtama is approved if all criteria are met: Plaque Psoriasis Indication: - Patient is 18 years if age or older - The patient has a diagnosis of plaque psoriasis. - The medication is being prescribed by or in consultation with a dermatologist. - The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following: - at least one moderate to high potency topical corticosteroid (e.g., clobetasol propionate 0.05% ointment, cream, solution and gel; fluocinonide 0.05% ointment, cream, solution) AND - at least one topical calcineurin inhibitor (e.g. tacrolimus, pimecrolimus) Atopic Dermatitis Indication: Patient is 2 years of age and older The drug is prescribed by a dermatologist, allergist, or immunologist The patient has moderate to severe atopic dermatitis The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: Topical Corticosteroids: For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) For patients 2 to 17 years of age: any topical corticosteroid Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy Non-FDA approved uses are not approved. PA does not expire for plaque psoriasis indication. PA expires in 1 year for atopic dermatitis indication. <u>Renewal criteria:</u> Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies: The patient's disease severity has improved and stabilized to warrant continued therapy.
nemolizumab-ilto (Nemluvio) TIBs: Miscellaneous Interleukins	Updates from the February 2025 meeting are in bold. Manual PA criteria apply to all new users of nemolizumab (Nemluvio) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Prurigo Nodularis Indication: - Patient is 18 years of age or older - Nemluvio is prescribed by an allergist, immunologist, or dermatologist - Patient has a diagnosis of prurigo nodularis - Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk - Patient has experienced pruritus for 6 weeks or longer - Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR the patient has a secondary cause of prurigo nodularis that has been identified and adequately managed - The patient has a contraindication to, intolerance to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)

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	- The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with phototherapy Atopic Dermatitis Indication: Patient is 12 years of age or older The drug is prescribed by a dermatologist, allergist, or immunologist The patient has moderate to severe atopic dermatitis The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: Topical Corticosteroids: For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) For patients 12 to 17 years of age: any topical corticosteroid Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy Non-FDA approved uses are not approved PA does not expire for prurigo nodularis indication PA expires in 1 year for atopic dermatitis indication Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if the following applies: The patient's disease severity has improved and stabilized to warrant continued therapy
bimekizumab-bkzx (Bimzelx) TIBs: IL-17s	Updates from February 2025 are in bold and strikethrough. Manual PA criteria apply to all new users of bimekizumab-bkzx (Bimzelx) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - The provider acknowledges that Taltz is the Department of Defense's preferred IL-17 agent. The patient must have tried Taltz, Humira and Cosentyx - The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with Bimzelx OR the patient has a contraindication to Humira AND - Patient had an inadequate response to Taltz OR had an adverse reaction to Taltz to not expected to occur with Bimzelx, OR has a contraindication to Taltz AND - Patent had an inadequate response to Taltz or had an adverse reaction to Taltz that is not expected to occur with Bimzelx or has a contraindication to Taltz AND - Patient had an inadequate response to Cosentyx OR had an adverse reaction to Cosentyx that is not expected to occur with Bimzelx OR the patient has a contraindication to Cosentyx AND - Patient is 18 years of age or older with: - Moderate to severe plaque psoriasis who is a candidate for systemic therapy or phototherapy - Active psoriatic arthritis - Active ankylosing spondylitis - Active non-radiographic axial spondyloarthritis with objective signs of inflammation Active hidradenitis suppurativa (Note: Taltz step does not apply) - For plaque psoriasis and psoriatic arthritis: Patient had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) (Note: AS and nr-axSpA indications do not apply)

Appendix C—Table of Prior Authorization (PA) Criteria

	- For ankylosing spondylitis and non-radiographic axial spondylarthritis: Patient had inadequate response to at least two NSAIDs over a period of at least two months - Patient will not be receiving any other targeted immunomodulatory biologics with bimekizumab, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-23, IL-36, JAK inhibitors Non-FDA approved uses are NOT approved PA does not expire
tirzepatide (Zepbound) Weight Loss Agents	Updates from February 2025 are in bold Manual PA criteria apply to all new users of Wegovy and Zepbound <u>Manual PA Criteria:</u> Coverage for Wegovy or Zepbound is approved if: For Wegovy and Zepbound for adults for obesity - Patient is 18 years of age or older - Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) - Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy - Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response - Phentermine: Date _____ Duration of therapy _____ OR - The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension) OR - The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) for obesity - Patient is 12 years of age or older and younger than 18 years of age - Patient has a BMI greater than or equal to 95th percentile standardized for age - Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity: Patient is 18 years of age or older Patient has moderate to severe OSA (documented apnea-hypopnea index greater than 15 events per hour) and a BMI greater than 30 Patient has engaged in behavioral modification and dietary restriction for at least 6 months For all patients - Concomitant use of this medication with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) - The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 - Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus PA expires in 12 months for initial therapy; annual renewal required

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	<u>Renewal PA Criteria:</u> Initial TRICARE PA approval required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met: For Obesity: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication with full dosage titration • For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant For OSA: • The patient has shown improvement in OSA symptoms based on the improvement of apnea hypopnea index
• vortioxetine (Trintellix) Antidepressants and Non-Opioid Pain Syndrome Agents: SSRI	Updates from the February 2025 meeting are in bold Manual PA criteria apply to all new users of Trintellix. <u>Automated PA Criteria:</u> The patient has filled a prescription for two formulary antidepressants e.g., citalopram, escitalopram, fluoxetine, venlafaxine, desvenlafaxine succinate ER, amitriptyline, desipramine, imipramine, nortriptyline, mirtazapine, bupropion, trazodone IR, nefazodone, and monoamine oxidase inhibitors) at any MHS pharmacy point of service (MTFs, Retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days OR <u>Manual PA criteria:</u> If automated criteria are not met, Trintellix is approved if all criteria are met: • Patient is 18 years of age or older • Provider acknowledges that patient and provider have discussed that nonpharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication • Patient is being treated for depression • The patient has a contraindication to, intolerance to, or has failed a trial of TWO formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose) ▪ SSRI (e.g. citalopram, escitalopram, fluoxetine) ▪ SNRI (venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER) ▪ TCA (amitriptyline, desipramine, imipramine, nortriptyline) ▪ mirtazapine ▪ bupropion ▪ trazodone IR ▪ nefazodone ▪ MAOI Non-FDA-approved uses are not approved Prior Authorization does not expire

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• lisdexamfetamine capsule, chew tab (Vyvanse) Attention Deficit Hyperactivity Disorder (ADHD): Stimulant	Updates from the February 2025 meeting are in bold Manual PA apply to all new users of Vyvanse Automated PA Criteria: The patient has filled a prescription for one amphetamine and one methylphenidate at any MHS pharmacy point of service (MTFs, Retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days OR <u>Manual PA Criteria:</u> If automated criteria are not met, Vyvanse is approved if all criteria are met: ADHD • Patient is 6 years of age or older • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed mixed amphetamine salts ER(Adderall XR, generics) or other long acting amphetamine or amphetamine derivative type drug • Patient has tried and failed methylphenidate OROS and other (Concerta, generics) or other long-acting methylphenidate or methylphenidate derivative type drug Binge Eating Disorder • Note: If patient is an Active Duty Service Member (ADSM), the provider acknowledges the need to consult service specific policy for Binge Eating Disorder (BED) <i>(For ADSM, if the above is acknowledged, continue following remaining criteria; non-ADSM may by-pass this note and go directly to the criteria below)</i> • Patient is 18 years of age or older • Patient has a diagnosis of moderate to severe Binge Eating Disorder • Prescribed by or in consultation with a psychiatrist or other behavioral specialist • Patient has failed, does not have access to, or has had an inadequate response to cognitive behavioral therapy or other psychotherapy • Patient has tried and failed OR has a contraindication to an SSRI (e.g., citalopram, fluoxetine, sertraline) • Patient has tried and failed OR has a contraindication to topiramate or zonisamide • Provider acknowledges that Vyvanse will be discontinued if the patient does not respond by having a positive clinical response of meaningful decrease of binge eating episodes or binge days per week from baseline or improvement in signs and symptoms of binge eating disorder after taking Vyvanse Non-FDA-approved uses are NOT approved to include weight loss/obesity Prior authorization does not expire
• upadacitinib (Rinvoq) Atopy: Oral Janus Kinase Inhibitors (JAK-1)	Updates from the February 2025 meeting are in bold and strikethrough Manual PA apply to all new users of Rinvoq <u>Manual PA criteria:</u> Rinvoq is approved if all criteria are met: • Patient is 18 years of age or older and has a diagnosis of: ▪ Atopic Dermatitis ▪ Moderate to severely active rheumatoid arthritis ▪ Active psoriatic arthritis ▪ Ankylosing spondylitis ▪ Non-radiographic axial spondyloarthritis with objective signs of inflammation ▪ Moderately to severely active ulcerative colitis ▪ Moderately to severely active Crohn's disease • Patient is 2-17 years of age and either: ▪ Atopic dermatitis (Age 12 or older) ▪ Active polyarticular juvenile idiopathic arthritis OR ▪ Active psoriatic arthritis • Provider acknowledges that Humira is the Department of Defense preferred targeted biologic agent for approved indications AND patient has had an inadequate response

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	OR experienced an adverse reaction that is not expected to occur with the requested agent OR has a contraindication to Humira (Atopic dermatitis does not apply) AND • Provider acknowledges that for rheumatoid arthritis a trial of Xeljanz or Olumiant is required before Rinvoq. Patient has had an inadequate response OR experienced an adverse reaction that is not expected to occur with the requested agent OR has a contraindication to Xeljanz or Olumiant • Provider acknowledges that for psoriatic arthritis a trial of Xeljanz is required before Rinvoq. Patient has had an inadequate response OR experienced an adverse reaction that is not expected to occur with the requested agent OR has a contraindication to Xeljanz. • Provider acknowledges that for ankylosing spondylitis and non-radiographic axial spondyloarthritis a trial of Cosentyx Taltz is required before Rinvoq. Patient has had an inadequate response OR experienced an adverse reaction that is not expected to occur with the requested agent OR has a contraindication to Cosentyx Taltz. For atopic dermatitis only: • The patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent) • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 12 to 17 year of age: any topical corticosteroid AND ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy For all indications unless noted • Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine) (Note: Does not apply to UC, CD, ax-SpA, nr-axSpA, atopic dermatitis) • Patient experienced an inadequate response to at least TWO Nonsteroidal anti-inflammatory drugs (NSAIDs) (for example: ibuprofen, naproxen, diclofenac) over a period of at least two months? (Note: Applies to ax-SpA and nr-axSpA only) • ~~Patient has no evidence of active TB infection within the past 12 months~~ • ~~Patient has no history of venous thromboembolic (VTE) disease~~ • ~~Provider is aware of the FDA safety alerts AND Boxed Warnings~~ • ~~Patient has no evidence of neutropenia (ANC < 1000)~~ • ~~Patient has no evidence of lymphocytopenia (ALC < 500)~~ • ~~Patient has no evidence of anemia (Hgb < 8)~~ • Patient will not be receiving other targeted immunomodulatory biologics with Rinvoq, except for Otezla, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Stelara, Taltz, Xeljanz or Xeljanz XR or Tremfya TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, or JAK inhibitors Non-FDA-approved uses are not approved PA does not expire
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abrocitinib (Cibinqo) Oral Janus Kinase Inhibitors (JAK-1)	Updates from the February 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of abrocitinib (Cibinqo). Coverage is approved if all criteria are met: - The patient is 18 years of age and older - The medication is prescribed by an allergist, dermatologist, or immunologist - The drug is used to treat moderate to severe atopic dermatitis - The patient failed, has a contraindication, or intolerance to one medication in EACH of the following two categories: - Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - The patient is unable to access, has a contraindication to, or intolerance to UVB phototherapy ~~The patient had a negative TB test in the last 12 months (or is adequately managed)~~ ~~The patient does not have history of VTE~~ ~~The provider is aware of the boxed FDA warnings~~ ~~The patient does not have evidence of neutropenia (ANC < 1000)~~ ~~The patient does not have evidence of lymphocytopenia (ALC < 500)~~ ~~The patient does not have evidence of anemia (Hgb < 8)~~ - The patient is not taking concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulators ~~except Otezla~~, including but not limited to TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, or JAK inhibitors Non-FDA-approved uses are not approved PA expires in 1 year <u>Renewal criteria:</u> Initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies: - The patient's disease severity has improved and stabilized to warrant continued therapy.
levacetylleucine (Aqneursa) Neurological Agents Miscellaneous	Updates from the February 2025 meeting are in strikethrough Manual PA criteria apply to all new users of levacetylleucine (Aqneursa) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient weighs 15 kilograms or greater - Prescribed by a physician who specializes in the treatment of Niemann-Pick disease type C - Patient has a genetically confirmed diagnosis of Niemann-Pick disease type C - Patient has one or more neurologic symptoms (e.g., loss of motor function, difficulty swallowing, and speech and cognitive impairment) ~~Concomitant use of this medication with arimoclomol (Miplyffa) is not allowed~~ Non-FDA approved uses are not approved PA does not expire

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• tafamidis (Vyndaqel) • tafamidis meglumine (Vyndamax) Neurological Agents Miscellaneous	Updates from the February 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Vyndaqel and Vyndamax <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis • Prescribed by or in consultation with a specialist who manages hereditary transthyretin amyloidosis (e.g., cardiologist, geneticist, neurologist) • The patient is not receiving concurrent treatment with acoramidis (Attruby), Tegsedi (inotersen), Onpatro (patisiran), Amvuttra (vutrisiran) or eplontersen (Wainua) ~~• If the patient is female, she is not pregnant or planning to become pregnant~~ ~~• Female patients will not breastfeed~~ ~~• Female patients of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose~~ Non-FDA-approved uses ~~(other than ATTR disease manifestations)~~ are not approved, including ATTR-polyneuropathy PA does not expire
• eplontersen (Wainua) Neurological Agents Miscellaneous	Updates from the February 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Wainua. <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • The patient is 18 years of age or older • Drug is prescribed by or in consultation with a specialist who manages hereditary transthyretin amyloidosis (such as neurologist, cardiologist, and/or medical geneticist) • The patient has documented evidence of hATTR polyneuropathy as confirmed by the following: ▪ Genetically confirmed transthyretin mutation resulting in Coutinho stage 1 or 2 hereditary transthyretin-mediated amyloidosis (hATTR) ▪ The patient has polyneuropathy secondary to hereditary transthyretin-mediated amyloidosis ▪ The patient has a Neuropathy Impairment Score between 10-130 • The patient is not receiving concurrent treatment with Tegsedi (inotersen), Onpatro (patisiran), Amvuttra (vutrisiran), Vyndaqel/Vyndamax (tafamidis) or acoramidis (Attruby) • The provider acknowledges that the patient will receive an oral Vitamin A supplement at the recommended daily allowance while receiving the requested medication Non-FDA approved uses are NOT approved including hATTR cardiomyopathy PA expires in one year <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met • Patient has demonstrated improvement in neuropathy
• encorafenib (Braftovi) Oncological Agents	Updates from the February 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Braftovi <u>Manual PA criteria:</u> Braftovi is approved if all criteria are met: • Patient is greater than or equal to 18 years of age • Prescribed by or in consultation with an oncologist • Patient has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test • Patient has a diagnosis of: ▪ Unresectable or metastatic melanoma

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	▪ Unresectable or metastatic colorectal cancer ▪ Metastatic non-small cell lung cancer • Bravtovi is being taken in combination with Mektovi, Vectibix, or Erbitux • Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version and page number _____. • ~~Patient is not pregnant~~ • ~~Female patients of childbearing age will take highly effective contraception while taking the requested medication and for 2 weeks after the last dose~~ • ~~Patient will not breastfeed during treatment or within two weeks after the cessation of treatment~~ • ~~Male patients are aware that there is an increased chance of male infertility if the requested medication becomes suprathreshold~~ Other non-FDA-approved uses are not approved except as noted above PA does not expire
• cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose) Ophthalmic: Dry Eye Agents	Updates from the February 2025 meeting are in bold and strikethrough • When prescribed by an ophthalmologist or optometrist, prior authorization is not required • Once therapy is initiated by an ophthalmologist or optometrist, an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days Manual PA criteria apply to all new users of cyclosporine 0.05% ophthalmic emulsion unit-dose (Restasis unit-dose, generic) <u>Manual PA Criteria:</u> If automated criteria are not met, Restasis is approved if all manual criteria are met: • ~~If the physician is an ophthalmologist or optometrist, then PA is not required~~ • The drug is prescribed by an ophthalmologist or optometrist • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: ▪ Positive symptomatology screening for moderate to severe dry eye disease from an appropriate measure ▪ At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is nonpreserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. • Restasis unit-dose is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) Other Non-FDA-approved uses are not approved. PA does not expire.

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etanercept (Enbrel) TIBs: TNFs	Updates from the February 2025 meeting are in bold and strikethrough Step therapy and manual PA criteria apply to all new users. ~~Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND~~ Manual PA criteria: ~~If automated criteria are not met,~~ Coverage is approved if the following: - Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent. Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira. - Patient has a contraindication to Humira AND Taltz, OR had inadequate response to Humira AND Taltz (need for different anti-TNF or non-TNF) OR adverse reactions to Humira AND Taltz not expected with requested non-step preferred TIB Note that a trial of non-biologic systemic therapy, adalimumab (Humira) and ixekizumab (Taltz) is required for both Adult and Pediatric Indications when indicated AND - Coverage approved for patients 18 years of age or older with: - Moderate to severe active rheumatoid arthritis (Note Taltz step does not apply) - Moderate to severe active psoriatic arthritis, or active ankylosing spondylitis - Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy - Coverage approved for pediatric patients 2–17 years of age with: - Moderate to severe active polyarticular Juvenile Idiopathic Arthritis (Note Taltz step does not apply) - Juvenile Psoriatic Arthritis (Note Taltz step does not apply) - Coverage approved for pediatric patients 4-17 years of age with: - Plaque psoriasis. Note that a trial of ustekinumab Stelara-AND Taltz is required for pediatric patients 6 years of age or older, however for patients 4-5 years of age, a trial of ustekinumab Stelara-or Taltz is not required for this age group. Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) (Note: AS and nr-axSpA indications do not apply) Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS and nr-axSpA indication ONLY) ~~Provider is aware that worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including ENBREL~~ ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ - Coverage is NOT provided for concomitant use with other TIBs including but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, PDE4, or JAK inhibitors adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Non-FDA-approved uses are not approved Prior Authorization does not expire.
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• baricitinib (Olumiant) TIBs: Miscellaneous	Updates from the February 2025 meeting are in bold and strikethrough. Step therapy and manual PA criteria apply to all new users of baricitinib (Olumiant). <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND <u>Manual PA Criteria:</u> Coverage for Olumiant is approved if all criteria are met: • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent. • The patient must have tried Humira AND the patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira AND • Patient is 18 years of age or older with a diagnosis of: ▪ Moderate to severe active rheumatoid arthritis (RA) • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.) • ~~The patient will not be receiving other biologic DMARDs or potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly~~ • ~~Patient has no history of thromboembolic disease~~ • ~~Provider is aware of the FDA safety alerts AND Boxed Warnings~~ • ~~Patient hemoglobin (Hgb) must be > 9 g/dL~~ • ~~Patient absolute neutrophil count (ANC) < 1,000/mm³~~ • ~~Patient absolute lymphocyte count (ALC) < 500/ mm³~~ • ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ • Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, or JAK inhibitors • ~~May not be used concomitantly with other TIBs agents except for Otezla~~ Non-FDA-approved uses are not approved Prior authorization does not expire.
• deucravacitinib (Sotyktu) TIBs	Updates from the February 2025 meeting are in bold and strikethrough Step therapy and manual PA criteria apply to all new users of deucravacitinib (Sotyktu). <u>Manual PA Criteria:</u> Coverage is approved for Sotyktu if: • The patient has a contraindication or has had an inadequate response to Humira, Taltz, and Cosentyx OR • The patient has had an adverse reaction to Humira, Taltz, and Cosentyx that is not expected with the requested non-step-preferred TIB AND • ~~Patient is ≥ 18 years of age~~ Patient is 18 years of age or older • Patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy. • Patient had an inadequate response to non-biologic systemic therapy (i.e., methotrexate, corticosteroids).

Appendix C—Table of Prior Authorization (PA) Criteria

	~~The patient will not be receiving other potent immunosuppressants concomitantly. Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, or JAK inhibitors~~ ~~Provider is aware of the FDA safety alerts and boxed warnings and precautions.~~ ~~Patient has negative TB test result in past 12 months (or TB is adequately managed).~~ Non-FDA-approved uses are not approved PA does not expire
tofacitinib (Xeljanz) TIBs: Miscellaneous	Updates from the February 2025 meeting are in bold and strikethrough. ~~Step therapy and Manual PA criteria apply to new users of tofacitinib (Xeljanz, Xeljanz XR, Xeljanz oral solution).~~ Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria: If automated criteria are not met, Coverage for Xeljanz, Xeljanz XR, or Xeljanz oral solution is approved if all criteria are met:</u> Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent. - The patient must have tried Humira AND the patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira AND - Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication: - Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate ~~The prescription is for 5 mg BID or 11 mg once a day~~ - Active psoriatic arthritis (PsA) OR - Active ankylosing spondylitis (AS) ~~The prescription is for 5 mg BID or 11 mg once a day~~ - Moderately to severely active ulcerative colitis (UC) ~~Will allow doses up to 10 mg BID OR up to 22mg once a day~~ - Coverage approved for pediatric patients 2 years of age or older with: - Active polyarticular ~~course~~ juvenile idiopathic arthritis (pJIA) The prescription is for 5 mg BID or weight-based equivalent BID (oral solution and IR tablet may be converted on a mg-to-mg equivalent; for example, 5 mg oral solution may be switched to 5 mg IR tablet) - Below criteria applies to all patients unless noted: ~~Patient has no history of thromboembolic disease~~ ~~Patient hemoglobin (Hgb) must be > 9 g/dL~~ ~~Patient absolute neutrophil count (ANC) < 1,000/mm³~~ ~~Patient absolute lymphocyte count (ALC) < 500/mm³~~ ~~The patient is not receiving potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly~~

Appendix C—Table of Prior Authorization (PA) Criteria

	~~• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine) (Note: Does not apply to UC, RA, ax-SpA, pJIA) ▪ Patient experienced an inadequate response to at least TWO Nonsteroidal anti-inflammatory drugs (NSAIDs) (for example: ibuprofen, naproxen, diclofenac) over a period of at least two months? (Note: Applies to ax-SpA only) ▪ Patient will not be receiving other targeted immunomodulatory biologics with Rinvoq, except for Otezla, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kinorot, Olumiant, Orencia, Remicade, Rituxan, Siliq, Stelara, Taltz, Xeljanz or Xeljanz XR or Tremfya TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, or JAK inhibitors ~~• Provider is aware of the FDA safety alerts and boxed warnings~~ Non-FDA-approved uses are not approved Prior Authorization does not expire
• ustekinumab (Stelara) TIBs: IL-23s	Updates from the February 2025 meeting are in bold. <u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. Manual PA criteria apply to all new users of ustekinumab (Stelara) <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved if all criteria are met: • Provider acknowledges that Taltz is available for the treatment of plaque psoriasis without the requirement to try Humira • The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira • A trial of IV infliximab may be used in lieu of Humira for Ulcerative Colitis and Crohn's Disease • Coverage approved for patients 18 years of age or older with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ▪ Moderately to severely active Crohn's disease (CD) ▪ Moderately to severely ulcerative colitis (UC) • Coverage approved for patients ages 6 to 17 years with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy • The below criteria apply to all patients unless noted: ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to CD, UC) ▪ Coverage is NOT provided for concomitant use with other TIBs including, but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors

Appendix C—Table of Prior Authorization (PA) Criteria

	Non-FDA-approved uses are not approved PA does not expire
guselkumab (Tremfya) TIBs: IL-23s	Updates from the February 2025 meeting are in bold. Manual PA Criteria apply to all new users of guselkumab (Tremfya). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira - Patient had an inadequate response to Humira OR had adverse reaction to Humira that is not expected to occur with the requested agent OR has a contraindication to Humira A trial of IV infliximab may be used in lieu of Humira for Ulcerative colitis AND - Patient is 18 years of age or older with the following indication/diagnosis: - Active psoriatic arthritis (PsA) - Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - Moderate to severely active ulcerative colitis (UC) - Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosaliclates, corticosteroids, immunosuppressants etc.) (Note does not apply to UC) - Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
risankizumab on-body injector (Skyrizi OBI) TIBs: IL-2s	Updates from the February 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of risankizumab On-Body Injector (Skyrizi OBI). <u>Manual PA Criteria:</u> Coverage is approved if ALL criteria are met: - The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira A trial of IV infliximab may be used in lieu of Humira for Ulcerative Colitis and Crohn's Disease AND - Patient ≥ 18 years old with the following diagnoses: - Moderately to severely active Crohn's disease - Moderately to severely active ulcerative colitis ~~Patient has tried and had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (e.g., methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) (Note: does not apply to CD))~~ - Coverage NOT provided for concomitant use with other TIBs, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Use of the on-body injector for non-FDA-approved indications, plaque psoriasis, or psoriatic arthritis is not approved. Providers should fill out the PA for Skyrizi pen and syringes for indications other than Crohn's disease or ulcerative colitis. Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• mirikizumab (Omvoh) TIBs: IL-23s	Updates from the February 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of mirikizumab-mrkz Omvoh <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older with a diagnosis of: ▪ Moderate to severely active ulcerative colitis ▪ Moderately to severely active Crohn's disease • Patient had an inadequate response to Humira, ustekinumab Stelara, Tremfya, and Skyrizi OR had adverse reaction to Humira, ustekinumab Stelara, Tremfya, and Skyrizi that is not expected to occur with the requested agent OR has a contraindication to Humira, ustekinumab Stelara, Tremfya, and Skyrizi • A trial of IV infliximab may be used in lieu of Humira • ~~Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example—methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc.~~ • Patient will not be receiving any other targeted immunomodulatory biologics with mirikizumab including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
• vedolizumab (Entyvio) TIBs: Non-TNF Inhibitors	Updates from the February 2025 meeting are in bold and strikethrough <u>Automated PA Criteria:</u> When prescribed by a gastroenterologist to a patient aged 18 years or older a prior authorization is not required. Once therapy is initiated by a gastroenterologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA criteria apply to all new users of vedolizumab <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved if all criteria are met: • Patient is 18 years of age or older • ~~When prescribed by a gastroenterologist, prior authorization is not required~~ • Medication is prescribed by or in consultation with a gastroenterologist • Patient has moderately to severely active ulcerative colitis • Patient has moderately to severely active Crohn's disease • ~~Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis~~ • ~~Patient had inadequate response to Humira~~ • ~~Patient had adverse reaction to Humira that is not expected to occur with the requested agent~~ • ~~Patient has a contraindication to Humira~~ • ~~Patient tried and failed or had an inadequate response to infliximab (Remicade)~~ • ~~Patient has had an inadequate response to nonbiologic systemic therapy (for example—methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g. azathioprine), etc.~~ • Patient has received induction dosing with two intravenous doses of vedolizumab (Entyvio) ~~OR patient has been receiving intravenous vedolizumab (Entyvio)~~ and achieved clinical response or remission beyond week 6 • Patient is currently stable on IV Entyvio beyond 14 weeks of therapy and is transitioning to a self-administered dosage form

Appendix C—Table of Prior Authorization (PA) Criteria

	Patient will not be receiving any other targeted immunomodulatory biologics with vedolizumab including but not limited to the following: TNF inhibitors, interleukins, or JAK inhibitors certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi) or upadacitinib (Rinvoq ER) Non-FDA approved uses are not approved PA does not expire
infliximab-dyyb injection (Zymfentra) TIBs: TNF inhibitors	Updates from the February 2025 meeting are in bold and strikethrough Automated PA Criteria: When prescribed by a gastroenterologist to a patient aged 18 years of age or older a prior authorization is not required. Once therapy is initiated by a gastroenterologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA criteria apply to all new users of infliximab-dyyb <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved if all criteria are met: - Patient is 18 years of age or older ~~When prescribed by a gastroenterologist, PA is not required~~ - Medication is in prescribed by or in consultation with a gastroenterologist - Patient has moderate to severely active ulcerative colitis or moderate to severe Crohn's disease ~~Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis and Crohn's disease~~ ~~Patient has one of the following:~~ ~~Patient had inadequate response to Humira~~ ~~Patient had adverse reaction to Humira that is not expected to occur with the requested agent~~ ~~Patient has a contraindication to Humira~~ ~~Patient is clinically stable on IV infliximab and changing to Humira would incur unacceptable risk~~ - Patient has received infliximab product administered intravenously as induction therapy and has demonstrated positive response ~~Patient has had an inadequate response to nonbiologic systemic therapy (for example methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc.~~ ~~Patient has negative TB test result in past 12 months (or TB is adequately managed)~~ - Coverage is NOT provided for concomitant use with other TIBs including but not limited to: TNF inhibitors, interleukins, or JAK inhibitors adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Non-FDA approved uses are not approved PA does not expire

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• pitolisant (Wakix) • sodium oxybate oral solution (Xyrem brand, authorized generics) • sodium oxybate calcium/magnesium/potassium oral solution (Xywav) • sodium oxybate ER packets for oral suspension (Lumryz) Sleep Disorders: Wakefulness Promoting Agents	▪ MTF/TMOP/Retail: 30-day supply
• solriamfetol (Sunosi) Sleep Disorders: Wakefulness Promoting Agents	Changes from February 2025 are in bold and strikethrough ▪ ~~All POS: 30 days~~ ▪ Retail: 30-day supply ▪ MTF/TMOP: 90-day supply
• buprenorphine transdermal patch (Butrans, generic) Buprenorphine and Combinations	▪ Retail: 4 units per 30 days ▪ MTF/TMOP: 12 units per 90 days
• acoramidis (Attruby) Neurological Agents Misc	▪ MTF/TMOP/Retail: 30-day supply
• arimoclomol (Miplyffa) Neurological Agents Misc	▪ MTF/TMOP/Retail: 60-day supply
• crinecerfont (Crenessity) Endocrine Misc	▪ MTF/TMOP/Retail: 60-day supply
• marstacimab-hncq (Hypavzi) Antihemophilic Factors	▪ MTF/TMOP/Retail: 30-day supply
• imatinib oral solution (Imkeldi) Oncological Agents: Chronic Myelogenous Leukemia	▪ MTF/TMOP/Retail: 60-day supply
• inavolisib (Itovebi) Oncological Agents: Breast Cancer	▪ MTF/TMOP/Retail: 60-day supply
• nilotinib tartrate tabs (Danziten) Oncological Agents: Chronic Myelogenous Leukemia	▪ Retail/MTF/TMOP: 60-day supply

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
olezarsen (Tryngolza) Antilipidemics-2	MTF/TMOP/Retail: 60-day supply
Omnipod 5 Pods and Kits - Omnipod 5 G6/67 - Omnipod 5 Intro G6/Libre2 Plus Insulins: Miscellaneous Insulin Device	- MTF/TMOP/Retail: 1 kit/ 2 years - Retail: 15 pods/30 days - MTF/TMOP: 45 pods/90 days
revumenib (Revuforj) Oncological Agents	MTF/TMOP/Retail: 60-day supply
ustekinumab-auub (Wezlana) TIBs: IL-23s	- Retail: 1 syringe Per fill - MTF/TMOP: 3 syringes Per fill
vanzacaftor/ tezacaftor/ deutivacaftor (Alyftrek) Cystic Fibrosis Agents	MTF/TMOP/Retail: 28 day supply
- estradiol acetate vaginal ring (Femring) - estradiol vaginal system (Estring) Menopausal Hormone Therapy: Vaginal Agents	MTF/TMOP/Retail: 1 ring/90 days

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• Self-Monitoring Blood Glucose (SMBG) Test Strips (all products)	Changes from February 2025 are outlined in bold (no changes made to the QL or over-ride criteria; automation added) ▪ Retail: 100 strips/30-day supply ▪ TMOP and MTF: 300 strips/90-day supply <u>Automated PA Criteria:</u> When prescribed by an obstetrician/gynecologist specialist, the QL over-ride authorization form is not required. OR <u>Automated PA Criteria:</u> The patient has filled a prescription for a prenatal vitamin at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE Mail Order Pharmacy) during the previous 365 days. OR Manual QL Over-ride criteria if automated criteria are not met: Over-ride criteria include the following situations: ▪ receiving insulin ▪ using an insulin pump ▪ gestational diabetes ▪ requires more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, non-islet cell tumor) ▪ history of poorly-controlled blood glucose levels with history of adverse outcomes (e.g., ketoacidosis or hypoglycemic episode) requiring medical intervention ▪ Patient is not using a continuous blood glucose monitoring (CGM) system, unless a clinical explanation is provided_____ (write-in)

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
acoramidis (Attruby) Neurological Agents Misc	tafamidis (Vyndaqel, Vyndamax)	- Tablet: 356 mg - Dosing: 712 mg orally twice daily	Treatment of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults	ADRs (> 5%): - diarrhea - upper abdominal pain	- Second drug approved for ATTR-CM therapy. Mechanism of action is similar to tafamidis (Vyndaqel, Vyndamax) in that it targets unstable TTR tetramers (TTR stabilizers), which lead to cardiomyopathy - Phase 3 study (ATTRIBUTE-CM) showed improvement in the four-step hierarchical composite of all-cause death, CV-related hospitalization, change in NT-proBNP levels, and 6-minute walk distance test - While acoramidis does achieve more complete stabilization of TTR, it remains unknown if this is clinically relevant - ATTR-CM clinical practice guidelines have not been updated yet to include acoramidis - No one treatment is approved for both ATTR-CM and ATTR-Polyneuropathy (ATTR-PN), however trials are underway for eplontersen and inotersen (both currently approved for ATTR-PN) for ATTR-CM - The trial demonstrated improvement over placebo; however, due to the absence of head-to-head trials with other TTR-CM medications, Attruby's place in therapy remains uncertain	- UF - PA - QL - Specialty Drug List
arimoclomol (Miplyffa) Neurological Agents Misc	Aqneursa	- Caps: 47 mg, 62 mg, 93 mg, 124 mg - Dosing: weight-based three times daily	In combination with miglustat for treatment of neurological manifestations of Niemann-Pick Disease type C disease in patients 2 years and older	ADRs ($\geq 15\%$): - upper respiratory tract infection - diarrhea - decreased weight	- Phase 2/3 study demonstrated Miplyffa resulted in a statistically significant slowing of neurologic disease progression vs. placebo as measured by the Niemann-Pick Disease Type C Clinical Severity Scale at 1 year - Most patients were taking migalastat at baseline and subgroup analyses support the importance of concomitant miglustat with Miplyffa - Miplyffa offers a therapeutic alternative for the treatment of neurologic manifestations of a rare condition	- UF - PA - QL - Specialty Drug List - Tricare Maintenance Drug List - Rapid Response Program

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
aripiprazole oral film (Opipza) Antipsychotic Agents: Atypical	aripiprazole solution and orally dissolving tablets	- Oral film: 2 mg, 5 mg, 10 mg - Dosing: indication based, once daily	- Treatment of schizophrenia $\geq$ 13 years - Adjunctive to MDD in adults - Irritability in autistic $\geq$ 6 years - Tourette's $\geq$ 6 years	ADR ($\geq$5%) - akathisia - extrapyramidal disorder - somnolence - tremor - restlessness - insomnia - constipation - fatigue - blurred vision - sedation - pyrexia - drooling - decreased appetite - lethargy - headache - nasopharyngitis	- Opipza is another formulation of aripiprazole available as an oral film - Approved via 505(b)(2) with no new clinical studies available - Offers no significant clinical advantage compared to other aripiprazole products, including the ODT	- NF - PA - MN - Rapid Response Program
crinecerfont (Crenessity) Endocrine Miscellaneous	N/A	- Capsule: 25 mg, 50 mg, 100 mg - Dosing: 100 mg orally twice daily	Adjunctive treatment to glucocorticoid replacement to control androgens in patient 4 years of age and older with classic congenital adrenal hyperplasia (CAH)	ADR ($\geq$4%) - fatigue - headache - dizziness - arthralgia - back pain - decreased appetite - myalgia	- First agent approved for the treatment of classic CAH - Phase 3 studies demonstrated significantly greater reduction in the glucocorticoid dose and significantly lower serum androstenedione levels from baseline with crinecerfont vs. placebo - Lifelong treatment with open-label extension studies ongoing - Crenessity provides an option to suppress androgen excess and reduce doses of glucocorticoids in CAH	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
filgrastim-txid (Nypozi) White Blood Cell Stimulants: Filgrastims	- Granix - Nivestym - Releuko - Zarxio - Neupogen	- Syringe: 300 mcg/ 0.5 ml; 480 mcg/ 0.8 ml - Dosing: weight-based	- Decreased incidence of infection - Reduced time to neutrophil recovery - Mobilizes autologous hematopoietic progenitor cells	ADR varies by indication	6th filgrastim; another biosimilar to Neupogen - No new clinical data - Available as a latex-free prefilled syringe - Offers no compelling clinical advantage over existing formulary agents	- NF, non-step-preferred - PA - MN - Specialty Drug List - Rapid Response Program

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
imatinib oral solution (Imkeldi) Oncological Agents: Chronic Myelogenous Leukemia	Gleevec Tab	- Oral Solution: 80 mg/mL - Dosing: indication based, orally daily	Same as imatinib mesylate (Gleevec)	ADR ($\geq 30\%$) - edema - nausea - vomiting - muscle cramps - musculoskeletal pain - diarrhea - rash - fatigue - abdominal pain	- Oral solution formulation of imatinib - No new clinical studies were completed - Has same indications and dosing as Gleevec - Gleevec can be dispersed in a glass of water or apple juice for those who have difficulty swallowing - Provides no compelling clinical advantage over existing agents	- NF - PA - MN - QL - Specialty Drug List - TRICARE Maintenance Drug List - Rapid Response Program
inavolisib (Itovebi) Oncological Agents: Breast Cancer	- Piqray - Truqap	- Tablets: 3 mg, 9mg - Dosing: 9 mg orally daily	In combination with palbociclib and fulvestrant for endocrine resistant HR-positive, HER2-negative breast cancer following recurrence on or after completing adjuvant endocrine therapy	ADR ($\geq 20\%$) - decreased neutrophils, hemoglobin, platelets, lymphocytes - increased fasting glucose - stomatitis - diarrhea - decreased calcium, potassium, sodium, magnesium - fatigue - increased creatinine - increased ALT - nausea - rash - decreased appetite - COVID-19 infection - headache	- Itovebi in combination with lbrance and fulvestrant is the only PIK3CA-targeted therapy approved in the first-line setting for the treatment of endocrine resistant HR-positive, HER2-negative breast cancer following recurrence on or after completing adjuvant endocrine therapy - Phase 3 study demonstrated fewer patients with progression events in the Itovebi group compared with the placebo group and the progression free survival duration was more than double with Itovebi compared with placebo - Piqray and Truqap are the other two FDA-approved therapies for PIK3CA mutation-positive breast cancer; however, both agents are recommended for second-line use - Addition of Itovebi to lbrance and fulvestrant resulted in higher incidences of adverse events compared with placebo in combination with lbrance and fulvestrant - Provides a first line option for the treatment of endocrine resistant HR-positive, HER2-negative breast cancer following recurrence on or after completing adjuvant endocrine therapy	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
marstacimab-hncq (Hypavzi) Antihemophilic Factors	- Hemlibra - Altuviiro - Idelvion	- Syringe: 150 mg/mL - Dosing: 300 mg loading dose followed by 150 mg or 300 mg weekly	Treatment of adults and pediatrics ≥ 12 years with hemophilia A (HA) without factor VIII inhibitors, or hemophilia B (HB) without factor IX inhibitors	ADR ($\geq 3\%$) - injection site reaction - headache - pruritus	- First nonfactor replacement therapy available for patients with hemophilia B without inhibitors - Due to its mechanism of action inhibitor formation is not expected - For patients with HA or HB without inhibitors, Hypavzi demonstrated noninferiority of the annual bleeding rate (ABR) for prophylaxis compared to prophylaxis with corresponding factor - For patients with HA (with or without inhibitors), Hemlibra, the other nonfactor formulary agent available, demonstrated superiority of ABR during prophylaxis with corresponding factor; both for primary outcome of treated bleeds - Hypavzi provides the first subcutaneous prophylactic option for patients with HB and a second option (only formulation available in a pen) for patients with HA without inhibitors	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
minocycline 40 mg ER caps (Emrosi) Antibiotics: Tetracyclines	- minocycline (generic) - doxycycline - Oracea gel - Zilxi gel	- Capsule: 40 mg - Dosing: 40 mg orally daily	Treat inflammatory lesions (papules and pustules) of rosacea in adults	ADR ($\geq 1\%$) dyspepsia	- Emrosi is another minocycline formulation for rosacea - Phase 3 study demonstrated an 18% to 28% difference in the investigator global assessment treatment success and -5 to -3.4 difference in inflammatory lesion count of Emrosi over doxycycline - There are numerous other formulary medications, both oral and topical, for rosacea. Emrosi is another tetracycline product that does not provide compelling advantages over other products.	- NF - PA - MN

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
nilotinib tartrate tabs (Danziten) Oncological Agents: Chronic Myelogenous Leukemia	Tasigna	Capsule: 150 mg Dosing: 2 caps orally twice daily	Treatment with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase	ADR ($\geq 20\%$) - nausea - rash - headache - fatigue - pruritus - vomiting - diarrhea - cough - constipation - arthralgia - nasopharyngitis - pyrexia - night sweats	- Danziten is a new nilotinib formulation that can be administered without mealtime restrictions - No new clinical studies were completed - Tasigna must be taken on an empty stomach to limit cardiotoxicity - Does not share Tasigna's indication to treat pediatric patients ≥ 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy - Provides another formulation of nilotinib but this one does not require fasting	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
olezarsen (Tryngolza) Antilipidemics -2	N/A	Autoinjector: 80 mg/0.8 ml Dosing: 80 mg SC once monthly	Adjunct to diet to reduce triglycerides (TG) in adults with familial chylomicronemia syndrome (FCS)	ADR ($\geq 5\%$) - injection site reactions - decreased platelet count - arthralgia	- Phase 3 study demonstrated a treatment difference of over 40% between Tryngolza and placebo among adults with FCS with baseline TG levels of $\sim 2,600$ mg/dL - Study limitations include small sample size; it is unknown whether pts followed dietary restrictions (< 20 grams fat/day) - Although TG levels were reduced by $> 40\%$, the ending TG levels were still $> 1,000$ mg/dL - Durability unknown; study was 12 months - Patients given Tryngolza also had a decrease in the numerical incidence of acute pancreatitis vs. placebo - Long-term safety profile remains to be determined. - Although this is the first FDA-approved product for FCS, the treatment efficacy was modest, and more data is needed to determine the full benefit of Tryngolza. Another agent is in the pipeline with the same mechanism of action	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
- Omnipod Intro Libre 2 Plus/G6 - Insulins: Misc Insulin Devices	Omnipod 5	Dosing: change POD every 48 to 72 hours	Type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) in adults	N/A	- Omnipod 5 Intro (G6/Libre2Plus) is a tubeless insulin delivery device that can integrate with FreeStyle Libre 2 plus sensor - Does not work with FreeStyle Libre 2, FreeStyle Libre 3, or FreeStyle Libre 3 Plus - Is only used with the wireless personal diabetes manager (PDM) - Omnipod 5 is indicated for both T1DM and T2DM patients on multiple daily injections (MDI) - American Diabetes Association guidelines has an “A” rating for the use in type 2 diabetes on multiple daily injections (MDI); where in 2021 it was a “B” rating - Smartphone control is not available with this version. The dedicated controller in the kit is required. - Provides an automated insulin delivery (AID) system for T1DM and T2DM patients receiving multiple daily injections (MDI) and is compatible with the FreeStyle Libre 2 plus sensor	- Device added to TRICARE Pharmacy benefit - UF - PA - QL
- revumenib (Revuforj) - Oncological Agents	Venclexta	- Tablet: 25 mg, 110 mg, 160 mg - Dosing: weight-based orally twice daily	Treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year and older	ADR (≥20%) - hemorrhage - nausea - decreased phosphate, potassium - increased phos, AST, ALT, TG, AP - increased msk pain - infection - febrile neutropenia - increased PTH - bacterial infection - diarrhea - differentiation syndrome - prolonged QT - decreased appetite - constipation - edema	- First-in-class menin inhibitor for acute leukemia - Phase 1/2 study demonstrated a 22% rate of complete remission (CR) plus CR with partial hematological recovery (CRh) with a median duration of response of 6.4 months - Labeling has a black box warning for differentiation syndrome - Provides an FDA approved option for relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation	- UF - PA - QLs - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
				• fatigue		
ustekinumab-auub (Wezlana) Targeted Immuno-modulator Biologics: IL-23	Stelara	- Syringe: 45 mg/0.5 ml, 90 mg/ml - Dosing: weight and indication based	Adults with: - moderate to severe plaque psoriasis - active psoriatic arthritis - moderately to severely active Crohn's disease or active ulcerative colitis Pediatric patients 6 years and older with: - moderate to severe plaque psoriasis - active psoriatic arthritis	ADR ($\geq 3\%$): - nasopharyngitis - upper respiratory tract infection - headache - fatigue - N/V/D - injection site erythema - vulvovaginal candidiasis/mycotic infection - bronchitis - pruritus - UTI - sinusitis - abdominal pain - influenza - fever	- First biosimilar to Stelara - No new clinical studies were completed - Provides no compelling clinical advantage over existing agents	- UF, non-step-preferred - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List - Rapid Response Program
vanzacaftor, tezacaftor, deutivacaftor (Alyftrek) Cystic Fibrosis Agents	Trikafta	- Tablet: 4 mg/20 mg/50 mg, 10 mg/50 mg/125 mg - Dosing: age/weight-based orally daily	Treatment of cystic fibrosis in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene	ADR ($\geq 5\%$) - cough - nasopharyngitis - upper respiratory tract infection - headache - oropharyngeal pain - influenza - fatigue - increased ALT, AST - rash - sinus congestion	- Alyftrek is approved for use in patients ≥ 6 years of age for Cystic Fibrosis (CF) - Pivotal trial demonstrated a non-inferior change in lung function compared with Trikafta in patients ≥ 12 years of age with CF - Another pivotal study involving patients ≥ 6 years of age demonstrated lung function was maintained with Alyftrek after run period of 4 weeks with Trikafta - Alyftrek and Trikafta have the same Boxed Warning regarding drug-induced injury and liver failure - Alyftrek covers 31 cystic fibrosis transmembrane conductance regulator (CFTR) mutations that are not covered by other agents - Alyftrek provides an additional treatment option to CF patients who have at least one F508del mutation or have another mutation sensitive to Alyftrek	- UF - PA - QL - Specialty Drug List

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes*

DoD P&T Meeting		Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from TMOP Requirement)
February 2025	Drug Class Reviews Sleep Disorder: Wakefulness Promoting Agents subclass Designated UF <i>Retain current status on the TRICARE Maintenance Drug List</i> solriamfetol (Sunosi)	Drug Class Reviews Sleep Disorder: Wakefulness Promoting Agents subclass Designated UF <i>Do not add</i> - sodium/calcium/magnesium/potassium oxybate packets for oral suspension (Xywav) Designated NF <i>Exempt from NF requirement (not available at TMOP)</i> - sodium oxybate ER (Lumryz) - sodium oxybate authorized generic (Xyrem authorized generics) - sodium oxybate (Xyrem) Narcotic Analgesics and Combinations: Buprenorphine and Combinations Designated UF <i>Do not add</i> - buprenorphine transdermal (Butrans) - buprenorphine oral film (Belbuca) - buprenorphine/naloxone SL tabs (Zubsolv) - buprenorphine/naloxone oral film (Suboxone) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Do not add – not cost advantageous to government</i> - acoramidis (Attruby) <i>Do not add – requires further evaluation</i> - Omnipod 5 Libre2/G6 - vanzacافتor/tezacافتor/deutivacافتor (Alyftrek) Designated NF – exempt from NF requirement <i>Acute or limited duration of use</i> - filgrastim-txid (Nypozi) <i>Established exemption for antipsychotics</i> - aripiprazole oral film (Opipza) <i>Not cost advantageous to government</i> - minocycline 40mg ER caps (Emrosi)

*Legal/Regulatory Authorities

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

- 10 USC 1074g(a)(9) requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to these requirements are listed on the TRICARE Maintenance Drug List (TMDL).
- 32 CFR 199.21(r) implements 10 USC 1074g(a)(9) and sets out operation of the TMDL in detail.
- 32 CFR 199.21(h)(2)(ii) requires that non-formulary pharmaceutical agents be “generally not available in military treatment facilities or in the retail point of service.” As a result, NF/Tier 3 agents (including generics) must be on the TMDL unless a reason exists to exempt the agent from the NF TMOP requirement (e.g., acute use, clinical considerations, not available at TMOP, cost effectiveness).
- 32 CFR 199.21(g)(5) covers formulary status and review of newly approved drugs (other than generics), which are added to the UF unless the P&T Committee recommends NF/Tier 3 status within 120 days of approval. In the meantime, newly approved drugs are considered to be in a classification pending status and available under the same terms as NF/Tier 3 medications.

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from TMOP Requirement)
February 2025	Drug Class Reviews Sleep Disorders – Wakefulness Promoting Agents Subclass Designated NF No reason to exempt from NF to TMOP requirement • pitolisant (Wakix) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF • arimoclomol (Miplyffa) • marstacimab-hncq (Hympavzi) • ustekinumab-auub (Wezlana) • crinecerfont (Crenessity) • inavolisib (Itovebi) • nilotinib tartrate tablets (Danziten) • olezarsen (Tryngolza) • revumenib (Revuforj) Designated NF No reason to exempt from NF to TMOP requirement • imatinib oral solution (Imkeldi)	

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions* †

Due to the volume of recommendations requiring implementation due to the UF Beneficiary Advisory Panel pause, one week was added to implementation, which is reflected in the dates below.

Upon signing: July 20, 2026

Two weeks after signing: August 12, 2026

30 days after Signing: August 26, 2026

60 days after signing: September 29, 2026

90 days after signing: October 28, 2026

120 days after signing: not applicable

* Note that implementation occurs the first Wednesday following “X” days after signing of the minutes in all points of service.

† P&T Committee Administrative Authorities were used to implement some recommendations not requiring UF BAP comment. See the November 2023 Table of Administrative Authorities.

DoD P&T Committee Updates to Approval Authorities

Note that updates are in bold font.

**Table 1. Processes and Recommendation/Approval Authorities
For the February 2025 DoD P&T Committee Meeting**

Process	Function
Administrative (not part of DoD P&T Committee process; Uniform Formulary Beneficiary Advisory Panel (UF BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm5 (Mail Order Pharmacy and Retail pharmacies) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; P&T Committee Chair and others as needed	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTs] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing PA requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non-step-preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to PA forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Implementing temporary PA requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting) and to institute and/or change existing PAs, as necessary, to comply with governing federal law and policy.

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	▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator” drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be “grandfathered” when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the TRICARE Maintenance Drug List. ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the TRICARE Maintenance Drug List from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing “brand over generic” authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon PA. The branded product will adjudicate at the Tier 1 co-pay at Retail pharmacies and the Mail Order Pharmacy. The “brand over generic” authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating “line extension” products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties
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	of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended-release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTs coding for TPharm5, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA “health.mil” website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying or revising manual PA criteria, MN criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs, MNs and/or QLs implemented in these situations will be removed when the situation has resolved. ▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA-approved devices or supplies and determination as to whether a new FDA-approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination is made to consider for coverage, the timeline for review by the DoD P&T Committee will be established. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed
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	periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. ▪ Designating “line extension” devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication with complete exclusion status (not covered) on the Uniform Formulary, for products that provide very little or no clinical effectiveness relative to similar agents, and implementation plan (including effective date). ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing PA (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as nonformulary (Tier 3 co-pay). ▪ The Director may approve devices or supplies as recommended by the P&T Committee and the UF BAP; however, approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. ▪ Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with PA criteria and implementation plans as recommended by the DoD P&T Committee and UF BAP.
Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to UF BAP for comments)	▪ Establishment of quantity limits for a medication, device or supply or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs, devices or supplies. ▪ Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes, devices or supplies on the TRICARE Maintenance Drug List. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver.

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	▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail pharmacies.
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**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

May 2025

I. CONVENING

The DoD Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 7th and 8th, 2025.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February 2025 Meeting Minutes— On March 10, 2025, the Secretary of Defense directed a pause of all DoD Advisory Committees, including the Uniform Formulary Beneficiary Advisory Panel meeting (UF BAP). As a result, the UF BAP meeting is delayed, and the signing of the February 2025 P&T Committee meeting minutes will also be delayed.

B. Clarification of previous meeting minutes

- **Feb 2025**
 - **Wakefulness Promoting Agents—solriamfetol (Sunosi) Prior Authorization (PA) criteria**—it is not operationally feasible to solely have specialist criteria, therefore clinical PA criteria were added back to the PA.
 - **Ophthalmic: Dry Eye Agents—cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose)** – it is not operationally feasible to solely have specialist criteria, therefore clinical PA criteria were added back to the PA.
 - **Pain Agents: Topical—lidocaine 5% patch Tridacaine XL** – this product is supplied by a re-packing company and is not part of TRICARE pharmacy benefit.
 - **Narcotic Analgesics and Combinations Tramadol 75 mg PA criteria**—implementation occurred on May 30, 2025, using the P&T Committee Administrative Authorities.
- **November 2024**
 - **Hematological Agents—iptacopan (Fabhalta) PA criteria**—The criteria regarding previous medication history were updated to read the patient has not received immunosuppressants including corticosteroids or Filspari in the past 90 days (instead of 2 weeks), consistent with the clinical trial used to gain FDA approval for immunoglobulin A nephropathy.
 - **Targeted Immunomodulatory Biologics (TIBs): Interleukin IL-23 Inhibitors—ustekinumab (Stelara) 45 mg/0.5 mL single dose vials: Clarification of TRICARE Pharmacy Benefit Inclusion**—The Stelara 45 mg/0.5 mL vials are covered under the pharmacy benefit, as this formulation is intended for self-

administration. The 130 mg/26 mL single dose vials are labeled for IV infusion and are covered under the TRICARE medical benefit.

- **May 2024**
 - **Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound) PA criteria** – Minor changes were made to the PA form to collect information on body mass index ranges and comorbidities. No changes were made to the actual PA coverage criteria and the PA forms reflect the intent of the Committee as outlined at the May 2024 class review. The updates were implemented on April 11, 2025.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to Section 199.21(g)(5) of Title 32 Code of Federal Regulations (CFR) and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All pharmaceutical agents selected for complete exclusion status were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All pharmaceutical agents recommended for uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and complete exclusion status considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018, permanently codified at Section 1074g(a)(10) of Title United States Code (USC). Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, 10 USC 1074g(a)(9) requires beneficiaries to generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List formerly known as the Select Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

A. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses

Background—The Targeted Immunomodulatory Biologics (TIBs) class is comprised of several subclasses, including the tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab [Humira]) non-TNF inhibitors, and miscellaneous interleukin subclasses. The entire TIBs class was last reviewed at the August 2014 P&T Committee meeting and branded adalimumab (Humira) is currently step-preferred for most indications. Since the original review, 18 new drugs with multiple new mechanisms of action have entered the market. These newer agents have strong clinical evidence in specific

disease states. Two subclasses were reviewed at the November 2024 meeting, the interleukin (IL)-17s, and the IL-23s.

Biosimilar entrants have now entered the market for the originator tocilizumab (Actemra) formulation and are on the horizon for abatacept (Orencia). The advent of biosimilars is expected to reshape treatment options and create opportunities to participate in a Joint National Contract (JNC) with other Federal partners to align formularies for continuity of care and produce cost avoidance. Therefore, to address the growing complexity of the TIBs class, additional subclasses were created, the Interleukin-1 inhibitors (IL-1), Interleukin-6 inhibitors (IL-6), and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig).

The drugs in the subclasses include the following:

- IL-1: anakinra (Kineret), rilonacept (Arcalyst)
- IL-6: tocilizumab (Actemra), tocilizumab-aazg (Tyenne, a biosimilar for Actemra), sarilumab (Kevzara), satralizumab (Enspryng)
- CTLA4-Ig: abatacept (Orencia)

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, meta-analyses and systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1 Agents

- **anakinra (Kineret)** is indicated for rheumatoid arthritis (RA), cryopyrin-associated periodic syndromes (CAPS), neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA). There is substantial supporting evidence for off-label utilization for systemic juvenile idiopathic arthritis (sJIA), Adult-Onset Still's Disease (AOSD), familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells Syndrome (MWS), and recurrent pericarditis (RP). Despite carrying the FDA approval anakinra is not recommended by contemporary guidelines for use in RA. Limitations include frequent dosing intervals, requiring daily injections.
- **rilonacept (Arcalyst)** is indicated for CAPS, DIRA, FCAS, MWS, and RP. Most indications are approved for patients aged 12 and older, with the exception of DIRA which is indicated for use in infants weighing 10 kilograms (kg) or more. Limitations include lack of approval for more common disease states, including RA or JIA.

Interleukin-6 Agents

- **tocilizumab (Actemra, and the biosimilar Tyenne)** is FDA indicated for RA, pJIA, sJIA, giant cell arteritis (GCA), and systemic sclerosis-associated interstitial lung disease (SSc-ILD) which are available as part of the TRICARE pharmacy benefit. Indications available as IV infusions under the medical benefit include treatment of cytokine release syndrome

(CRS) and hospitalized patients with COVID-19 (C19). There is substantial off-label evidence for AOSD, neuromyelitis optica spectrum disorder (NMOSD), and polymyalgia rheumatica (PMR). Advantages include evidence to support use in young children, while limitations include multiple uses without formal FDA-approved labeling. Biosimilars are considered identical to the reference product for efficacy and safety, based on the conclusions from the August 2024 DoD P&T Committee meeting minutes' "Process for Evaluating Biosimilars and Biologics" section.

- *Biosimilars:* There are currently three FDA-approved biosimilars to the reference tocilizumab (Actemra). These include Tofidence, Tyenne, and Avtozma. Tofidence infusion is available under the TRICARE medical benefit. Tyenne has both a subcutaneous (SC) injection (available under the TRICARE pharmacy benefit) and a vial for infusion (available under the TRICARE medical benefit.) Avtozma is FDA-approved but had not launched at the time of the meeting and was not reviewed for formulary status. *(Refer to the November 2022 and August 2024 DoD P&T Committee meeting minutes for the "Process for Evaluating Biosimilars and Biologics" for additional information on biosimilars in TRICARE).*
- **sarilumab (Kevzara)** is indicated for RA, pJIA in patients two years of age or older and weighing at least 63 kg and is the only FDA-approved therapy for PMR.
- **satralizumab (Enspryng)** is indicated for treatment of neuromyelitis optica spectrum disorder in adult patients who are aquaporin-4 immunoglobulin G (AQP4-IgG) positive. Advantages include that it is the only FDA-approved outpatient medication for this indication. Disadvantages include approval for adults only and lack of approval or data in AQP4-IgG negative disease.

Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin Agents

- **abatacept (Orencia)** is indicated for RA, pJIA, and psoriatic arthritis (PsA) under the pharmacy benefit and under the medical benefit as an IV infusion for graft versus host disease (GVHD). Advantages include approval for use in pediatrics as young as two years old as well as the risk of causing less immunosuppression than the other TIBs. Disadvantages include a relatively lower level of efficacy per rheumatoid arthritis and psoriatic arthritis guidelines. Orencia additionally carries risk for unique side effects including cytomegalovirus (CMV) and Epstein-Barr virus (EBV), which was primarily seen in the studies for GVHD.
 - *Biosimilars:* Based on patent expiration, abatacept (Orencia) will likely have the next biosimilar within this subclass.

Rheumatoid Arthritis (IL-1s, IL-6s, and CTLA4-Ig)

- After failure of a TNF inhibitor, use of the IL-6s tocilizumab and sarilumab (Kevzara) are equally recommended in professional treatment guidelines. The CTLA4-Ig (abatacept) is also recommended after failure of other agents or in patients at very high risk of infections, specifically non-tuberculosis mycobacterium infections.
- Although anakinra (Kineret) is FDA-approved for rheumatoid arthritis, it is not mentioned or recommended in the RA guidelines by the American College of Rheumatology (ACR), European Alliance of Associations for Rheumatology (EULAR), or French rheumatoid arthritis guidelines

Polyarticular Juvenile Idiopathic Arthritis (IL-6, CTLA4-Ig)

- ACR guidelines recommend non-biologics including non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and methotrexate as first-line therapy. A biologic can be considered after failure of a non-biologic disease modifying antirheumatic drug (DMARD). These guidelines indicate a TNF inhibitor is the most commonly used biologic in children, and that all agents approved at the time of publication were equally recommended, including both the IL-6 tocilizumab and IL-1 abatacept.

Systemic Juvenile Idiopathic Arthritis, Adult-Onset Still's Disease (IL-1, IL-6)

- Literature within the space of systemic juvenile idiopathic arthritis (sJIA) and Adult-Onset Still's Disease (AOSD) is rapidly evolving. Newly published joint EULAR/PreS (Paediatric Rheumatology European Society) guidelines have combined these two, previously considered distinct, disease states into one disease called Still's Disease. These new guidelines recommend for patients without macrophage activation syndrome (MAS), early treatment with either anakinra, an IL-1, or tocilizumab, an IL-6 is clinically appropriate. For patients with MAS, the European guidelines indicate treatment with an IL-1 is preferred due to the amount of clinical experience by the guideline committee, specifically in those patients aged 16 years or older.
- ACR guidelines from 2021 for sJIA, prior to the European combination of the disease recommend early treatment of sJIA with anakinra, an IL-1, or tocilizumab, an IL-6 as clinically appropriate for patients with or without MAS.
- Tocilizumab is FDA-approved for treating sJIA, while anakinra (Kineret) is approved by the European Medicines Agency (EMA) for treating Adult-Onset Still's Disease. This EMA approval and guideline statement recommending IL-1 therapy over IL-6 therapy is likely reflective of the approval status of anakinra in Europe. Based on the published literature and guidelines, it is unclear whether therapy with anakinra or tocilizumab is more safe or efficacious than the other at this time.

Psoriatic Arthritis (CTLA4-Ig)

- Various guidelines for psoriatic arthritis recommend TNF-inhibitors, IL-23 inhibitors and IL-17 inhibitors as first-line. Contemporary guidelines from both the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis

(GRAPPA) and EULAR list abatacept (Orencia) as an option only after failure of one or more other targeted therapies due to limited efficacy.

Neuromyelitis optica spectrum disorder (IL-6)

- Satralizumab (Enspryng) is the only FDA-approved pharmacy benefit drug approved for treating adult patients with AQP4-IgG positive NMOSD. There are several additional medical benefit products, including eculizumab (Soliris), ravalizumab (Ultomiris) and rituximab (Rituxan and biosimilars) which are labeled for NMOSD. Additionally, tocilizumab has substantial evidence for efficacy and safety in treating AQP4-IgG positive and negative NMOSD, despite lack of formal FDA-approval.
- A systematic review evaluating safety and efficacy of IL-6 therapy with either satralizumab or tocilizumab was published in 2021, but included studies published prior to the FDA-approval of satralizumab for NMOSD. It concluded that both tocilizumab and satralizumab were effective at decreasing the annualized relapse rate in NMOSD. Additionally, tocilizumab, but not satralizumab, significantly improved both pain and fatigue compared to placebo. Adverse events were similar between the two agents.

Polymyalgia Rheumatica (IL-6)

- Guidelines for polymyalgia rheumatica (PMR) are outdated and were last published in 2015. The British Society of Rheumatology is currently working on an update with an anticipated 2025 release. The scoping document states both tocilizumab and sarilumab have data in new-onset and refractory PMR. Sarilumab (Kevzara) is the only FDA-approved biologic pharmacy benefit drug for treating patients with PMR but does not carry this labeling in Europe or the UK.
- There are ongoing studies for additional treatment mechanisms for PMR and a closely related condition, giant cell arteritis (GCA). Tocilizumab is FDA-approved for GCA, and Rinvoq, a JAK inhibitor not included in this review, recently gained FDA approval for this indication.

Recurrent Pericarditis (IL-1)

- Rilonacept (Arcalyst) is the only FDA-approved biologic pharmacy benefit item for treating patients aged 12 years and older with recurrent pericarditis. Arcalyst was not yet under broad investigation during the most recent recurrent pericarditis guideline update from 2015. Guidelines at that time from the European Society of Cardiology (ESC) recommended the standard of care including NSAIDs, colchicine, and corticosteroids. The ESC guidelines also recommended anakinra (Kineret) as a category IIB level of evidence. It is unknown when the guidelines will be updated to include Arcalyst.
- Since the publication of the 2015 ESC guidelines, both anakinra (Kineret) and rilonacept (Arcalyst) have completed additional clinical trials demonstrating their effectiveness in decreasing instances of recurrence and increasing time to recurrence. One published study continues to recommend either anakinra

(Kineret) or rilonacept (Arcalyst) for the treatment of colchicine-refractory recurrent pericarditis (2021 Journal of the American Heart Association).

Safety

- Published clinical practice guidelines do not make a distinction among individual IL-1, IL-6, or CTLA4-Ig agents in terms of safety, with the distinction of abatacept (Orencia) as potentially preferred if the patient has a history of non-tuberculosis mycobacterium infection.
- Noted adverse events for all the products include hypersensitivity risk, increased risk of infections including tuberculosis, injection site reactions, and warnings against concurrent use of live vaccines. IL-6 agents all carry the additional risk for hepatotoxicity and gastrointestinal perforation. Unique safety concerns were discussed with the individual product summaries.
- A review of the package inserts, guidelines, and other published literature of the adverse events with IL-1, IL-6, and CTLA4-Ig found the following:
 - The most common adverse drug reactions across all therapies included injection site reactions, infections, nasopharyngitis or upper respiratory tract infection, and headaches.
 - Overall, agents within this subclass appear well-tolerated with acceptable safety profiles.

Other Factors

- Special populations:
 - The agents are generally considered safe during the pregnancy planning phase but are discontinued once pregnancy is confirmed. There is no compelling evidence that one IL-1, IL-6, or CTLA4-Ig should be preferred over another during pregnancy. TNF inhibitors are also considered safe and effective in pregnancy.
 - All agents are approved for use in the pediatric patient population with the exception of satralizumab (Enspryng), based on FDA-labeling.
- Provider opinion:
 - Military Health System (MHS) rheumatologists voiced that a TNF inhibitor should remain first-line for RA and pJIA, while subsequent therapy with an IL-6, CTLA4-Ig, or a JAK inhibitor is appropriate based on patient characteristics. Pediatric providers are more likely to utilize tocilizumab for pJIA rather than sarilumab (Kevzara), due to the minimum weight requirement with Kevzara. Providers did note that SC administration of abatacept (Orencia) is less effective than other choices.

- For treatment of psoriatic arthritis, providers were in agreement that abatacept was less effective than drugs with other mechanisms of action. Providers were supportive of the requirement to utilize an IL-17 prior to use of a CTLA4-Ig for treatment of psoriatic arthritis.
- For treatment of Still's Disease, encompassing both systemic JIA and AOSD, rheumatologists were highly supportive of increasing access to both the IL-1 anakinra (Kineret) and the IL-6 tocilizumab as first-line agents. The providers agreed that a step requirement was not appropriate due to the multitude of patient factors, including those currently stabilized on therapy.
- Ophthalmologists and neuroimmunologists relayed opinions on using tocilizumab and satralizumab (Enspryng) for NMOSD and MOGAD. While feedback was mixed on the use of tocilizumab in adults, for the pediatric population there was full support for utilizing tocilizumab as the preferred outpatient therapy for NMOSD as it is useful in both AQP4-Ig positive and negative disease, as well as MOGAD. Since Enspryng is the only FDA-approved agent for this condition, a step requirement was not recommended.
- MHS rheumatologists were supportive of increasing options for evidence-based treatment of polymyalgia rheumatica. At this time, only sarilumab (Kevzara) carries the FDA-approved labeling for this condition, however other agents, including tocilizumab are used off-label, therefore a step requirement was not recommended.
- For treatment of recurrent pericarditis, providers were in agreement with increasing access to multiple treatment options. Rilonacept (Arcalyst) is the only FDA-approved biologic treatment, however older guidelines and current treatment algorithms recommend therapy with either anakinra (Kineret) or rilonacept (Arcalyst). Due to off label utilization of anakinra, a step requirement was not recommended.

Overall Conclusion

- Based on FDA indication and published guidelines it is reasonable to continue to require a trial of Humira first for many rheumatologic diseases including rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, consistent with the previous class review in 2014.
- Biosimilars are interchangeable to the reference product. Market launch of tocilizumab biosimilars in 2024 provides an opportunity for contracting initiatives with other Federal agencies via a Joint National Contract. Abatacept (Orencia) is the next biosimilar expected to enter the market.

- Within the subclass, when the agents are compared to one another, there are no compelling differences in efficacy and safety. Individual patients may show variability in response to different agents.
- Provider feedback overwhelmingly supported increasing accessibility to several agents, including optimizing PA pathways to allow off-label indications for which these medications are considered standard of care.
- For clinical coverage, at least one IL-1, IL-6, and CTLA4-Ig agent is needed on the formulary to cover each indication of RA, pJIA, and Still's Disease (sJIA, AOSD) to meet the needs of MHS beneficiaries. Additional options should be considered to provide more choices for providers based on individual patient characteristics.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1s, Interleukin-6s, Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin

- CMA results showed that the formulary placement of tocilizumab (Tyenne) as UF and step-preferred was cost-effective.
- BIA and sensitivity results showed cost avoidance by designating Tyenne as step-preferred and all the other IL-1s, IL-6s, and CTLA4-Ig as non-step-preferred.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended for the IL-1, IL-6s, and CTLA4-Igs (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF and step-preferred
 - IL-6: tocilizumab-aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*
- UF and non-step-preferred
 - IL-1: anakinra (Kineret) *moves from NF non-step-preferred to UF non-step-preferred*
 - IL-6: sarilumab (Kevzara) *moves from NF non-step-preferred to UF non-step-preferred*
- NF and non-step-preferred
 - IL-6: tocilizumab (Actemra)
 - CTLA-4Ig: abatacept (Orencia)
 - IL-1: rilonacept (Arcalyst) *moves from UF to NF non-step-preferred*

- IL-6: satralizumab (Enspryng) *moves from UF to NF (no step required)*
- Complete Exclusion: None
- Note, as part of this recommendation a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, and CTLA4-Ig products in all new patients, depending on the clinical indications.
- Enspryng is not subject to the step therapy requirements for its indication of NMOSD.

2. COMMITTEE ACTION: MANUAL PA CRITERIA—Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updated manual and step therapy PA criteria for the IL-1, IL-6, and CTLA4-Ig products as outlined below. See Appendix C for the full criteria.

- *General Changes:*
 - Updating the step therapy requirements as outlined in the formulary recommendation and adding new indications as necessary.
 - Streamlining the list of medications that should not be used concurrently by drug classes rather than individual agents (new medications, biosimilars).
- *IL-1s:* Current PA criteria for the IL-1s require a trial of Humira first for all overlapping indications. The recommended PA changes for the IL-1s include the following:
 - For Kineret, which is now the UF non-step-preferred IL-1, clarifying that a trial of Tyenne and Humira are both required for rheumatoid arthritis only, unless the patient has had an inadequate response, contraindication or adverse reaction to Humira and Tyenne. Neither Humira nor Tyenne will be required prior to Kineret for non-RA indications. The indications for recurrent pericarditis and chronic infantile neurological cutaneous and articular (CINCA) disease will be added.
 - For Arcalyst, a trial of Kineret is now required first for treatment of deficiency of interleukin receptor 1 antagonist (DIRA). Rheumatologists will also be able to prescribe Arcalyst for recurrent pericarditis, in addition to cardiologists. Kineret is not required prior to use of Arcalyst for recurrent pericarditis.
- *IL-6s:* For the IL-6 agents, currently Humira is required first for all overlapping indications. The recommended PA changes include the following:

- For Tyenne, which is now UF step-preferred, an automated drug lookback for utilization of either Humira or Actemra will be added. New indications for Still's Disease, polymyalgia rheumatica (PMR), neuromyelitis optica spectrum disorder (NMOSD), and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) were added to the PA form.
- For Actemra, which is the NF non-step-preferred tocilizumab product, all new and current users will be required to move to Tyenne. The current automated Humira lookback will be removed. A trial of Tyenne will be required for all indications, and a trial of Humira will be required for appropriate indications. All new and current users of Actemra and the other tocilizumab biosimilars (when they are marketed) will require a trial of Tyenne first.
- For Kevzara, which moves to UF non-step-preferred status, a trial of Tyenne will be added for the conditions of RA and pJIA; the Humira step requirement will remain.
- Enspryng will not be subject to step-therapy requirements as there are currently no overlapping FDA-approved indications with either Humira or Tyenne. Any future indications that may overlap with Humira or Tyenne will require step-therapy. Documentation will now be required to demonstrate aquaporin-4 immunoglobulin G (AQP4-IgG) positivity.
- *CTLA4-Igs*: For the CTLA4-Ig agents, currently Humira is required first for all indications. The recommended PA changes include the following:
 - Orencia will maintain the requirement for a trial of Humira first. A Tyenne step will be added for rheumatoid arthritis and pJIA. A trial of the IL-17 ixekizumab (Taltz) will be added for adult psoriatic arthritis. The automated drug lookback for Humira will be removed. The PA changes will apply to new users.
 - Biosimilars for the CTLA4-Ig Orencia are expected to launch in 2026. This will allow formulary addition of a cost effective abatacept product in a future review.
- 3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) new MN criteria for Enspryng and Arcalyst, and updated MN criteria for Actemra and Orencia. See Appendix B.
- 4. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs of a 60-day supply at all points of service for all the drugs in the subclass. See Appendix D.

5. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining all the drugs in the subclass on the Specialty Drug List and TRICARE Maintenance Drug List, if feasible. See Appendix F for the TRICARE Maintenance Drug List details.
6. **RAPID RESPONSE**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) adding satralizumab (Enspryng) and rilonacept (Arcalyst) to the Rapid Response (Safety Net program) maintained by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.
7. **COMMITTEE ACTION: UF, PA, MN, QLs, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, , RAPID RESPONSE and IMPLEMENTATION PERIOD**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving Enspryng and Arcalyst who will be affected by the formulary status change and to beneficiaries receiving Actemra due to the PA changes affecting both new and current users. See Appendix G.

B. Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the CDK inhibitor subclass used for advanced or metastatic hormone receptor-positive (HR(+)), human epidermal growth factor receptor 2-negative (HER2(-)) breast cancer. The drugs in the class include abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali). The drugs were last reviewed for formulary status in February 2021. Since the last review, the formulation of ribociclib co-packaged with the aromatase inhibitor letrozole (Kisqali Femara Co-Pack) has been removed from the market. Updates to clinical practice guidelines and FDA-approved indications were reviewed.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 1 abstained, 0 absent) the following:

Efficacy

- A comprehensive review of the evidence shows that each CDK inhibitor offers a statistically and clinically significant advantage in median progression free survival and objective response rate (ORR) relative to the respective controls used in the individual clinical trials.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) both provide a statistically and clinically significant advantage in invasive disease-free survival (iDFS), relative to the respective controls used in the individual clinical trials for

early breast cancer treatment. This is a new indication for both agents that was not present in the prior class review.

- There are no high-quality head-to-head trials available directly comparing one CDK inhibitor with another.

Professional Treatment Guidelines

- The National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines recommend abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali) in the treatment of advanced or metastatic HR(+)/HER2(-) breast cancer as preferred first-line, second-line, or subsequent therapy. In the NCCN Guidelines, all agents carry a Category 1 recommendation in specific settings.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) are now also recommended in the setting of early breast cancer. Both agents carry the same level of recommendations in this setting by the NCCN and ESMO Guidelines.
- Other guidelines (e.g., American Society of Clinical Oncology, European Society for Medical Oncology) are in agreement with one another and make no distinction in the choice of a particular agent. Each CDK inhibitor has the same preference and strength of recommendation.

Safety

- There is no one clearly superior CDK inhibitor in terms of safety or tolerability.
- The safety profiles of the CDK inhibitors overlap, however, there are unique adverse events associated with each agent. Hematologic adverse events (e.g., neutropenia, anemia, and thrombocytopenia) are considered class effects.
 - Palbociclib (Ibrance) has the highest rate of thrombocytopenia.
 - Abemaciclib (Verzenio) has a higher relative risk for diarrhea and unique warnings for venous thromboembolism (VTE).
 - Ribociclib (Kisqali) has a higher relative risk for QT interval prolongation.

Overall Clinical Conclusion

- Treatment choice in HR(+)/HER2(-) advanced or metastatic breast cancer depends on several factors, including the safety profile of the individual CDK inhibitor, comorbidities, and disease burden.

Relative Cost Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that ribociclib, abemaciclib and palbociclib were all cost-effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating all CDK inhibitors as UF demonstrated significant cost avoidance for the MHS.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following.

- UF
 - abemaciclib (Verzenio)
 - palbociclib (Ibrance)
 - ribociclib (Kisqali)
- NF – none
- Complete Exclusion – none

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**— Manual PA currently apply to all three CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) streamlining the criteria by removing questions on detailed indication criteria, removing the safety and monitoring questions, and standardizing the verbiage for updates to NCCN criteria, consistent with the actions taken for other oncology drug PA criteria. See Appendix C for the full criteria.

3. **COMMITTEE ACTION: QLs**—QLs currently apply to the class. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining a 28 day supply QL at all points of service for Ibrance, Verzenio, and Kisqali. See Appendix D.

4. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining Ibrance, Verzenio and Kisqali on the both lists. See Appendix F for the TRICARE Maintenance Drug List details.

5. **COMMITTEE ACTION: UF, PA QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS and IMPLEMENTATION PERIOD**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G.

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

The products were divided into two groups when presented at the DoD P&T Committee meeting. The generic names are included below. Group 1 included Zunveyl, Alhemo, Inzirco, Xromi, Prevymis, Gomekli, Raldesy, and six ustekinumab biosimilars (Steqeyma, Otulfi, Pyzchiva, Yesintek, Selarsdi, and an ustekinumab-ttwe unbranded private label). Group 2 included Journavx, Vykat extended release (XR) and Romvimza.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 16 for, 0 opposed, 1 abstained, and 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 2025 DoD P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the TRICARE Maintenance Drug List.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
 - concizumab-mtci (Alhemo) – Antihemophilic Agents
 - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
 - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
 - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection
 - mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
 - suzetrigine (Journavx) – Pain Agents
 - ustekinumab-aaaz (Otulfi) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors; biosimilar for Stelara
 - ustekinumab-stab (Steqeyma) – TIBs IL-23s; biosimilar for Stelara
 - vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor
- NF
 - hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirco) – Diuretic Agents
 - trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor

- ustekinumab-ttwe (Pyzchiva) – TIBs IL-23s; biosimilar for Stelara
- ustekinumab-kfce (Yesintek) – TIBs IL-23s; biosimilar for Stelara
- ustekinumab-aekn (Selardsi) – TIBs IL-23s; biosimilar for Stelara
- Complete Exclusion
 - ustekinumab-ttwe (unbranded private label) – TIBs IL-23s; biosimilar for Stelara by Quallent
 - The ustekinumab-ttwe private label brand was recommended for complete exclusion status as it has little to no clinical benefit relative to other ustekinumab biosimilars, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include ustekinumab-auub (Wezlana), ustekinumab-aaaz (Otulfi), ustekinumab-stab (Steqeyma), and ustekinumab (Stelara).
 - benzgalantamine (Zunveyl) – Alzheimer’s Agents
 - Zunveyl was recommended for complete exclusion status as it has little to no clinical benefit relative to the other Alzheimer’s Agents, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include galantamine, galantamine ER and donepezil.

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Inzirco, Raldesy, Pyzchiva, Yesintek, and Selardsi. See Appendix B for the full criteria.

3. **COMMITTEE ACTION: PA CRITERIA**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria. See Appendix C for the full criteria.

- Applying manual PA criteria to new users of the UF ustekinumab products Otulfi and Steqeyma, similar to what is required for all non-step-preferred Interleukin-23 inhibitors, where a trial of adalimumab (Humira) will be required first. These products are non-step-preferred.
 - For the NF ustekinumab products Pyzchiva, Yesintek, and Selardsi, the PA will also apply to new users and require a trial of Humira, plus a trial of all the UF ustekinumab products. These products are non-step-preferred.

- Additionally, PA criteria will apply to unbranded ustekinumab-ttwe, until implementation of the complete exclusion status. Providers will need to document why the unbranded product is required, rather than using the UF and NF ustekinumab products.
 - Applying manual PA criteria to new users of Alhemo, similar to the PA requirements for other hemophilia agents.
 - Applying temporary manual PA criteria to new users of Zunvey1, until implementation of complete exclusion status.
 - Applying manual PA criteria to new users of Vyk1t XR, Xromi, Gomekli, Inzirqo, Raldesy, and Romvimza.
4. **COMMITTEE ACTION: QLs**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent QLs for Alhemo, Vyk1t XR, Prevymis, Gomekli, Journavx, and the six ustekinumab biosimilars. See Appendix D for the QLs.
5. **COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent – all Group 1 agents) adding Zunvey1, Gomekli, Otufli, Steqeyma, Pyzchiva, Selardsi, Yesintek, and ustekinumab-ttwe (unbranded) to the Rapid Response program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill after the initial reject.
6. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List which includes the NF medications subject to the TMOP requirement. Drugs recommended to be added to the Specialty Drug List are listed in Appendix E.
7. **COMMITTEE ACTION: UF, MN, PA, QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, and IMPLEMENTATION PERIOD**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:
- **New Drugs Recommended for UF and NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.
 - **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service; and 2) DHA will send letters to

beneficiaries who are affected by the complete exclusion status at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

- a) **Anti-infectives: Anthelmintics—mebendazole (Emverm)**—Emverm is indicated to treat a variety of parasitic worm infections. The price of Emverm has increased exponentially in recent years and some commercial health plans require a PA for Emverm. MTF providers support the addition of a PA restricting use to parasitic indications and requiring a step of over-the-counter (OTC) pyrantel pamoate, ivermectin, or albendazole. Off-label uses for indications other than parasitic infections will not be allowed.
- b) **Keratolytics—urea 41% cream**—Topical urea is used as a moisturizer and keratolytic and is available in a variety of strengths including 10%, 20%, and 40%. The 41% strength is notably not cost-effective. The committee recommended PA criteria requiring providers to explain why the 41% strength is needed.
- c) **Endocrine Agents Miscellaneous: Antihyperglycemic-Glucocorticoid Receptor Blocker—mifepristone (Korlym)**—Korlym is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym is more costly than other alternatives used to treat Cushing's syndrome. A manual PA was recommended for Korlym to restrict use to its FDA-approved indication in new and current users, to require prescribing by an endocrinologist, and a trial of at least one other agent for Cushing's syndrome in new users. MTF providers supported establishment of PA criteria.
- d) **Leukotriene Modifying Agents—zileuton (Zyflo), zileuton ER generic**—Zileuton is indicated to treat asthma and is less cost-effective than other agents in the class. Hepatic monitoring is required for zileuton due to liver function test elevations. A manual PA affecting new and current users was recommended requiring a trial of montelukast (generic Singulair) and zafirlukast (generic Accolate) first, due to safety concerns. Zyflo will be added to the Rapid Response/Safety Net program, which will provide additional outreach to beneficiaries who have not received a prescription after an initial PA reject.

COMMITTEE ACTION: NEW PA CRITERIA AND

IMPLEMENTATION PERIOD—The P&T Committee recommended

(17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Emverm in new users and for urea 41% cream, Korlym, and zileuton in new and current users. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients currently receiving urea 41%, Korlym, zileuton IR and zileuton ER. See Appendix C for the full criteria.

2. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for two recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for the newly approved drug reviews and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

- a) **Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet—** Numerous other more cost-effective generic metformin IR and ER tablets are available.
- b) **Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet—** There are other tramadol formulations available, including tramadol 50 mg tablets, that are more cost-effective than this 100 mg strength.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for metformin 750 mg IR tablets and tramadol 100 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA and MN Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- a) **Miscellaneous Metabolic Agents—setmelanotide (Imcivree)—** The manual PA criteria were expanded to include children 2 years of age and older with certain syndromic or monogenic forms of obesity.
- b) **Immunological Agents Miscellaneous: Oral Agents—house dust mite allergen extract (Odactra)—** The manual PA criteria were expanded to include children ages 5 to 11 years old.

- c) **TIBs: IL-23— guselkumab (Tremfya)**—Tremfya is now indicated for the treatment of Crohn’s Disease in adults. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the Ulcerative Colitis criteria for this drug.
- d) **Leukemia and Lymphoma Agents: BTK Inhibitors—acalabrutinib (Calquence)**—The manual PA criteria were updated to allow for treatment of a subset of previously untreated mantel cell lymphoma patients.
- e) **Oncological Agents: Lung Cancer—sotorasib (Lumakras)**—Lumakras received a new indication for KRAS G12C-mutated metastatic colorectal cancer. The manual PA was updated to include this indication and require coadministration with panitumumab in patients who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy based on the FDA label. Additionally, edits were made to match the recent changes in other oncology PAs as part of the ongoing oncology standardization process.
- f) **Diabetes Non-Insulin: GLP-1RAs—semaglutide (Ozempic)**—Semaglutide under the trade name Ozempic is now indicated to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, and cardiovascular death in adults with chronic kidney disease and type 2 diabetes. Current treatment guidelines recommend a renin angiotensin system inhibitor (ACE inhibitor or angiotensin receptor blocker) and sodium-glucose co-transporter 2 (SGLT-2) inhibitor. The Ozempic PA and MN criteria were updated to require use of the cost effective guideline-recommended therapies first.
- g) **Diabetes Non-Insulins: GLP-1RAs – semaglutide (Ozempic) and tirzepatide (Mounjaro) MN criteria**—The MN criteria for the NF diabetic GLP1-RAs was updated to include that the patient has tried and failed dulaglutide (Trulicity), based on provider feedback.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic in new users, and recommended (17 for, 0 opposed, 0 abstained, 1 absent) the MN updates for the diabetic GLP-1RAs Ozempic and Mounjaro in new users. Implementation for the MN criteria updates for the diabetic GLP-1RAs will be effective on signing, and implementation for the new PA criteria for the agents listed above will be effective the first Wednesday 60 days after the signing of the minutes. See Appendices B and C for the full criteria.

4. Updated PA and MN Criteria for Reasons other than New Indications

Updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

- a) **Corticosteroids-Immune Modulators: Atopic Dermatitis—crisaborole (Eucrisa)**—An age edit was added allowing patients two years of age and younger to bypass the PA as other non-steroid treatments are only approved for children older than age two.
- b) **Antigout Agents: Chronic—febuxostat (Uloric)**—An automated drug lookback for allopurinol 300 mg was added to the Uloric PA. Patients with a prescription claim for allopurinol in the past 180 days will bypass the Uloric PA. In addition, the safety questions were removed.
- c) **Oncological Agents—fedratinib (Inrebic), selumetinib (Koselugo), pomalidomide (Pomalyst), ripretinib (Qinlock), midostaurin (Rydapt), capmatinib (Tabrecta), tepotinib (Tepmetko), pexidartinib (Turalio), quizartinib (Vanflyta), larotrectinib (Vitrakvi), dacomitinib (Vizimpro), and gilteritinib (Xospata)**— Updates were made as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for National Cancer Care Network (NCCN) guideline updates. For more details on oncology PA standardization, please refer to the November 2024 meeting minutes. Additionally, the PA for Pomalyst was updated to add the Kaposi Sarcoma indication.
- d) **Metabolic Agents Miscellaneous—odevixibat (Bylvay) and maralixibat (Livmarli)**—Bylvay and Livmarli are FDA-approved to treat pruritus due to progressive familial intrahepatic cholestasis or Alagille syndrome. The drugs treat the pruritic symptoms, but do not change the underlying disease course. Both drugs were reviewed as innovators and were designated as NF with a PA requiring a trial of five other generic, well-established agents first. Bylvay and Livmarli are not yet included in professional treatment guidelines. Based on a review of MHS prescription claims, the PA will expand the options to the six drugs included in the current treatment guidelines, but only require a trial of three products first, prior to Bylvay or Livmarli. Other updates included standardizing the new nomenclature for non-alcoholic fatty liver disease (NAFLD), now known as metabolic dysfunction-associated steatotic liver disease (MASLD).
- e.) **Antipsychotic Agents: Parkinson's Psychosis—pimavanserin (Nuplazid)**—Nuplazid will now require a trial of clozapine first, unless the patient has a contraindication, intolerance to, or has failed treatment with clozapine. The reasons for the clozapine step are due to removal of the previous clozapine Risk Evaluation and Mitigation System (REMS) program, network meta-analysis data supporting its use before Nuplazid, and provider feedback supporting using Nuplazid as a later-line agent. Additionally, clozapine is more cost-effective than Nuplazid.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vitrakvi, Vizimpro, Xospata, Bylvay, Livmarli, and Nuplazid in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

5. Removal of PAs

- a) **Multiple Sclerosis Agents: Methyl Fumarate—dimethyl fumarate (Tecfidera)**—Tecfidera is designated as UF. Generic formulations of Tecfidera are now available and dimethyl fumarate is the most cost-effective methyl fumarate agent. The Tecfidera PA will be removed for these reasons.
- b) **Alzheimer’s Agents—memantine ER (Namenda XR)**—Currently, memantine IR (Namenda) is designated as UF while memantine ER (Namenda XR) is designated as NF with a PA. Namenda XR is administered once daily and is available as a generic. Due to clinical and cost considerations, the PA will be removed for Namenda XR, but Namenda XR will remain as NF.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for Tecfidera and Namenda XR. Implementation will be effective the first Wednesday two weeks after signing of the minutes.

B. Quantity Limits

- 1. **Anti-infectives: Anthelmintics—mebendazole (Emverm)**—QLs of 12 tablets per 30 days, with no refills allowed, were recommended for Emverm. The QLs will allow for two treatment courses at the FDA-labeled dosing regimen. Infectious Disease specialists will be able to bypass the QL if the prescription is used to treat parasitic infections.

COMMITTEE ACTION: EMVERM QLs and IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding QLs for Emverm. Implementation will occur the first Wednesday two weeks after signing of the minutes. See Appendix D.

C. Line Extensions

The P&T Committee clarified the formulary status for two product line extensions by the original manufacturer. Line extensions have the same FDA indication(s) as the “parent” drug and retain the same formulary and copayment status as the “parent” drug.

1. **Neurological Agents Miscellaneous**—designating **risdiplam (Evrysdi) tablet** with the same formulary status (UF), PA, and Specialty drug list as the parent Evrysdi solution. However, the current QL for the solution is 36 days' supply at all points of service (POS); for the tablet it will be 30 tablets for 30 days at all POS. See Appendix D.
2. **Continuous Glucose Monitoring (CGM) Systems: Therapeutic CGM Systems**—designating **Dexcom G7 15 Day Sensor** with the same formulary status (UF), PA, and QL as the Dexcom G7 Sensor. The QLs will be adjusted as the Dexcom G7 Sensor lasts 10 days and the new sensor lasts 15 days. The QL will be 2 sensors/30 days at retail and 6 sensors/90 days at MTF and TMOP. The PA will be adjusted to reflect the FDA approved age of the new sensor (18 years of age or older). The committee also voted to add the Dexcom G7 15 Day Sensor to the TRICARE pharmacy benefit. See Appendices C and D.

COMMITTEE ACTION: LINE EXTENSION, ADDITION OF DEXCOM G7/15 DAY SENSOR TO THE BENEFIT AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, MN, and Specialty and TRICARE Maintenance Drug Lists status for Evrysdi tablet and Dexcom G7 15 Day Sensor. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR ADDITION FOR SACUBITRIL/VALSARTAN (ENTRESTO)

Renin-Angiotensin Antihypertensives: Combinations—Sacubitril/valsartan (Entresto) tablets are designated as UF without a PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, the branded Entresto tablets will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. The Tier 1 copay for brand Entresto is recommended.

COMMITTEE ACTION: ENTRESTO BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) requiring brand Entresto tablets over the generics in new users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Entresto tablets. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

VIII. WEIGHT LOSS DRUGS REGULATORY AND STATUTORY REQUIREMENTS, AND PA UPDATE

The P&T Committee reviewed utilization and cost trends for the weight loss drugs, which are covered under the TRICARE Pharmacy benefit based on an Interim Final Rule published on September 29, 2017, (DOD-2017-HA-RIN 0720). The Final Rule authorizes coverage for

TRICARE Prime and TRICARE Select beneficiaries for medically necessary treatment of obesity, even if it is the sole or major condition treated when prescribed by a network provider. Obesity drugs were added to the TRICARE pharmacy benefit at the November 2017 P&T Committee meeting.

A. Regulatory and Statutory Requirements

The PA criteria for the weight loss drugs were updated to explicitly define which TRICARE beneficiaries are eligible to receive a weight loss drug and to clarify that weight loss drugs must be prescribed by network providers. The revised PA criteria will apply to the older amphetamine derivatives (phentermine, benzphetamine, diethylpropion, and phendimetrazine IR and SR), phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), phentermine 8 mg (Lomaira), orlistat (Xenical) and the injectable glucagon-like peptide-1 receptor agonists (GLP1-RAs) liraglutide (Saxenda), semaglutide (Wegovy), and tirzepatide (Zepbound).

The following statements will be added to the PA criteria for all the weight loss drugs, to ensure alignment with statutory and regulatory requirements. The changes will apply to all new and current users and will be implemented immediately following patient notification.

1. The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge.”
2. Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan? If the answer is “no” then coverage will be denied. Affirmative answers are subject to verification.
3. What TRICARE plan is the patient enrolled in? For more information see <https://tricare.mil/Plans/HealthPlans>. TRICARE Select and TRICARE Prime will be approved. Other TRICARE health plan enrollment that is not TRICARE Select or TRICARE Prime will not be approved. If the patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, the provider should consider these alternatives.

See Appendix C for the updates noted above. PA criteria are not currently in place for the amphetamine derivatives, therefore new PA criteria with the above three questions will apply for phentermine, benzphetamine, diethylpropion and phendimetrazine IR and SR.

A plan edit will apply for all weight loss drugs; coverage is not approved for Non-TRICARE Prime or Non-TRICARE Select patients.

B. PA Updates for the Weight Loss Drugs – Comprehensive Lifestyle Intervention

The current PA criteria for the weight loss drugs was reviewed. The Committee recommended adding to the PA criteria that the patient has had verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of

weight management: diet, physical activity, and behavioral changes on both treatment initiation and annual renewal. This will apply to all drugs in the class.

COMMITTEE ACTION: PA CRITERIA TO REQUIRE COMPREHENSIVE LIFESTYLE INTERVENTION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) to require documentation of verifiable participation in a comprehensive lifestyle intervention (including dietary, exercise and behavioral health programs) for all new users and for all current users on the annual PA renewal period for all the weight loss drugs. Implementation will occur the first Wednesday 60 days after signing of the minutes in all three points of service. See Appendix C.

IX. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

The P&T Committee reviewed one drug from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; this drug was not in compliance with FY08 NDAA, Section 703, permanently codified at 10 USC 1074g(f). If a drug is not compliant, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail point of service (POS) and medical necessity at MTFs.

A. COMMITTEE ACTION: DRUGS DESIGNATED NF—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) that the Section 703 non-compliant national drug code numbers (NDCs) of the following product remain designated as NF on the UF:

- Wokhardt: bupropion extended release 450 mg (*New Drug Application-NDC 64679-0830-01*) authorized generic for Forfivo XL

B. COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs:

1. Use of the formulary alternatives are contraindicated. The formulary alternatives include bupropion immediate release, sustained release and extended-release generic and Forfivo XL 450 mg.
2. Obtaining the product by home delivery would be detrimental to the patient.

These pre-authorization criteria do not apply to any other point of service other than retail network pharmacies.

C. COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the MN criteria currently in place for Forfivo XL. See Appendix B for the full criteria.

COMMITTEE ACTION: IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes for the non-compliant NDCs and

that DHA send letters to the affected beneficiaries. After the pricing agreement is signed, this drug will be automatically returned to the previous formulary status.

X. DoD P&T COMMITTEE ADMINISTRATIVE AUTHORITY

Background—The Administrative Authorities document outlines which P&T Committee functions can be performed administratively prior to the quarterly meeting, and subsequently presented to the P&T Committee for formal recommendation; those functions which require both Uniform Formulary Beneficiary Advisory Panel (UF BAP) and Director, DHA review; and those which solely require Director, DHA review and do not fall under the purview of the UF BAP panel. The administrative authorities document was most recently updated at the February 2025 P&T Committee meeting.

Recommendation—Terminology included in the new Specialty program and TPharm 5 contract language has prompted an update to the Administrative Authorities document. Changes include removing outdated language and updating to current terms: the specialty agent reporting list to the TRICARE Specialty Drug List; Tier 4 to “complete exclusion”; changing from the Expanded MTF Mail Pharmacy Initiative ("EMMPI") or the maintenance medication list to "TRICARE Maintenance Drug List"; and changing to Retail Pharmacies from "Retail Network Pharmacies"

Justification—The changes will align with updated terminology.

COMMITTEE ACTION: P&T COMMITTEE ADMINISTRATIVE AUTHORITY UPDATE

—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) to update the Administrative Authorities document to as outlined above, including modifications based on the Specialty program and TPharm5 terminology changes. See Appendix H, page 81.

XI. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

- A. Annual Utilization Management Review:** The Committee reviewed a summary of 164 UM actions from the four P&T Committee meetings held in FY2024 (November 2023 to August 2024). A focused review of actions showed that there were more PA removals than additions. Additionally, specialist provider bypass was highlighted as a new tool to decrease provider administrative requirements for PAs. The Committee reviewed analysis of the effects of PAs on MHS utilization and spend.
- B. Therapeutic Interchange:** The P&T Committee discussed how the direct care network could optimize current utilization management through formal therapeutic interchange recommendations for MTF providers to MTF pharmacies.
- C. Medications used in the treatment of Gender Dysphoria:** The P&T Committee was notified of the changes to coverage of Gender Dysphoria for minors and for initiation of therapy for active duty as directed by law, executive order, regulation, and direction from DoD leadership.

- D. Oncological Agents – Second Generation Anti-Androgens darolutamide (Nubeqa)**—The P&T Committee briefly evaluated the prostate cancer medications and no updates to the Nubeqa PA were recommended at this time.

XII. ADJOURNMENT

The meeting adjourned at 1430 hours on May 8th. The next meeting will be in August 2025.

Appendix A—Attendance: May 2025 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary during the May 2025 DoD P&T Committee Meeting

Appendix G—Implementation Dates

Appendix H—Drugs with Complete Exclusion Status and Formulary Alternatives

Appendix I—DoD P&T Committee Administrative Authority

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

Signed/Signature on file

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

- X** concurs with all recommendations.
- O** concurs with the recommendations, with the following modifications:

- O** concurs with the recommendations, except for the following:

Signed/Signature on file
Bill A. Soliz
BG, USA
Acting Assistant Director
Health Care Administration and
Operations

July 20 *2026*
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
LTC Megan Donahue, MC	Army, Physician at Large
LTC Ryan Burkhart, MC	Army, Internal Medicine Physician
COL James Masterson, MSC	Army, Pharmacy Consultant
CDR Todd Hansen, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
MAJ Loraine Baraki, MC	Army, OBGYN
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Lt Col Sara DeSpain, MC	Air Force, Physician at Large
Col Soo Sohn, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
LCDR Shira Paul, MC	Navy, Oncology Physician
Lara Au, PharmD, BCOP	DHA, Oncology Pharmacist
CDR Chris McKnight, USCG	Coast Guard, Pharmacy
CDR Jackie Finocchio, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA (Day #2)	TRICARE Health Plan Chief Medical Officer
COL Yang Xia, MC (Day #1)	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Peter Glassman, MD	Department of Veteran’s Affairs
Marsha Peterson	DHA Contracting Officer
Eugene Moore, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integration Branch
Lt Col Francisco Boral	Defense Logistics Agency
Guests	
CAPT Tiffany Cline, MSC	DHA POD Beneficiary Advisory Panel DFO
CPT Ji Yoon Kim, MSC	Army Pharmacist
CAPT Marisol Martinez, USPHS	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
Hazel Richardson, PharmD	CDC WTCHP
CDR Kendra Jenkins, PharmD	BoP Pharmacy
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
CDR Giao Phung, MSC	DHA POD Formulary Management Branch
Heather Johnson, PharmD, BCCP, BCCP	DHA POD Formulary Management Branch
Lt Col Pansy Uberoi, MC	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
Kirk Stocker, BS Pharm, MBA, MHSA	DHA POD Formulary Management Branch
Michael Lee, RPh, MBM, MPharm-Econ	DHA POD Formulary Management Branch

Appendix A—Attendance

David Folmar, RPh, MS, MBA	DHA POD Formulary Management Branch
Eric Parsons, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integrative Branch
Tracy Banks	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Stephanie Erpelding	DHA Contracting
Jules Canaley	DHA Contracting
Dwight Bonham	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity (MN) Criteria
Drug Class Reviews MN Criteria	
abatacept (Orencia) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from May 2025 are in bold and strikethrough - Use of all formulary agents ~~adalimumab (Humira)~~ is contraindicated - The patient has experienced ~~or is likely to experience~~ significant adverse effects from all formulary agents ~~adalimumab (Humira)~~ Formulary agents ~~adalimumab (Humira)~~ have resulted ~~or is likely to result~~ in therapeutic failure. - The patient previously responded to the nonformulary agent and changing to a formulary agent ~~adalimumab (Humira)~~ would incur unacceptable risk for patients currently stabilized on IV abatacept ~~No alternative formulary agent applies only to:~~ ~~abatacept (Orencia): The patient is transitioning from IV abatacept or has symptomatic congestive heart failure CHF.~~ Formulary alternatives: adalimumab (Humira), tocilizumab-aazg (Tyenne), ixekizumab (Taltz)
rilonacept (Arcalyst) TIBs: IL-1s, IL-6-s, CTLA4-Igs	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Use of formulary agents has resulted in therapeutic failure - The patient previously responded to the non-formulary agent and changing to a formulary agent would incur unacceptable risk - No alternative formulary agent Formulary alternatives: anakinra (Kineret)
satralizumab (Enspryng) TIBs: IL-1s, IL-6-s, CTLA4-Igs	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Use of formulary agents has resulted in therapeutic failure - The patient previously responded to the non-formulary agent and changing to a formulary agent would incur unacceptable risk - No alternative formulary agent Formulary alternatives: tocilizumab-aazg (Tyenne)
tocilizumab (Actemra) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from May 2025 are in bold and strikethrough ~~Use of formulary agents is contraindicated~~ - Patient has experienced significant adverse effects from formulary agents Formulary alternatives: adalimumab (Humira), tocilizumab-aazg (Tyenne)
New Drugs MN Criteria	
hydrochlorothiazide 10 mg/mL oral suspension (Inzirqo) Diuretic Agents	No alternative formulary agent: patient has documented swallowing difficulties and cannot take a loop diuretic and thiazide in tablet form Formulary alternatives: HCTZ tablets and capsules; chlorthalidone tabs; furosemide tabs

Appendix B—Table of Medical Necessity Criteria

• trazadone 10 mg/mL oral solution (Raldesy) Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Agonist and Reuptake Inhibitor	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure Formulary alternatives: trazadone tablets, SSRIs: citalopram, escitalopram, fluoxetine, sertraline, fluvoxamine, paroxetine hydrochloride IR); SNRIs: venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER,
• ustekinumab-ttwe (Pyzchiva) • ustekinumab-kfce (Yesintek) • ustekinumab-aekn (Selarsdi) • ustekinumab-ttwe (unbranded, until moves to complete exclusion status) TIBs: IL-23	• Patient has experienced or is likely to experience significant adverse effects from formulary agents Formulary alternatives: adalimumab (Humira), ixekizumab (Taltz), ustekinumab-stab (Steqeyma), ustekinumab-aauz (Otulfi), ustekinumab-aaub (Wezlana), ustekinumab (Stelara)
• semaglutide (Ozempic) Non-Insulin Diabetes Drugs: GLP-1RAs	Updates from the May 2025 meeting are in bold For Type 2 Diabetes Mellitus: • Patient has experienced or is likely to experience significant adverse effects from dulaglutide (Trulicity) which is not expected to occur with Ozempic • All formulary agents have resulted in therapeutic failure. Formulary alternatives for T2DM: dulaglutide (Trulicity) For Chronic Type 2 Diabetes Mellitus (T2DM) with Chronic Kidney Disease (CKD): • All formulary agents have resulted in therapeutic failure. Formulary alternatives for T2DM with CKD: ACE inhibitors, Angiotensin Receptor Blockers, SGLT2 inhibitors (empagliflozin, dapagliflozin, canagliflozin) PA does not expire
• tirzepatide (Mounjaro) Non-Insulin Diabetes Drugs: GLP-1RAs	Updates from the May 2025 meeting are in bold For Type 2 Diabetes Mellitus: • Patient has experienced or is likely to experience significant adverse effects from dulaglutide (Trulicity) which is not expected to occur with Mounjaro • All formulary agents have resulted in therapeutic failure. Formulary alternatives for T2DM: dulaglutide (Trulicity)
Section 703 Drugs MN Criteria	
• bupropion 450 mg ER authorized generic for Forfivo XL Antidepressants	• Use of formulary agents is contraindicated and treatment with other formulary antidepressants is not clinically appropriate Formulary alternatives: bupropion SR, bupropion IR, bupropion ER

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
abatacept (Orencia) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold. Manual PA criteria apply to all new users of abatacept (Orencia). ~~Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND~~ ~~Manual PA Criteria: If automated criteria are not met, Orencia is approved if all criteria are met.~~ Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND The patient has had an inadequate response to Tyenne OR The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR The patient has a contraindication to Tyenne A trial of Tyenne is not required for adult or pediatric psoriatic arthritis Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: - The patient had an inadequate response to Humira OR - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR - The patient has a contraindication to Humira The patient must have tried Taltz AND: The patient had an inadequate response to Taltz OR The patient experienced an adverse reaction to Taltz that is not expected to occur with the requested agent OR The patient has a contraindication to Taltz A trial of Taltz is not required for adult or pediatric psoriatic arthritis - Coverage approved for patients 18 years of age or older with one of the following diagnoses/indications: - Moderate to severely active rheumatoid arthritis - Active psoriatic arthritis ~~Patient has had an inadequate response to non-biologic systemic therapy. (For example—methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine], etc.)~~ - Coverage approved for patients 2 to 17 years of age with one of the following diagnoses/indications: - Moderately to severely active polyarticular juvenile idiopathic arthritis - Active psoriatic arthritis. Note that a trial of non-biologic systemic therapy and Humira is required ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ ~~May not be used concomitantly with other TIBs agents~~ Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, C5 inhibitors, or rituximab

Appendix C—Table of Prior Authorization (PA) Criteria

	Non-FDA-approved uses are not approved. Prior Authorization does not expire
anakinra (Kineret) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria applies to all new users of anakinra (Kineret). <u>Manual PA Criteria:</u> Kineret is approved if all criteria are met: Provider acknowledges the Department of Defense-requires a trial of Humira. The patient must have tried Humira AND The patient has had an inadequate response to Humira OR The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR The patient has a contraindication to Humira AND Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND The patient has had an inadequate response to Tyenne OR The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR The patient has a contraindication to Tyenne AND - Patient is 18 years of age or older with: ~~Adult Onset Still's Disease (AOSD) with active systemic features of moderate to high disease activity (Trial of Humira not required) OR~~ - Moderate to severe active rheumatoid arthritis AND ~~Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications~~ ~~The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent~~ ~~The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])~~ Patients 12 years of age or older with Recurrent pericarditis Prescription has been written by or in consultation with a cardiologist or rheumatologist AND Patient has a contraindication to colchicine and at least ONE of the following drug classes aspirin NSAIDs OR Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes aspirin NSAIDs corticosteroids ~~Pediatric Patients~~ Pediatric Patients (all ages) with: ~~Neonatal-Onset Multisystem Inflammatory Disease (NOMID) a subset of cryopyrin-associated periodic syndrome (Trial of Humira not required)~~ Chronic Infantile Neurological Cutaneous and Articular (CINCA) disease

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Cryopyrin-Associated Periodic Syndrome (CAPS). (~~Trial of Humira not required~~) ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) (~~Trial of Humira not required~~). ▪ ~~Adult-Onset~~ Still's Disease with active systemic features of moderate to high disease activity ▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (~~Trial of Humira not required~~). • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: ~~adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER)~~ TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire
• rilonacept (Arcalyst) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of rilonacept (Arcalyst) <u>Manual PA criteria:</u> Arcalyst is approved if all criteria are met: • Patient is 12 years of age or older with one of the following diagnoses: ▪ Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) ~~— Patient is 12 years of age or older~~ ▪ Recurrent pericarditis ~~— Patient is 12 years of age or older~~ - Prescription is written by or in consultation with a cardiologist or rheumatologist - Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR - Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids • Patients of all ages with ▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA) - The patient weighs at least 10 kg (22 pounds) - Patient has had an inadequate response to anakinra OR - Patient has experienced an adverse reaction to anakinra that is not expected to occur with the requested agent OR - Patient has a contraindication to anakinra ~~• The patient is not concurrently receiving a TNF inhibitor (e.g., Humira, Enbrel, Cimzia, and Simponi) due to the increased risk of serious infections.~~ • Coverage is not provided for concomitant use with other TIBs including, but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA-approved uses are not approved, including rheumatoid arthritis, neonatal-onset multisystemic inflammatory disease (NOMID), cardiovascular disease other

Appendix C—Table of Prior Authorization (PA) Criteria

	than pericarditis (MI, acute coronary syndrome, atherosclerosis, heart failure, and Kawasaki disease), and gout. Prior authorization does not expire.
sarilumab (Kevzara) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Kevzara <u>Manual PA criteria:</u> Kevzara is approved if all criteria are met: - Kevzara is prescribed by or in consultation with a rheumatologist - Provider acknowledges ~~Humira~~ Tyenne is the Department of Defense's preferred ~~targeted biologic agent~~ IL-1, IL-6, CTLA4-Ig agent. The patient must have tried Humira AND: - The patient had an inadequate response to ~~Humira~~ Tyenne OR - The patient experienced an adverse reaction to ~~Humira~~ Tyenne that is not expected to occur with the requested agent OR - The patient has a contraindication to ~~Humira~~ Tyenne Note that a trial of Tyenne is not required for Polymyalgia Rheumatica - The patient requires a trial of Humira. - The patient has had an inadequate response to Humira OR - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR - The patient has a contraindication to Humira Note that a trial of Humira is not required for Polymyalgia Rheumatica - Patient has a diagnosis of: - Moderately to severely active rheumatoid arthritis OR AND ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~ - Active polyarticular juvenile idiopathic arthritis (pJIA) and weighs 63 kg or more OR AND ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~ - Polymyalgia Rheumatica (PMR) (Trial of Tyenne and Humira is not required) AND - Patient has tried and/or failed ONE systemic corticosteroid; OR - The patient is not a candidate for corticosteroid therapy ~~Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR~~ Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA-approved uses are not approved ~~PA for non-PMR indications approved indefinitely.~~ PA does not expire for indications other than Polymyalgia Rheumatica For Polymyalgia Rheumatica, PA expires after 12 months. Renewal criterion: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if the following criteria are met:

Appendix C—Table of Prior Authorization (PA) Criteria

	The patient has had a positive response to therapy
satralizumab (Enspryng) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold and strikethrough Manual PA is required for all new users of Enspryng <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - The patient is 18 years of age or older - The drug is prescribed by or in consultation with a neurologist - The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig product is tocilizumab-aazg (Tyenne). Tyenne is available for the treatment of aquaporin-4 (AQP4) seropositive or seronegative NMOSD - Patient has aquaporin-4 (AQP4) antibody positive NMOSD documentation must be submitted - Patient has clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening ~~Patient has laboratory evidence of HBV negative and TB negative~~ ~~Patient and provider are enrolled in the REMS program~~ Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, C5 inhibitors, or rituximab Non-FDA-approved uses are not approved PA does not expire
tocilizumab-aazg (Tyenne) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold and strikethrough <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) or tocilizumab (Actemra) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne) <u>Manual PA criteria:</u> if automated criteria are not met coverage is approved if all criteria are met: ~~Provider acknowledges the Department of Defense preferred targeted immune biologic is~~ requires a trial of Humira. The patient must have tried Humira AND - The patient has had an inadequate response to Humira OR - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR - The patient has a contraindication to Humira AND ~~Patient has moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs OR~~ - Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR - Patient has a diagnosis for which adalimumab is not approved including - Giant cell arteritis (GCA) - Systemic sclerosis-associated lung disease (SSc-ILD) - Systemic Juvenile Idiopathic Arthritis (sJIA) Still's Disease with active systemic features of moderate- to high- disease activity

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Polymyalgia Rheumatica (PMR) AND – Patient has tried and failed ONE systemic corticosteroid OR – Patient is not a candidate for corticosteroid therapy ▪ Neuromyelitis Optica Spectrum Disorder (NMOSD), aquaporin-4 (AQP4) seropositive or seronegative ▪ Myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD) • ~~If “other” diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~ • Patient is not receiving other targeted immunomodulatory biologics with Tyenne Non-FDA approved uses are not approved, except as noted above PA does not expire
• tocilizumab (Actemra) TIBs: IL-1s, IL-6-s, CTLA4-Igs	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new and current users of tocilizumab (Actemra) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges the Department of Defense’s preferred targeted immune biologic is requires a trial of Humira. The patient must have tried Humira AND ▪ The patient has had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Humira AND • Provider acknowledges the Department of Defense’s preferred ~~tocilizumab~~ IL-1, IL-6, CTLA4-Ig product is Tyenne. The patient must have tried Tyenne AND ▪ The patient has had an inadequate response to Tyenne OR ▪ The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Tyenne AND • Patient has tried Humira and has a diagnosis of ▪ Moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs for example: methotrexate, aminosalicylates [for example, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [for example, azathioprine]~~ ▪ Active polyarticular Juvenile Idiopathic Arthritis (pJIA) • Patient has not tried Humira and has a diagnosis for which adalimumab is not approved: ~~AND is greater than 18 years of age:~~ ▪ Giant cell arteritis ▪ Systemic sclerosis-associated lung disease ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) • ~~If “other” diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~ • Patient is not receiving other targeted immunomodulatory biologics with ~~tocilizumab~~ the requested agent, included but not limited to the following; TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, rituximab Non-FDA approved uses are not approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

abemaciclib (Verzenio) Breast Cancer Agents: CDK Inhibitors	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Verzenio. <u>Manual PA Criteria:</u> Verzenio is approved if all of the following criteria are met: • Drug is prescribed by or in consultation with an oncologist ~~• The patient is not currently taking another cyclin dependent kinase inhibitor~~ ~~• For Verzenio only, the patient has hormone receptor HR(+)/HER2(-), node(+/-) early breast cancer at high risk of recurrence as determined by an FDA approved test.~~ • The patient has advanced or metastatic hormone receptor (HR(+))/HER2(-) breast cancer ~~• If the patient is female, the patient meets one of the following criteria:~~ ~~• Verzenio will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~ ~~• Verzenio will be as first line or later line endocrine therapy in combination with fulvestrant; OR~~ ~~• Verzenio will be used as monotherapy following metastatic progression on chemotherapy~~ ~~• If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trellstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~ ~~• Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~ ~~• Provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity~~ ~~• Female patients of childbearing age are not pregnant confirmed by (-) HCG~~ ~~• Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~ ~~• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~ ~~• Male patients have been informed of the risk of infertility~~ • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis: _____. To facilitate approval please list the diagnosis, guidelines version and page number _____ Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire
palbociclib (Ibrance) Breast Cancer Agents: CDK Inhibitors	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Ibrance <u>Manual PA Criteria:</u> Ibrance is approved if <u>all</u> of the following criteria are met: • Drug is prescribed by or in consultation with an oncologist ~~• The patient is not currently taking another cyclin dependent kinase inhibitor~~ • The patient has ~~advanced or metastatic~~ hormone receptor (HR(+))/HER2(-) breast cancer ~~• If the patient is female, the patient meets one of the following criteria:~~ ~~• Ibrance will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~ ~~• Ibrance will be as first line or later line endocrine therapy in combination with fulvestrant~~

Appendix C—Table of Prior Authorization (PA) Criteria

	• If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation. • Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease • For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only • Male patients have been informed of the risk of infertility • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis: _____. To facilitate approval please list the diagnosis, guidelines version and page number. Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire
• ribociclib (Kisqali) • ribociclib co-packaged with letrozole (Kisqali Femara Co-Pack) Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Kisqali, ~~and Kisqali Femara Co-Pack.~~ <u>Manual PA Criteria:</u> Kisqali ~~or Kisqali Femara Co-Pack~~ is approved if <u>all</u> of the following criteria are met: • Drug is prescribed by or in consultation with an oncologist • ~~The patient is not currently taking another cyclin dependent kinase inhibitor~~ • The patient has ~~advanced or metastatic~~ hormone receptor (HR(+))HER2(-) breast cancer • If the patient is female, the patient meets one of the following criteria: • ~~Kisqali, or Kisqali Femara Co-Pack will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~ • ~~Kisqali or Kisqali Femara Co-Pack will be as first line or later line endocrine therapy in combination with fulvestrant; OR~~ • If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation. • Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease • For Kisqali and Kisqali Femara Co-Pack only: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only • Male patients have been informed of the risk of infertility • For Kisqali Femara Co-Pack only, female patients have been informed of the risk of infertility from letrozole

Appendix C—Table of Prior Authorization (PA) Criteria

	The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis: _____.~~ To facilitate approval please list the diagnosis, guidelines version and page number _____ Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire
Newly Approved Drug PAs	
benzgalantamine (Zunveyl) Alzheimer's Agents	Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of Zunveyl <u>Manual PA criteria:</u> Coverage is approved if all criteria are met Provider acknowledges that Zunveyl will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T Committee meeting minutes by the Director, DHA - The patient is 18 years of age or older - The medication is being prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine - The patient is being treated for mild or moderate dementia of the Alzheimer's type - Provider must document why the patient cannot use galantamine immediate release and galantamine extended release and donepezil products. (blank write-in) - Acceptable responses include the patient has had an adverse reaction to galantamine immediate release and galantamine extended-release products that are not likely to occur with benzgalantamine (Zunveyl) or - The patient has had an inadequate response, experienced an adverse effect, or has a contraindication to donepezil Non-FDA approved uses are not approved ~~PA expires in 120 days, when the complete exclusion status is implemented~~ PA does not expire until after implementation of Complete Exclusion status
concizumab-mtci (Alhemo) Antihemophilic Factors: Non-Factor Agents	Manual PA criteria apply to all new users of Alhemo <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by or in consultation with a hematologist - Patient has hemophilia A with factor VIII inhibitors or hemophilia B with factor IX inhibitors - Patient is not concurrently receiving factor VIII or factor IX therapy unless for the treatment of breakthrough bleeding Non-FDA approved uses are not approved PA does not expire
diazoxide choline (Vykat XR) Metabolic Agents Miscellaneous	Manual PA criteria apply to all new users of diazoxide choline (Vykat XR) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 4 years of age or older - Prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome - Patient has a diagnosis of Prader-Willi Syndrome confirmed by genetic testing

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient is being treated for hyperphagia • Patient weighs between 20 kg and 135 kg Non-FDA approved uses are not approved Initial PA expires in 6 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met: • The patient's hyperphagia has improved and stabilized to warrant continued therapy • Medication continues to be prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome
• hydrochlorothiazide 10 mg/mL oral suspension (Inzirgo) Diuretic Agents	Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of hydrochlorothiazide suspension (Inzirgo) who are over 12 years of age PA does not apply to patients 12 years of age and younger (age edit) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met • Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease • Provider must write in why the patient requires Inzirgo and cannot take a loop diuretic AND a thiazide diuretic in a tablet formulation ▪ Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience Non-FDA-approved uses are not approved PA does not expire
• hydroxyurea 100 mg/mL oral solution (Xromi) Oncological Agents	Manual PA criteria apply to all new users of hydroxyurea oral solution (Xromi) who are 18 years of age and older PA does not apply to patients younger than 18 years of age (age edit) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient has sickle cell anemia with recurrent moderate to severe painful crises • Patient is not using Xromi for malignancy, including chronic myelocytic leukemia or other cancers • The provider must explain why the patient cannot use the preferred products generic hydroxyurea or Siklos dispersed in water ▪ Acceptable responses include the patient has swallowing difficulties, not just for convenience AND patient has sickle cell disease Non-FDA approved uses are not approved PA expires after 12 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient continues to have swallowing difficulties that preclude the use of hydroxyurea capsules AND Siklos tablets dispersed in water

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mirdametinib (Gomekli) Oncologic Agents	Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of mirdametinib <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 2 years of age or older - Prescribed by or in consultation with a hematologist or oncologist - Patient has a diagnosis of neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas Patient has tried and had an inadequate response, adverse effect, or has a contraindication to selumetinib (Koselugo) - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire
trazodone 10 mg/mL oral solution (Raldesy) Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor	Manual PA criteria apply to all new users of trazodone oral solution (Raldesy) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient has major depressive disorder (MDD) - Provider must explain why the patient requires Raldesy and cannot take trazadone tablets - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia) and not due to convenience Non-FDA approved uses are not approved PA does not expire
- ustekinumab-stab (Steqeyma) - ustekinumab-aaaz (Otulfi) - ustekinumab-auub (Wezlana) - ustekinumab (Stelara) TIBs: IL-23	Recommendations below are superseded by the recommendations from the February 2026 P&T Committee meeting Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of ustekinumab-stab (Steqeyma), ustekinumab-aaaz (Otulfi), ustekinumab-auub (Wezlana), ustekinumab (Stelara) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira - The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira - Patients may have used infliximab in lieu of Humira for UC and CD - Coverage is approved for patients 18 years of age or older with: - Active psoriatic arthritis - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy - Moderately to severely active Crohn's Disease (CD) - Moderately to severely active ulcerative colitis (UC) - Coverage is approved for patients ages 6 to 17 years of age with: - Active psoriatic arthritis - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

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	- The criteria below apply to all patients unless noted: - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC) - Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
- ustekinumab-ttwe (Pyzchiva) - ustekinumab-kfce (Yesintek) - ustekinumab-aekn (Selarsdi) TIBs: IL-23	Recommendations below are superseded by the recommendations from the February 2026 P&T Committee meeting Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of ustekinumab-ttwe (Pyzchiva), ustekinumab-kfce (Yesintek), ustekinumab-aekn (Selarsdi) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira - The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira The patient had an inadequate response to Steqeyma, Otulfi, Wezlana, and Stelara OR the patient experienced an adverse reaction to Steqeyma, Otulfi, Wezlana, and Stelara that is not expected to occur with the requested ustekinumab OR the patient has a contraindication to Steqeyma, Otulfi, Wezlana, and Stelara - Patients may have used infliximab in lieu of Humira for UC and CD - Coverage is approved for patients 18 years of age or older with: - Active psoriatic arthritis - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy - Moderately to severely active Crohn's Disease (CD) - Moderately to severely active ulcerative colitis (UC) - Coverage is approved for patients ages 6 to 17 years of age with: - Active psoriatic arthritis - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy - The criteria below apply to all patients unless noted: - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC) - Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire

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ustekinumab-ttwe (unbranded) TIBs: IL-23	Recommendations below are superseded by the recommendations from the February 2026 P&T Committee meeting Manual PA criteria apply to all new users of ustekinumab-ttwe (unbranded) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges that this unbranded ustekinumab ttwe will be completely excluded from the TRICARE Pharmacy benefit 120 days after signing of the P&T Committee meeting minutes by the Director, DHA. - Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira - The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira - The provider must write-in trial dates for Humira and the formulary ustekinumab products - Humira Date_____ Duration of therapy _____ - Otulf Date_____ Duration of therapy _____ - Steqeyma Date_____ Duration of therapy _____ - Wezlana Date_____ Duration of therapy _____ - Stelara Date_____ Duration of therapy _____ - The provider must explain why the patient requires unbranded ustekinumab-ttwe (unbranded) and cannot use on of the other ustekinumab biosimilar products. - Acceptable response: Patient has an allergy to one or more inactive ingredients found in formulary ustekinumab products that is not found in unbranded ustekinumab-ttwe Non-FDA approved uses are not approved ~~PA expires in 120 days, when the complete exclusion status is implemented~~ PA does not expire until after implementation of complete exclusion status
vimseitinib (Romvimza) Oncological Agents	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of vimseitinib (Romvimza) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by or in consultation with a hematologist, or oncologist ~~or orthopedic surgeon~~ - Patient has symptomatic tenosynovial giant cell tumor - Tumor is not amenable to treatment with surgery - Patient has tried and had an inadequate response to pexidartinib (Turalio) OR - Patient has tried and had an adverse effect to pexidartinib (Turalio) OR - Patient has a contraindication to use of pexidartinib (Turalio) - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire

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Utilization Management PAs	
mebendazole (Emverm) Anti-infectives: Anthelmintics	Manual PA criteria apply to all new users of Emverm <u>Manual PA criteria:</u> Emverm is approved if all criteria are met: - Patient has a diagnosis of pinworm (<i>Enterobius vermicularis</i>), hookworm (<i>Ancylostoma duodenale</i> or <i>Necator americanus</i>), roundworm (<i>Ascaris lumbricoides</i>), or whipworm (<i>Trichuris trichiura</i>) OR - Medication is prescribed by an infectious disease specialist for another parasitic infection AND - For all indications, patient has a failure, contraindication, or intolerance to at least one of the following: OTC pyrantel pamoate, ivermectin, or albendazole Other non-FDA approved uses are not approved except as noted above including prostate cancer PA expires in one month. A new PA is required for each course of therapy
mifepristone (Korlym) Endocrine Agents Miscellaneous: Antihyperglycemic- Glucocorticoid Receptor Blocker	The following manual PA criteria apply to all new users of Korlym <u>Manual PA criteria:</u> Korlym is approved if all criteria are met: - Patient is 18 years of age or older - Prescription is written by an endocrinologist - Patient has a diagnosis of endogenous Cushing's syndrome AND - Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND - Patient has failed surgery or is not a candidate for surgery - Patient has tried and failed one of the following for the treatment of endogenous Cushing's syndrome: ketoconazole tablets, mitotane (Lysodren), pasireotide (Signifor), osilodrostat (Isturisa) or cabergoline Non-FDA-approved uses are not approved including type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome PA expires in 1 year <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met: - Patient has had a positive clinical response while on Korlym The following manual PA criteria apply to all current users of Korlym <u>Manual PA criteria:</u> Korlym is approved if all criteria are met: - Patient has a diagnosis of endogenous Cushing's syndrome AND - Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND - Patient has failed surgery or is not a candidate for surgery Non-FDA-approved uses are not approved including type 2 diabetes mellitus to endogenous Cushing's syndrome. PA expires in 1 year <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met: - Patient has had a positive clinical response while on Korlym

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zileuton (Zyflo), zileuton ER generic Leukotriene Modifying Agents	Manual PA criteria apply to all new and current users <u>Manual PA criteria:</u> zileuton is approved if all criteria are met: - Patient is being treated for asthma - Patient is 12 years of age or older - Patient has a contraindication to, intolerance to, or has failed treatment with both of the following: - montelukast AND - zafirlukast Non-FDA-approved uses are not approved PA expires in 1 year <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if the following apply: - The patient has had a positive response to therapy, as defined by one of the following: - a decrease in asthma exacerbations - improvements in forced expiratory volume in one second (FEV1) - decrease in oral corticosteroid use
metformin 750 mg IR tablet Diabetes Non-Insulin: Biguanides	Manual PA criteria apply to all new and current users of metformin 750 mg IR tablet. <u>Manual PA criteria:</u> metformin 750 mg IR Tablet is approved if all criteria are met: - Provider acknowledges other formulations of metformin are available without prior authorization. - Provider must explain why the patient requires metformin 750 mg IR Tablet and cannot take the cost-effective generic metformin formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin formulations Non-FDA-approved uses are not approved Prior authorization does not expire
tramadol 100 mg tablet Narcotic Analgesics and Combinations	Updates from the May 2025 meeting are in bold Manual PA criteria apply to all new and current users of tramadol 25 mg, 75 mg and 100 mg tablet <u>Manual PA criteria:</u> tramadol 25, 75 mg and 100 mg tablet is approved if ALL criteria are met: - Provider is aware and acknowledges that tramadol 50 mg is available to TRICARE beneficiaries without the need of prior authorization and providers are encouraged to change the prescription to the preferred tramadol 50 mg product - This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives. (blank write in) - Acceptable responses are that the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg IR tablets Non-FDA approved uses are not approved PA does not expire

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• setmelanotide (Imcivree) Miscellaneous Metabolic Agents	Updates from May 2025 are in bold and strikethrough Manual PA criteria apply to all new users of Imcivree. <u>Manual PA criteria:</u> Imcivree is approved if all criteria are met: • Patient is two ~~six~~-years of age or older • Patient has a confirmed diagnosis (via genetic testing) of POMC-, PCSK1-, or LEPR-deficiency that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) OR • The patient has monogenic or syndromic obesity due to Bardet-Beidl syndrome (BBS) • Patient and provider agree to evaluate weight loss after 12-16 weeks of treatment. Imcivree should be discontinued if a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential Non-FDA approved uses are NOT approved including Alström Syndrome, POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity Initial prior authorization expires in 4 months. <u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Imcivree is approved for 1 year for continuation of therapy for POMC-, PCSK1-, or LEPR deficiency or BBS if all criteria are met: • The patient has a documented improvement (a decrease from baseline) in at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential.
• house dust mite allergen extract (Odactra) Immunological Agents Miscellaneous: Oral Agents	Updates from May 2025 are in bold and strikethrough Manual PA criteria apply to all new users of Odactra <u>Manual PA criteria:</u> Coverage will be approved if all criteria are met: • Odactra is prescribed by an allergist/immunologist • The patient is between the ages of five ~~12~~ and 65 years • The patient has a diagnosis of house dust mite (HDM) allergic rhinitis confirmed with either a positive skin test or an in vitro test for pollen-specific for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites • The patient's symptoms of allergic rhinitis have not been controlled with a nasal corticosteroid (e.g., fluticasone) AND at least one of the following: oral antihistamine, nasal antihistamines, or a leukotriene receptor antagonist (montelukast) OR • The patient has a diagnosis of house dust mite-related allergic rhinitis and allergic asthma that has not responded to an adequate trial of inhaled steroids, and the patient's • Forced Expiratory Volume in 1 second (FEV1) is greater than 70% • The patient has received the first dose in the office setting and was observed for 30 minutes with no allergic reactions noted • The patient has a prescription for self-administered SC epinephrine • The patient does not have a history of severe local allergic reaction to sublingual immunotherapy • Patient is not receiving co-administered SC immunotherapy • Patient does not have severe, uncontrolled, unstable asthma Other off-label uses other than allergic asthma are not approved PA expires in 6 months

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	Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be continued indefinitely if all the following apply: • The patient has responded positively to treatment • The patient is not receiving co-administered SC immunotherapy • The patient does not have severe, uncontrolled unstable asthma.
• guselkumab (Tremfya) TIBs: IL-23s	Updates from the May 2025 meeting are in bold. Step therapy and Manual PA Criteria apply to all new users of guselkumab (Tremfya). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira • Patient had an inadequate response to Humira OR had adverse reaction to Humira that is not expected to occur with the requested agent OR has a contraindication to Humira • A trial of IV infliximab may be used in lieu of Humira for Ulcerative colitis or Crohn's disease AND • Patient is 18 years of age or older with the following indication/diagnosis: ▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy ▪ Moderate to severely active ulcerative colitis (UC) ▪ Moderately to severely active Crohn's Disease (CD) • Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosaliclates, corticosteroids, immunosuppressants etc.) (Note does not apply to UC or Crohn's disease) • Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
• acalabrutinib (Calquence) Leukemia and Lymphoma Agents: BTK Inhibitors	Updates from the May 2025 meeting are in bold. <u>Automated PA Criteria:</u> When prescribed by a hematologist or oncologist, prior authorization is not required. Once therapy is initiated by a hematologist or oncologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA apply to all new users of Calquence <u>Manual PA Criteria:</u> If automated criteria are not met for hematologist or oncologist specialist prescribing, coverage is approved if all criteria are met: • If the physician is a hematologist or oncologist, PA is approved OR • If the prescriber is not a hematologist or oncologist and the drug is prescribed in consultation with a hematologist/oncologist, then continue with the questions below: • Patient is 18 years of age or older • Patient has a diagnosis of either chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or Mantle Cell Lymphoma (MCL) and received at least one prior therapy OR • Patient has previously untreated Mantel Cell Lymphoma (MCL) and is ineligible for autologous hematopoietic stem cell transplantation (HSCT)

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	and acalabrutinib will be used in combination with bendamustine and rituximab (BR) The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA-approved uses are not approved, except as noted above PA does not expire
sotorasib (Lumakras) Oncological Agents: Lung Cancer	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Lumakras. <u>Manual PA criteria:</u> Lumakras is approved if all criteria are met: - Patient is 18 years of age or older - The drug is prescribed by or in consultation with a hematologist/oncologist - Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); ~~as determined by an FDA approved test~~ and has received at least one prior systemic therapy OR Patient has laboratory evidence of KRAS G12C-mutated metastatic colorectal cancer (mCRC) AND will be used in combination with panitumumab in patients who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy ~~The patient will be monitored for interstitial lung disease and hepatotoxicity~~ ~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~ - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Other non-FDA-approved uses are not approved Prior authorization does not expire
semaglutide (Ozempic) Non-Insulin Diabetes Drugs: Glucagon- Like Peptide-1 Receptor Agonists (GLP1RAs)	Updates from the May 2025 meeting are in bold <u>Manual PA criteria</u>—Coverage is approved if all criteria are met For Type 2 diabetes mellitus - The provider acknowledges that Trulicity is available to TRICARE beneficiaries at a lower copay than Ozempic. Trulicity also has an indication to reduce the risk of adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors. - The patient has a confirmed diagnosis of Type 2 diabetes mellitus - The patient has tried metformin (alone or in combination) and failed to achieve blood glucose control OR - The patient has experienced any of the following issues on metformin: - impaired renal function precluding treatment with metformin - history of lactic acidosis OR - The patient has a contraindication to metformin For Type 2 diabetes mellitus with chronic kidney disease The patient has a diagnosis of type 2 diabetes and chronic kidney disease The patient's estimated glomerular filtration rate (eGFR) is between 50 – 70 mL/min/m²)

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	• The patient is currently receiving a renin angiotensin inhibitor (ACE inhibitor or ARB blocker) or has a contraindication, has had an adverse effect, or has failed therapy • The patient is currently receiving an SGLT-2 inhibitor or has a contraindication, has had an adverse effect or has failed therapy Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• crisaborole (Eucrisa) Corticosteroids- Immune Modulators: Atopic Dermatitis	Updates from the May 2025 meeting are in bold <u>Age Edit:</u> PA does not apply to children 2 years of age and younger Manual PA Criteria: Coverage approved if all criteria are met: • Prescribed by a dermatologist, allergist, immunologist • Patient has mild to moderate atopic dermatitis • Patient has a contraindication to, intolerance to, or failed treatment with a two-week trial of at least one medium- to high-potency topical corticosteroid • Patient has a contraindication to, intolerance to, or failed treatment with a two-week trial of a second agent including ▪ An additional medium- to high-potency topical corticosteroid OR ▪ Topical calcineurin inhibitor (i.e., tacrolimus, Elidel) Off-label uses are not approved Prior Authorization does not expire
• febuxostat (Uloric) Miscellaneous Antigout Agents: Chronic	Updates from the May 2025 meeting are in bold and strikethrough. <u>Automated PA Criteria:</u> The patient has received a prescription for at least 300 mg per day of allopurinol at any Military Health System pharmacy point of service (Military Treatment Facilities, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, manual PA criteria apply to all new users of febuxostat (Uloric) is approved (e.g., a trial of allopurinol is not required) if: • The patient has experienced any of the following issues with at least one of the following with allopurinol, which is not expected to occur with febuxostat (Uloric): ▪ The patient has had an inadequate response to allopurinol (failure to achieve serum uric acid levels less than 6 mg/day) after an adequate trial (at least 300 mg per day of allopurinol) ▪ The patient has had intolerable adverse effects (e.g., hypersensitivity) to allopurinol ▪ The patient has a contraindication to allopurinol (e.g., renal impairment) • ~~Patients with major cardiovascular (CV) disease should be informed of the potential CV risks when using this drug~~ • ~~The Healthcare provider should consider CV safety information from the CARES trial and the label when prescribing febuxostat~~ Non-FDA-approved uses are NOT approved Prior authorization does not expire

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fedratinib (Inrebic) Oncological Agents: Myelofibrosis	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of fedratinib (Inrebic) Manual PA Criteria: Coverage is approved if all criteria are met: - The drug is prescribed by or in consultation with a hematologist/oncologist - Patient is age 18 years of age or older - Fedratinib will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis ~~Provider acknowledges that serious and fatal encephalopathy including Wernicke's encephalopathy has occurred in patients treated with fedratinib. If thiamine deficiency is expected or confirmed, fedratinib should be discontinued immediately and the patient should receive emergent parenteral thiamine.~~ ~~Patient does not have vitamin B1 deficiency.~~ ~~Thiamine (Vitamin B1), CBC with platelets, Serum creatinine and BUN, hepatic panel and amylase and lipase will be assessed prior to starting fedratinib and periodically while patient is taking fedratinib~~ ~~Nutritional status will be assessed prior to starting fedratinib and periodically while patient is taking edratinib~~ ~~If the patient is female, she is not pregnant or planning to become pregnant.~~ ~~Female patients will not breastfeed during treatment and for at least 1 month after discontinuation.~~ ~~Females of reproductive potential will use effective contraception during treatment and for at least 1 month after discontinuation.~~ - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis. To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
selumetinib (Koselugo) Oncological Agents	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of selumetinib (Koselugo) Manual PA Criteria: Coverage is approved if all criteria are met: - The drug is prescribed by or in consultation with a hematologist/oncologist - Patient diagnosed with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas. ~~Patient will be monitored for cardiomyopathy including a left ventricular functional assessment prior to initiation and at regular intervals during treatment~~ ~~Monitor for ocular toxicity including retinal vein occlusion and retinal detachment via ophthalmic exams prior to initiation and at regular intervals during treatment.~~ ~~Monitor for gastrointestinal toxicity and co-administer an anti-diarrheal if patient develops loose stools.~~ ~~Monitor for severe skin rashes.~~ ~~Monitor for rhabdomyolysis.~~ ~~Provider is aware that Koselugo contains Vitamin E which can increase bleeding risk if co-administered with a Vitamin K antagonist.~~ ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG.~~

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	~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment.~~ ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.~~ - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis.~~ To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
pomalidomide (Pomalyst) Oncological Agents: Multiple Myeloma	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of pomalidomide (Pomalyst) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - The drug is prescribed by or in consultation with a hematologist/oncologist - Patient is 18 years of age or older - Patient is diagnosed with: - Relapsed/refractory multiple myeloma that is refractory to lenalidomide <u>AND</u> all of the following: - Patient has previously trialed bortezomib, carfilzomib, OR ixazomib - Patient will be starting pomalidomide as third (or higher) line of therapy - Must be used in combination with dexamethasone AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy or in patients with Kaposi sarcoma who are HIV-negative - Myelofibrosis refractory to or with contraindications to alternative therapies (including lenalidomide) and erythropoietin levels ≥ 500 mU/ml - Systemic light chain amyloidosis <i>with organ involvement</i> refractory to or with contraindications to alternative therapies including lenalidomide - Patient is not using concurrent lenalidomide NOR thalidomide - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~if so, please list the diagnosis.~~ To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• ripretinib (Qinlock) Oncological Agents	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of ripretinib (Qinlock) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is age 18 years of age or older • Patient has a pathologically confirmed advanced gastrointestinal stromal tumor (GIST) AND ▪ Patient has experienced disease progression on imatinib (Gleevec), sunitinib (Sutent) AND regorafenib (Stivarga) OR ▪ Patient has documented intolerance to any of these treatments • ~~If the patient is female, she is not pregnant or planning to become pregnant.~~ • ~~Female patients have lack of pregnancy confirmed by (-) HCG testing~~ • ~~Both male and females of reproductive potential will use effective contraception during treatment and for at least 6 weeks after discontinuation.~~ • ~~Female patients will not breastfeed during treatment and for at least 2 weeks after discontinuation.~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• midostaurin (Rydapt) Oncological Agents	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Rydapt <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient uses Rydapt in combination with standard chemotherapy protocols AND • Patient has a diagnosis of acute myeloid leukemia (AML) AND tyrosine kinase 3 (FLT3)-positive ~~as detected by an FDA-approved test~~ • Patient has a diagnosis of advanced systemic mastocytosis (aggressive systemic agents mastocytosis; systemic mastocytosis associated with hematologic neoplasm) or mast cell leukemia • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved PA does not expire ~~PA expires in one year~~

Appendix C—Table of Prior Authorization (PA) Criteria

	Renewal criteria: Rydapt is approved indefinitely for continuation of therapy if patient documents clinical and/or symptom improvement.
capmatinib (Tabrecta) Oncological Agents: Lung Cancer	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of capmatinib (Tabrecta). <u>Manual PA criteria:</u> Coverage is approved if <u>all</u> criteria are met: - Must be prescribed by or in consultation with a hematologist/oncologist - Patient is 18 years or older - Patient has metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping ~~as detected by an FDA-approved test~~ ~~Monitor for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity~~ ~~Provider is aware and has counseled patient that capmatinib can cause photosensitivity and has counseled patients to avoid direct UV exposure~~ ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG.~~ ~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment.~~ ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.~~ - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis. To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA approved uses are not approved except as noted above PA does not expire
tepotinib (Tepmetko) Oncological Agents: Lung Cancer	Updates from the May 2025 meeting are in bold and strikethrough Manual PA applies to all new users of tepotinib (Tepmetko). <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - Must be prescribed by or in consultation with a hematologist/oncologist - Patient is 18 years or older - Patient has metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to laboratory-confirmed mesenchymal-epithelial transition (MET) exon 14 skipping. ~~Provider will monitor for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity~~ ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG.~~ ~~Female patients will not breastfeed during treatment~~ ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy~~ - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis. To facilitate approval,

Appendix C—Table of Prior Authorization (PA) Criteria

	please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• pexidartinib (Turalio) Oncological Agents: Chronic Myelogenous Leukemia	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of pexidartinib (Turalio) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and is not amenable to improvement with surgery and has not progressed on Turalio • ~~Patient will be monitored for hepatotoxicity~~ • ~~Prescriber is certified with REMS program~~ • ~~Patient is enrolled in REMS program~~ • ~~If the patient is female, she is not pregnant or planning to become pregnant.~~ • ~~Female patients will not breastfeed.~~ • ~~All patients (females AND males) of reproductive potential will use effective contraception during treatment and for 1 month after discontinuation in females and 1 week after discontinuation in males with female partners.~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• quizartinib (Vanflyta) Oncological Agents: Acute Myelogenous Leukemia	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Vanflyta Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has newly diagnosed acute myeloid leukemia (AML) that is tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive as detected by an FDA-approved test • ~~The provider is aware of all warnings, monitoring and screening precautions for Vanflyta~~ • ~~Provider is certified to prescribe Vanflyta per REMS requirements~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

larotrectinib (Vitrakvi) Oncological Agents	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Larotrectinib (Vitrakvi) capsules or oral solution <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - The drug is prescribed by or in consultation with a hematologist/oncologist - Patient is diagnosed with either: - Advanced or metastatic NSCLC with NTRK gene fusion without a known acquired resistance mutation - OR - a solid tumor that meets all three of the following criteria: - has a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion without a known acquired resistance mutation - is metastatic OR where surgical resection is likely to result in severe morbidity - has no satisfactory alternative treatments OR that has progressed following such treatment(s) ~~Female patients will not breastfeed during treatment and for 1 week after cessation of treatment~~ ~~All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for at least 1 week after cessation of treatment~~ - For use of the oral solution, patient must have difficulty swallowing capsules - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
dacomitinib (Vizimpro) Oncological Agents: EGFR+ Non-Small Cell Lung Cancer	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of dacomitinib (Vizimpro) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - The drug is prescribed by or in consultation with a hematologist/oncologist - Patient is 18 years of age or older - Patient has histologically or cytopathologically confirmed stage IIIB/IV or recurrent non-small cell lung cancer with the presence of at least one documented epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutation as detected by an FDA-approved test ~~No evidence of: active infection, non-infectious pneumonitis, nor interstitial lung disease~~ - Patient has no previous epidermal growth factor kinase inhibitor use (for example Tarceva, Iressa, Gilotrif, or Tagrisso) - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

gilteritinib (Xospata) Oncological Agents: Acute Myelogenous Leukemia	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of gilteritinib (Xospata). <u>Manual PA criteria:</u> Coverage is approved if <u>all</u> criteria are met: - Must be prescribed by or in consultation with a hematologist/oncologist - Patient is 18 years or older - Patient has a diagnosis relapsed or refractory acute myeloid leukemia - Patient has laboratory confirmed evidence of Ferline McDonough Sarcoma (FMS)-like tyrosine kinase 3 (FLT3) mutation, ~~as detected by an FDA-approved test~~ ~~The patient will be monitored for posterior reversible encephalopathy syndrome (PRES), prolonged QTc, and pancreatitis~~ ~~Patient is not pregnant or actively trying to become pregnant~~ - The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
odevixibat (Bylvay) Metabolic Agents Miscellaneous	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of odevixibat (Bylvay) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist - Patient is 3 months of age and older and weighs at least 5 kg and has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus OR - Patient is 12 months of age and older and has diagnosed Alagille Syndrome with severe refractory pruritus (ALGS) AND - Has been evaluated for possible orthotopic liver transplant (OLT) - Has previously tried and failed three all of the following: - ursodiol - cholestyramine - rifampin - naltrexone sertraline At least one One antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as ~~non-alcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD),~~ metabolic dysfunction-associated steatohepatitis (MASH), metabolic dysfunction-associated liver disease (MASLD), biliary atresia, and other cholestatic diseases are not approved PA expires every 6 months <u>Renewal criteria:</u> Initial TRICARE PA approval required. PA will be approved for an additional 6 months if: - Patient must demonstrate significant improvement in pruritus symptoms

Appendix C—Table of Prior Authorization (PA) Criteria

maralixibat (Livmarli) Metabolic Agents Miscellaneous	Updates from the May 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of maralixibat (Livmarli) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist - Patient is 3 months of age or older and has diagnosed Alagille Syndrome with severe refractory pruritus OR - Patient is 12 months of age and older and has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus AND - Has been evaluated for possible orthotopic liver transplant (OLT) - Has previously tried and failed three all of the following: - ursodiol - cholestyramine - rifampin - naltrexone sertraline At least one One antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as ~~non-alcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD)~~, metabolic dysfunction-associated steatohepatitis (MASH), metabolic dysfunction-associated liver disease (MASLD), biliary atresia, and other cholestatic diseases are not approved PA expires every 6 months <u>Renewal criteria:</u> Initial TRICARE PA approval required. PA will be approved for an additional 6 months if: - Patient must demonstrate significant improvement in pruritus symptoms
pimavanserin (Nuplazid) Antipsychotic Agents: Parkinson's Psychosis	Updates from the May 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of pimavanserin (Nuplazid) <u>Manual PA Criteria:</u> Nuplazid is approved if all of the following criteria are met: - Patient is age 18 years of age or older - Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's Disease psychosis - Nuplazid is being prescribed by or in consultation with a neurologist, psychiatrist, or gerontologist (i.e., geriatric medicine specialist) Patient has a contraindication to, intolerability to, or has failed treatment with clozapine - Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin - Provider acknowledges black box warning for Nuplazid which states elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death - Provider acknowledges the FDA safety alerts, warnings, precautions, and drug interactions - Patient is not taking additional antipsychotics Non-FDA approved uses are not approved Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

sacubitril/valsartan (Entresto) Renin-Angiotensin Antihypertensives: Combinations	Manual PA criteria applies to new users of sacubitril/valsartan tablets at all points of service. <u>Manual PA criteria:</u> sacubitril/valsartan generics are approved if all criteria are met: - Provider acknowledges that the brand Entresto tablet is the preferred product over generic sacubitril/valsartan tablets and is covered at the lowest copayment, which is the generic formulary copayment for non-Active-Duty patients, and at no cost share for Active-Duty patients. (Although Entresto is a branded product, it will be covered at the generic formulary copayment or cost share) - Please provide a patient-specific justification as to why the brand Entresto cannot be used in this patient. _____ (fill-in the blank). - Acceptable reasons to include the patient has had an adverse reaction to an excipient in brand Entresto that would not be likely to occur with the generic sacubitril/valsartan PA does not expire
- FreeStyle Libre 2 and 3 - Dexcom G6 and G7 Dexcom G7 15 day sensor CGMs	Updates from the May 2025 meeting are in bold Automated and manual PA criteria apply to all new users of Abbott FreeStyle Libre 2 and 3 and Dexcom G6 and G7. <u>Automated PA criteria:</u> The patient has filled a prescription for insulin (including basal or rapid acting insulin) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved coverage is approved for FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6 and Dexcom G7 and Dexcom G7 15 day sensor if all criteria are met: <i>Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria</i> - Patient has a diagnosis of diabetes - Patient is currently being treated with insulin. Please document the following: - Insulin product: _____ - Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days. For the Dexcom G7 15-day sensor – the patient is 18 years of age or older Initial PA Expiration: annual Renewal expiration: annual for the manual PA <u>Annual manual PA renewal criteria:</u> - Patient has utilized CGM daily - Provider and patient will assess the usage of self monitoring of blood glucose (SMBG) at every visit with the goal of minimizing/discontinuing use - Patients with T2DM continue to require basal or prandial insulin injections daily - Patient continues to share data with managing healthcare professional for the purposes of clinical decision making - Patient continues to be treated with insulin. Please document the following: - Insulin product: _____

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days.
• semaglutide (Wegovy) • tirzepatide (Zepbound) Weight Loss Agents	Updates from May 2025 are in bold Manual PA criteria apply to all new users of Wegovy and Zepbound <u>Manual PA Criteria:</u> Coverage for Wegovy or Zepbound is approved if: • The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge” • Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan? ○ If yes subject to verification, proceed to the next question ○ If no, coverage is not approved • What TRICARE Plan is the patient enrolled in? ○ TRICARE Select – proceed to the next question ○ TRICARE Prime – proceed to the next questions ○ TRICARE For Life – Coverage not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives. • The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested. • The provider will document the major condition and comorbidities treated selecting all that apply: ○ Obesity ○ Diabetes or impaired glucose tolerance ○ Obstructive sleep apnea ○ Osteoarthritis ○ Metabolic syndrome ○ Dyslipidemia ○ Hypertension ○ Metabolic dysfunction-associated steatohepatitis (MASH) ○ Established cardiovascular disease with a history of stroke ○ Established cardiovascular disease with a history of myocardial infarction ○ Established cardiovascular disease with a history of peripheral artery disease For Wegovy and Zepbound for adults for obesity • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity (~~diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea~~) ○ The provider will document the BMI

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ For BMI less than 27, coverage is not approved ▪ For BMI ranging between 27 and 29 with a comorbidity ▪ For BMI ranging between 30 to 34 ▪ For BMI ranging between 35 to 39 ▪ For BMI greater than or equal to 40 • Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response • Phentermine: Date _____ Duration of therapy _____ OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension) OR • The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) for obesity • Patient is 12 years of age or older and younger than 18 years of age • Patient has a BMI greater than or equal to 95th percentile standardized for age For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity: • Patient is 18 years of age or older • Patient has moderate to severe OSA (documented apnea-hypopnea index greater than 15 events per hour) and a BMI greater than 30 For all patients • Concomitant use of this medication with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus PA expires in 12 months for initial therapy; annual renewal required <u>Renewal PA Criteria:</u> Initial TRICARE PA approval required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met: • The provider will document the BMI for renewal: ○ BMI less than 27, ○ BMI ranging between 27 and 29 ○ BMI ranging between 30 to 34 ○ BMI ranging between 35 to 39 ○ BMI greater than or equal to 40 For Obesity: • ~~The patient is currently engaged in behavioral modification and on a reduced-calorie diet~~ • Per P&T recommendation: The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that
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Appendix C—Table of Prior Authorization (PA) Criteria

	includes diet, exercise, and behavioral health modification. Medical record documentation will be made available to TRICARE for audit, if requested. - For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication with full dosage titration - For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication - The patient is not pregnant For OSA: - The patient has shown improvement in OSA symptoms based on the improvement of apnea hypopnea index
- phentermine/topiramate (Qsymia) - bupropion/ naltrexone (Contrave) - orlistat (Xenical) - liraglutide (Saxenda) Weight Loss Agents	Updates from May 2025 are in bold. The following questions will be added to the existing PA criteria. Automated criteria identifying those beneficiaries with other TRICARE health plan enrollment that is not TRICARE Select or TRICARE PRIM will result in no coverage and a claim denial. Manual PA criteria apply to all new users of the weight loss drug <u>Manual PA Criteria:</u> Coverage for the weight loss drug is approved if: The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge” Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan? - If yes subject to verification, proceed to the next question - If no, coverage is not approved What TRICARE Plan is the patient enrolled in? - TRICARE Select – proceed to the next question - TRICARE Prime – proceed to the next questions - TRICARE For Life—Coverage not approved The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested.

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• concizumab-mtci (Alhemo) Antihemophilic Factors: Non-Factor Agents	▪ MTF/TMOP/Retail: 30-day supply
• diazoxide choline (Vykat XR) Metabolic Agents Miscellaneous	▪ MTF/TMOP/Retail: 30-day supply
• letermovir oral pellets (Prevymis) Antivirals	▪ MTF/TMOP/Retail: 30-day supply
• mirdametinib (Gomekli) Oncologic Agents	▪ MTF/TMOP/Retail: 30-day supply
• suzetrigine (Journavx) Pain Agents	Updates are in bold and strikethrough ▪ MTF/TMOP/Retail: ~~30 tablets/fill and no refills~~, 30 tablets/180 days with no refills
• vimseltinib (Romvimza) Oncological Agents	▪ MTF/TMOP/Retail: 60-day supply
• ustekinumab-stab (Steqeyma) • ustekinumab-aaaz (Otulfi) • ustekinumab-ttwe (Pyzchiva) • ustekinumab-kfce (Yesintek) • ustekinumab-aekn (Selarsdi) • ustekinumab-ttwe (unbranded) TIBs: IL-23	▪ Retail: 1 syringe/vial per fill ▪ MTF/TMOP: 3 syringes/vials per fill (Note these QLs allow for loading doses for pertinent indications)
• mebendazole (Emverm) Anti-infectives: Anthelmintics	▪ MTF/TMOP/Retail: 12 tablets per 30 days with no refills
• Dexcom G7 15 Day Sensor Therapeutic CGM Systems	▪ Retail: 2 sensors per 30 days ▪ MTF/TMOP: 6 sensors per 90 days
• risdiplam (Evrysdi) tablets Neurological Agents Miscellaneous	▪ tablets: MTF/TMOP/Retail: 30 tablets per 30 days ▪ solution: MTF/TMOP/Retail: 36-day supply

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
benz-galantamine (Zunveyl) Alzheimer's Agents	- galantamine - Adlarity - galantamine ER - donepezil	- Delayed release (DR Tablet: 5, 10, 15 mg - Dosing: 5 mg orally twice daily	Treatment of mild to moderate dementia of the Alzheimer's type in adults	- nausea - vomiting - diarrhea - dizziness - headache - decreased appetite	- New prodrug formulation of galantamine for Alzheimer's disease - No new clinical efficacy studies - Provide no clinical advantage over existing agents	- Complete Exclusion - Interim PA
concizumab-mtci (Alhemo) Anti-hemophilic Factors: Non-Factor Agents	- Hemlibra - Idelvion - Altuviiio	- Pen: 60, 150, 300 mg - Dosing: weight-based daily	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years old with hemophilia A with FVIII inhibitors or hemophilia B with FIX inhibitors	- injection site reaction - urticaria	- Alhemo is the second tissue factor pathway inhibitor (IFPI) antagonist but first one indicated as routine prophylaxis - Phase 3 open-label study demonstrated 86% bleed reduction for patients given Alhemo as routine prophylaxis vs. on-demand treatment only - Alhemo is given once daily while other non-factor agents are given once weekly or less often - Alhemo is an alternative to Hemlibra for hemophilia A patients with inhibitors and offers an option for hemophilia B patients with inhibitors who have limited options	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
diazoxide choline (Vykat XR) Metabolic Agents Miscellaneous -Willi	None	XR tablet: 25/75/150 mg	Treatment of hyperphagia in patients ≥ 4 years with Prader-Willi Syndrome	- hypertrichosis - edema - hyperglycemia - rash	- Vykat is the first FDA-approved treatment for hyperphagia in Prader-Willi syndrome - A phase 3 double-blinded study did not demonstrate improvement in the hyperphagia endpoint but did result in statistically significant improvement in those with severe baseline hyperphagia - A phase 3 withdrawal study demonstrated statistically significant worsening of hyperphagia in the placebo group relative to Vykat XR - Vykat is generally well tolerated with mostly grade 1 adverse events - Vykat XR provides an option for hyperphagia associated with this rare disorder	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
hydro-chorothiazide powder 10 mg/mL for oral suspension (Inzirqo) Diuretic Agents	- HCTZ tablet - Norliqva solution - Qbrelis Solution - Carospir Suspension	10 mg/mL with total volume 80 mL after reconstitution	Approved for adults and pediatrics with hypertension or edema associated with congestive heart failure, hepatic cirrhosis and renal disease including nephrotic syndrome	- hypokalemia - hyponatremia - hypomagnesemia - hyperglycemia - hyperuricemia - hyperlipidemia - hypotension	- New oral suspension formulation of hydrochlorothiazide (HCTZ) - No clinical efficacy studies were conducted; approval was based on clinical trial data with HCTZ tablets - HCTZ tablets can be crushed and mixed with fluids for patients who cannot swallow - Supplied as 10 mg/mL in 80 mL bottles; typical adult patient will need 50 mg daily and will go through 1 bottle in about 2 weeks - Provides no compelling clinical advantage over existing agents	- NF - PA - MN - TRICARE Maintenance Drug List
hydroxyurea 100 mg/mL oral solution (Xromi) Oncologic Agents	- hydroxyurea capsule - Droxia capsule - Siklos tablet	solution: 100 mg/mL	Approved to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients 6 months of age and older with sickle cell anemia with recurrent moderate to severe painful crises	- neutropenia - thrombocytopenia - papular rash	- New oral solution formulation of hydroxyurea for sickle cell disease - Xromi and Siklos can be used in patients who cannot swallow - Xromi is used in pediatrics 6 months and older while Siklos can be used in children 2 years of age or older and in adults - Is not approved for malignancy (e.g., chronic myelocytic leukemia or other cancers) - Provides an oral solution formulation for pediatric patients 6 months and older	- UF - PA - TRICARE Maintenance Drug List
letermovir ER oral pellets (Prevymis) Antivirals	letermovir tablets (Prevymis)	20 mg or 120 mg ER packet; each carton has 30 packets	- Prophylaxis of cytomegalovirus (CMV) infection and disease in ≥ 6 months of age and weighing ≥ 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) - Prophylaxis of CMV disease in ≥ 12 years of age and weighing ≥ 40 kg who are	- nausea - diarrhea - vomiting - peripheral edema - cough - headache - fatigue - abdominal pain	- New oral pellet formulation of Prevymis for prophylaxis of CMV in adult and pediatric patients ≥ 6 months of age and weighing at least 6 kg who are CMV-seropositive recipients HSCT and prophylaxis of CMV disease in adult and pediatric patients ≥ 12 years of age and weighing at least 40 kg who are kidney transplant recipients at high risk - Can be administered via NG or G tube - Provides an alternative oral dosage formulation for patients who cannot swallow tablets or patients who weigh < 30 kg	- UF - QL - Specialty Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
			kidney transplant recipients at high risk			
mirdametininib (Gomekli) Oncologic Agents	Koselugo	- Capsule: 1, 2 mg - Tab for suspension: 1 mg	Treatment of patients 2 years of age and older with neurofibromatosis type 1 who have symptomatic plexiform neurofibromas not amenable to complete resection	- rash - diarrhea - nausea - msk pain - vomiting - fatigue	- Second MEK1/2 inhibitor for neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas - Phase 2b open label study demonstrated objective response rate (ORR) in 24 (41%) and 29 (52%) of adults and pediatrics, respectively - Gomekli is available as a tablet for suspension for patients who cannot swallow - Gomekli is an additional treatment option for neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List - Rapid Response Program
suzetrigine (Journavx) Pain Agents	- tramadol tab - oxycodone tab	Tab: 50mg	Treatment of moderate to severe acute pain in adults	- pruritis, - muscle spasms - increased CPK - rash	- Journavx is a sodium channel blocker indicated for the treatment of moderate to severe acute pain in adults - Recommended to use for shortest duration; use beyond 14 days has not been studied - Two phase 2 studies demonstrated statistically significant reduced pain scores 48 hours after abdominoplasty and bunionectomy when compared to placebo; baseline populations were predominantly white, young, & female; there is no data regarding special populations of interest such as pregnancy, pediatrics, or geriatrics - Guidelines recommend trial of standard, widely available uniform formulary medications for post operative pain management (e.g. NSAIDs, COX2 inhibitors, gabapentinoids, or acetaminophen) - Provides an additional non-opioid pain treatment for short term use	- UF - QL

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
trazodone 10 mg/mLoral solution (Raldesy) Anti-depressants And Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor	- Zoloft concentrate - Prozac solution	Solution: 10mg/mL	Treatment of major depressive disorder in adults	- edema - blurred vision - syncope - drowsiness - fatigue - diarrhea - nasal congestion - weight loss	- New oral solution formulation of trazodone hydrochloride - No new clinical efficacy studies conducted for approval - Provides an option for patient who cannot swallow trazodone tablet	- NF - PA - MN
- ustekinumab-aekn (Selarsdi) - ustekinumab-aauz (Otulfi) - ustekinumab-kfce (Yesintek) - ustekinumab-stab (Steqeyma) - ustekinumab-ttwe (Pyzchiva) - ustekinumab-ttwe (unbranded) TIBs: IL-23s	- Wezlana - Stelara	- SC-pre filled syringe as 45mg/0.5mL, 90mg/1mL: Selarsdi, Otulfi, Yesintek, Steqeyma, Pyzchiva - SC-single dose vial as 45mg/0.5mL: Yesintek	<u>Adults</u>: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderate to severely active Crohn's, moderate to severely active ulcerative colitis. <u>≥ 6 years old</u>: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis	indication specific	- Biosimilars to Stelara - ustekinumab-ttwe unbranded is a private label for Quellent Pharmaceuticals - All approved via 351(k); No new clinical studies were completed - Provides no compelling clinical advantage over existing agents	- UF, non-step-preferred - Steqeyma - Otulfi - NF, non-step-preferred - Pyzchiva - Yesintek - Selarsdi - Complete Exclusion: - unbranded (private label) ustekinumab-ttwe - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
vimseltinib (Romvimza) Oncological Agents	- Gleevec - Turalio - Tasigna	Capsule: 14, 20, 30 mg	Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	- hepatotoxicity - embryofetal toxicity - reaction to yellow dyes number 5 and number 6 - increased SCr	- Second CSF1 receptor inhibitor approved for symptomatic treatment of TGCT - Phase 3 study demonstrated efficacy in the Romvimza group vs. placebo (40% vs. 0%) - Efficacy of Turalio appears similar to Romvimza - Romvimza has a warning for hepatotoxicity; Turalio has a Boxed Warning and REMS for serious and fatal hepatotoxicity - Romvimza may be taken with or without food; Turalio requires administration with a low-fat meal - Romvimza provides an alternative to Turalio	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes*

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
May 2025	Drug Class Reviews Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors Designated UF <i>Retain current status (all agents on the list)</i> - abemaciclib (Verzenio) - palbociclib (Ibrance) - ribociclib (Kisqali) Targeted Immunomodulatory Biologics: IL-1, IL-6, and CTLA4-Ig subclasses Designated UF <i>Add or retain current status for all agents on the list</i> - anakinra (Kineret) <i>on contingent list</i> - sarilumab (Kevzara) <i>on the list</i> - tocilizumab (Tyenne) <i>on contingent list</i> Designated NF <i>Add or retain current status for all agents on the list (no reason to exempt from NF TMOP requirement)</i> - abatacept (Orencia) <i>on the list</i> - rilonacept (Arcalyst) <i>on contingent list</i> - satralizumab (Enspryng) <i>on list</i> - tocilizumab (Actemra) <i>on list</i> Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF - hydroxyurea solution (Xromi) Designated NF (no reason to exempt from NF TMOP requirement) - hydrochlorothiazide suspension (Inzirgo)	Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Do not add—acute or limited duration of use</i> - letermovir (Prevymis) - suzetrigine (Journavx) Designated NF <i>Exempt from NF TMOP requirement (established general exception for antidepressants)</i> - trazodone oral solution (Raldesy)

*Legal/Regulatory Authorities

- 10 USC 1074g(a)(9) requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to these requirements are listed on the TRICARE Maintenance Drug List (TMDL).
- 32 CFR 199.21(r) implements 10 USC 1074g(a)(9) and sets out operation of the TMDL in detail.
- 32 CFR 199.21(h)(2)(ii) requires that non-formulary pharmaceutical agents be “generally not available in military treatment facilities or in the retail point of service.” As a result, NF/Tier 3 agents (including generics) must be on the TMDL unless a reason exists to exempt the agent from the NF TMOP requirement (e.g., acute use, clinical considerations, not available at TMOP, cost effectiveness).
- 32 CFR 199.21(g)(5) covers formulary status and review of newly approved drugs (other than generics), which are added to the UF unless the P&T Committee recommends NF/Tier 3 status within 120 days of approval. In the meantime, newly approved drugs are considered to be in a classification pending status and available under the same terms as NF/Tier 3 medications.

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
May 2025	Drug Class Reviews Targeted Immunomodulatory Biologics: IL-1, IL-6, and CTLA4-Ig subclasses – maintain TIBs class as generally suitable for inclusion on the contingent list; retain/add any agent not already on the TDML to the contingent list Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors – maintain this subclass as generally suitable for inclusion on the contingent list; retain/add any agent not already on the TMDL to the contingent list Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF • concizumab-mtci (Alhemo) • diazoxide choline (Vykat XR) • mirdametinib (Gomekli) • ustekinumab-aauz (Otulfi) • ustekinumab-stba (Steqeyma) • vimseltinib (Romvimza) Designated NF <i>No reason to exempt from TMOP requirement</i> • ustekinumab-aekn (Selarsdi) • ustekinumab-kfce (Yesintek) • ustekinumab-ttwe (Pyzchiva)	

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Due to the volume of recommendations requiring implementation due to the UF Beneficiary Advisory Panel pause, one week was added to implementation, which is reflected in the dates below.

Upon signing: July 20, 2026

Two weeks after signing: August 12, 2026

30 days after Signing: August 26, 2026

60 days after signing: September 29, 2026

90 days after signing: October 28, 2026

120 days after signing: December 2, 2026, due to the Thanksgiving Day holiday

* Note that implementation occurs the first Wednesday following “X” days after signing of the minutes in all points of service.

† P&T Committee Administrative Authorities were used to implement some recommendations not requiring UF BAP comment. See the November 2023 Table of Administrative Authorities.

Appendix H—Drugs with Complete Exclusion Status and Formulary Alternatives

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
May 2025	Alzheimer's Agents	• benzgalantamine (Zunveyi)	• galantamine • galantamine ER • ~~Adlarity Patch~~ (D/C'd from market) • donepezil	• 120 days
May 2025	Interleukin-23 Agents	• ustekinumab-ttwe (unbranded private label)	• adalimumab (Humira) • ixekizumab (Taltz) • ustekinumab (Stelara) • ustekinumab-stab (Steqeyma) • ustekinumab-aaaz (Otulfi) • ustekinumab-auub (Wezlana)	• 120 days

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3).

Drugs recommended for complete exclusion will not be available at the MTFs or TMOP points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the complete exclusion agents at the Retail points of service.

For a cumulative listing of all completely excluded agents to date, refer to previous versions of the P&T Committee quarterly meeting minutes, found on the health.mil website.

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DoD P&T Committee Updates to Approval Authorities

Note that updates are in bold font and strikethrough.

**Table 1. Processes and Recommendation/Approval Authorities
For the May 2025 DoD P&T Committee Meeting**

Process	Function
Administrative (not part of DoD P&T Committee process; Uniform Formulary Beneficiary Advisory Panel (UF BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm5 (Mail Order Pharmacy and Retail Pharmacies Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; P&T Committee Chair and others as needed	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing PA requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non-step-preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to PA forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Implementing temporary PA requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting) and to institute and/or change existing PAs, as necessary, to comply with governing federal law and policy. (from the February 2025 meeting)

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	▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator” drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be “grandfathered” when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative TRICARE Maintenance Drug List. ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative TRICARE Maintenance Drug List from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing “brand over generic” authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon PA. The branded product will adjudicate at the Tier 1 co-pay at the Retail Pharmacies Pharmacy Network and the Mail Order Pharmacy. The “brand over generic” authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating “line extension” products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug and must be from the same manufacturer. Line extensions
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	may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm5, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA “health.mil” website. ▪ ~~Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting.~~ ▪ Adding or deleting drugs or drug classes from the Clinical Services TRICARE Specialty Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List. Addition or deletion of drugs or drug classes from the Clinical Services TRICARE Specialty Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying or revising manual PA criteria, MN criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs, MNs and/or QLs implemented in these situations will be removed when the situation has resolved. ▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA-approved devices or supplies and determination as to whether a new FDA-approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination is made to consider the device for coverage, then the timeline for review by DoD P&T
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	Committee will be established. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. Designating “line extension” devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments	- Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). - Classification of a medication Complete Exclusion status (not covered) on the Uniform Formulary, for products ~~selected for complete exclusion~~ that provide very little or no clinical effectiveness relative to similar agents, and formulation of an implementation plan (including effective date). - Establishment of PA requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). - Changes to existing PA (e.g., due to the availability of new efficacy or safety data). - Discontinuation of PA requirements for a drug. - Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). - Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. - Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. - Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). - Designating individual generic drugs as nonformulary (Tier 3 co-pay). - The Director may approve devices or supplies as recommended by the P&T Committee and the UF BAP; however, approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. - Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with PA criteria and implementation plans as recommended by the DoD P&T Committee and UF BAP.
Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to UF BAP for comments)	- Establishment of quantity limits for a medication, device or supply or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). - Establishment and changes of MN criteria for nonformulary drugs, devices or supplies. - Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF).

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	▪ Addition or deletion of drugs or drug classes, devices or supplies on the ~~Expanded MTF/Mail Order Pharmacy Initiative~~ TRICARE Maintenance Drug List ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the ~~Clinical Services~~ TRICARE Specialty Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. ~~The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.~~ The list is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List.
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**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS ADDENDUM TO THE MAY 2025
MEETING HELD JULY 10, 2025**

Addendum July 10, 2025

Therapeutic Substitution for Tocilizumab (Tyenne and biosimilars) and Interleukin-23 (IL-23) Inhibitors (Stelara and biosimilars)

I. THERAPEUTIC SUBSTITUTION AT MILITARY TREATMENT FACILITIES (MTFs) AND APPLICATION TO TOCILIZUMAB AND USTEKINUMAB

A virtual meeting was held on July 10th, 2025, to recommend therapeutic substitution for tocilizumab and ustekinumab, and to clarify processes for implementing the anticipated upcoming ustekinumab Joint National Contract (JNC) with other Federal partners, as originally outlined in the November 2024 DoD P&T Committee meeting minutes.

Background: The principles of therapeutic interchange were discussed at the May 2025 DoD P&T Committee meeting, including how the direct care network could optimize current utilization management activities through formal recommendations for Military Treatment Facility (MTF) providers to MTF pharmacies. Additional discussion and recommendations are warranted, due to opportunities to participate in JNCs with other Federal partners and to maximize implementation of DoD P&T Committee formulary changes in drug classes, especially those with biosimilars.

Therapeutic substitution is defined as switching from one drug to another within the same therapeutic class or from different classes that have an expected similar pharmacological outcome.

To ensure high quality, effective operation of the TRICARE Pharmacy benefit and to optimize drug selection and maximize cost avoidance, standardized therapeutic substitution programs will be utilized at the MTFs, as directed by the DoD P&T Committee. Therapeutic substitution will only apply to orders/prescriptions written by MTF providers and filled/dispensed at an MTF pharmacy.

At the virtual meeting, the P&T Committee was further briefed on the benefits of therapeutic substitution from both a local MTF and Military Health System (MHS) perspective. A recommended procedure for therapeutic substitution, along with specific recommendations for two drugs, tocilizumab (Actemra originator) and ustekinumab (Stelara originator) were discussed. Providers and pharmacies are notified when the P&T Committee meeting minutes are approved prior to implementation. When a therapeutic substitution occurs, if the original prescription is written for the non-preferred medication, the patient is notified, with subsequent dispensing of the preferred product. This process will occur automatically at the MTF pharmacy, without additional administrative burden for the provider or patient. Benefits include providing an efficient and effective process for maximizing use of cost-effective pharmaceuticals recommended by the DoD P&T Committee and reducing duplicative work for each individual MTF to develop local therapeutic substitution programs or contacting providers on every prescription that needs to be changed.

Therapeutic Substitution for ustekinumab and tocilizumab: Previous DoD P&T Committee conclusions regarding biosimilars are found in the November 2022 and August 2024 DoD P&T Committee meeting minutes. In summary:

- FDA approved biosimilar products, whether officially designated as interchangeable or not, are equally safe and efficacious when compared to the reference product.
- Similar to the U.S. FDA, European Medicines Agency, and the United Kingdom Medicines and Healthcare Regulatory Agency guidance, the DoD P&T Committee will consider all approved biosimilars as highly interchangeable to the reference product for both efficacy and safety.
- The evidence supports the statement that biosimilars, including but not limited to adalimumab, etanercept, certolizumab, golimumab, tocilizumab, ustekinumab and infliximab are equivalent to the originator product and respective biosimilars for efficacy and safety and may be interchanged based on cost effectiveness.
 - *tocilizumab:* The IL-6 subclass was reviewed at the May 2025 DoD P&T Committee meeting. Tocilizumab-aazg (Tyenne) was selected as Uniform Formulary (UF) and step-preferred, while the tocilizumab originator Actemra was recommended for nonformulary (NF), non-step-preferred placement, pending signing of the May P&T committee minutes document. A trial of Tyenne will be required first before the non-step-preferred tocilizumab products, including Actemra, in all new and current users.
 - *ustekinumab:* The IL-23 subclass was reviewed at the November 2024 DoD P&T Committee meeting. The JNC ustekinumab biosimilar (pending selection) was chosen as the UF step-preferred IL-23 agent. At the February 2025 and May 2025 DoD P&T Committee meetings, newly approved ustekinumab biosimilars were reviewed for formulary placement and considered therapeutically equivalent to the reference product and each other. A trial of the JNC-selected ustekinumab biosimilar will be required before use of the other UF non-step-preferred and NF non-step-preferred products.

Conclusion

- Tocilizumab and ustekinumab biosimilars are equally safe and efficacious to their respective biosimilar and reference products. Any new market entrants will be added to the UF only after DoD P&T Committee review.
- Therapeutic substitution for medications filled at MTF pharmacies written by MTF providers will improve efficiency and facilitate cost avoidance by increasing patient movement to the DoD P&T Committee preferred products, while maintaining clinically appropriate care.
- The DoD P&T Committee will ensure appropriate implementation through DHA Pharmacy Operations Division actions, including:
 - Determining clinically appropriate and cost-effective care

- Notifying MTF providers and MTF pharmacies prior to implementation
- Collaborating with the Department of Veteran's Affairs regarding monitoring patient safety reports

COMMITTEE ACTION: RECOMMENDATION ON THERAPEUTIC SUBSTITUTION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) with implementing therapeutic substitution for new and current users to the step-preferred tocilizumab (August 2024 minutes) and ustekinumab (i.e., JNC selected product), contingent on the Director, DHA granting authority. Implementation timeline specifics will be detailed when the JNC award is known and include notification of current patients.

II. **IL-23 INHIBITORS: USTEKINUMAB AND THE UPCOMING JNC SELECTION – PRIOR AUTHORIZATION, MEDICAL NECESSITY CRITERIA AND IMPLEMENTATION PERIOD**

Background: In anticipation of the ustekinumab JNC selection, updates to the Prior Authorization (PA) criteria, Medical Necessity (MN) criteria, and implementation period are required.

- For several years, branded ustekinumab (Stelara) has been designated as UF, non-step-preferred, requiring a trial of adalimumab (Humira) first. Note that at the time of the November 2024 P&T Committee meeting, ustekinumab biosimilars had not yet entered the market. Market entrance of ustekinumab biosimilars first occurred in January 2025 and these biosimilars were subsequently reviewed as new drugs at the February 2025 and May 2025 quarterly DoD P&T Committee meetings.
- In collaboration, the DoD and the Department of Veteran's Affairs (VA) are soliciting for a Joint National Contract (JNC) for ustekinumab. At the November 2024 DoD P&T Committee meeting, the product that will be selected as the JNC-awarded ustekinumab was selected as UF, step-preferred. Stelara was recommended for UF non-step-preferred placement at the meeting. Bids for the JNC solicitation are anticipated in late July 2025, with an anticipated award date of late September 2025, and subsequent effective date of late 2025.
- PA criteria
 - The JNC-awarded ustekinumab will be UF and step-preferred. Automated specialist bypass for gastroenterologists and dermatologists, and automated lookback for adalimumab (Humira) and other ustekinumabs will be added.
 - The UF non-step-preferred ustekinumab products will require a trial of the JNC-awarded ustekinumab first.
 - The NF non-step-preferred ustekinumab products will require a trial of the JNC-awarded ustekinumab and UF non-step-preferred ustekinumab products first.

- The completely excluded ustekinumab products will have interim PA criteria apply, requiring a trial of the JNC- awarded ustekinumab and UF non-step-preferred ustekinumab products first.
- Removing the current wording in the PA criteria for the IL-23 Inhibitor regarding acknowledgement that ixekizumab (Taltz) is the MHS preferred IL-17 product.
- MN criteria
 - For the ustekinumab non-step-preferred products, updating the MN criteria to allow use if there is an adverse reaction to the step-preferred products.
- Implementation Period
 - For the JNC-awarded ustekinumab step-preferred product, an implementation within two weeks of the JNC effective date.
 - For the UF and NF non-step-preferred products, UF formulary status will be effective 60 days after the effective date.
 - For the UF and NF non-step-preferred products, the PA update will be effective 90 days after the effective date.

COMMITTEE ACTION: USTEKINUMAB PA, MN CRITERIA AND IMPLEMENTATION PERIOD RECOMMENDATION ON THERAPEUTIC SUBSTITUTION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) with updates to the ustekinumab PA, MN criteria and implementation period, as outlined above.

SUBMITTED BY:

Signed/Signature on file

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

- X** concurs with all recommendations.
- O** concurs with the recommendations, with the following modifications:

- O** concurs with the recommendations, except for the following:

Signed/Signature on file
Bill A. Soliz
BG, USA
Acting Assistant Director
Health Care Administration and
Operations

July 20th, 2026

Date

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

**MINUTES AND RECOMMENDATIONS
August 2025**

I. CONVENING

The DoD Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on August 6th and 7th, 2025.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February and May 2025 Meeting Minutes— On March 10, 2025, the Secretary of Defense directed a pause of all DoD Advisory Committees, including the Uniform Formulary Beneficiary Advisory Panel meeting (UF BAP). As a result, the UF BAP meeting is delayed, and the signing of the February and May 2025 P&T Committee meeting minutes will also be delayed.

B. Clarification of previous meeting minutes

- **Weight Loss Agents**
 - **May 2025—Prior Authorization regulatory and statutory updates:** Implementation of the regulatory changes to the weight loss PA forms and the new PA criteria for the phentermine, benzphetamine, diethylpropion and phendimetrazine immediate release (IR) and sustained release (SR) occurred on August 31, 2025.
 - **May 2024—Weight Loss Agents Quantity Limits (QLs):** QLs also apply to tirzepatide (Zepbound), consistent with what is currently in place for liraglutide (Saxenda) and semaglutide (Wegovy), with implementation occurring on September 15, 2025.
- **May 2025**
 - **Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet—** Numerous other more cost-effective generic metformin IR and ER tablets are available. This recommendation was implemented May 30, 2025 using administrative authorities
 - **Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet—** There are other tramadol formulations available, including tramadol 50 mg tablets, that are more cost-effective than this 100 mg strength. This recommendation was implemented May 30, 2025 using administrative authorities
- **November 2024**

- **Rapid Acting Insulins**—A Joint National Contract was not awarded. No changes were made to the formulary status or step therapy (PAs) as outlined in the meeting minutes.
- **Miscellaneous Ophthalmic Agents**—Clobetasol ophthalmic emulsion was designated with complete exclusion status. The formulary alternative is dexamethasone 0.01% ophthalmic, and not 0.1%.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to Section 199.21(g)(5) of Title 32, Code of Federal Regulations (CFR) and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All pharmaceutical agents selected for complete exclusion status were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All pharmaceutical agents recommended for uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and complete exclusion status considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018, permanently codified at Section 1074g(a)(10) of Title 10, United States Code (USC). Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, 10 USC 1074g(a)(9) requires beneficiaries to generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List formerly known as the Select Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

A. Atopy Agents: Interleukin (IL)-13 and IL-31 Subclass

Background—The IL-13 and IL-31 subclasses include four biologic agents, dupilumab (Dupixent), lebrikizumab (Ebglyss), nemolizumab (Nemluvio) and tralokinumab (Adbry). All four agents are indicated for treatment of moderate to severe atopic dermatitis; additionally, Dupixent and Nemluvio are indicated for treatment of prurigo nodularis. Dupixent also has several additional indications.

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, meta-analyses and systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles for atopic dermatitis and prurigo nodularis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Atopic Dermatitis

- There are no head-to-head trials comparing Dupixent, Adbry, Ebglyss or Nemluvio.
- Guidelines from the American Academy of Dermatology (AAD) (2023) and the American Academy of Allergy, Asthma & Immunology (2023) support the use of multiple systemic and biologic treatments to treat moderate to severe atopic dermatitis refractory to topical treatments.
 - Both Dupixent and Adbry are recommended in the 2023 AAD guidelines with a high certainty for their evidence for efficacy and that they appear safe. Nemluvio and Ebglyss are not yet included in the guidelines due to their more recent FDA approval in November 2024.
 - Topical agents including corticosteroids and calcineurin inhibitors (i.e., tacrolimus and pimecrolimus) are recommended for mild to moderate atopic dermatitis. Topical agents can be used with phototherapy and systemic therapies for maintenance of response or treatment of flares.
- A 2023 network meta-analysis evaluating the four agents along with the oral Janus kinase (JAK) inhibitors in 149 trials with over 28,000 patients concluded the following:
 - Dupixent, Ebglyss, and Adbry are of intermediate effectiveness and have favorable safety profiles.
 - For the Patient Oriented Eczema Measure, Pruritus Numeric Rating Scale, and Dermatology Life Quality Index all four agents were statistically significant when compared to placebo.
 - For the Eczema Area Severity Index, Dupixent, Ebglyss, and Adbry were all statistically significant in relieving symptoms, with Dupixent and Ebglyss also showing clinical significance.
 - In terms of safety, all four agents did not demonstrate a significant increase in frequency of any adverse event. However, Dupixent, Adbry and Ebglyss did show an increased frequency of conjunctivitis, compared with standard care. Dupixent demonstrated a reduced odds of serious adverse events and adverse events leading to discontinuation when compared to placebo.
- Additional literature review included two placebo-controlled trials published in 2024 evaluating Nemluvio and reported statistically significant results for the four rating scales discussed above, with similar outcomes as reported in the 2023 NMA reviewed.

Prurigo Nodularis

- Dupixent and Nemluvio are currently approved to treat prurigo nodularis. A 2021 U.S. expert consensus panel recommends Dupixent or Nemluvio for disease refractory to topical treatments, or for patients with more severe presentation. Topical corticosteroids and topical calcineurin inhibitors are recommended for mild disease. Other supported treatments include methotrexate, azathioprine, mycophenolate, and cyclophosphamide.
- An indirect efficacy analysis between Dupixent and Nemluvio is challenging due to varying inclusion criteria among the trials. The Dupixent data includes two randomized trials over 24 weeks allowing continuation of stable topical treatments, while Nemluvio includes 2 randomized trials over 16 weeks excluding use of topicals.
- For the proportion of patients achieving Investigator Global Assessment scores of 0 to 1 (clear to near clearance of lesions), the two Dupixent trials and a single Nemluvio trial achieved a statistically significant proportion of responders compared to placebo. For the endpoint of daily quality of life, all the studies showed that treatment with Dupixent and Nemluvio achieved a statistically significant, similar outcome.
- For the individual prurigo nodularis trials, treatment emergent adverse events occurred in over half of the patients across all trials. A higher proportion of patients had disease flare in the Nemluvio trials compared to those in the Dupixent trials.

Other Factors

- Dupixent carries the most FDA-approved indications (eight). The most recent label updates include bullous pemphigoid in adults and chronic spontaneous urticaria in children down to the age of 12 years. For atopic dermatitis, it is approved for children as young as 6 months of age. The package insert lists more warnings and adverse events compared to other agents in the subclass, including herpes simplex virus infection, conjunctivitis, eosinophilia and arthralgia. It is available in pre-filled syringes and pre-filled pens.
- Adbry and Ebglyss are only indicated for the treatment of atopic dermatitis for adults and children down to 12 years of age. Common adverse events for both include conjunctivitis and herpes simplex virus infection; Adbry can cause eosinophilia. Adbry is available in both an autoinjector and pre-filled syringe, while Ebglyss is supplied as prefilled pens and pre-filled syringes.
- Nemluvio is indicated for atopic dermatitis in adults and children as young as 12 years of age as well as prurigo nodularis for adults. Unique adverse events included in the label include headache, urticaria and myalgia. It

offers the longest dosing frequency of up to 8 weeks and is supplied as a pre-filled pen.

- In terms of therapeutic interchangeability, for efficacy for treating atopic dermatitis, Dupixent, Adbry, Ebglyss and Nemluvio have a high degree of therapeutic interchangeability; for safety, there is a moderate degree of therapeutic interchangeability. For prurigo nodularis, Dupixent and Nemluvio have a high degree of interchangeability for efficacy, and moderate degree of interchangeability for safety.

Overall Conclusion

- For clinical coverage, at least one agent is needed on the formulary to treat atopic dermatitis and prurigo nodularis in order to meet the needs of Military Health System (MHS) beneficiaries.

Relative Cost Effectiveness Analysis and Conclusion—The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) designating all four drugs as UF was cost-effective, based on the CMA and BIA.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - dupilumab (Dupixent)
 - lebrikizumab (Ebglyss)
 - nemolizumab (Nemluvio)
 - tralokinumab (Adbry) - *moves from NF to UF*
- NF: None
- Complete Exclusion: None

2. COMMITTEE ACTION: MANUAL PA CRITERIA—Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updated manual PA criteria as outlined in Appendix C for new users.

- In general, specialist prescribing is required, and renewal is recommended after one year, documenting improvement in symptoms.
- Guideline-recommend therapies are required first, including topical treatments and phototherapy for atopic dermatitis, and other therapies, depending on indication (e.g., pulmonary inhalers for asthma and chronic obstructive pulmonary disease for Dupixent; nasal saline irrigation and nasal steroids for nasal polyps).

- The new indications for Dupixent for bullous pemphigoid and chronic spontaneous urticaria were added to the PA.
 - For Ebglyss, automated specialist bypass for patients 12 years of age and older when prescribed by a dermatologist, allergist or immunologist was added to bypass the PA. Additionally, an automated drug look back was added for Ebglyss, to allow continuation of coverage by any other prescriber if the patient has received a prescription for Ebglyss in the past 720 days.
3. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QL of a 60-day supply at all points of service for all four drugs. See Appendix D.
 4. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining all the drugs on the Specialty Drug List and maintaining Dupixent and Adbry on the TRICARE Maintenance Drug List; Ebglyss and Nemludio were not added to the list. See Appendix F for the TRICARE Maintenance Drug List details.
 5. **COMMITTEE ACTION: UF, PA, QLs, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. See Appendix G.

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the mineralocorticoid receptor antagonists (MRAs). The subclass is comprised of two generic medications, eplerenone and spironolactone (available in tablets and oral suspension), and branded finerenone (Kerendia). Kerendia was previously reviewed as a new drug in November 2021 and is designated as NF.

In terms of FDA-approved indications, eplerenone and spironolactone are both indicated for treating hypertension, and all three drugs are approved for heart failure. Finerenone is also approved for treating type 2 diabetic chronic kidney disease (CKD). Spironolactone has several additional indications including edema due to nephrotic syndrome or cirrhosis, and primary hyperaldosteronism. The clinical review focused on the place in therapy for type 2 diabetic CKD and heart failure.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

Efficacy for Type 2 diabetic CKD

- In patients with type 2 diabetes receiving therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), finerenone is approved to reduce the composite endpoint of decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction and heart failure hospitalization, based on the FIDELIO and FIGARO studies.
 - Limitations to the results include the low use (4%) of current guideline-accepted background therapy with sodium-glucose transporter-2 (SGLT-2) inhibitors. Additionally, in the FIDELIO study, the results were driven by the reduction in eGFR; no difference was noted in progression to end-stage kidney disease or the other individual components of the composite endpoint.
- Studies with eplerenone and spironolactone report that both drugs reduce proteinuria, but do not reduce adverse renal outcomes (e.g., progression to end-stage kidney disease). There was a significantly increased risk of hyperkalemia. Overall, the long-term effects of eplerenone and spironolactone on renal outcomes, mortality, and safety for type 2 diabetic CKD remain to be established.
- Finerenone is now included in several clinical practice guidelines to slow the progression of CKD in patients with Type 2 diabetes. However, ACE inhibitors or ARBs remain the mainstay of therapy as first-line treatment. Guidelines also state the SGLT-2 inhibitors are preferred and more-established therapies, before adding finerenone. Guidelines reviewed included, but were not limited to, the following: 2024 American Diabetes Association, 2024 Kidney Disease Improving Global Outcomes, 2025 VA/DoD, and the 2023 United Kingdom National Institute for Clinical Effectiveness.

Efficacy for heart failure

- In July 2025, finerenone received approval for patients with heart failure and preserved ejection fraction (HFpEF) based on the FINEARTS trial. Treatment with finerenone resulted in a 16% risk reduction in the composite of worsening heart failure event and CV death. No significant difference was noted for the individual endpoints of mortality or kidney outcomes. The results were driven by a reduction in heart failure events. As with CKD, the study is limited by low background use of SGLT-2 inhibitors.
- Spironolactone showed a 30% reduction in all-cause death in patients with heart failure and reduced ejection fraction (HFrEF) in the landmark RALES study. Reduced mortality (20% risk reduction) was seen for HFpEF in the TOPCAT study, when the results were limited to North America.

- Eplerenone showed a 15% reduction in all-cause death in patients with heart failure after myocardial infarction (EPHESUS).
- For HFpEF, SGLT-2 inhibitors remain the mainstay of therapy, based on results from several large trials. Other drug classes, including diuretics, eplerenone or spironolactone, sacubitril/valsartan or ARBs are added, based on individual patient clinical presentation (2023 American College of Cardiology.) Finerenone is not specifically mentioned in the guidelines.
- For HFrEF, spironolactone and eplerenone hold a Class I recommendation (strong evidence) for patients with New York Heart Association (NYHA) class II-IV heart failure (2023 American College of Cardiology).

Safety

- Adverse events associated with all three MRAs include hyperkalemia, hypotension, and hyponatremia.
- Finerenone has different receptor affinity than spironolactone, which may account for some differences in the adverse event profile. Lack of head-to-head trials and study design run-in criteria complicates ability to determine if the hyperkalemia risk with finerenone is favorable or unfavorable compared to eplerenone or spironolactone.
- Gynecomastia does not appear to be an issue with eplerenone or finerenone.

Other factors

- MHS providers requested UF placement of finerenone, due to inclusion in national guidelines for T2DM and CKD but acknowledged other guideline-recommended therapies should be used first.

Clinical Coverage

- In order to meet the needs of MHS patients, finerenone should be included on the formulary, despite limitations in clinical trial data.
- Spironolactone oral suspension is required for the pediatric population for edema and heart failure.

Relative Cost Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) that designating finerenone as UF rather than NF would be cost-effective.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following.

- UF

- eplerenone (Inspra, generics)
 - finerenone (Kerendia) - *moves from NF to UF*
 - spironolactone (Aldactone, generics)
 - spironolactone/hydrochlorothiazide (Aldactazide, generics)
 - spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*
- NF – None
 - Complete Exclusion – None
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA criteria currently apply to Kerendia and for spironolactone oral suspension. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) revising the PA criteria for Kerendia in new users to incorporate feedback from MHS providers for the CKD indication, to modify the safety questions, and to add the new indication for HFpEF based on the inclusion and exclusion criteria from the FINEARTS trial. Other guideline-directed therapies are required first, based on clinical practice guidelines. No changes were recommended for the PA for spironolactone suspension. See Appendix C for the full criteria.
 3. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS**—Spironolactone and eplerenone are not currently included on the list. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) removing spironolactone oral suspension from the list. Kerendia was not added to the list. See Appendix F.
 4. **COMMITTEE ACTION: UF, PA, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G.

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (19 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 2025 DoD P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the TRICARE Drug Maintenance List.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF

- acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent
- atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
- avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
- berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
- efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)
- ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
- fitusiran (Qfitlia) – Antihemophilic Agent
- insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
- nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph⁺ CML)
- taletrectinib (Ibtrozi) – Oncological Agent for NSCLC
- treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension (PAH) Agent

- NF

- chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
- garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
- hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
- losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
- terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent
- ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara

- ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara
- Complete Exclusion: See Appendix H for additional detail regarding complete exclusion agents and formulary alternatives.
 - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent
 - Combogesic was recommended for complete exclusion status as it has little to no clinical benefit relative to administering acetaminophen and ibuprofen separately, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include acetaminophen 325 mg and ibuprofen 200 mg.
 - meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent
 - Symbravo was recommended for complete exclusion status as it has little to no clinical benefit relative to administering meloxicam and rizatriptan separately, and the needs of TRICARE beneficiaries are met by alternative agents. Alternatives include meloxicam, rizatriptan, and sumatriptan/naproxen (Treximet).
 - ustekinumab-aekn (unbranded ustekinumab-aekn Selarsdi private label by Teva) – TIBs IL-23s
 - The ustekinumab-aekn private label brand was recommended for complete exclusion status as it has little to no clinical benefit relative to other ustekinumab biosimilars, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include ustekinumab-auub (Wezlana), ustekinumab-auuz (Otulfi), ustekinumab-stab (Stequeyma), and ustekinumab (Stelara).

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Andembry, Arbli, Hemiclor, Khindivi, Tezruly, ustekinumab (unbranded Stelara by Janssen) and ustekinumab-slrf (Imuldosa). The MN criteria for NF ustekinumab products will also allow a trial of branded Stelara. See Appendix B for the full criteria.

3. **COMMITTEE ACTION: PA CRITERIA**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria. See Appendix C for the full criteria.

- Applying manual PA criteria to new users of the NF ustekinumab products ustekinumab (unbranded Stelara by Janssen) and

ustekinumab-slr (Imuldosa), similar to what is required for all non-step-preferred Interleukin-23 inhibitors, where a trial of adalimumab (Humira) will be required first. These products are non-step-preferred.

- Additionally, PA criteria will apply to private label ustekinumab-aekn, until implementation of the complete exclusion status. Providers will need to document why the unbranded private label product is required, rather than using the UF and NF ustekinumab products.
 - Applying manual PA criteria to new users of Qfitlia, similar to the PA requirements for other hemophilia agents.
 - Applying manual PA criteria to new users of Andembry, Arbli, Avmapki Fakzynja, Ensacove, Ibtrozi, Khindivi, nilotinib d-tartrate 50, 150, 200 mg capsules, Tezruly, Tryptyr, Vanrafia, Vyvgart Hytrulo, Yutrepia, and Zelsuvmi.
 - Applying temporary manual PA criteria to new and current users of Combogesic and Symbravo, until implementation of complete exclusion status.
4. **COMMITTEE ACTION: QLs**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) QLs for Andembry, Avmapki Fakzynja, Ensacove, Hemiclor, Ibtrozi, Imuldosa, nilotinib d-tartrate, Qfitlia, Tryptyr, ustekinumab by Janssen, Vyvgart Hytrulo, and Yutrepia. See Appendix D for the QLs.
5. **COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) adding Andembry and Khindivi to the Rapid Response program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill after the initial reject.
6. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LIST REQUIREMENTS**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List which includes the NF medications subject to the TMOP requirement. Drugs recommended to be added to the Specialty Drug List are listed in Appendix E.
7. **COMMITTEE ACTION: UF, MN, PA, QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LIST, and IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF and NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.
- **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service; and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion status at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for seven recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for the newly approved drug reviews and cannot be reviewed for formulary status. Numerous cost effective formulary alternatives are available that do not require prior authorization.

- Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablet**—There are other bisoprolol formulations available, including bisoprolol 5 mg tablets (scored), that are more cost-effective than this 2.5 mg strength.
- Antianxiety Agents—buspirone (Bucapsol)**—These buspirone capsules are less cost-effective than currently available buspirone tablets. Buspirone tablets are available in the same strengths or can be split to achieve the same strengths as these buspirone capsules.
- Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tablets (Clemasz)**—This clemastine tablet is less cost-effective than other clemastine tablets that are available in the same strength.
- Pain Agents: NSAIDs—diflunisal 375 mg tablet (Dolobid)**—Numerous other more cost-effective generic NSAIDs are available.
- Pain Agents: NSAIDs—flurbiprofen (Lurbipr)**—There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.
- Antidepressants and Non-opioid Pain Syndrome Agents: SSRIs—escitalopram 10 mg/10 mL dosing cups**—Various other more cost-effective generic escitalopram mg/10 mL solutions are available.
- Diabetes Non-Insulin: Biguanides—metformin 625 mg immediate release (IR) tablet**—Numerous other more cost-effective generic metformin IR and extended release (ER) tablets are available.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for bisoprolol 2.5 mg tablets, buspirone capsules (Bucapsol), clemastine (Clemasz), diflunisal (Dolobid) 375 mg tablets, escitalopram 10 mg/10 mL dosing cups, flurbiprofen (Lurbipr), and metformin 625 mg IR tablets in new users, due to the significant cost differences compared with other available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

2. New Manual PA Criteria

- a) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists—leuprolide acetate (Lutrate Depot) 22.5 mg**—Lutrate Depot is a new formulation similar to other leuprolide products (Lupron Depot, Eligard). It is less cost-effective than the preferred leuprolide (Eligard), so new PA criteria will apply, requiring a trial of Eligard first, similar to Lupron Depot.

COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Lutrate Depot in new users. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

3. Updated PA and MN Criteria for New FDA-Approved Indications

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- a) **Atopy—mepolizumab (Nucala)**—Nucala is now indicated for the treatment of COPD. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the COPD criteria for other biologics, requiring use of traditional oral inhalers first.
- b) **Atopy: Oral JAK-1—upadacitinib (Rinvoq)**—The manual PA criteria were updated to allow for the new giant cell arteritis indication. Specialists supported requiring a trial of glucocorticoids and tocilizumab first, for this indication.
- c) **Endocrine Agents Miscellaneous—osilodrostat (Isturisa)**—The manual PA criteria were updated to reflect minor changes in the FDA label and to remove the warnings and precautions language as this drug is restricted to specialists.

- d) **Hematological Agents—iptacopan (Fabhalta)**—The manual PA was updated to include the new indication of Complement 3 Glomerulopathy (C3G). In addition, the PA for IgAN was updated to require a trial of Vanrafia or Filspari. The list of formulary alternatives were expanded in the MN criteria, as Fabhalta is currently designated as NF.
- e) **Immunosuppressives—belimumab (Benlysta)**—Benlysta is now indicated in children as young as 5 years old with lupus nephritis. The PA criteria were updated accordingly.
- f) **Oncological Agents—belzutifan (Welireg)**—Welireg received a new indication for locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma. Additionally, the FDA revised the renal cell carcinoma indication to clarify use for a clear cell component. The manual PA was updated to reflect these changes.
- g) **Psoriasis Agents—roflumilast 0.3% foam (Zoryve)**—The manual PA criteria were updated to include the new indication for plaque psoriasis with the PA mirroring standard plaque psoriasis criteria.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Zoryve, Nucala, Benlysta, Isturisa, Welireg, Rinvoq, and the Fabhalta PA and MN updated criteria in new users. Implementation for the PA and MN criteria updates will be effective the first Wednesday 60 days after the signing of the minutes. See Appendices B and C for the full criteria.

4. Updated PA and MN Criteria for Reasons other than New Indications

Updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

- a) **Insulins: Rapid-Acting Agents—glulisine (Apidra) and lispro (Admelog)**—Insulin aspart-szjj (Merilog) was added as a preferred agent on the Apidra and Admelog PAs. Additionally, the MN criteria were updated to include Merilog.
- b) **GI-1 Agent—budesonide oral suspension (Eohilia)**—The Eohilia PA was modified to allow use by general surgeons due to MTF provider feedback.
- c) **Hematological Agents: Platelets—avatrombopag (Doptelet)**—The manual PA criteria were updated based on MTF provider feedback, expanding the specialists to allow hematologist and oncologist prescribing in addition to gastroenterologists, regardless of indication.
- d) **Overactive Bladder (OAB) Agents: Beta-3 Adrenergic Agonists—mirabegron tablets (Myrbetriq) and vibegron (Gemtesa)**—Myrbetriq and Gemtesa are beta-3 agonists used to treat OAB. Currently, both drugs

are UF with a PA requiring a trial of generic anticholinergics. Efficacy is similar between anticholinergics and beta-3 agonists. PA automation was added to both PAs, to include specialist bypass for Myrbetriq tablets and an automated lookback for anticholinergics for both Myrbetriq and Gemtesa.

- e) **White Blood Cell Stimulants: Filgrastims—filgrastim-sndz (Zarxio)—**
Zarxio was moved from step-preferred to non-step-preferred status on the filgrastim PA. This change was due to Zarxio no longer being cost-effective and due to a high degree of therapeutic interchangeability in this biosimilar class.
- f) **Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound)—**
The definition of uncontrolled hypertension was clarified on the Wegovy and Zepbound PAs, based on provider feedback and hypertension professional treatment guidelines. Patients are considered to have uncontrolled hypertension if they do not meet individual blood pressure goal on two or more antihypertensive drugs.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Apidra, Admelog, Doptelet, Eohilia, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy and updates to the MN criteria for Apidra, Admelog, and Genotropin in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

5. Removal of PAs

- a) **Cardiovascular Agents Miscellaneous—ivabradine (Corlanor)—**
Currently, ivabradine (Corlanor) tablets are UF, with cost effective generic formulations now available. There is stable utilization of the drug and a low risk of inappropriate use. The PA will be removed for ivabradine (Corlanor) tablets.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for ivabradine (Corlanor) tablets. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Line Extensions

The P&T Committee clarified the formulary status for two product line extensions by the original manufacturer. Line extensions have the same FDA indication(s) as the “parent” drug and retain the same formulary and copayment status as the “parent” drug.

1. Metabolic Agents Miscellaneous—designating maralixibat (Livmarli)

tablet with the same formulary status (NF), PA and MN criteria, QL, and Specialty Drug List as the parent Livmarli solution.

2. **Antiretrovirals: Non-nucleoside Reverse Transcriptase Inhibitors**—designating **rilpivirine (Edurant Ped) tablet for oral suspension** with the same formulary status (UF) as the Edurant tablets.

COMMITTEE ACTION: LINE EXTENSION AND

IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, MN criteria and Specialty and TRICARE Maintenance Drug Lists for Livmarli tablets and Edurant Ped tablets for oral suspension. Implementation will occur the first Wednesday two weeks after signing of the minutes.

C. Prostate Cancer Agents: CYP-17 Inhibitors—abiraterone acetate (Zytiga)

Abiraterone acetate 250 mg and 500 mg tablets (Zytiga) are available in generic formulations and require administration on an empty stomach. Abiraterone acetate micronized (Yonsa) is only available as a branded agent and is taken without regard to meals. Provider feedback and prostate cancer guidelines suggest that there is a high degree of therapeutic interchangeability between these two products. Yonsa has a tier 1 copay from when the class was last reviewed in February 2019. PA criteria apply to all three abiraterone formulations. At the August 2024 meeting, the PA for Zytiga and generic formulations were given automated PA specialist bypass and drug lookback criteria to allow PA approval if the prescriber is an oncologist, hematologist or urologist and continuation by a non-specialist.

Generic Zytiga 250 mg is now the most cost effective abiraterone formulation, compared with the generic Zytiga 500 mg strength and Yonsa. The following changes were recommended:

- abiraterone acetate 250 mg (Zytiga and generic)
 - Remove PA
- abiraterone acetate 500 mg Zytiga and generic)
 - Remove automated specialist bypass and the automated drug lookback
 - Require a trial of abiraterone acetate 250 mg in new and current users
 - Send letters to current users
- abiraterone acetate micronized (Yonsa)
 - Remove Tier 1 copay
 - Require a trial of generic abiraterone 250 mg in new and current users
 - Send letters to current users

COMMITTEE ACTION: ONCOLOGICAL AGENTS: CYP-17

INHIBITORS PA CRITERIA, TIER 1 COPAY REMOVAL, RAPID RESPONSE PROGRAM, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent)

the following effective dates, as outlined below. Additionally, abiraterone acetate 500 mg (Zytiga and generic) and abiraterone acetate micronized (Yonsa) will be added to the Rapid Response (safety net) program. (See Appendix C).

- *abiraterone acetate 250 mg (Zytiga and generic) PA removal*: an effective date of the first Wednesday 2 weeks after signing of the minutes.
- *abiraterone acetate 500 mg (Zytiga and generic) and abiraterone acetate micronized (Yonsa)*: 1) an effective date of the first Wednesday 120 day after signing of the minutes, and that 2) DHA send letters to the patients affected by the PA changes.

VII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA)

Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease—

Umeclidinium/vilanterol (Anoro Ellipta) inhaler is designated as UF without a PA. An authorized generic has entered the market; however, this product is less cost-effective compared to the branded agent. Therefore, the branded Anoro Ellipta inhaler will continue to be dispensed at all three points of service, and the authorized generic will only be available with prior authorization. The brand Anoro Ellipta will continue to have the Tier 2 copay, as the authorized generic umeclidinium/vilanterol has a Tier 2 copay.

COMMITTEE ACTION: ANORO ELLIPTA BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) requiring brand Anoro Ellipta inhalers over the authorized generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The effective date will be the first Wednesday 60 days after signing of the minutes. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. See Appendix C.

VIII. MHS GENESIS OVER-THE-COUNTER (OTC) LIST UPDATE

Background—Over-the-counter (OTC) products dispensed at MTFs comprise 1) those explicitly included as part of the pharmacy benefit (e.g., diabetic supplies), 2) those added to the pharmacy benefit after P&T Committee review under provisions of 32 CFR 199.21(h)(5) as cost effective and clinically effective compared to other drugs in the same class (e.g., loratadine tabs, cetirizine tabs, fexofenadine, levonorgestrel 1.5 mg, doxylamine 25 mg, naloxone, and norgestrel 0.075 mg), and 3) OTC products on the MHS GENESIS OTC list, which identifies drugs that will adjudicate through the Pharmacy Data Transaction Service under GENESIS and are dispensed only at MTFs.

The MHS GENESIS OTC list was instituted as an operational list to facilitate MHS GENESIS implementation; it was standardized across MTFs by DHA Administrative Instruction 6025.17 (MTF Formulary Policy, 17 July 2023), which states that “Over-the-counter (OTC) agents, on the MHS-GENESIS OTC list, will be made available when ordered by a provider. A subset of OTC medications may be made available to beneficiaries without a prescriber order upon request as part of an OTC-self-care program.” The Director, DHA, has authority to expand, limit, or eliminate the MHS GENESIS OTC list.

The P&T Committee discussed concerns regarding prescription volume, personnel resources, and medical appointments associated with dispensing OTC products at MTFs, as well as pros and cons associated with dispensing products on the MHS GENESIS OTC list at MTFs. OTC drugs with no MTF dispensing in the last quarter were evaluated for potential removal from the list.

COMMITTEE ACTION: REMOVAL OF AGENTS ON THE MHS GENESIS

OTC—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the following OTC products on the MHS GENESIS list with no dispensing over the last 3 months (3QFY25), comprising the following 15 generic code names (GCNs) (products defined at drug/strength/dosage form level), out of 265 GCNs total. Implementation will occur two weeks after signing of the minutes.

- 91071 – piperonyl butoxide/pyrethrins 4%-0.33% shampoo
- 97298 – omega-3 fatty acids/fish oil 340-1000 mg cap
- 52693 – omega-3/DHA/EPA/fish oil 300-1000 mg cap
- 53466 – omega-3/DHA/EPA/fish oil 115-172 mg cap delayed release
- 08380 – lactobacillus acidophilus cap (e.g., Acidophilus)
- 28678 – lactobacillus reuteri 100 mm/5drp drops susp (e.g., Gerber Soothe)
- 41197 – L. acidophilus/pectin, citrus 7.5-100 mg cap (e.g., Acidophilus)
- 36830 – petrolatum, white oint (g) (e.g., Hydrolatum)
- 77729 – mineral oil/petrolatum, white cream (e.g., Dermacerin)
- 52269 – Vit C/E/Zn/copper/lutein/zeaxan 250mg-90mg cap (e.g., Eye Health)
- 28080 – dibucaine 1% ointment
- 78090 – parab/cet alc/stearyl alc/pg/sls cleanser

IX. COMPLETELY EXCLUDED DRUGS DESIGNATED WITH COMPLETE EXCLUSION: ANNUAL REVIEW

Background— P&T Committee reviewed all drugs designated with complete exclusion from the pharmacy benefit program under 32 CFR 199.21(e)(3), which allows the Committee to recommend special Uniform Formulary actions “to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending.” This specifically includes “a complete or partial exclusion from the pharmacy benefits

program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD.”

Drugs designated with complete exclusion are not available at the MTFs or TMOP points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies. The Committee plans to review complete exclusion status drugs on an annual basis.

The P&T Committee reviewed all the drugs currently designated with complete exclusion. The P&T Committee found no significant new clinical data, guidelines, or indications for any of the products that would change the previous conclusion that the drug offers little or no clinical effectiveness relative to similar agents. The Committee also found that all the complete exclusion drugs remain substantially more costly than similar agents, although prices have decreased for a few generically available products, which will continue to be monitored.

Two drugs were discussed in detail.

- *Diuretics—furosemide SC injection (Furoscix)*: This single-use, on-body infusor administers 80 mg of furosemide over 5 hours. In addition to treating patients with congestion due to New York Heart Association Class II/III heart failure, the FDA indication was expanded to include treatment of adults with edema due to chronic kidney disease, including the nephrotic syndrome. No new clinical trials were conducted for this indication, and no studies are available to show that this device reduces heart failure hospitalizations. Furoscix is not currently mentioned in heart failure clinical practice guidelines. Feedback from cardiologists did not support a clinical need for Furoscix in practice.
- *Miscellaneous Anti-Infectives—omeprazole magnesium, amoxicillin and rifabutin (Taliaia)*: Talicia is approved to treat *Helicobacter pylori* (*H. pylori*) infections. The primary difference between this product, which combines all three components in one capsule (to be administered as 4 capsules three times daily), and the individual components taken separately, is that Talicia provides rifabutin 50 mg three times daily, while generic rifabutin is available only as a 150-mg tablet.

The 2024 American College of Gastroenterology guidelines for treatment of *H. pylori* cite a pharmacokinetic modeling study to suggest that rifabutin 50 mg administered three times daily may have advantages relative to 150 mg administered once daily in terms of duration of time above minimum inhibitory concentration (MIC₉₀) and lower risk of transient myelosuppression. However, it is not clear from the evidence that either effect is clinically relevant, and the optimal dose of rifabutin is unknown. The guidelines suggest rifabutin triple therapy as an option for both treatment-naïve and treatment-experienced patients, with “optimized bismuth quadruple” therapy (proton pump inhibitor, bismuth, tetracycline, and metronidazole) recommended in treatment-naïve patients and patients with a penicillin allergy and suggested in treatment-experienced patients.

Gastroenterologists and infectious disease providers did not see a need for Talicia to be on the formulary. They preferred optimized bismuth quadruple therapy and stated that they could use the individual components of Talicia instead.

COMMITTEE ACTION: UF RECOMMENDATION FOR DRUGS CURRENTLY DESIGNATED WITH COMPLETE EXCLUSION

STATUS—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) no changes to the drugs currently designated with complete exclusion status, as the products have little to no clinical benefit relative to other drugs in their respective classes, and the needs of TRICARE beneficiaries are met by alternative agents.

IX. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

- A. Fertility Medications**—32 CFR 199.4 excludes from coverage “services and supplies related to noncoital reproductive technologies, including but not limited to artificial insemination (including cost related to donors and semen banks), In Vitro Fertilization (IVF) and Gamete Intrafallopian Transfer (GIFT).” PAs currently apply to limit coverage of noncoital reproductive technologies for the following drugs Gonal-F (alpha), Follistim (beta), Bravelle (highly purified), Luveris, Menopur, and Repronex. Additional drugs were identified as requiring PA, due to policy. These drugs include the chorionic gonadotropins (Pregnyl, Novarel, and Ovidrel), GnRH agonists (Lupron), and GnRH antagonists (Cetrotide, Antagon). A PA will be added to these agents for new users. See Appendix C.
- B. Pulmonary Arterial Hypertension: Endothelin Receptor Agonists**—Pulmonary arterial hypertension (PAH) endothelin receptor agonists (ERAs) as a class require risk evaluation and mitigation strategies (REMS) due to fetal toxicity. These drugs also contain a black box warning. In April 2025, the FDA removed REMS requirements for the following ERAs: ambrisentan (Letairis, generics), macitentan (Opsumit), and macitentan/tadalafil (Opsynvi). A REMS program is still required for bosentan (Tracleer, generics). REMS criteria were removed from the PA criteria for ambrisentan (Letairis, generics), macitentan (Opsumit), and macitentan/tadalafil (Opsynvi). See Appendix C.
- C. Growth Stimulating Agents—growth hormone (Genotropin) MN Criteria**—Genotropin is a step-preferred growth hormone with a potential supply shortage. The non-step-preferred growth hormone MN criteria require a trial of all step-preferred growth hormone agents. In light of anticipated shortage, the MN criteria were modified to only require three short-acting and two long-acting agents.
- D. DoD/VA Continuity of Care List:** The DoD/VA Continuity of Care Drug List is a joint list of medications for pain, sleep disorders, psychiatric conditions, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by Section 715 of the NDAA 2016. Additions, deletions, and clarifications to the list are based on active duty service member prescription utilization patterns, formulary status and clinical considerations, and discussions between DoD and VA subject matter experts. The P&T Committee was notified that no new additions or deletions were

identified for the list during this year's review of FY 24 utilization trends. The list is posted on www.health.mil.

E. Therapeutic Continuous Glucose Monitoring Systems (CGMS)—FreeStyle Libre 2 and FreeStyle Libre 3 sensors market discontinuation in late 2025:

The manufacturer intends to transition patients to the newest Libre 2 Plus and Libre 3 Plus systems. As of this meeting, FreeStyle Libre 2 Plus is not yet part of the TRICARE pharmacy benefit due to the UF Beneficiary Advisory Panel pause. (The TRICARE medical benefit is the primary coverage route for the CGMs.) Formulary alternatives include FreeStyle Libre 3 Plus (which is not compatible with the Omnipod systems), or Dexcom G6 or Dexcom G7 (which are compatible with Omnipod systems). Traditional fingersticks are also an option.

F. Benefit Clarification: Keratolytics—urea cream—Topical urea is used as a moisturizer and keratolytic and is available over-the-counter (OTC) and as a legend product but is not FDA approved. The legend-only strengths include urea 35%, 39%, 40%, 41%, 45%, and 47%. MTF dermatologists stated that they only used the OTC and 40% strengths and that the other strengths are not needed clinically. The 40% strength is cost-effective, while the other strengths are less cost-effective. The 41% strength is notably not cost-effective and was addressed with a PA addition at the May 2025 meeting. However, given that these products are not FDA approved, they will be excluded from the TRICARE pharmacy benefit, and the PA recommendation will not be implemented. The cost-effective urea 40% cream will remain available to beneficiaries. These changes align with commercial standards from other health plans. Current users of the 35%, 39%, 41%, 45% and 47% urea formulations will receive letters notifying them of the change, 60 days after signing of the minutes.

G. TPHARM5 Specialty Drug Update: The P&T Committee was updated on the current status of specialty products dispensed through the TMOP under the 5th Generation Pharmacy Services (TPharm5) contract, which has resulted in cost avoidance related to movement of specialty prescriptions to lower cost points of service (MTFs or TMOP), as well as lower TMOP point of service copays and enhanced clinical services for beneficiaries.

XII. ADJOURNMENT—The meeting adjourned at 1430 hours on August 7th. The next meeting will be in November 2025.

Appendix A—Attendance: August 2025 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary during the Aug 2025 DoD P&T Committee Meeting

Appendix G—Implementation Dates

Appendix H—Complete Exclusion Drugs and Formulary Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

Signed/Signature on file

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

BG Soliz/Signed/Signature on file

Acting Assistant Director
Health Care Administration and
Operations

Date 20 July 2026

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
MAJ Donald Rees, MC, for LTC Megan Donahue, MC	Army, Physician at Large
LTC Ryan Burkhardt, MC	Army, Internal Medicine Physician
COL James Masterson, MSC	Army, Pharmacy Consultant
CDR Todd Hansen, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
MAJ Loraine Baraki, MC	Army, OBGYN
CAPT Peter Cole, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Lt Col Sara DeSpain, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
David Nowinski, PharmD, BCOP	DHA, Oncology Pharmacist
CDR Jackie Finocchio, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA (Day #2)	TRICARE Health Plan Chief Medical Officer
COL Yang Xia, MC (Day #1)	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Peter Glassman, MD	Department of Veteran’s Affairs
Eric Dill, PharmD	Department of Veteran’s Affairs
Marsha Peterson	DHA Contracting Officer
Eric Parsons, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integration Branch
Lt Col Josh Stallings	Defense Logistics Agency
Guests	
COL Thurman Saunders	Deputy, Deputy Assistant Director, Health Care Operations
CAPT Tiffany Cline, MSC	DHA POD Beneficiary Advisory Panel DFO
CPT Ji Yoon Kim, MSC	Army Pharmacist
CDR Katie Jaudon	DHA POD, Direct Car Branch
Hazel Richardson, PharmD	CDC WTCHP
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
Lt Col Pansy Uberoi	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
CPT Ji Yoon Kim	DHA POD Formulary Management Branch
Michael Lee, RPh, MBM, MPharm-Econ	DHA POD Formulary Management Branch
David Folmar, RPh, MS, MBA	DHA POD Formulary Management Branch

Appendix A—Attendance

Helen Feinstein, PharmD	DHA POD Formulary Management Branch
Fakhrudin Valibhai, PharmD	DHA POD Pharmacy Benefit Integration Branch
Lt Col Brandy Renner, BSC	DHA Direct Care Branch
Maj Alex Patlovany, BSC	DHA POD Direct Care Brach
LT Sarina Acharya, MSC	Navy Pharmacy Resident San Diego
Col Lisa Seltman, BSC	DHA POD
Tracy Banks	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Stephanie Erpelding	DHA Contracting
Jules Canaley	DHA Contracting
Dwight Bonham	DHA Contracting
Kirk Heyen	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity (MN) Criteria
New Drugs MN Criteria	
chlorthalidone 12.5 mg tabs (Hemictlor) Diuretics	No alternative formulary agent: Patient requires a thiazide diuretic and cannot take hydrochlorothiazide 25 mg or cut chlorthalidone 25 mg tablets in half Formulary alternatives: chlorthalidone 25 mg tabs, hydrochlorothiazide tabs
garadacimab injection (Andembry) Corticosteroids-Immune Modulators	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Use of formulary agents has resulted in therapeutic failure Formulary alternatives: C1-inhibitor (Haegarda), C1-inhibitor (Cinryze), lanadelumab (Takhzyro)
hydrocortisone 1 mg/mL oral solution (Khindivi) Corticosteroids-Immune Modulators	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents Formulary alternatives: generic hydrocortisone 5 mg tablets, prednisone intensol oral solution, hydrocortisone 100 mg act-O-vials
losartan 10 mg/mL oral suspension (Arbli) Renin-Angiotensin Antihypertensives	No alternative formulary agent: Patient requires a liquid losartan formulation due to a documented medical condition and not due to convenience Formulary alternatives: losartan tabs, telmisartan, valsartan
terazosin 1 mg/mL oral solution (Tezruly) BPH Agents	No alternative formulary agent: Patient requires a liquid alpha blocker formulation due to a documented medical condition and not due to convenience Formulary alternatives: tamsulosin, alfuzosin, terazosin caps, doxazosin
- ustekinumab (unbranded Stelara) by Janssen - ustekinumab-srlf (Imuldosa) TIBs: IL-23	- Patient has experienced significant adverse effects from formulary agents - No alternative formulary agent: Patient has tried brand Stelara Formulary alternatives: adalimumab (Humira), ixekizumab (Taltz), ustekinumab-stab (Steqeyma), ustekinumab-auuz (Otulfi), ustekinumab-auub (Wezlana), ustekinumab (Stelara)
Other MN Criteria	
iptacopan (Fabhalta) Hematological Agents	Updates from the August 2025 meeting are in bold - Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Formulary agents resulted in therapeutic failure No alternative formulary agent –patient is not able to access an infusion center or patient has C3G glomerulopathy

Appendix B—Table of Medical Necessity Criteria

	Formulary alternatives for PNH pegcetacoplan (Empaveli); for IgAN: Filispari, Vanrafia, empagliflozin, dapagliflozin
- glulisine (Apidra) - lispro (Admelog) Insulins: Rapid-Acting Agents	Updates from the August 2025 meeting are in bold Use of insulin aspart (Novolog), insulin lispro (Humalog or authorized generic insulin lispro) and Insulin aspart-szjj (Merilog) have resulted in therapeutic failure Formulary alternatives: insulin aspart (Novolog), insulin lispro (Humalog or authorized generic lispro), and insulin aspart-szjj (Merilog)
growth hormone (Genotropin) Growth Stimulating Agents	Updates from the August 2025 meeting are in bold ~~Use of all step-preferred formulary agents is contraindicated~~ Use of 3 short-acting and 2 long-acting step-preferred formulary agents are contraindicated - Patient has experienced significant adverse effects from ~~all-3 short-acting~~ and 2 long-acting step-preferred formulary agents Formulary alternatives: short-acting: somatropin (Norditropin), somatropin (Genotropin), somatropin (Omnitrope), somatropin (Zomacton); long-acting: somatogon-ghla (Ngenla); somapacitan-beco (Sogroya)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• dupilumab (Dupixent) Atopy: IL-13, IL-31	Updates from the August 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Dupixent <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: For all indications • Non-FDA-approved uses are not approved • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair]) Atopic Dermatitis indication • The patient is at least 6 months of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe or uncontrolled atopic dermatitis • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 6 months to 17 years of age: any topical corticosteroid ▪ For patients 2 years of age and older: topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires after 12 months <u>Renewal criteria for atopic dermatitis:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy Asthma indication • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist or pulmonologist, ~~or~~ asthma specialist • The patient has one of the following ▪ Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils $\geq$ 150 cells/microliter OR ▪ Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months • For eosinophilic asthma, the patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following; ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • For eosinophilic asthma, the patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi), ▪ Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zflo) Non-FDA-approved uses are not approved Prior authorization expires after 12 months <u>Renewal criteria for asthma:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • The patient's disease severity has improved and stabilized to warrant continued therapy ~~has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use~~ Chronic rhinosinusitis with nasal polyposis indication • The patient is 12 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: • Presence of nasal polyposis is confirmed by imaging or direct visualization AND • At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments: ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND • The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength Non-FDA-approved uses are not approved Prior authorization expires in 12 months <u>Renewal criteria for rhinosinusitis:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • The patient's disease severity has improved and stabilized to warrant continued therapy • ~~There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score~~
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Appendix C—Table of Prior Authorization (PA) Criteria

	Eosinophilic Esophagitis (EoE) indication • The patient is one year of age or older and weighs at least 15 kilograms (approximately 33 lbs) • The drug is prescribed by or in consultation with a gastroenterologist ~~or allergy/immunology specialist~~ allergist or immunologist • Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy • For EoE, the patient has tried and failed an adequate course of both the following: ▪ Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND ▪ Topical glucocorticoids [e.g., fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, or clinically significant adverse effects are experienced, ~~or in children maximal doses cannot be reached due to concerns for growth suppression or adrenal insufficiency~~ Non-FDA approved uses are not approved Prior authorization expires after 12 months <u>Renewal criteria for EoE:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met: • ~~Eosinophilic Esophagitis (EoE):~~ The patients disease severity has improved and stabilized to warrant continued therapy • ~~For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e):~~ • ~~Reduced intraepithelial eosinophil count; OR~~ • ~~Decreased dysphagia/pain upon swallowing; OR~~ • ~~Reduced frequency/severity of food impaction; OR~~ • ~~Reduced vomiting/regurgitation; OR~~ • ~~Improvement in oral aversion/failure to thrive~~ • ~~For relapse: prior authorization form or chart notes documenting relapse after treatment was discontinued since last approval~~ Prurigo Nodularis Indication: • Patient is 18 years of age or older • The drug is prescribed by an allergist, immunologist, or dermatologist • Patient has a diagnosis of prurigo nodularis • Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk • Patient has experienced pruritus for 6 weeks or longer • Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR • The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed • The patient has a contraindication to, intolerance to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
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Appendix C—Table of Prior Authorization (PA) Criteria

	- The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with phototherapy The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved ~~Prior authorization does not expire for prurigo nodularis~~ Prior authorization expires after 12 months <u>Renewal criteria for prurigo nodularis:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met: ~~Prurigo nodularis:~~ The patient's disease severity has improved and stabilized to warrant continued therapy Chronic Obstructive Pulmonary Disease (COPD) indication - Patient is 18 years of age or older - Prescribed by a pulmonologist - Patient has moderate to severe chronic obstructive pulmonary disease (COPD) with both chronic bronchitis and an eosinophilic phenotype (greater than 300 cells/microliter) - Patient has uncontrolled COPD symptoms despite the use of all of the following: long-acting muscarinic antagonists (e.g., tiotropium bromide); long-acting-beta agonists (e.g., formoterol); inhaled corticosteroid (e.g., budesonide) - Medication is being requested for add-on maintenance therapy for management of COPD The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved Prior authorization expires after 12 months <u>Renewal Criteria for COPD:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - Patient's disease severity has improved and stabilized to warrant continued therapy Chronic Spontaneous Urticaria indication Patient is 12 years of age or older Prescribed by an allergist, immunologist or dermatologist Patient has a diagnosis of chronic spontaneous urticaria with symptoms lasting longer than 6 weeks Patient remains symptomatic despite a trial of at least 4 weeks up to 4 times the standard dosing of a second-generation histamine H-1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine) The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved Prior authorization expires after 12 months
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Appendix C—Table of Prior Authorization (PA) Criteria

	<u>Renewal criteria for chronic spontaneous urticaria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy Bullous Pemphigoid indication • Patient is 18 years of age or older • Prescribed by a dermatologist, allergist, or immunologist • Patient has a confirmed diagnosis of bullous pemphigoid • Patient has an initial bullous pemphigoid disease area index (BPDAI) score greater than or equal to 24 • Patient has an initial Peak Pruritus Numeric Rating Scale score of greater than or equal to 4 • The patient has a contraindication to, intolerance to, or has failed treatment with all the following: ▪ One high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream) ▪ One oral corticosteroid (e.g., prednisone, prednisolone) ▪ Two additional adjuncts (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide, doxycycline) Non-FDA approved uses are not approved Prior authorization expires after 12 months <u>Renewal criteria for bullous pemphigoid:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• Ikbrikizumab (Ebglyss) Atopy: IL-13, IL-31	Updates from the August 2025 meeting are in bold <u>Automated PA criteria:</u> When the patient is 12 years of age and older AND when prescribed by a dermatologist, allergist or immunologist, prior authorization is not required. Once therapy is initiated by a dermatologist, allergist or immunologist, an automated drug lookback will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days OR Manual PA criteria apply to all new users of Ikbrikizumab-Ibkz (Ebglyss) if automated criteria are not met <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Atopic Dermatitis Indication • Patient is 12 years of age or older • Patient's weight is 40 kg or greater • The drug is prescribed by a dermatologist, allergist or immunologist • Patient has diagnosis of moderate to severe atopic dermatitis • Patient has contraindication to, intolerance to, or has failed treatment with ONE medication in EACH of the following categories: ▪ Topical corticosteroids – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) or – For patients 12 to 17 years of age: any topical corticosteroid ▪ Topical calcineurin inhibitors (i.e., tacrolimus, pimecrolimus)

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient has a contraindication to, intolerance to, inability to access treatment, or patient failed treatment with Narrowband UVB phototherapy • For all indications the patient is not currently receiving another immunobiologic therapy (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved PA expires after 12 months <u>Renewal criteria for atopic dermatitis:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• tralokinumab (Adbry) Atopy: IL-13, IL-31	Note that there were no changes from the August 2025 meeting Manual PA criteria apply to all new users of Adbry. <u>Manual PA criteria:</u> Adbry is approved if all criteria are met: • Patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 12 to 17 years of age: any topical corticosteroid. ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy • The patient is not currently receiving another immunobiologic therapy (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires in 12 months <u>Renewal criteria:</u> Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• nemolizumab (Nemluvio) Atopy: IL-13, 31	Updates from the August 2025 meeting are in bold Manual PA criteria apply to all new users of nemolizumab (Nemluvio) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Prurigo Nodularis Indication: • Patient is 18 years of age or older • Nemluvio is prescribed by an allergist, immunologist, or dermatologist • Patient has a diagnosis of prurigo nodularis • Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient has experienced pruritus for 6 weeks or longer • Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR • The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed • The patient has a contraindication to, intolerance to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with phototherapy • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved ~~Prior authorization does not expire for prurigo nodularis~~ Prior authorization expires in 12 months <u>Renewal criteria for prurigo nodularis:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy Atopic Dermatitis Indication: • Patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 12 to 17 years of age: any topical corticosteroid ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved Prior authorization expires in 12 months <u>Renewal criteria for atopic dermatitis:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following applies: • Patient's disease severity has improved and stabilized to warrant continued therapy
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Appendix C—Table of Prior Authorization (PA) Criteria

finerenone (Kerendia) Mineralocorticoid Receptor Antagonists	Updates from the August 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Kerendia <u>Manual PA criteria:</u> Kerendia is approved if all criteria are met: - Patient is 18 years of age or older For Type 2 Diabetes Mellitus and Chronic Kidney Disease - Kerendia is prescribed by or in consultation with a nephrologist - The patient has a diagnosis of type 2 diabetes mellitus (T2DM) - The patient has documented diabetic kidney disease with albuminuria, defined as ~~one of the following~~ - An estimated glomerular filtration rate (eGFR) of 25-75 AND urinary albumin-to-creatinine ratio of ≥ 30 mg/g ~~OR~~ ~~eGFR 25-60 with albuminuria > 30 mg/g plus diabetic retinopathy~~ - Patient has been taking max-dose ACE inhibitor or ARB ~~for at least 4 weeks or has a contraindication to ACE inhibitor or ARB or is unable to tolerate ACE or ARB~~ - Patient is maintained on an ~~has tried DoDs preferred~~ sodium-glucose-co-transporter 2 (SGLT-2) inhibitor [e.g., empagliflozin (Jardiance) note that-empagliflozin is TRICARE's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor - The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease Patient's potassium is less than 5 mEq/mL at initiation of therapy Provider agrees to discontinue Kerendia if the patient begins renal replacement therapy ~~Patient does not have uncontrolled hypertension ($>170/110$ mmHg) at initiation of Kerendia therapy~~ ~~Patient does not have renal artery stenosis~~ ~~Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc)~~ ~~Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception~~ For Heart Failure with Preserved Ejection Fraction (HFpEF) Prescribed by or in consultation with a cardiologist Patient has a documented diagnosis of chronic heart failure (New York Heart Association (NYHA) class II-IV) with a left ventricular ejection fraction (LVEF) greater than 40% and with continued heart failure symptoms Patient is maintained on an SGLT2 inhibitor [e.g., empagliflozin (Jardiance) note that-empagliflozin is TRICARE's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor Patient is maintained on other guideline-directed therapy for heart failure Patient's potassium is less than 5 mEq/mL at initiation of therapy Non-FDA approved uses are not approved including patients undergoing renal transplant Prior authorization does not expire
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Appendix C—Table of Prior Authorization (PA) Criteria

spironolactone oral suspension (Carospir, generic) Mineralocorticoid Receptor Antagonists	Manual PA criteria apply to all new users of spironolactone oral suspension (Carospir) Age Edit: PA does not apply to children 12 year of age and younger Manual PA criteria—Coverage is approved if all criteria are met: - The patient has heart failure, hypertension or edema from cirrhosis - The provider must write in why the patient requires CaroSpir and cannot take an aldosterone blocker / potassium-sparing diuretic in a tablet formulation - Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience Non-FDA approved uses are not approved Prior Authorization does not expire
Newly Approved Drug PAs	
acetaminophen 325 mg/ ibuprofen 97.5 mg (Combogesic) Analgesics and Combinations	Updates from the current PA are in bold Manual PA criteria apply to all new and current users of acetaminophen and ibuprofen tablets (Combogesic) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that Combogesic will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T Committee meeting minutes by the Director, DHA Provider acknowledges that other formulations of acetaminophen and ibuprofen are available to TRICARE beneficiaries and do not require prior authorization - Patient is 18 years of age or older - Patient is being treated for short-term mild to moderate acute pain - Provider must document why the patient cannot take formulary alternatives or OTC products - Acceptable responses include: the patient has tried all the listed agents including acetaminophen 325 mg tablet, acetaminophen 500 mg tablet, acetaminophen 160 mg/5ml solution/suspension, ibuprofen 200 mg tablet, ibuprofen 800 mg tablet, ibuprofen 100 mg/5ml solution/suspension Non-FDA approved uses are not approved PA does not expire until after implementation of complete exclusion status
acoltremon 0.003% ophthalmic solution (Tryptyr) Ophthalmic: Dry Eye	Updates from the current PA are in bold and strikethrough Manual PA criteria apply to all new users of acoltremon 0.003% ophthalmic solution (Tryptyr) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by an ophthalmologist or optometrist - Patient has signs and symptoms of dry eye disease as supported by both of the criteria below: - Positive symptomology screening for dry eye disease from an appropriate measure - At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) - Patient must try and fail the following:

Appendix C—Table of Prior Authorization (PA) Criteria

	- At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvise, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) - Followed by at least 1 month of a different ocular lubricant that is nonpreserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) 3-month trial of cyclosporine 0.05% (Restasis, generics), cyclosporine 0.09% (Cequa), and lifitegrast (Xiidra) Non-FDA approved uses are not approved PA does not expire
atrasentan (Vanrafia) Nephrology Agents Miscellaneous	Manual PA criteria apply to all new users of Vanrafia <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Drug is prescribed by a nephrologist - The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli - Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/gram - Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m² - Patient is not currently receiving dialysis or has not undergone kidney transplant - Patient has not received immunosuppressants, including corticosteroids, in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months - Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and is at high risk for disease progression - The patient's baseline liver aminotransferase (AST and ALT) levels are not elevated to greater than 3 times the upper limit of normal - If patient is a female of child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation - If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation Non-FDA approved uses are not approved, including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires in 9 months <u>Renewal criteria:</u> Coverage will be approved indefinitely if all the following apply - Patient has had a response to Vanrafia defined by: - reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR - reduction in proteinuria from baseline AND - Patient's eGFR rate ≥ 30 mL/min/1.73 m²
avutometinib / defactinib (Avmapki Fakzynja Co-pack) Oncological Agents	Manual PA criteria apply to all new users of avutometinib capsules/defactinib tablets (Avmapki Fakzynja Co-Pack) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Patient is 18 years of age or older

Appendix C—Table of Prior Authorization (PA) Criteria

	• Prescribed by or in consultation with a hematologist or oncologist • Patient has recurrent low-grade serous ovarian cancer • The cancer has a KRAS mutation • Patient has tried at least one systemic therapy • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire
• berdazimer 10.3% topical gel (Zelsuvmi) Anti-infectives	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of berdazimer 10.3% (Zelsuvmi) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 2 years of age or older • Prescribed by a dermatologist • Patient has a diagnosis of molluscum contagiosum which fulfills all the following criteria: ▪ Treatment is not solely due to cosmetic concern ▪ The lesions must be symptomatic (e.g. painful, itchy) • A single lesion will be treated with Zelsuvmi for no more than 12 weeks • Provider must explain why this agent is required and cannot be treated with ALL the following: cryotherapy, AND curettage, AND two additional topical agents ▪ Acceptable responses include the following: Patient has contraindication to, intolerance to, or has failed treatment with cryotherapy, AND curettage, AND two additional topical treatments (e.g. salicylic acid, cantharidin (Ycanth)) Non-FDA approved uses are not approved. PA expires after 3 months. Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA ~~Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for 3 months for continuation of therapy if all the criteria are met:~~ ~~• Patient has documentation of positive clinical response defined as clearance or reduction in number of lesions with Zelsuvmi treatment~~ ~~• Patient requires ongoing treatment of molluscum contagiosum lesions which must be symptomatic (e.g. painful, itchy)~~ • Prescribed by a dermatologist
• chlorthalidone 12.5 mg tabs (Hemiclor) Diuretics	Updates from the current PA are in bold Manual PA criteria apply to all new users of Hemiclor <u>Manual PA criteria:</u> Coverage is approved if all criteria are met • Provider acknowledges that generic chlorthalidone 25 mg and 50 mg tablets can be split or crushed and are available to TRICARE beneficiaries without Prior Authorization • Patient is 18 years of age or older • Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease

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	- Provider must write in why the patient requires Hemiclor and cannot take a loop diuretic AND a thiazide diuretic in a tablet formulation - Acceptable responses: Patient has tried and failed chlorthalidone 25 mg and 50 mg tablets or hydrochlorothiazide 25 mg tablets. Non-FDA-approved uses are not approved PA does not expire
efgartigimod alfa-fcab injection (Vyvgart Hytrulo) Miscellaneous Neurological Agent	Updates from the current PA criteria are in bold Manual PA criteria apply to all new users of efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by a neurologist - Patient is being treated for chronic inflammatory demyelinating polyneuropathy OR - Patient is being treated for generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive - For patients being treated for generalized myasthenia gravis: - Patient had insufficient response or intolerance to pyridostigmine AND - Patient had insufficient response or intolerance to glucocorticoid sparing therapy such as azathioprine, mycophenolate, cyclosporine, or tacrolimus - Patient is not receiving concomitant neonatal Fc receptor antagonists or other C5 inhibitors with Vyvgart Hytrulo including but not limited to the following: efgartigimod injection for intravenous use (Vyvgart), eculizumab (Soliris), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), or zilucoplan (Zilbrysq) Non-FDA approved uses are not approved PA expires in 6 months <u>Renewal criteria:</u> Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies: - The patient's disease severity has improved and stabilized to warrant continued therapy
ensartinib (Ensacove) Oncological Agent	Manual PA criteria apply to all new users of ensartinib (Ensacove) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by or in consultation with a hematologist or oncologist - Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC) - Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved test - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire

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fitusiran injection (Qfittia) Antihemophilic Factors	Updates from the current PAg are in bold Manual PA criteria apply to all new users of fitusiran (Qfittia) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by or in consultation with a hematologist - Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors - Patient is not concurrently receiving factor VIII or factor IX therapy after initial transition period unless for the treatment of breakthrough bleeding For patients with hemophilia A, patient has had an inadequate response, intolerance, or contraindication to emicizumab-kxwh (Hemlibra) Non-FDA approved uses are not approved PA does not expire
garadacimab injection (Andembry) Corticosteroids Immune Modulators	Updates from the current PA are in bold Manual PA criteria apply to all new users of garadacimab (Andembry) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - The patient has a diagnosis of hereditary angioedema (HAE) - Andembry is prescribed for prophylaxis to prevent attacks of hereditary angioedema - Prescribed by an allergist, immunologist, rheumatologist, or HAE specialist - The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., two or more HAE attacks/month, or laryngeal attacks, etc.) - The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly) - The patient has had an inadequate response, adverse reaction, or contraindication to all of the following: - One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest) - One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo) Non-FDA-approved uses not approved Prior Authorization does not expire
hydrocortisone 1mg/mL oral solution (Khindivi) Corticosteroids- Immune Modulators	Updates from the current PA are in bold Manual PA criteria apply to all new of hydrocortisone oral solution (Khindivi) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is at least 5 years of age - Patient is not older greater than 18 years of age - Provider acknowledges that the following products are available without a prior authorization: 5 mg generic hydrocortisone tablets, hydrocortisone 100 mg act-O-vials, and prednisone Intensol oral solution. Please consider changing the prescription to one of these agents - Patient is using Khindivi as replacement therapy for adrenocortical insufficiency - Provider acknowledges that the patient's dosing regimen requires small doses of hydrocortisone and cannot accurately split the dose using 5 mg hydrocortisone tablets

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	Provider must explain why this agent is required and patient cannot take generic hydrocortisone tablets, Alkindi Sprinkle, hydrocortisone 100 mg act-O-vials, and prednisone Intensol oral solution. Blank write in _____ Acceptable response: patient requires a g-tube Non-FDA approved uses are not approved PA does not expire
losartan 10 mg/mL oral suspension (Arbli) Renin Angiotensin Antihypertensives	Manual PA criteria apply to all new users of losartan oral suspension (Arbli) <u>Automated PA Criteria:</u> Age Edit: PA not required if patient is 12 years of age and younger <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - Provider must write in why the patient requires Arbli oral suspension and cannot take losartan tablets - Acceptable response: Patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience Non-FDA approved uses are not approved PA does not expire
meloxicam 20 mg/ rizatriptan 10 mg tabs (Symbravo) Migraine Agents: Triptans	Updates from the current meeting are in bold Manual PA criteria apply to all new and current users of meloxicam and rizatriptan (Symbravo) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that Symbravo will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T Committee meeting minutes by the Director, DHA Provider acknowledges that other formulations of triptans are available to TRICARE beneficiaries and do not require prior authorization including eletriptan, sumatriptan, rizatriptan - Patient is 18 years of age or older - Patient is being treated for acute treatment of migraine with or without aura - Provider must document why the patient cannot use rizatriptan tablet and meloxicam tablet. - Acceptable responses include: the patient has had an adverse reaction to an excipient in either rizatriptan tablet and/or meloxicam tablet that would not be likely to occur with Symbravo Non-FDA approved uses are not approved. PA does not expire until after implementation of complete exclusion status
nilotinib d-tartrate 50 mg, 150 mg and 200 mg caps (no brand name) Oncological Agents	Manual PA criteria apply to all new users of nilotinib tartrate capsule <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges Prior Authorization is not required for Tassigna capsules. Please consider changing the prescription to Tassigna. - Prescribed by or in consultation with a hematologist or oncologist - Patient is 18 years of age or older - Patient has a diagnosis of either: - Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR - Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib

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	- The patient has tried nilotinib tartrate tablet (Danziten) and had an adverse reaction to an excipient that would not be likely to occur with nilotinib tartrate capsule - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number:_____ Other non-FDA approved uses are not approved except as noted above PA does not expire
taletrectinib (Ibtrozi) Oncological Agents	Manual PA criteria apply to all new users of taletrectinib (Ibtrozi) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by or in consultation with a hematologist or oncologist - Patient has locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire
terazosin 1 mg/mL oral solution (Tezruly) BPH Agents	Manual PA criteria apply to all new users of terazosin oral solution (Tezruly) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider must write in why the patient requires Tezruly and cannot tolerate the terazosin capsules - Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience Non-FDA approved uses are not approved PA does not expire
treprostinil inhalation powder (Yutrepia) PAH Agents	Manual PA criteria apply to all new users of treprostinil inhalation powder (Yutrepia) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Prescribed by or in consultation with a cardiologist or a pulmonologist - Patient has WHO Group 1 pulmonary arterial hypertension (PAH) OR WHO Group 3 pulmonary hypertension with interstitial lung disease (PH-ILD) - Patients with WHO Group 1 PAH have had a right heart catheterization - Documentation was provided to confirm that patient had the procedure and confirmed diagnosis of WHO Group 1 PAH Non-FDA approved uses are not approved PA does not expire
- ustekinumab (ustekinumab by Janssen) - ustekinumab-srlf (Imuldosa) TIBs: IL-23	Updates from the August meeting are in bold Manual PA criteria apply to all new users of ustekinumab (ustekinumab by Janssen) and ustekinumab (Imuldosa) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: - The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira The patient had an inadequate response to Steqeyma, Otulfi, Wezlana, and Stelara OR the patient experienced an adverse reaction to

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	Steqeyma, Otulfi, Wezlana, and Stelara that is not expected to occur with the requested ustekinumab OR the patient has a contraindication to Steqeyma, Otulfi, Wezlana, and Stelara • Patients may have used infliximab in lieu of Humira for UC and CD • Coverage is approved for patients 18 years of age or older with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ▪ Moderately to severely active Crohn's Disease (CD) ▪ Moderately to severely active ulcerative colitis (UC) • Coverage is approved for patients ages 6 to 17 years of age with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy • The criteria below apply to all patients unless noted: ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC) ▪ Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
• ustekinumab-aekn (unbranded Selarsdi private label) TIBs: IL-23	Manual PA criteria apply to all new users of ustekinumab-aekn (unbranded Selarsdi) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that this unbranded ustekinumab aekn will be completely excluded from the TRICARE Pharmacy benefit 120 days after signing of the P&T Committee meeting minutes by the Director, DHA. • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira • The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira • The provider must write-in trial dates for Humira and the formulary ustekinumab products ▪ Humira Date_____ Duration of therapy _____ ▪ Otulfi Date_____ Duration of therapy _____ ▪ Steqeyma Date_____ Duration of therapy _____ ▪ Wezlana Date_____ Duration of therapy _____ ▪ Stelara Date_____ Duration of therapy _____ • The provider must explain why the patient requires unbranded ustekinumab-aekn (unbranded Selarsdi) and cannot use on of the other ustekinumab biosimilar products. ▪ Acceptable response: Patient has an allergy to one or more inactive ingredients found in formulary ustekinumab products that is not found in unbanded ustekinumab-ttwe Non-FDA approved uses are not approved

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	~~PA expires in 120 days, when the complete exclusion status is implemented-PA does not expire-until after implementation of complete exclusion status~~
Utilization Management PAs	
bisoprolol 2.5 mg tablet Beta Blockers and Hydrochlorothiazide Combinations	Manual PA criteria apply to all new users of bisoprolol 2.5 mg tablet. <u>Manual PA criteria:</u> bisoprolol 2.5 mg tablet is approved if all criteria are met: - Provider acknowledges other formulations of bisoprolol tablets are available without prior authorization. - Provider must explain why the patient requires bisoprolol 2.5 mg tablet and cannot take the cost-effective generic bisoprolol 5 mg formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available bisoprolol formulations Non-FDA-approved uses are not approved Prior authorization does not expire
buspirone capsules (Bucapsol) Antianxiety Agents	Manual PA criteria apply to all new users of buspirone capsules (Bucapsol). <u>Manual PA criteria:</u> buspirone (Bucapsol) is approved if all criteria are met: - Provider acknowledges other formulations of buspirone tablets are available without prior authorization. - Provider must explain why the patient requires buspirone capsules (Bucapsol) and cannot take the cost-effective generic buspirone tablet formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available buspirone formulations Non-FDA-approved uses are not approved Prior authorization does not expire
clemastine (Clemasz) Antihistamine-1: First Generation and Combos	Manual PA criteria apply to all new users of clemastine (Clemasz). <u>Manual PA criteria:</u> clemastine (Clemasz) is approved if all criteria are met: - Provider acknowledges other formulations of clemastine are available without prior authorization. - Provider must explain why the patient requires clemastine (Clemasz) and cannot take the cost-effective generic clemastine formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available clemastine formulations Non-FDA-approved uses are not approved Prior authorization does not expire
diflunisal (Dolobid) 375 mg tablet Pain Agents: NSAID	Manual PA criteria apply to all new users of diflunisal 375 mg tablets (Dolobid). <u>Manual PA criteria:</u> diflunisal (Dolobid) is approved if all criteria are met: - Provider acknowledges other formulations of diflunisal are available without prior authorization. - Provider must explain why the patient requires diflunisal 375 mg tablets (Dolobid) and cannot take the cost-effective generic diflunisal 250 mg or 500 mg formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available diflunisal formulations Non-FDA-approved uses are not approved Prior authorization does not expire

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flurbiprofen (Lurbipr) Pain Agents: NSAIDs	Manual PA criteria apply to all new users of flurbiprofen (Lurbipr). <u>Manual PA criteria:</u> flurbiprofen (Lurbipr) is approved if all criteria are met: - Provider acknowledges other formulations of flurbiprofen are available without prior authorization. - Provider must explain why the patient requires flurbiprofen (Lurbipr) and cannot take the cost-effective generic flurbiprofen formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available flurbiprofen formulations Non-FDA-approved uses are not approved Prior authorization does not expire
metformin 625 mg IR tablet Diabetes Non-Insulin: Biguanides	Manual PA criteria apply to all new users of metformin 625 mg IR tablet. <u>Manual PA criteria:</u> metformin 625 mg IR tablet is approved if all criteria are met: - Provider acknowledges other formulations of metformin are available without prior authorization. - Provider must explain why the patient requires metformin 625 mg IR tablet and cannot take the cost-effective generic metformin formulations - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin formulations Non-FDA-approved uses are not approved Prior authorization does not expire
leuprolide acetate (Lutrate Depot) 22.5 mg (3 month) Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists	Manual PA criteria apply to all new users of Lupron Depot, Lutrate Depot, and leuprolide acetate (no brand name) Manual PA criteria: Coverage is approved if all criteria are met: - If patient is 18 years of age or younger, PA is not approved if indication is gender dysphoria - For patients 18 years of age or older, or for younger patients using for other indications besides gender dysphoria, proceed with the following questions: - Provider is aware leuprolide acetate SQ (Eligard) is the preferred leuprolide product and does not require PA - Patient has tried and failed or has not been able to tolerate Eligard PA does not expire
mepolizumab (Nucala) Atopy	Updates from the August 2025 meeting for COPD are listed below Note that there were no changes to the PA criteria for eosinophilic asthma, eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyps and hyper-eosinophilic syndrome (HES) Manual PA criteria apply to all new users of Nucala <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by a pulmonologist - Patient has moderate to severe COPD and an eosinophilic phenotype (>150 cells/ul) - Patient has uncontrolled COPD symptoms despite the use of long-acting muscarinic antagonists (e.g., tiotropium bromide); long-acting-beta agonists (e.g., formoterol); or inhaled corticosteroid (e.g., budesonide) - Medication is being requested for add-on maintenance therapy for management of COPD

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	Non-FDA approved uses are not approved PA expires following 12 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• upadacitinib (Rinvoq) Atopy: Oral JAK-1	Updates from the August 2025 meeting for Giant Cell Arteritis are listed below. Note that there were no changes to the current Rinvoq criteria for the other indications (rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's Disease, ankylosing spondylitis, or atopic dermatitis) Manual PA criteria apply to all new users of upadacitinib (Rinvoq). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a rheumatologist • Patient has a diagnosis of giant cell arteritis • Patient has tried and failed, or has a contraindication to, or has had an adverse reaction to both of the following: ▪ glucocorticoid ▪ tocilizumab (Tyenne; Actemra) • Patient is not receiving other targeted immunomodulatory biologics with Rinvoq Non-FDA approved uses are not approved PA does not expire
• osilodrostat (Isturisa) Endocrine Agents Miscellaneous	Updates from August 2025 are in bold and strikethrough. Manual PA is required for all new users of Isturisa. <u>Manual PA Criteria:</u> Isturisa is approved if all criteria are met: • Patient is 18 years of age of older • Patient has documented diagnosis of endogenous hypercortisolemia with Cushing's disease • Patient has persistent or recurrent Cushing's disease despite ~~pituitary~~ surgery OR • Patient in whom ~~pituitary~~ surgery is not indicated • Drug is prescribed by an endocrinologist, oncologist, or neurosurgeon • ~~Provider agrees to correct hypokalemia or hypomagnesemia prior to starting Isturisa~~ • ~~Provider agrees to obtain baseline electrocardiogram (ECG) prior to starting Isturisa and use with caution in patients with risk factors for QTc prolongation~~ • ~~Patient will be monitored closely for hypocortisolism and potentially life threatening adrenal insufficiency. Dosage reduction or interruption may be necessary~~ • ~~Patient will be monitored for hypokalemia, worsening of hypertension, edema, and hirsutism~~ Non-FDA-approved uses are not approved. Prior authorization does not expire.

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• iptacopan (Fabhalta) Hematological Agents	Updates from the August 2025 meeting are in bold. Note that there are no changes recommended to the current PA criteria for PNH. <u>Manual PA</u> criteria apply to all new users of Fabhalta • All indications • Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements • Patient is not receiving C3 or C5 inhibitors with Fabhalta, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or pegcetacoplan (Empaveli) • Patient is 18 years of age or older • Complement 3 glomerulopathy (C3G) • Prescribed by a nephrologist • The patient has a diagnosis of C3G confirmed by biopsy • Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gram • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m² • Patient has not undergone kidney transplant • Patient is on maximally tolerated RAS inhibitor (ACE/ARB) • Patient has not received complement inhibitors within the past 6 months • Corticosteroids (prednisone doses less than or equal to 7.5 mg/day) or mycophenolate are allowed if the patient has been stable on these therapies for 90 days. • Paroxysmal Nocturnal Hemoglobinuria (PNH) • Prescribed by a hematologist or oncologist • Patient has a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • Patient has tried and failed treatment with a C5 inhibitor for three months(e.g., eculizumab (Soliris), ravulizumab (Ultomiris)), and has residual anemia • IgAN • Prescribed by a nephrologist • The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli • Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gram • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m² • Patient is not currently receiving dialysis or has not undergone kidney transplant • Patient has not received immunosuppressants, including corticosteroids in the past 90 days and is not expected to need immunosuppressants in the next 6 months • Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and an SGLT-2 inhibitor (e.g., empagliflozin, dapagliflozin) and is at high risk for disease progression
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	• Patient has failed therapy with, or has a contraindication to, or has had intolerable adverse effects with Filspari or Vanrafia • Patient will not use Fabhalta concomitantly with Filspari or Vanrafia Non-FDA approved uses are not approved including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schoenlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires after 9 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • For IgAN • Patient has had a response to Fabhalta defined by • reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR • reduction in proteinuria from baseline • Patient's eGFR rate ≥ 30 mL/min/1.73 m² • For PNH: • Patient has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, or reductions in hemolysis • For Complement 3 glomerulopathy (C3G), patient has had a response to Fabhalta defined by: • Reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR • Reduction in proteinuria from baseline AND • Patient's eGFR rate ≥ 30 mL/min/1.73 m²
• belimumab (Benlysta) Immunosuppressives	Updates from the August 2025 meeting are in bold and strikethrough Manual PA Criteria apply to all new users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta <u>Manual PA criteria:</u> Coverage is approved for Benlysta if all of the following are met: • Benlysta is prescribed by or in consultation with a specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist • The patient is ~~18-5~~ 5 years of age or older ~~for active lupus nephritis or the patient is 5 years of age or older for SLE~~ • Must have one of the following documented diagnoses: ▪ Active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE ▪ Class III, IV, or V active lupus nephritis • For SLE, the patient is concurrently taking standard therapy (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)

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	- For active lupus nephritis, patient is concurrently receiving either mycophenolate mofetil or cyclophosphamide followed by azathioprine - The patient does not have severe active central nervous system lupus - The patient is not taking concomitant biologics (e.g., rituximab) Off-label uses are not approved Prior Authorization expires in 2 years. <u>Renewal PA Criteria:</u> Benlysta will be approved on a yearly basis if all of the following are met: - For SLE, treatment with Benlysta has shown documented clinical benefit (i.e., improvement in number/frequency of flares, improvement in Safety of Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.) - The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) - The patient does not have severe active central nervous system lupus - The patient is not taking concomitant biologics (e.g., rituximab)
belzutifan (Welireg) Oncological Agents	Updates from August 2025 are in bold Manual PA criteria apply to all new users of Welireg <u>Manual PA criteria:</u> Welireg is approved if all criteria are met: - Welireg is prescribed by or in consultation with a hematologist/oncologist Patient is 12 years of age or older and has locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL) OR - Patient is 18 years of age or older - The patient has von Hippel-Landau disease and requires therapy for associated renal cell carcinoma (RCC), CNS hemangioblastomas or pancreatic neuroendocrine tumors (pNET) not requiring immediate surgery OR - The patient has advanced renal cell carcinoma (RCC) with a clear a cell component following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version, and page number: _____. Non-FDA approved uses are not approved, other than noted above PA does not expire
roflumilast 0.3% foam (Zoryve) Psoriasis Agents	Updates from the August 2025 meeting for plaque psoriasis are listed below. Note that there were no changes to the PA criteria for the seborrheic dermatitis indication. Manual PA criteria apply to all new users of Zoryve foam. <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by or in consultation with a dermatologist - Patient has a diagnosis of plaque psoriasis - The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following:

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ A topical corticosteroid – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) OR – For patients 12-17 years of age: any topical corticosteroid ▪ A topical vitamin D analog (e.g. calcipotriene foam) Non-FDA approved uses are NOT approved PA does not expire
• glulisine (Apidra) • lispro (Admelog) Insulins: Rapid-Acting Agents	Updates from the August 2025 meeting are in bold. <u>Automated PA Criteria:</u> The patient has filled a prescription for insulin aspart (Novolog), insulin lispro (Humalog or authorized generic lispro), and insulin aspart-szjj (Merilog) at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days. <u>Manual PA criteria:</u> if automated criteria are not met, Apidra or Admelog is approved if all criteria are met: • Provider acknowledges Novolog, Humalog and the authorized generic insulin lispro, and Merilog are TRICARE's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, or Merilog, prior authorization is not required. • The patient has diabetes AND ▪ The patient has tried and failed insulin aspart (Novolog) AND ▪ The patient has tried and failed insulin lispro (Humalog or authorized generic insulin lispro) AND ▪ The patient has tried and failed insulin aspart-szjj (Merilog) OR • The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog) Non-FDA-approved uses are not approved PA does not expire
• budesonide oral suspension (Eohilia) GI-1 Agent	Updates from the August 2025 meeting are in bold. Manual PA criteria apply to all new users of Eohilia <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Prescribed by a gastroenterologist, allergy/immunology specialist, or general surgeon • Patient has a documented diagnosis of eosinophilic esophagitis (EoE) by endoscopic biopsy • Patient has tried and had an inadequate response, intolerance, or contraindication to a Proton Pump Inhibitor Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• avatrombopag (Doptelet) Hematological Agents: Platelets	Updates from the August 2025 meeting are in bold and strikethrough. Manual PA is required for new users of Doptelet. <u>Manual PA Criteria:</u> Doptelet is approved if all criteria are met: • Drug is prescribed by or in consultation with a gastroenterologist or hematologist/oncologist Liver Disease Indication • Patient is 18 years of age or older • ~~Drug is prescribed by or in consultation with a gastroenterologist~~ • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 10⁹/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • The patient has tried, failed, has a contraindication to, or is expected to have an intolerance to lusutrombopag (Muplesta)? OR ITP Indication • Patient is 18 years of age or older with a diagnosis of chronic immune thrombocytopenia (ITP) and has failed to adequately respond to previous therapy • ~~Drug is prescribed by or in consultation with a hematologist/oncologist~~ • Patient has tried and failed Nplate or Promacta OR Has a contraindication to both Nplate and Promacta OR Is expected to have an adverse effect to both Nplate and Promacta that would not be anticipated by Avatrombopag • Doptelet is not being used concomitantly with other chronic ITP therapy Non-FDA-approved uses are not approved. For thrombocytopenia associated with liver disease: PA expires in 60 days. New PA required per prescription fill For ITP: PA does not expire.
• mirabegron tablets (Myrbetriq) Overactive Bladder Agents: Beta-3 Adrenergic Agonists	Updates from the August 2025 meeting are in bold. PA Criteria apply to all new users of Myrbetriq. <u>Automated PA Criteria:</u> The patient has filled a prescription for oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine within the last 720 days. OR <u>Automated PA Criteria:</u> When prescribed by a urologist, urogynecologist, or geriatrician prior authorization is not required. Once therapy is initiated by a urologist, urogynecologist, or geriatrician an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. <u>Manual PA criteria:</u> If automated criteria are not met, coverage of Myrbetriq is approved if all criteria are met: • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 1 generic antimuscarinic medication (oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such <u>central nervous</u>

Appendix C—Table of Prior Authorization (PA) Criteria

	<u>system effects</u> due to comorbid conditions, advanced age, or other medication The patient's estimated creatinine clearance (CrCl)/glomerular filtration rate (eGFR) is ≥ 15 mL/min/1.73m² Non-FDA-approved uses are not approved. Prior authorization does not expire.
vibegron (Gemtesa) Overactive Bladder Agents: Beta-3 Adrenergic Agonists	Updates from the August 2025 meeting are in bold. PA Criteria apply to all new users of Gemtesa. <u>Automated PA Criteria:</u> The patient has filled a prescription for oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine within the last 720 days. <u>Manual PA criteria:</u> If automated criteria are not met, coverage of Gemtesa is approved if all criteria are met: - The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency - The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, - The patient has had a 12-week trial with 1 generic antimuscarinic medication (oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine) and had therapeutic failure OR - The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such <u>central nervous system effects</u> due to comorbid conditions, advanced age, or other medication - The patient's estimated creatinine clearance (CrCl)/glomerular filtration rate (eGFR) is ≥ 15 mL/min/1.73m² Non-FDA-approved uses are not approved. Prior authorization does not expire.
filgrastim-sndz (Zarxio) White Blood Cell Stimulants: Filgrastims	Updates from the August 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of filgrastim-sndz (Zarxio) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges that tbo-filgrastim (Granix), and filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) are the preferred filgrastims and are available without a PA. Please consider changing the prescription to a formulary preferred medication. Note: Granix and Nivestym are available at the generic (Tier 1) copay at the TRICARE Mail Order and Retail Pharmacies. - Prescribed by or in consultation with a hematologist or oncologist - Patient has experienced an inadequate treatment response or intolerance to tbofilgrastim Granix), and filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) and is expected to respond to filgrastim (Neupogen), filgrastim-ayow (Releuko), filgrastim-txid (Nypozi), or filgrastim-sndz (Zarxio). PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• semaglutide (Wegovy) • tirzepatide (Zepbound) Weight Loss Agents	Updates from August 2025 are in bold for the definition of uncontrolled hypertension Manual PA criteria apply to all new users of Wegovy and Zepbound <u>Manual PA Criteria:</u> Coverage for Wegovy or Zepbound is approved if: • The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge” • Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan? ▪ If yes subject to verification, proceed to the next question ▪ If no, coverage is not approved • What Tricare Plan is the patient enrolled in? ▪ TRICARE Select – proceed to the next question ▪ TRICARE Prime – proceed to the next questions ▪ TRICARE For Life–Coverage not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives. • The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested. • The provider will document the major condition and comorbidities treated selecting all that apply: ▪ Obesity ▪ Diabetes or impaired glucose tolerance ▪ Obstructive sleep apnea ▪ Osteoarthritis ▪ Metabolic syndrome ▪ Dyslipidemia ▪ Hypertension ▪ Metabolic dysfunction-associated steatohepatitis (MASH) ▪ Established cardiovascular disease with a history of stroke ▪ Established cardiovascular disease with a history of myocardial infarction ▪ Established cardiovascular disease with a history of peripheral artery disease For Wegovy and Zepbound for adults for obesity • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity ▪ The provider will document the BMI – For BMI less than 27, coverage is not approved – For BMI ranging between 27 and 29 with a comorbidity – For BMI ranging between 30 to 34 – For BMI ranging between 35 to 39
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Appendix C—Table of Prior Authorization (PA) Criteria

	– For BMI greater than or equal to 40 • Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response ▪ Phentermine: Date _____ Duration of therapy _____ OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension or a patient not meeting blood pressure goal on 2 or more antihypertensives) OR • The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) for obesity • Patient is 12 years of age or older and younger than 18 years of age • Patient has a BMI greater than or equal to 95th percentile standardized for age For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity: • Patient is 18 years of age or older • Patient has moderate to severe OSA (documented apnea-hypopnea index greater than 15 events per hour) and a BMI greater than 30 For all patients • Concomitant use of this medication with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus PA expires in 12 months for initial therapy; annual renewal required <u>Renewal PA Criteria:</u> Note that initial TRICARE PA approval required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met: • The provider will document the BMI for renewal: ▪ BMI less than 27, ▪ BMI ranging between 27 and 29 ▪ BMI ranging between 30 to 34 ▪ BMI ranging between 35 to 39 ▪ BMI greater than or equal to 40 For Obesity: • The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification. Medical record documentation will be made available to TRICARE for audit, if requested. • For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication with full dosage titration
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Appendix C—Table of Prior Authorization (PA) Criteria

	- For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication - The patient is not pregnant For OSA: - The patient has shown improvement in OSA symptoms based on the improvement of apnea hypopnea index
abiraterone acetate (Zytiga and generic) 500 mg Oncological Agents: CYP-17 Inhibitors	Updates from the August 2025 meeting are in bold and strikethrough. ~~Automated PA Criteria: When prescribed by a hematologist, oncologist, or urologist prior authorization is not required. Once therapy is initiated by a hematologist, oncologist, or urologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.~~ Manual PA criteria applies to all new and current users of Zytiga 500 mg: Manual PA coverage, ~~if automated criteria are not met~~: Coverage approved if all criteria are met: ~~• If the physician is a hematologist, oncologist or urologist, PA is approved OR~~ ~~• If the prescriber is not a hematologist, oncologist or urologist and if the drug prescribed in consultation with a hematologist/oncologist or urologist, then continue with the questions below:~~ - Patient is 18 years of age or older Prescribed by or in consultation with a hematologist/oncologist Provider acknowledges that abiraterone 250 mg strength is available without a PA If the prescription is for abiraterone 500 mg strength, please state why the patient cannot take multiple of the 250 mg strength _____, then continue with the PA criteria below Acceptable responses: Patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in generic abiraterone 250 mg - Patient has documented diagnosis of non-localized disease including: - metastatic castration-resistant prostate cancer (mCRPC), OR - metastatic castration-sensitive prostate cancer (mCSPC), OR - regional disease (TxN1M0) - Patient must receive concomitant therapy with prednisone - Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog for example: Eligard, Lupron, Orgovyx, Trelstar, or Zoladex concomitantly OR have had a bilateral orchiectomy - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval If so, please list the diagnosis, guideline version, and page number: _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

abiraterone acetate micronized (Yonsa) Oncological Agents: CYP-17 Inhibitors	Updates from the August 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new and current users of Yonsa. Manual PA Criteria: Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by or in consultation with an oncologist or urologist - Provider is aware that Yonsa may have different dosing and food effects than other abiraterone acetate products (medication errors and overdose warning) Provider acknowledges that abiraterone 250 mg (generic Zytiga) is available without a PA and at a Tier 1 copay Please explain why patient cannot take the preferred generic abiraterone Acceptable response: Patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in generic abiraterone or patient is unable to comply with the fasting requirements with generic abiraterone - Patient has documented diagnosis of non-localized disease including: - Metastatic castration-resistant prostate cancer (mCRPC) - Metastatic castration-sensitive prostate cancer (mCSPC) - Regional disease (TxN1M0) OR - The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis-To facilitate approval, please list the diagnosis, guideline version, and page number:_____. - Patient must receive concomitant therapy with methylprednisolone - Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non-FDA-approved uses are NOT approved except as noted above PA does not expire.
umeclidinium/vilanterol (authorized generic for Anoro Ellipta) Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease	Manual PA criteria apply to new and current users of umeclidinium and vilanterol authorized generic at all points of service <u>Manual PA criteria:</u> umeclidinium and vilanterol authorized generic is approved if all criteria are met: - Provider acknowledges that the brand Anoro Ellipta is TRICARE's preferred product over authorized generic umeclidinium and vilanterol - The provider must document a patient-specific justification as to why the brand Anoro Ellipta cannot be used in this patient. _____ (fill-in the blank). - Acceptable reasons include the patient has had an adverse reaction to an excipient in brand Anoro Ellipta that would not be likely to occur with the authorized generic product
- chorionic gonadotropin, human (Pregnyl, Novarel) - choriogonadotropin alfa (Ovidrel) Follicle Stimulating Hormone (FSH) Luteinizing Hormone (LH) Fertility Agents	Sex edit: PA does not apply to males Manual PA is required for new users. <u>Manual PA Criteria:</u> PA is approved if all criteria are met: Fertility agent is not being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer. The TRICARE family planning benefit outlined in the Code of Federal Regulations does not include services and supplies related to noncoital reproductive technology Prior Authorization expires after 1 year; provider must fill out a new PA.

Appendix C—Table of Prior Authorization (PA) Criteria

leuprolide acetate Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists	Updates from the August 2025 meeting are in bold. Manual PA criteria apply to all new users of Lupron Depot, Lutrate Depot, and leuprolide acetate (no brand name) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - If patient is 18 years of age or younger, PA is not approved if indication is gender dysphoria - For patients 18 years of age or older, or for younger patients using for other indications besides gender dysphoria, proceed with the following questions Fertility agent is not being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer. The TRICARE family planning benefit outlined in the Code of Federal Regulations does not include services and supplies related to noncoital reproductive technology - Provider is aware leuprolide acetate SQ (Eligard) is the preferred leuprolide product and does not require PA - Patient has tried and failed or has not been able to tolerate Eligard PA does not expire
- ganirelix acetate (Fyremadel, Antagon) - cetorelix acetate (Cetrotide) FSH-LH Fertility Agents	Manual PA is required for new users. <u>Manual PA Criteria:</u> PA is approved if all criteria are met: Fertility agent is not being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer. The TRICARE family planning benefit outlined in the Code of Federal Regulations does not include services and supplies related to noncoital reproductive technology Prior Authorization expires after 1 year; provider must fill out a new PA.
- ambrisentan (Letairis) - macitentan (Opsumit) Pulmonary Arterial Hypertension: Endothelin Receptor Agonists	Updates from the August 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of ambrisentan and macitentan <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Prescribed or in consultation with cardiologist or a pulmonologist - Patent has a documented diagnosis of WHO group 1 PAH - Patient has had a right heart catheterization with documentation provided - Results of right heart catheterization confirm diagnosis of WHO Group 1 PAH ~~If patient is a female, then prescriber is enrolled in Risk Evaluation and Mitigation Strategy (REMS) program~~ - Female patient is not pregnant - Females of childbearing age are using adequate contraception up to 1 month after therapy - Patient has no history of LTF elevations on previous ERA therapy accompanied by symptoms of liver toxicity or increases in bilirubin > 2x upper limit of normal - Patient does not have moderate or severe liver impairment (e.g., Child-Pugh Class B or C) Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• macitentan/tadalafil (Opsynvi) Pulmonary Arterial Hypertension: Endothelin Receptor Agonists	Updates from the August 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of macitentan and tadalafil (Opsynvi). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed or in consultation with cardiologist or a pulmonologist • Patient has had a right heart catheterization with documentation provided • Results of right heart catheterization confirm diagnosis of WHO Group 1 PAH • Patient has WHO Functional Class II or III PAH • ~~If patient is a female, then prescriber is enrolled in Risk Evaluation and Mitigation Strategy (REMS) program~~ • Female patient is not pregnant • Females of childbearing age are using adequate contraception up to 1 month after therapy • Provider must describe why the patient requires a fixed dose combination and cannot take the individual components separately (write-in) ▪ Acceptable responses include the following: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience Non-FDA approved uses are not approved PA does not expire
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Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
acoltremon 0.003% ophthalmic solution (Tryptyr) Ophthalmic: Dry Eye	MTF/TMOP/Retail: 60 single dose vials (1 carton)/30 days supply
- avutometinib/ defactinib (Avmapi Fakzynja Co-pack) - ensartinib (Ensacove) - nilotinib d tartrate capsule Oncological Agents	MTF/TMOP/Retail: 60-day supply
chlorthalidone 12.5 mg tabs (Hemiclor) Diuretics	- Retail: 30 tabs/30 days - MTF/TMOP: 90 tabs/90 days
efgartigimod alfa-fcab injection (Vyvgart Hytrulo) Miscellaneous Neurological Agent	MTF/TMOP/Retail: 60-day supply
fitusiran injection (Qfitlia) Antihemophilic Factors	MTF/TMOP/Retail: 60-day supply
garadacimab-gxii (Andembry) Corticosteroids-immune modulators	MTF/TMOP/Retail: 30-day supply
taletrectinib (Ibtrozi) Oncological Agents	MTF/TMOP/Retail: 30-day supply
treprostinil inhalation powder (Yutrepia) Pulmonary Arterial Hypertension	MTF/TMOP/Retail: 30-day supply
- ustekinumab (ustekinumab by Janssen) - ustekinumab-srlf (Imuldosa) TIBs: IL-23	- Retail: 1 syringe/vial per fill - MTF/TMOP: 3 syringes/vials per fill (Note these QLs allow for loading doses for pertinent indications)
- liraglutide (Saxenda) - semaglutide (Wegovy) - tirzepatide (Zepbound) Weight Loss Agents	- Retail: 30 day supply - MTF/TMOP: 60-day supply

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
acetaminophen 325 mg/ ibuprofen 97.5 mg (Combogesic) Analgesics and Combinations	- acetaminophen - ibuprofen	aceta- minophen 325 mg with ibuprofen 200 mg tablets dosed 3 tablets PO Q6h PRN	Short-term management of mild to moderate acute pain in adults	Adverse Drug Reactions (ADRs) ≥2% - nausea - vomiting - headache - dizziness - somnolence	- Fixed dose combination acetaminophen and ibuprofen prescription product - Ibuprofen component contains lower dose than OTC ibuprofen - No new clinical efficacy studies - Unanimous agreement from providers that Combogesic is not needed on the formulary - Provides no compelling clinical advantage over existing agents	Complete Exclusion
acoltremon 0.003% ophthalmic solution (Tryptyr) Ophthalmic: Dry Eye	- Cyclosporine (generic Restasis) - Xiidra - Miebo - Vevye	Dosing: Instill one drop in each eye BID	Treatment of the signs and symptoms of dry eye disease	ADRs ≥50% instillation site pain	- New mechanism of action, but does not appear to confer any advantages over other available dry eye disease products - Two phase 3 studies demonstrated more patients in the Tryptyr group had a ≥10 mm increase in the Schirmer tear test sign from baseline at Day 14 vs. vehicle - Two phase 3 studies had mixed results for improvement in the symptoms measure, with only one study showing statistically significant difference from vehicle - Provides another option with a different mechanism of action for dry eye disease	- UF - PA - QL - Specialty Drug List
atrasentan (Vanrafia) Nephrology Agents Miscellaneous	- Fabhalta - Tarpeyo - Filspari	0.75 mg tablets; bottles #30 tabs - Dosing: 0.75 mg PO QD with or without food	Reduce proteinuria in adults with primary IgAN at risk of rapid disease progression	ADRs ≥5% - peripheral edema - anemia	- Fourth FDA-approved drug to reduce proteinuria in adults with immunoglobulin A nephropathy (IgAN) - The ALIGN Phase 3 study showed benefit in reducing proteinuria, in the surrogate outcome of the mean change in urinary protein to creatinine ratio (UPCR) from baseline vs. placebo with a geometric mean difference of 36% - Disadvantages include that full approval is contingent on confirmatory trial completion - Advantages are that patients can remain on ACE/ARB therapy and it does not have a REMS program - The formulary alternative Filspari has a REMS for pregnancy risk and concomitant ACE/ARBs are not allowed; however Filspari	- UF - PA - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
					has a confirmed trial showing slowed kidney decline. • Safety profile of Vanrafia has fluid retention and anemia as most common adverse effects • Vanrafia provides a therapeutic alternative to Fabhalta and Filspari for IgAN	
avutometinib/defactinib (Avmapi Fakzynja Co-pack) Oncological Agents	Mekinist	0.8 mg avutometinib capsules/200 mg defactinib tablets - Avutometinib: 3.2 mg PO twice weekly (Day 1 and Day 4) x first 3 weeks of each 4-week cycle. Defactinib: 200 mg PO BID x first 3 cycles of each 4-week cycle	Treatment of adults with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy	ADRs ≥25% ↑ CPK, ↑ bilirubin, ↑ TGs, - nausea, fatigue ↑ AST, ↑ALT, ↑ alk phos - diarrhea, vomiting ↓ HgB, ↓ platelets, ↓ lymphocytes, ↓ neutrophils - musculoskeletal pain, edema - abdominal pain, dyspepsia, stomatitis - dermatitis, acneiform, pruritus - vitreoretinal disorders, visual impairment	- Avmapi Fakzynja Co-Pack is recommended for low grade serous carcinoma, for KRAS-mutated tumors as “Useful in Certain Circumstances” (category 2A) per NCCN guidelines - Phase 2 open label study demonstrated a confirmed Objective Response Rate of 44%, with the duration of response ranging from 3.3 to 31.1 months - Monitoring is necessary for rhabdomyolysis and ocular, skin, and liver toxicities - Avmapi Fakzynja Co-Pack is new therapy for a cancer type that typically does not respond well to chemotherapy	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
berdazimer 10.3% topical gel (Zelsuvmi) Anti-Infectives: Misc	- hydroxyurea capsule - Droxia capsule - Siklos tablet	10.3% gel supplied as two tubes: Tube A contains berdazimer gel and Tube B contains hydrogel	Treatment of molluscum contagiosum in patients ≥1 year of age	application site reactions	- A phase 3 study demonstrated a statistically significant clearance of lesions at Week 12, compared to vehicle - A network meta-analysis indicates cantharidin 0.7% (Ycanth, medical benefit) is a top-ranked treatment, while Zelsuvmi ranks mid-range for treatments that achieve complete clearance of lesions compared to placebo - Zelsuvmi is overall well tolerated with localized skin reactions as common adverse events - Provides an additional treatment option for a condition that typically self-resolves	- UF - PA

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
chlorthalidone 12.5 mg tabs (Hemiclor) Diuretics	- chlorthalidone 25 & 50 mg tabs - azilsartan - HCTZ 25mg - Inzirgo liquid	12.5 mg tablets - Dosing: 12.5 mg or 25 mg PO QD (Max daily dose = 100 mg)	Treatment of hypertension in adults, to lower blood pressure	- electrolyte abnormalities - metabolic disturbances	- Contains ½ the dose (12.5 mg) of chlorthalidone 25 mg (1950 original approval) - No clinical efficacy studies; approved via 505(b)(2) pathway using data from the original chlorthalidone - Branded chlorthalidone (Thalitone-1988 original approval) is also available in 15 mg and 25 mg tabs; with enhanced bioavailability - FDA-approval is limited to adults with hypertension; not approved for pediatrics - Chlorthalidone does have cardiovascular (CV) outcomes data from the landmark ALLHAT and SHEP trials - Hemiclor provides no clinical advantage other than providing a lower dose of chlorthalidone; the original chlorthalidone 25 mg can be cut in half or crushed, despite not being scored, or branded Thalitone 15 mg can be used	- NF - PA - MN - QL
efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) Neurologic Agents Misc	- Rystiggo - Zilbrysq	Pre-filled syringe: efgartigimod alfa (1,000 mg) and hyaluronidase (10,000 U) per 5 mL	- Treatment of adults with generalized myasthenia gravis (MG) who are anti-acetylcholine receptor antibody positive - Treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP)	- injection reaction - respiratory infection - headache - UTI	- Vyvgart Hytrulo is self-administered via SC injection; the original formulation is IV - For MG, a single open label study demonstrated comparable pharmacodynamic effect of efgartigimod SQ to the IV formulation - For CIDP, a single randomized withdrawal study demonstrated a statistically significant reduced hazard ratio for risk of deterioration with Vyvgart vs. placebo - Alternative treatment with complement inhibitors (Soliris, Ultomiris and Zilbrysq) include a black boxed warning for serious infections and require REMS monitoring - Vyvgart Hytrulo does not include black box warnings or REMS requirements - Vyvgart Hytrulo provides another option for the treatment of these rare disorders	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
ensartinib (Ensacove) Oncological Agent	- Alecensa - Alunbrig - Lorbrena - Xalkori	25 mg, 100 mg capsules - Dosing: 225 mg PO QD	Treatment of adults with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor	- ADRs ≥20% - rash - musculoskeletal pain - constipation - pruritus - cough - nausea - edema - vomiting - fatigue - pyrexia	- Sixth targeted FDA-approved therapy for the treatment of non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK) rearrangements - Phase 3 open label study demonstrated Progression Free Survival (PFS) of 25.8 months vs. 12.7 months for Xalkori - NCCN guidelines recommend Alecensa, Alunbrig, Ensacove, and Lorbrena as first-line “Preferred” therapies for ALK-rearrangement positive NSCLC - Therapeutic alternative to the other approved ALK inhibitor therapies for this indication	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
fitusiran injection (Qfitlia) Antihemophilic Factors	- Hemlibra - Alhemo - Hypmavzi	20 mg/0.2 mL solution (vials) 50 mg/0.5 mL auto-injector pens - Dosing: 50 mg q 2 months, followed by dose and/or interval adjustment to maintain anti-thrombin (AT) activity between 15-35%	Prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years with hemophilia A or B with or without factor VIII or IX inhibitors	- ADRs >10% - viral infections - nasopharyngitis - bacterial infections	- First-in-class antithrombin-lowering agent, and first agent indicated as routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years of age who have hemophilia A or B with or without inhibitors - Alhemo is indicated as routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years of age with hemophilia A or B with or without inhibitors - Hypmavzi is similar to Alhemo but FDA-approved in patients without inhibitors - Hemlibra is indicated for routine prophylaxis to reduce or prevent the frequency of bleeding episodes in adults and pediatric patients ages newborn and older with hemophilia A with or without inhibitors - Phase 3 open label study, Qfitlia demonstrated 71% reduction in annualized bleeding rate (ABR) versus clotting factor concentrates (CFCs) on-demand in patients without inhibitors and 73% reduction in ABR versus bypassing agents (BPA) on-demand in patients with inhibitors	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
					- Blackbox warnings for thrombotic events and gallbladder disease - Offers the fewest doses for any prophylactic treatment with as few as six injections per year, and it is given subcutaneously - Qfitlia offers an alternative to Alhemo, Hemlibra and Hympavzi for either hemophilia A or B with or without inhibitors	
garadacimab-gxii (Andembry) Corticosteroids-Immune-modulator	- Haegarda - Orladeyo	Single dose prefilled autoinjector or prefilled syringe: 200mg/1.2 mL	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥12 years	- nasopharyngitis - abdominal pain	- Indicated for prophylaxis of HAE attacks - A single phase 3 trial demonstrated a statistically significant reduction in the number of attacks per month compared to placebo - An indirect network meta-analysis demonstrated that prophylactic HAE treatments (Andembry, Haegarda, Orladeyo, Takhzyro) were statistically significant in reducing the rate of attacks compared with placebo; additionally, all treatments were statistically significantly in reducing the rate of attacks treated with on-demand therapy compared with placebo - Andembry has a mild adverse event profile, with common events to include nasopharyngitis and abdominal pain - Offers an additional pharmacologic option for prophylaxis of this condition	- NF - PA - MN - QL - Specialty Drug List - TRICARE Maintenance Drug List - Rapid Response program
hydrocortisone 1mg/mL oral solution (Khindivi) Corticosteroids-Immune Modulators	- hydrocortisone oral granules (Alkindi Sprinkle) - hydrocortisone tablets (Cortef, generics)	1 mg/mL oral solution	Replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency	Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain	- Oral solution formulation of hydrocortisone for use as replacement therapy in pediatric patients ≥ 5 years of age with adrenocortical insufficiency - No new clinical efficacy studies; approved via 505(b)(2) pathway - Oral solution must be refrigerated and contains a warning regarding systemic adverse reactions due to inactive ingredients - Alkindi Sprinkle can also be used in patients who cannot swallow or achieve required dose with hydrocortisone tablets, but Khindivi can be used in a g-tube while Alkindi Sprinkle cannot	- NF - PA - MN - Specialty Drug List - TRICARE Maintenance Drug List - Rapid Response program

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
					Provides little compelling clinical advantage over existing agents	
insulin aspart-szjj (Merilog vial/pen) Insulins: Rapid Acting Agents	- insulin aspart (Novolog) - insulin lispro (Humalog) - insulin aspart (Lyumjev)	100 units/mL (U-100) - Vial: 10 mL multiple-dose vial - Pen: 3 mL single-patient-use SoloStar prefilled pen	Improve glycemic control in adults and pediatric patients with diabetes mellitus	hypoglycemia	- Biosimilar to Novolog - Approved via 351(k); No new clinical studies were completed - Available as 10 mL single dose vials and 3 mL SoloStar prefilled pen - Merilog can inject up to 80 units/dose - Novolog can be given via continuous SC infusion pump or intravenously. It can also be mixed with other insulins while Merilog has not yet received this indication - Merilog has not received interchangeability status from the FDA - Provides no compelling clinical advantage over existing agents	- UF - TRICARE Maintenance Drug List
losartan 10 mg/mL oral suspension (Arbli) Renin-Angiotensin Antihypertensive	- Inzirqo - Norliqva - Qbrelis - Carospir	10mg/ml - Dosing: 50 mg PO QD	- HTN in adults and children ≥ 6 years of age to lower blood pressure ↓ risk of stroke in patients with HTN and LV hypertrophy - Diabetic nephropathy with ↑ serum creatinine and proteinuria in T2DM and history of HTN	- ADR >2% - dizziness - upper respiratory infection - nasal congestion - back pain.	1st ready-to-use oral suspension formulation of the ARB losartan - No clinical efficacy studies; approved via 505(b)(2) pathway using data from Cozaar - Losartan tablets can be crushed and mixed into a suspension; compounded formulations are often available in 2.5 mg/mL, but Arbli is 10 mg/mL. Risk of 4-fold dosing error - Provides no compelling clinical advantage over generic losartan tablets or other angiotensin receptor blockers (ARBs)	- NF - PA - MN - TRICARE Maintenance Drug List
meloxicam 20 mg /rizatriptan 10 mg tabs (Symbravo) Migraine Agents: Triptans	- Treximet - meloxicam - rizatriptan	20 mg meloxicam and 10 mg rizatriptan - Dosing: One tablet PO PRN (max: 1 tablet per day)	Acute treatment of migraine with or without aura in adults	- dizziness - somnolence	- Fixed dose combination of a non-steroidal anti-inflammatory drug (NSAID) and triptan - Clinical data demonstrated a statistically significant achievement of headache pain freedom and most bothersome symptom freedom at 2 hours vs placebo - Guidelines recommend switching to a triptan for migraines not responding to analgesics or NSAIDs - Provides no compelling clinical advantage over existing agents	Complete Exclusion

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
nilotinib tartrate capsules (no brand name) Oncologic Agents	- nilotinib 71mg and 95 mg tabs (Danziten) - nilotinib capsules (Tasigna)	Capsule: 50, 150, or 200 mg	- Adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase - Adult with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib	- nausea - rash - headache - fatigue - pruritus - vomiting - diarrhea - cough - constipation - arthralgia - nasopharyngitis - pyrexia - night sweats	- Nilotinib tartrate capsules are a new formulation of nilotinib containing the tartrate salt - No new clinical efficacy studies; approved via 505(b)(2) - Provides no compelling clinical advantage over existing agents	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List
taletrectinib (Ibuprofen) Oncological Agents	- Xalkori - Rozlytrek - Augtyro - Lorbrena	200mg capsules - Dosing: 600 mg PO QD	Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	ADR ≥20% - diarrhea - nausea - vomiting - dizziness - rash - constipation - fatigue	- Fourth tyrosine kinase inhibitor (TKI) for ROS1-positive NSCLC; after Augtyro, Rozlytrek and Xalkori - Phase 2 open label, single arm studies demonstrated efficacy in both ROS1 treatment-naïve and ROS1 previously-treated patients - Based on indirect comparisons in the TKI-naïve population: Ibuprofen has numerically higher objective response rates (ORR) at 88% compared with Augtyro at 79%, Rozlytrek at 68% and Xalkori at 72% - NCCN guidelines state Ibuprofen, Augtyro, Rozlytrek, and Xalkori are all “preferred” first-line options for NSCLC with ROS1 rearrangement; however, the guidelines note that only Ibuprofen, Rozlytrek, or Augtyro are preferred for patients with brain metastases compared with Xalkori - Alternative to other FDA-approved kinase inhibitors, especially Augtyro or Rozlytrek, for the treatment of ROS1-positive NSCLC	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
terazosin 1 mg/mL oral solution (Tezruly) BPH Agents	- terazosin - tamsulosin - silodosin - Cardura	1 mg/mL - Dosing: 1mg QHS	- Treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adult males - Treatment of hypertension alone or with other antihypertensive agents in adults	ADRs $\geq 5\%$ - asthenia - back pain - headache - palpitations	- First oral solution formulation of terazosin - No new clinical efficacy studies - Provides an option for those who cannot swallow tablets <i>Note the manufacturer discontinued marketing in February 2026</i>	- UF - PA - Specialty Drug List - TRICARE Maintenance Drug List
treprostinil inhalation powder (Yutrepia) Pulmonary Arterial Hypertension	- Tyvaso - Ventavis - Orenitram - Uptravi	26.5 mcg, 53 mcg, 79.5 mcg, 106 mcg inhalation powder contained in capsules - Dosing: 26.5 mcg given 3 to 5 times daily	- Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise ability - Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability	ADRs $\geq 10\%$ - cough - headache - throat irritation - dizziness	- Third inhaled treprostinil product FDA-approved for PAH - No efficacy data; approved via 505(b)(2) based on nebulized treprostinil (Tyvaso) data - Supporting phase 3 open-label trial demonstrated tolerability - FDA-approval is limited to increased exercise capacity in PAH WHO Group 1 – does not alter disease course - All treprostinil products are also approved for PH-ILD - Second orally inhaled prostacyclin powder via disposable inhaler; powder is supplied in a capsule as opposed to a cartridge (Tyvaso dry powder inhaler - DPI) - Yutrepia administration requires 12 steps with potential for error (e.g., swallowing capsules instead of using the inhaler), compared to the 3-step process with Tyvaso DPI cartridges - Inhalation powder offers convenience to the patient, as nebulized products require additional time to administer and clean, but more complicated than Tyvaso DPI - Provides a therapeutic alternative to Tyvaso and Tyvaso DPI, but complicated delivery system	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
- ustekinumab (ustekinumab by Janssen) - ustekinumab-srlf (Imuldosa) - ustekinumab-aekn (ustekinumab-aekn unbranded Selarsdi private label) TIBs: IL-23s	- Wezlana - Stelara - Humira - Taltz	45 mg/0.5 mL, 90 mg/mL single-dose prefilled syringe	- Adults: moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy - Active psoriatic arthritis (PsA) - Moderately to severely active Crohn's disease (CD) - Moderately to severely active ulcerative colitis. - Pediatrics ≥ 6 years old: moderate to severe Ps who are candidates for phototherapy or systemic therapy - PsA	indication specific	- Biosimilars to Stelara - ustekinumab-ttwe unbranded is a private label for Quallent Pharmaceuticals - All approved via 351(k); No new clinical studies were completed - Provides no compelling clinical advantage over existing agents - The P&T Committee has concluded that biosimilar products are therapeutically interchangeable with other biosimilars and the reference product	- NF, after step - Imuldosa - ustekinumab-Janssen - Complete Exclusion: - unbranded (private label) ustekinumab-aken - PA - MN - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes*

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
Aug 2025	Drug Class Reviews Atopy: IL-13, IL-31 agents Designated UF <i>Retain current status on the TMDL</i> • dupilumab (Dupixent) • tralokinumab (Adbry) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF • insulin aspart-szjj (Merilog) Designated NF <i>Add – no reason to exempt from NF TMOP requirement</i> • chlorthalidone 12.5 mg tabs (Hemiclor) • losartan 10 mg/mL oral suspension (Arbli) • terazosin 1 mg/mL solution (Tezruly)	Drug Class Reviews Atopy: IL-13, IL-31 agents Designated UF <i>Do not add—not cost advantageous to government</i> • lebrikizumab (Ebglyss) • nemolizumab (Nemludio) Diuretics: Mineralocorticoid Receptor Antagonists Designated UF <i>Do not add—not cost advantageous to government</i> • finerenone (Kerendia) • spironolactone oral susp (Carospir) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Do not add—not cost advantageous to government</i> • acoltremone 0.003% (Tryptyr) <i>Do not add—short duration</i> • berdazimer 10.3% (Zelsuvmi)

*Legal/Regulatory Authorities

- 10 USC 1074g(a)(9) requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to these requirements are listed on the TRICARE Maintenance Drug List (TMDL).
- 32 CFR 199.21(r) implements 10 USC 1074g(a)(9) and sets out operation of the TMDL in detail.
- 32 CFR 199.21(h)(2)(ii) requires that non-formulary pharmaceutical agents be “generally not available in military treatment facilities or in the retail point of service.” As a result, NF/Tier 3 agents (including generics) must be on the TMDL unless a reason exists to exempt the agent from the NF TMOP requirement (e.g., acute use, clinical considerations, not available at TMOP, cost effectiveness).
- 32 CFR 199.21(g)(5) covers formulary status and review of newly approved drugs (other than generics), which are added to the UF unless the P&T Committee recommends NF/Tier 3 status within 120 days of approval. In the meantime, newly approved drugs are considered to be in a classification pending status and available under the same terms as NF/Tier 3 medications.

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
Aug 2025	Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) <i>Designated UF</i> • atrasentan (Vanrafia) • avutometinib; defactinib (Avmapki Fakzynja Co-pack) • efgartigimod alfa-fcab (Vyvgart Hytrulo) • ensartinib (Ensacove) • fitusiran (Qfitlia) • nilotinib tartrate 50,150,200 mg caps (unbranded; Cipla) • taletrectinib (Ibtrozi) • treprostinil oral inhalation (Yutrepia) <i>Designated NF</i> <i>No reason to exempt from TMOP requirement</i> • garadacimab-gxii (Andembry) • hydrocortisone 1 mg/mL solution (Khindivi) • ustekinumab-srlf (Imuldosa) • ustekinumab (unbranded; Janssen)	

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Due to the volume of recommendations requiring implementation due to the UF Beneficiary Advisory Panel pause, one week was added to implementation, which is reflected in the dates below.

Upon signing: July 20, 2026

Two weeks after signing: August 12, 2026

30 days after Signing: August 26, 2026

60 days after signing: September 29, 2026

90 days after signing: October 28, 2026

120 days after signing: December 2, 2026, due to the Thanksgiving Day holiday

* Note that implementation occurs the first Wednesday following “X” days after signing of the minutes in all points of service.

† P&T Committee Administrative Authorities were used to implement some recommendations not requiring UF BAP comment. See the November 2023 Table of Administrative Authorities.

Appendix H—Complete Exclusion Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Products designated with Complete Exclusion	Formulary Alternatives	Implementation
August 2025	Pain Agents	acetaminophen 325 mg and ibuprofen 97.5 mg tablets (Combogesic)	- acetaminophen (OTC) - ibuprofen 200 mg	120 days
August 2025	Migraine Agents	meloxicam 20 mg /rizatriptan 10 mg (Symbravo) tablets	- meloxicam - rizatriptan - sumatriptan/ibuprofen (Treximet)	120 days
August 2025	Interleukin-23 Agents	ustekinumab-aekn private label	- adalimumab (Humira) - ixekizumab (Taltz) - ustekinumab (Stelara) - ustekinumab-stab (Steqeyma) - ustekinumab-auuz (Otulfi) - ustekinumab-auub (Wezlana)	120 days

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3).

Drugs recommended for complete exclusion will not be available at the MTFs or TMOP points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the complete exclusion agents at the Retail points of service.

For a cumulative listing of all completely excluded agents to date, refer to previous versions of the P&T Committee quarterly meeting minutes, found on the health.mil website.

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

November 2025

I. CONVENING

The DoD Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on November 5th and 6th, 2025.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February, May and August 2025 Meeting Minutes—On March 10, 2025, the Secretary of Defense directed a pause of all DoD Advisory Committees, including the Uniform Formulary Beneficiary Advisory Panel meeting (UF BAP). As a result, the UF BAP meeting is delayed, and the signing of the February, May and August 2025 DoD P&T Committee meeting minutes will also be delayed.

B. Clarification of previous meeting minutes

- **August 2025**
 - **Weight Loss Agents**
 - **tirzepatide (Zepbound)**: Quantity limits were applied to Zepbound, consistent with what is already in place for liraglutide (Saxenda) and semaglutide (Wegovy) from the May 2024 Weight Loss drug class review. Implementation occurred on September 15, 2025. See Appendix D.
 - **Interleukin 23 Inhibitors**
 - **ustekinumab biosimilar Medical Necessity (MN) forms**: The criteria “The patient has tried brand Stelara” was added to the ustekinumab biosimilar MN forms. Implementation occurred Nov 12, 2025.
 - **Rapid Acting Insulin**
 - **insulin aspart-szjj (Merilog)**: Merilog was originally recommended for UF and step-preferred status when it was reviewed as a new drug. Merilog is now under review at this meeting with the Rapid Acting Insulins drug class review.
 - **insulin glulisine (Apidra) and insulin lispro (Admelog)**: Prior Authorization (PA) criteria and MN criteria were added to Apidra and Admelog to also require a trial of Merilog. Due to the UF BAP delay this was not implemented and is under review at this meeting with the Rapid Acting Insulins drug class review.
- **Antidepressants and Non-opioid Pain Syndrome Agents: SSRIs—escitalopram 10 mg/10 mL dosing cups PA criteria**: The dosing cups are

not intended for outpatient dispensing and are therefore not part of the TRICARE pharmacy benefit.

- **Hematological Agents—iptacopan (Fabhalta) MN Criteria:** At the August 2025 P&T Committee meeting Fabhalta was the sole agent approved for treating Complement 3 Glomerulopathy (C3G) and the MN criteria were updated to state “no formulary alternatives.” Following the meeting pegcetacoplan (Empaveli) received an indication for C3G, therefore the Fabhalta MN change was not implemented.
- **PAs not subject to CFR 32: bisoprolol 2.5 mg tablet, buspirone (Bucapsol), clemastine 2.68 mg tablets (Clemasz), diflunisal 375 mg tablet (Dolobid), flurbiprofen (Lurbipr), and metformin 625 mg immediate release (IR) tablets:** implementation occurred on September 30, 2025, using the P&T Committee Administrative Authorities.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to Section 199.21(g)(5) of Title 32, Code of Federal Regulations (CFR) and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All pharmaceutical agents selected for complete exclusion status were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All pharmaceutical agents recommended for uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and complete exclusion status considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018, permanently codified at Section 1074g(a)(10) of Title 10, United States Code (USC). Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, 10 USC 1074g(a)(9) requires beneficiaries to generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List formerly known as the Select Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass

Background: The last drug class review was in May 2024 and included both older oral weight loss medications (e.g., phentermine, phentermine/topiramate, bupropion/naltrexone and orlistat) and the injectable glucagon-like peptide-1 receptor agonists (GLP-1RAs). The drug class encompassing these GLP-1RAs is now termed

the Metabolic Dysfunction Agents, to more accurately reflect the physiologic properties of these drugs.

The class is divided into subclasses including the Injectable Weight Loss agents (discussed here), and the Injectable Diabetes agents (discussed in the next section). The drugs in the subclass include injectable liraglutide (Saxenda), semaglutide (Wegovy) and tirzepatide (Zepbound). Semaglutide, tirzepatide and liraglutide are also FDA-approved under distinct brand names for diabetes (Ozempic, Mounjaro, and Victoza, respectively).

Information regarding the regulatory controls for coverage of weight loss treatments is not within scope of the P&T Committee and is found at <https://newsroom.tricare.mil/News/TRICARE-News/Article/4266447/tricare-coverage-of-weight-loss-medications-what-to-know>.

Relative Clinical Effectiveness Conclusion—The clinical review focused on new information available since the last class review in May 2024, including updated clinical practice guidelines, meta-analyses, systematic reviews and published real-world evidence. The review also analyzed the literature for differences in the class with respect to weight loss, reduction in major adverse cardiovascular events, obstructive sleep apnea, and metabolic dysfunction-associated steatohepatitis. In accordance with the regulatory information above, evaluations for the treatment benefit for conditions other than weight loss considered whether weight loss was a sole or major component, not incidental, to treatment with the agent.

The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Clinical Practice Guidelines for Weight Loss

- When national and international weight loss guidelines were reviewed, there were no significant updates from the previous clinical conclusion from 2017 that comprehensive lifestyle intervention remains the foundation for obesity management.
- The 2025 American Diabetes Association (ADA) guideline recommends setting weight management goals with incorporation of nutrition, behavior, physical activity and an evidence-based weight management program, along with additional consideration for weight loss pharmacotherapy or surgery.

Weight Loss

- Liraglutide (Saxenda), semaglutide (Wegovy) and tirzepatide (Zepbound) are all indicated for weight loss.
- The 2025 American Diabetes Association (ADA) guidelines state that a relatively small degree of weight loss of approximately 3% to 7% of baseline weight improves glycemia and other intermediate cardiovascular (CV) risk factors.

- The 2025 ADA guidelines categorize the efficacy for weight loss as very high with semaglutide and tirzepatide, and as high with liraglutide.
- Individual placebo-controlled trials report that tirzepatide treatment results in greater weight loss than with liraglutide or semaglutide.
- A 2025 Annals of Internal Medicine network meta-analysis in over 15,000 patients without diabetes from 26 randomized controlled trials reported the greatest weight loss was demonstrated with semaglutide (Wegovy) and tirzepatide (Zepbound). The rates of severe adverse events (e.g. gastrointestinal [GI] or biliary disorders or pancreatitis) remained low. The most common adverse events were GI in nature and were mostly mild to moderate, with some evidence of a dose-response relationship.
- The 2025 Institute for Clinical and Economic Review (ICER) concluded semaglutide and tirzepatide when added on to lifestyle modifications resulted in substantial weight loss and improved cardiometabolic risk factors, which was rated as high certainty of a substantial net health benefit. When tirzepatide was compared with subcutaneous (SC) semaglutide, tirzepatide demonstrated greater weight loss and potentially improved GI tolerability, which was rated as moderate certainty of a small or substantial net health benefit.
- One head-to-head study (SURMOUNT-5) found tirzepatide treatment was superior to semaglutide for both body weight reduction at 72 weeks and change in waist circumference. The study results are limited by the open-label study design, small patient sample and manufacturer sponsorship.
- Real-world evidence from a retrospective cohort review (2025 Advanced Therapeutics) supports that there is less of a difference between semaglutide and tirzepatide with regard to weight loss, as patients receiving semaglutide achieved 14.1% weight loss compared to 16.5% with tirzepatide.
- A review of the evidence demonstrates that patients are more likely to reach maximal doses with semaglutide rather than tirzepatide. However, achievement of maximal dosages is not required to have meaningful weight loss.
- GI adverse effects are the most commonly reported side effect with all three agents. Indirect data suggests that tirzepatide may have improved GI tolerability over liraglutide or semaglutide.
- Although the magnitude of weight loss differs among the agents, particularly that liraglutide is less effective than semaglutide or tirzepatide, there is strong evidence that the weight loss benefits with the GLP-1RAs are a class effect. The drugs mechanistically all reduce appetite and promote weight loss.

Major Adverse Cardiovascular Events (MACE)

- Clinical practice guidelines from the ADA and American College of Cardiology (ACC) suggest that sustained weight loss above 10% of baseline weight confers benefits, including disease-modifying effects and possible remission of type 2 diabetes mellitus (T2DM), and may improve long-term CV outcomes and mortality.
- Semaglutide (Wegovy) is the only weight loss GLP-1RA also indicated to reduce the risk of MACE in adults with established CV disease and either obesity or overweight, based on the SELECT trial, which was conducted in over 17,000 patients with no history of diabetes.
 - Semaglutide was associated with a statistically significant 20% reduction in MACE (a composite of CV death, nonfatal myocardial infarction or non-fatal stroke), compared with placebo, after a mean follow-up of 40 months. The mean weight loss with semaglutide was approximately 9% in the trial.
 - Safety data reported a statistically significantly higher rate of GI adverse events leading to discontinuation with semaglutide compared to placebo. Reported adverse events of special interest (e.g. pancreatitis, gallbladder disease) remained equally low in both treatment arms.
- There is currently no data with tirzepatide to show MACE benefits. The ongoing SURMOUNT-MMO trial is investigating CV outcomes with tirzepatide in obese patients without diabetes who have atherosclerotic disease, with results expected in 2027.
- The 2025 ICER report concluded that there is substantial uncertainty regarding whether semaglutide or tirzepatide has greater CV benefit in overweight patients without diabetes.
- While weight loss contributes to the CV benefit, there is uncertainty as to size of the CV benefit independent of weight loss. More data is needed. Weight loss is not incidental to CV benefits.

Obstructive Sleep Apnea (OSA)

- Tirzepatide (Zepbound) is the only weight loss GLP1-RA also indicated for treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity.
- Guidelines for OSA recommend positive airway pressure (PAP) therapy as first line in treatment of OSA. (2025 VA/DoD; 2019 American Academy of Sleep Medicine [AASM]).

- The 2024 Australian guidelines report that weight loss of 10% from baseline is expected to result in a clinically meaningful reduction in apnea-hypopnea index.
- Data supporting tirzepatide use for OSA is from the SURMOUNT-OSA trials. Adults with obesity and moderate to severe OSA received Zepbound or placebo, with the change from baseline in the apnea-hypopnea index (AHI) evaluated as the primary outcome. After 52 weeks, Zepbound treatment led to a statistically significantly greater AHI reduction when compared to placebo.
 - The trial also showed a positive correlation between improvement in OSA symptoms and weight reduction. The average body mass index (BMI) of randomized patients was 39, while the lowest BMI was 30. The average weight loss with tirzepatide was 17.5% to 19.6%.
- There is limited clinical trial data with liraglutide showing a reduction in AHI compared to placebo and treatment with PAP.
- The 2024 AASM guidelines state that tirzepatide is only effective for cases of sleep apnea that are related to obesity.
- Overall, there is moderate evidence of a class effect for the GLP1-RAs for improving OSA.
- There is strong evidence that improvement in OSA from the GLP1-RAs is driven by weight loss, and the weight loss is not incidental to GLP1-RA treatment.

Metabolic dysfunction–associated steatohepatitis (MASH)

- Clinical practice guidelines suggest that a 5-10% reduction in body weight will improve markers of liver steatosis and fibrosis.
- Semaglutide (Wegovy) is the only weight loss GLP1-RA also indicated for the treatment of MASH in adults with moderate to advanced liver fibrosis. FDA-approval was via an accelerated approval pathway, and verification of clinical benefit is ongoing.
 - The ESSENCE trial evaluated semaglutide against placebo in patients with MASH. The primary outcomes included resolution of steatohepatitis and improvement in liver fibrosis. The trial found that after 72 weeks, treatment with semaglutide demonstrated statistically significantly higher rates of steatohepatitis resolution, as well as liver fibrosis reduction, when compared to placebo. Of note, a subgroup analysis by baseline BMI demonstrated that for those with BMI lower than 27, there was no difference in improvement in liver fibrosis when compared to placebo. Patients with weight loss greater than 10% from baseline showed the highest histologic response.

- Data is available with tirzepatide from the SYNERGY-NASH study and with liraglutide from the LEAN trial, however these are smaller studies and neither drug is currently indicated for MASH.
- Overall, it is uncertain whether there is a class effect with the GLP1-RAs for MASH with respect to reduction of liver fibrosis. However, GLP1-RAs as a class improve steatosis and liver enzymes.
- There is strong evidence that the benefit of GLP1-RAs in MASH is driven or driven at least partially by weight loss, and weight loss is not incidental to GLP1-RA treatment/MASH improvement.

Safety

- There was no significant new data to change the previous May 2024 conclusions that the three agents have minor differences in their individual safety profiles.
- The GLP1-RAs share the same precautions, warnings, and adverse events. GI adverse events are most commonly reported and include nausea and vomiting.

Individual Product Characteristics

- Liraglutide (Saxenda) is available as a prefilled pen and is given once daily. It is approved for pediatric patients as young as 12 years of age. Generic formulations of liraglutide are now marketed.
- Semaglutide (Wegovy) is available as a prefilled pen-injector, given once weekly. It carries the largest number of indications within this subclass (weight loss, MACE, and MASH). It is approved for pediatric patients as young as 12 years of age for weight loss. Wegovy currently is the only agent in the class to reduce MACE in obese patients who do not have diabetes. The dosing for weight loss differs than Ozempic formulation approved for treating T2DM.
- Tirzepatide (Zepbound) is available as a prefilled pen and is administered once weekly. It is approved for both weight loss and OSA in adults. The dosing formulation for weight loss is the same as the formulation for T2DM (Mounjaro).

Overall Clinical Conclusion

- In terms of efficacy
 - Weight loss: semaglutide and tirzepatide have a high degree of therapeutic interchangeability; liraglutide is less effective.
 - MACE/OSA/MASH, there is a moderate to low degree of therapeutic interchangeability, as only one drug is approved for these individual indications. [MACE (Wegovy); OSA (Zepbound); MASH (Wegovy)].

- In terms of safety, all three drugs have a high degree of therapeutic interchangeability.
- For clinical coverage, at least one injectable Metabolic Dysfunction-Weight Loss Agent is required in order to meet the majority of needs of DoD beneficiaries.

Relative Cost Effectiveness Analysis and Conclusion—The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent):

- CMA results showed that semaglutide (Wegovy) and tirzepatide (Zepbound) were cost effective relative to liraglutide (Saxenda, generic) under any formulary scenario.
- The BIA demonstrated that selecting both semaglutide (Wegovy) and tirzepatide (Zepbound) as UF without a step therapy requirement was more cost effective than selecting either semaglutide (Wegovy) or tirzepatide (Zepbound) as the sole UF step-preferred agent.
- A sensitivity analysis confirmed that the UF no step scenario resulted in more cost avoidance under any realistic assumption of switching to a given step-preferred agent.
- Placement of both agents as UF without a step therapy offers beneficiaries UF copays and allows for future entrants into this class to be designated as UF, if warranted.
- While continued increases in utilization and cost are anticipated in this drug class, manufacturer bids are expected to result in substantial cost avoidance relative to current pricing (lower cost per patient treated).

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
 - semaglutide (Wegovy)
 - tirzepatide (Zepbound)
- NF
 - liraglutide (Saxenda)
- Complete Exclusion: Note that tirzepatide vials (Zepbound vials) will continue to remain designated with complete exclusion status, as this

formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vials for patient self-pay only.

- Note that as part of the recommendation a trial of generic phentermine or one of the older generic phentermine derivatives is required first for Wegovy, Zepbound and Saxenda. (See the PA section below.)
- There were no changes to the formulary status for phentermine and derivatives, bupropion/naltrexone (Contrave) phentermine/topiramate (Qsymia) or orlistat (Xenical).

2. COMMITTEE ACTION: MANUAL PA CRITERIA—PA for the weight loss drugs has applied since the initial formulary review in 2017, with several subsequent updates. Updates made to the weight loss drug PAs are summarized below. Implementation of some of these changes is delayed, due to the UF BAP pause.

- February 2025: Zepbound new indication to treat moderate to severe OSA in adults with obesity
- May 2025: Definition of comprehensive lifestyle intervention expanded to include exercise
- August 2025: Uncontrolled hypertension definition for phentermine updated
- Revised PAs in accordance with 32 CFR 199.17(f)(3) were implemented on August 31, 2025. Additionally, the PAs were reinstated for phentermine, phendimetrazine, benzphetamine and diethylpropion.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria as discussed below in new users, while renewal criteria will apply to both new and current users. See Appendix C for the full criteria.

- Ongoing lifestyle modification remains a requirement prior to use of pharmacotherapy, based on clinical practice guidelines. PAs will explicitly require diet, exercise and behavioral components that are provider-led and documented in the medical record.
- A trial of generic phentermine, benzphetamine, diethylpropion immediate release/sustained release (IR/SR) or phendimetrazine IR/SR will remain.
- Patients with T2DM will be required to use a GLP1-RA specifically indicated for diabetes management [e.g., dulaglutide (Trulicity), liraglutide (Victoza), semaglutide (Ozempic) or tirzepatide (Mounjaro)].

- For the nonformulary drug Saxenda, the requirement for a trial of phentermine, phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), Wegovy and Zepbound remains.
 - Continuation of GLP1-RA therapy will be allowed for patients who have successfully lost weight with phentermine, but who require additional pharmacotherapy to reach a lower weight loss goal.
 - PA will expire annually, with yearly renewal required.
 - The Saxenda PA will have the BMI categories added, in order to align with the Wegovy and Zepbound PAs.
3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current MN criteria for Saxenda. For Saxenda a trial of all the formulary alternatives is required, including generic phentermine, phentermine/topiramate (Qsymia), naltrexone/bupropion (Contrave), Wegovy and Zepbound. See Appendix B for the full criteria.
 4. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QL of a 30-day supply at Retail pharmacies and a 60-day supply at MTFs and TMOP for Saxenda, Wegovy and Zepbound. See Appendix D.
 5. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) that Saxenda, Wegovy and Zepbound will not be subject to the TRICARE Maintenance Drug List. See Appendix F.
 6. **COMMITTEE ACTION: UF, PA, MN, QLs, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes. See Appendix G.

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass

Background—The drugs in the subclass class include exenatide (Byetta, Bydureon B-Cise), liraglutide (Victoza), lixisenatide (Adlyxin), dulaglutide (Trulicity), semaglutide (Ozempic) and tirzepatide (Mounjaro). The class was last reviewed in May 2022 as the “Non-Insulin Diabetes Drugs: GLP1-RA” class. At that time, dulaglutide was placed UF, with all other agents designated as NF. Since the last class review, exenatide once weekly (Bydureon BCise), lixisenatide, and branded exenatide twice daily (Byetta) were discontinued from the market, with generic exenatide twice daily and generic liraglutide now available. Additionally, in August 2022, tirzepatide (Mounjaro) was reviewed as an innovator drug and designated NF. Liraglutide, semaglutide and tirzepatide are also available under the brand names of

Saxenda, Wegovy and Zepbound, respectively for weight loss. Of note, the fixed dose combination GLP1-RA/insulin products (Soliqua, Xultophy) and oral semaglutide (Rybelsus) are categorized in different classes and are not reviewed here. Oral semaglutide (Rybelsus) was not included in this review but remains designated as UF.

The clinical effectiveness review focused on the primary literature, systematic reviews and meta-analyses, guidelines and specialist (endocrinologist, cardiologist) feedback regarding use of these agents.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

T2DM and Glycemic Control

- All agents within the subclass are approved for glycemic control.
- The 2025 ADA Pharmacologic Approaches to Glycemic Treatment guideline recommends individualized hemoglobin A1C (HbA1C) or glycemic goals with an aim to avoid symptomatic hypoglycemia, although a HbA1C goal of less than 7% is appropriate for the majority of non-pregnant adults. Metformin or other agents (including combination therapy) can be considered to achieve glycemic treatment goals. Metformin continues to have an established place in therapy as it is effective, safe, inexpensive, available in a variety of oral formulations, is weight neutral, and does not cause hypoglycemia.
 - Dulaglutide (high-dose), semaglutide, tirzepatide and insulin were categorized as having very high efficacy for glucose lowering. The other GLP1-RAs (exenatide, liraglutide and lixisenatide) have high glucose-lowering efficacy.
- A 2025 network meta-analysis from the Journal of Diabetes, Obesity, and Metabolism compared efficacy and tolerability of the injectable diabetic drugs. All agents demonstrated clinically meaningful reductions of HbA1c to less than 7%, with a general trend towards greater efficacy with newer agents (e.g., dulaglutide, semaglutide and tirzepatide). Safety concerns predominantly included GI adverse events with a greater trend for discontinuation reflected with higher doses.

T2DM and MACE Reduction

- Liraglutide (based on the LEADER trial), dulaglutide (based on the REWIND trial), and semaglutide (based on the SUSTAIN-6 trial) are approved for reducing MACE outcomes in patients with T2DM.
- The 2025 ADA Cardiovascular Disease and Risk Management guideline recommends that adults with T2DM and atherosclerotic CV disease (ASCVD) or multiple risk factors for ASCVD should consider use of a

GLP1-RA (dulaglutide, semaglutide, liraglutide) or a sodium–glucose cotransporter-2 (SGLT2) inhibitor (empagliflozin, dapagliflozin, canagliflozin) with proven CV benefit, irrespective of background metformin use or HbA1C level. However, the guideline notes that most individuals enrolled in relevant trials were receiving metformin at baseline as glucose-lowering therapy.

- A 2025 network meta-analysis from the Journal of the American College of Cardiology (JACC) reviewed CV effects and tolerability of the GLP1-RAs. The results for liraglutide and semaglutide SC demonstrated a statistically significant reduction in the incidence rate ratio for T2DM and MACE outcomes; dulaglutide was not statistically significant in this review. However, in the REWIND trial, dulaglutide did demonstrate a statistically significant reduction in the hazard ratio for composite MACE outcomes.
- Overall, the JACC meta-analysis safety review concluded that the GLP1-RAs are generally well tolerated, although associated with an increase in GI and gallbladder events, and showed no increased risk of severe complications such as pancreatitis.

T2DM and Chronic Kidney Disease (CKD)

- Semaglutide is the sole GLP1-RA approved for adult patients with T2DM and CKD. Ozempic received FDA approval for CKD based on the FLOW trial, which was terminated early for benefit. The endpoint was a reduction in the composite of estimated glomerular filtration rate (eGFR) decline, end stage renal disease (ESRD), and CV death.
- The 2025 ADA Chronic Kidney Disease and Risk Management guideline recommends either an SGLT-2 inhibitor, metformin, or a GLP1-RA in patients with T2DM. The 2024 Kidney Disease: Improving Global Outcomes (KDIGO) guideline for CKD states that a GLP1-RA may be considered in patients with T2DM for those unable to achieve glycemic control on metformin and SGLT2 inhibitor treatment.
- A 2025 network meta-analysis from the Cochrane group reviewed GLP1-RAs for CKD and diabetes; tirzepatide was not included in the analysis. The conclusion found that evidence for GLP1-RAs in CKD and diabetes is limited and had little or no effect on kidney failure or composite kidney outcomes. Additionally, adverse events were inconsistently reported. However, many of the trials primarily analyzed CV outcomes data, and not renal endpoints. The semaglutide FLOW study included a dedicated renal population with T2DM and CKD; the agent reached statistically significant reduction for composite major kidney disease events, mean

annual rate of change in eGFR, major CV events, and all-cause death when compared to placebo.

Safety

- GI events including nausea, vomiting, diarrhea and constipation are most commonly reported. All the agents except exenatide include a black box warning for thyroid tumor risk, and avoidance in those with Multiple Endocrine Neoplasia syndrome type 2.

Individual Product Characteristics

- Exenatide is only available as a generic product and is administered twice daily. (The once-weekly Bydureon BCise formulation is currently discontinued from the market). Exenatide's warning and adverse event profile uniquely lists drug-induced thrombocytopenia, headache, asthenia, and dizziness. It is not recommended for use in ESRD.
- Liraglutide (Victoza) is available in both branded and generic formulations and is administered once daily. The label does not include a warning for retinopathy, in contrast to the labeling for dulaglutide, semaglutide and tirzepatide. It has not been studied for use in ESRD but is approved to reduce MACE.
- Dulaglutide (Trulicity) is brand-only and is given once weekly. Advantages include that dosage adjustment is not required for renal impairment and the FDA indication to reduce MACE.
- Semaglutide (Ozempic) is brand-only and is given once weekly; of note, the dosing for diabetes is different than that for weight loss treatment. Semaglutide currently includes the largest number of indications amongst agents within the class – glycemic control, MACE and CKD. It does not require dose adjustment for renal or hepatic impairment.
- Tirzepatide (Mounjaro) is brand-only and is given once weekly. It does not require dose adjustment for renal or hepatic impairment. Dosing is similar for diabetic patients and for weight loss. One disadvantage is the limited number of FDA-approved indications (glycemic control); however, studies are ongoing for reduction of MACE events in patients with T2DM (SURPASS-CVOT trial) as well as T2DM and CKD (TREASURE trial). *Note that following the meeting, on December 17, 2025, the results of the SURPASS-CVOT were published. Tirzepatide was noninferior to dulaglutide for MACE outcomes in patients with T2DM and CV disease).*

Overall Conclusions

- In terms of efficacy for glycemic control, there is a high degree of therapeutic interchangeability for all the drugs in the subclass.
- In terms of efficacy for MACE reduction, dulaglutide, liraglutide and semaglutide have a high degree of therapeutic interchangeability.
- In terms of efficacy for CKD outcomes, there is a low degree of therapeutic interchangeability, as semaglutide is the sole drug approved for this indication.
- In terms of safety: for all reviewed indications, all agents have a high degree of therapeutic interchangeability.

Relative Cost Effectiveness Analysis and Conclusion—The P&T Committee reviewed the solicited bids from manufacturers and CMA and BIA were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- The two generically available products—exenatide (generic Byetta) and liraglutide (generic Victoza)—were not substantially lower in cost overall and showed markedly low utilization, consistent with clinical disadvantages relative to the other agents.
- CMA results showed that of the three most-used agents, dulaglutide (Trulicity) was the most cost-effective agent if selected either as a sole UF step-preferred agent or as one of three agents selected as UF with no step therapy requirement, followed by tirzepatide (Mounjaro) and semaglutide (Ozempic).
- The BIA demonstrated that selecting all three agents UF without a step therapy requirement was more cost effective than selecting any one of the three as the sole UF step-preferred product.
- A sensitivity analysis confirmed that the UF no step scenario resulted in more cost avoidance under any realistic assumption of switching to a given step-preferred agent.
- Placement of all three agents as UF without a step therapy requirement offers beneficiaries UF copays and allows for future entrants into this class to be placed UF if warranted.
- While continued increases in utilization and cost are anticipated in this drug class, manufacturer bids are expected to result in substantial cost avoidance relative to current pricing (lower cost per patient treated).

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following.

- UF

- dulaglutide (Trulicity)
 - semaglutide (Ozempic) *moves from NF to UF*
 - tirzepatide (Mounjaro) *moves from NF to UF*
 - NF
 - exenatide twice daily (generic Byetta)
 - liraglutide (generic Victoza)
 - Complete Exclusion – None
 - Note that if generic or branded formulations of lixisenatide (Adlyxin), exenatide once weekly (Bydureon BCise) or Victoza return to the market they will be designated as NF.
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**— PA criteria apply to all agents within the class, requiring a trial of metformin first. Additionally, exenatide and liraglutide require a trial of both Trulicity and Ozempic. Trulicity currently has an automated look back allowing coverage if the patient has received any diabetic drug in the past 720 days. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the subclass for new users. An initial trial of metformin is still required first. For exenatide and liraglutide, Trulicity, Ozempic and now Mounjaro are required first. The automated lookback for any diabetic drug will remain for dulaglutide. See Appendix C for the full criteria.
 3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) minor updates to the current MN criteria for generic exenatide and generic liraglutide. Mounjaro was added to the list of formulary alternatives. See Appendix B for the full criteria.
 4. **COMMITTEE ACTION: QLS**—QLs currently apply to liraglutide, but not the remainder of the class. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) removing the QL for liraglutide, for consistency with the class.
 5. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST**— The injectable diabetic drugs are currently included on the TRICARE Maintenance Drug list. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) removing Trulicity, Ozempic and Mounjaro from the list; generic exenatide and liraglutide will not be subject to the TRICARE Maintenance Drug List requirements. See Appendix F.
 6. **COMMITTEE ACTION: UF, MN, PA, QL TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD**—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G.

C. Insulins: Rapid-Acting Insulin (RAI) Analogs Subclass

Background—The Rapid Acting Insulin (RAI) subclass was last reviewed at the November 2024 DoD P&T Committee meeting, in preparation for a Joint National Contract (JNC) with the Department of Veterans Affairs (VA). A JNC solicitation was not awarded due to manufacturer-projected supply fluctuations and market changes.

The RAIs class is comprised of insulin lispro (Humalog), insulin aspart (Novolog), insulin glulisine (Apidra) and biosimilars and unbranded biologics, which are identical to the originator product. Two new insulin biosimilar formulations have entered the market since the last review, insulin aspart-szjj (Merilog) and insulin aspart-xjhz (Kirsty). The clinical analysis focused on professional treatment guidelines and new information published since November 2024.

The DoD P&T Committee concluded in November 2022 and reaffirmed at the August 2024 meeting (“Process for Evaluating Biosimilars and Biologics”) that by FDA approval and definition, biosimilars are equally safe and efficacious, which provides strong competition within products for drug classes with biosimilars. Switching between biosimilar agents and the reference product has not demonstrated clinically meaningful differences in outcomes. Indications may be extrapolated between reference products and biosimilars.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

Efficacy and Safety

- The clinical conclusions from the 2024 class review remain unchanged, finding no clinically relevant differences between insulin aspart and insulin lispro in ability to lower HbA1c or cause hypoglycemia.
- A review of several professional guidelines confirmed that one RAI is not recommended over another.
- Although there are subtle differences between RAIs in pharmacokinetic profiles in terms of onset and duration of action, there are no clinically relevant differences between the products in outcomes including glycemic control or hypoglycemia.
- A 2025 Expert Consensus Review funded by the manufacturer of insulin lispro-aabc (Lyumjev) and insulin aspart/niacinamide (Fiasp) failed to prove compelling benefits of these two products compared to other RAIs. Lyumjev and Fiasp were possibly beneficial in certain populations and have a quicker onset of action; however, the clinical evidence does not show sustained effectiveness or superior outcomes. This was not a systematic review.

Individual Product Characteristics

- *Insulin aspart (Novolog)* is the originator aspart product and is available in pens, vials, and cartridges; it is approved in children down to two years of age. Novolog has a long history of use in the MHS.
- *Insulin lispro (Humalog)* is the originator lispro product and is available in pens, vials, and cartridges. It is approved in children as young as three years of age. Available products include a U-200 formulation and Junior Kwikpen for half-unit dosing in the pediatric space. U-200 insulin formulations are sometimes used in patients with highly elevated HbA1c levels who require more than 60 units of insulin in multiple daily doses.
 - An unbranded biologic insulin lispro formulation is available, which also includes a Junior Kwik pen that is the identical product as the originator Humalog Junior Kwik pen and from the same manufacturer.
- *Insulin lispro (Admelog)* is a “follow-on” lispro product approved via the FDA 505(b)(2) pathway using data from Humalog (prior to the establishment of the biosimilar pathway) in 2017. It does not display clinical superiority over Humalog based on previous P&T Committee drug class reviews.
- *Insulin glulisine (Apidra)* demonstrated more adverse events when used in insulin pumps along with higher rates of documented hypoglycemia compared to the other RAIs.
- *Insulin lispro-aabc (Lyumjev)* is available in two strengths. The U-100 formulation is compatible with insulin pumps; the U-200 formulation is available for patients requiring larger doses but is not compatible with pumps.
- *Insulin aspart/niacinamide (Fiasp)* is an insulin aspart formulation containing niacinamide, a form of vitamin B3. There is no data to show that Fiasp is superior to other rapid-acting insulins, and it has been completely excluded from the formulary since November 2019.
- *The new biosimilars insulin aspart-szjj (Merilog) and insulin aspart-xjhz (Kirsty)* do not provide a compelling clinical advantage over existing agents. Merilog is not approved for use in insulin pumps and Kirsty is non-Trade Agreement Act compliant.
- *TEMPO formulations* are available for two lispro formulations – Humalog and Lyumjev. The TEMPO pens are identical to the Kwik Pens, however when the TEMPO Smart Button is attached, it can transmit data via Bluetooth to a smart phone application. The TEMPO system also includes a phone app, glucometer, and TEMPO Smart button; these components are not part of the TRICARE pharmacy benefit.

Therapeutic Interchangeability and Clinical Coverage

- Overall, there is a high degree of interchangeability among the RAIs.
- One RAI is needed on the formulary to meet the needs of the majority of DoD beneficiaries. A “Junior” formulation should remain on formulary to provide small doses for pediatric patients. Additionally, an RAI compatible with insulin pumps is required.
- Due to a history of national shortages, consideration of an additional RAI on the formulary is necessary to meet healthcare demand.

Relative Cost Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- The cost analysis for the RAIs included the influence of shortages and termination of pricing agreements on current pricing.
- CMA results showed U-100 and U-200 rapid acting insulins recommended for UF were more cost-effective than those recommended for NF, as outlined below. Those recommended for complete exclusion were not cost-effective.
- BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as UF, NF or completely excluded from the formulary. BIA results showed that the below UF, NF and completely excluded recommendations demonstrated the greatest cost avoidance for the MHS.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following.

U-100 Insulins

- UF
 - insulin aspart (Novolog Flexpen and vial)
 - insulin lispro (Humalog Kwikpen and vial)
 - insulin lispro (Humalog Kwikpen unbranded biologic)
 - Insulin lispro Junior (Humalog Kwikpen Junior unbranded biologic)
 - insulin lispro – aabc (Lyumjev Kwikpen and vial)
 - insulin aspart–szjj (Merilog)
- NF
 - insulin lispro Junior Kwikpen branded (Humalog Kwikpen Junior) – *moves from UF to NF*

- insulin lispro TEMPO (Humalog TEMPO) – *moves from UF to NF*
- insulin aspart–xjhz (Kirsty)
- insulin aspart (Admelog)
- insulin glulisine (Apidra)
- Complete Exclusion
 - insulin aspart/niacinamide (Fiasp)
 - insulin lispro-aabc TEMPO (Lyumjev TEMPO) – *moves from NF to complete exclusion status*

U-200 Insulins

- UF
 - insulin lispro U-200 (Humalog Kwikpen)
- NF
 - insulin lispro-aabc U-200 (Lyumjev Kwikpen) – *moves from UF to NF*
- Complete Exclusion – None

2. COMMITTEE ACTION: MANUAL PA CRITERIA—PA currently applies to Apidra, Admelog and the Lyumjev TEMPO and Humalog TEMPO pens. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PAs as outlined below, in new users. See Appendix C.

- PA is not required for the branded insulin lispro Humalog Junior Kwik pen, intended for pediatric patients.
- PA will apply to the RAIs recommended for NF status (with the exception of branded Humalog Junior), as these products currently have or are expected to have low utilization in the MHS. PA will only apply to new users of Apidra, Admelog, Kirsty, Humalog TEMPO, Lyumjev TEMPO pens, and Lyumjev U-200.
- For Apidra and Admelog, the current automated lookback will be removed, however patients are still required to try Novolog, Humalog or unbranded biologic insulin lispro.
- For Kirsty and the Humalog TEMPO pen, a trial of Novolog, Humalog and insulin lispro unbranded biologic will be required in new users.

- The PA currently in place for Lyumjev TEMPO pen will remain until implementation of the complete exclusion status.
- For the Lyumjev U-200 product, a trial of Humalog U-200 is required first in new users.

3. COMMITTEE ACTION: MEDICAL NECESSITY (MN)

CRITERIA—The current MN criteria for Admelog and Apidra allow use if the patient has had an inadequate response to Novolog, Humalog or unbranded biologic insulin lispro. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updating the current MN criteria for Admelog and Apidra to also require a trial of Lyumjev U-100 and Merilog, which are added to the list of formulary alternatives. The new MN criteria for Kirsty and Lyumjev TEMPO will mirror the Apidra and Admelog MN criteria. See Appendix B for the full criteria.

4. COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST—

The RAIs are currently on the TRICARE Maintenance Drug list. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) removing Humalog, Novolog and Merilog from the list. Admelog, Apidra, Humalog TEMPO, Humalog Junior and Lyumjev U-200 will be added to/maintained on the list, Kirsty will be added to the list, contingent on feasibility, as this product is currently non-Trade Agreement Act compliant. See Appendix F.

5. COMMITTEE ACTION: RAPID RESPONSE PROGRAM—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding branded Humalog Kwikpen Junior to the rapid response program (safety net program) maintained by the TPharm 5 contractor.

6. COMMITTEE ACTION: UF, MN, PA, TRICARE MAINTENANCE DRUG LIST, RAPID RESPONSE and IMPLEMENTATION

PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) DHA send letters to patients affected by the recommendation for NF status for branded Humalog Kwikpen Junior, Humalog TEMPO pen and Lyumjev U-200 pen; and 3) DHA send letters at 60 and 30 days prior to implementation for the patients affected by the recommendation for Complete Exclusion status for Lyumjev TEMPO pen. See Appendix G.

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5)

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (20 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the November 2025 DoD P&T Committee meeting, a brief summary of their

clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the TRICARE Drug Maintenance List.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - brensocatib (Brinsupri) – Pulmonary I Agent for non-cystic fibrosis bronchiectasis
 - delgocitinib 2% cream (Anzupgo) – Atopy Agent for chronic hand eczema
 - dordaviprone (Modeyso) – Oncological Agent for glioma
 - gepotidacin (Blujepa) – Antibiotic for urinary tract infections (UTI)
 - imlunestrant (Inluriyo) – Oncological Agent for breast cancer
 - lecanemab-irmb injection (Leqembi Iqlik) – Alzheimer’s Agent
 - nalmefene injection (Zurnai) – Alcohol Deterrents-Narcotic Antagonists
 - rilzabrutinib (Wayrilz) – Hematological Agents: Platelets, for thrombocytopenia
 - sebetralstat (Ekterly) – Hereditary Angioedema (HAE)– Acute treatment
 - sepiapterin oral powder (Sephience) – Miscellaneous Metabolic Agents for hyperphenylalaninemia in phenylketonuria
 - sitagliptin 25 mg/mL oral solution (Brynovin) – Non-Inulin Diabetes Drugs – Dipeptidyl Peptidase-4 (DPP-4) inhibitor
 - sulopenem etzadroxil /probenecid (Orlynvah) – Beta lactam Antibiotic for UTI
 - zongertinib (Hernexeos) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2)
- NF
 - dasatinib (Phyrago) – Oncological Agent for Chronic Myelogenous Leukemia and Acute Lymphocytic Leukemia
 - dihydroergotamine mesylate injection (Brekiya) – Migraine Agent
 - donidalorsen injection (Dawnzera) – HAE - prophylaxis Agent

- gepirone (Exxua) – Antidepressants and Non-Opioid Pain Syndrome Agents
- metoprolol tartrate 10 mg/mL oral solution (Lopressor) – Beta Blockers and Hydrochlorothiazide Combination Agents
- Complete Exclusion: See Appendix H for additional detail regarding complete exclusion agents and formulary alternatives.
 - bumetanide nasal spray (Enbumyst) – Diuretics
 - Enbumyst was recommended for complete exclusion status as it has little to no clinical benefit relative to the other loop diuretics, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include bumetanide tablets, furosemide tablets, and torsemide tablets.
 - escitalopram 15 mg caps (no brand name) – Antidepressants and Non-Opioid Pain Syndrome Agents
 - Escitalopram 15 mg capsules were recommended for complete exclusion status as it has little to no clinical benefit relative to the other selective serotonin reuptake inhibitors (SSRIs), and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include other selective serotonin reuptake inhibitors SSRIs, including citalopram, escitalopram, sertraline, and fluoxetine tablets and oral solutions.
 - nitisinone (Harliku) – Miscellaneous Replacement Enzymes for alkaptonuria-associated urine homogentisic acid
 - Harliku was recommended for complete exclusion status as it has little to no clinical benefit relative to the other nitisinone formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include other nitisinone products such as Orfadin and generic Nityr.

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Phyrago, Brekiya, Dawnzera, Exxua, and Lopressor oral solution. See Appendix B for the full criteria.

3. **COMMITTEE ACTION: PA CRITERIA**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria. See Appendix C for the full criteria.

- Applying manual PA criteria to new users of Brinsupri, requiring specialist prescribing and a trial of azithromycin.

- Applying manual PA criteria to new users of Orlynvah, and Blujepa, requiring culture-proven bacterial UTI, and contraindications to or antibiotic resistance to standard UTI antimicrobials. Automated specialist bypass was added to allow PA approval if the prescriber is a urologist, urogynecologist or infectious disease specialist.
 - Applying manual PA criteria to new users of Leqembi, requiring specialist prescribing and medical documentation that the patient has completed 18 months of initial treatment with intravenous lecanemab-irmb (Leqembi).
 - Applying manual PA criteria to new users of Exxua, requiring a trial of three formulary antidepressants first.
 - Applying manual PA criteria to new users of Anzupgo, requiring a trial of topical corticosteroids, and topical calcineurin inhibitors, consistent with the PA criteria for other products used to treat eczema.
 - Applying manual PA criteria to the hematology/oncology drugs Modeyso, Inluriyo, Wayrilz, Hernexeos, and Phyrago.
 - Applying manual PA criteria to new and current users of Brekiya, requiring a trial of two triptans and nasal dihydroergotamine spray first.
 - Applying manual PA criteria to new users of Ekterly, Brynovin, Dawnzera, Sephience and Lopressor oral solution.
 - Applying temporary manual PA criteria to new and current users of Enbumyst nasal spray, escitalopram 15 mg capsules and Harliku until implementation of complete exclusion status.
4. **COMMITTEE ACTION: QLs**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) QLs for Anzupgo, Blujepa, Brekiya, Brinsupri, Dawnzera, Ekterly, Hernexeos, Inluriyo, Leqembi, Modeyso, Phyrago, Orlynvah, Sephience, Wayrilz and Zurnai. See Appendix D for the QLs.
5. **COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding, Dawnzera, Blujepa, Ekterly, and Orlynvah to Rapid Response program managed by the TRICARE pharmacy benefits contractor. The program identifies beneficiaries who have not received a prescription fill after the initial reject.
6. **COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List which includes the NF medications subject to the TMOP requirement.

Drugs recommended for addition to the Specialty Drug List are found in Appendix E.

7. **COMMITTEE ACTION: UF, MN, PA, QL, TRICARE MAINTENANCE DRUG LIST, and IMPLEMENTATION PERIOD**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF and NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.
- **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service; and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion status at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for three recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for the newly approved drug reviews and cannot be reviewed for formulary status. Numerous cost effective formulary alternatives are available that do not require prior authorization.

- a) **Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tabs (Clemsza)**—This clemastine tablet formulation is less cost-effective than other clemastine tablets that are available in the same strength.
- b) **Anticholinergics-Antispasmodics—dicyclomine 40 mg tablet**—This dicyclomine tablet formulation is less cost-effective than currently available dicyclomine tablets and capsules. The 40 mg dose can be achieved using other available formulations.
- c) **Pain Agents: NSAIDs—flurbiprofen 100 mg tabs (Lurbiro)**—There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for manual PA criteria for clemastine (Clemsza), dicyclomine 40 mg tablet, and flurbiprofen (Lurbiro) in new users, due to the significant cost differences compared with other available alternative agents. The new PAs will become

effective the first Wednesday 60 days after the signing of the minutes.
See Appendix C for the full criteria.

2. Updated PA and MN Criteria for New FDA-Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- a) **Antihemophilic Agents: Non-Factor Agents—concizumab-mtci (Alhemo)**—The PA for Alhemo was updated to allow for the new indication for hemophilia A or B without inhibitors. Previously, Alhemo was only indicated in hemophilia A or B with inhibitors.
- b) **Hematological Agents: Platelets—avatrombopag (Doptelet)**—Doptelet received an expanded age indication for thrombocytopenia in pediatric patients one year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The Doptelet manual PA criteria were updated to remove a minimum age for ITP. (Note that Doptelet sprinkles were addressed as a line extension at this meeting. See page 28.)
- c) **Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Preventative—fremanezumab (Ajovy)**—The manual PA was updated to allow for an expanded age indication for episodic migraine prevention to include pediatric patients 6-17 years old and weighing greater than or equal to 45 kg.
- d) **Atopy—ruxolitinib 1.5% cream (Opzelura)**—Opzelura is now indicated in children as young as 2 years old with atopic dermatitis. The PA criteria were updated accordingly.
- e) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors—apremilast (Otezla)**—The manual PA for Otezla was updated to allow for an expanded age indication for psoriatic arthritis to include pediatric patients 6-17 years old.
- f) **Oncological Agents: Poly ADP-Ribose Polymerase (PARP) Inhibitors—niraparib (Zejula)**—The FDA narrowed Zejula's indication for first-line maintenance treatment of advanced ovarian cancer to those with homologous recombination deficiency (HRD)-positive tumors only. Additional edits were made to the Zejula PA to align with ongoing oncology standardization efforts. For more information on oncology standardization, please refer to the November 2024 P&T meeting minutes.
- g) **Diabetes Non-Insulin: Oral Glucagon-Like Peptide-1 Receptor Agonists—semaglutide (Rybelsus)**—Rybelsus is now indicated to reduce the risk of MACE in type 2 diabetic adults. The current PA states that Rybelsus has not been proven for MACE. This line will be removed due to this new indication and supporting data.

- h) Hematological Agents—pegcetacoplan (Empaveli)**—The manual PA criteria for Empaveli were updated to allow for treatment of complement 3 glomerulopathy (C3G) and immune-complex membranoproliferative glomerulonephritis (IC-MPGN). The PA criteria are based on the VALIANT study. As a result of this new indication, the Fabhalta MN criteria were updated to allow Empaveli as a formulary alternative; previously at the August 2025 meeting the Fabhalta MN criteria were changed to allow for the C3G/IC-MPGN indication as a reason to use Fabhalta, but this no longer applies with the new Empaveli indication. (See Appendix B for the Fabhalta MN update.)

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Alhemo, Doptelet, Ajovy, Opzelura, Otezla, Zejula, Rybelsus, and Empaveli in new users, plus the update to the Fabhalta MN. Implementation of the PA criteria updates will be effective the first Wednesday 60 days after the signing of the minutes. See Appendices C for the full criteria.

3. Updated PA Criteria for Reasons other than New Indications

Updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

- a) Oncological Agents: 2nd Generation Antiandrogens—darolutamide (Nubeqa)**—The Nubeqa PA was updated based on provider feedback and National Comprehensive Cancer Network (NCCN) guideline updates. The PA now aligns with NCCN guidelines on Nubeqa use with docetaxel and on high vs. low volume metastases.
- b) Pulmonary Arterial Hypertension Agents—sotatercept (Winrevair)**—The manual PA was updated to remove the current diuretic requirement. In the STELLAR trial used to gain FDA approval, not all the participants were receiving diuretics. The P&T Committee also reviewed an analysis of background medications for patient dispensed Winrevair. Winrevair will also now be available for dispensing through the specialty mail pharmacy and will be added to the TRICARE Maintenance Drug List. See Appendix F.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Nubeqa and Winrevair in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

4. Removal of PAs

Anti-infectives: Anti-Helminthics—ivermectin (Stromectol, generics)—In 2021, a PA and QL were added to ivermectin due to increased utilization during the COVID-19 pandemic. MTF providers are now requesting access to ivermectin to treat scabies. The PA will be removed for ivermectin.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND

IMPLEMENTATION PERIOD—The P&T Committee recommended (12 for, 6 opposed, 2 abstained, 0 absent) removing the PA criteria for ivermectin. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes. The reasons for the opposing votes were due to an alternative recommendation of adding a specialist bypass and drug lookback, rather than removing the PA, however the P&T Committee members did recommend to remove the PA.

B. Quantity Limits (QLs)

Pain Agents: Pain Miscellaneous—suzetrigine (Journavx)—Journavx is a non-opioid acute pain medication that was reviewed as an innovator at the May 2025 P&T meeting. QLs of 30 tablets/30 days with no refills were applied at that time. A review of dispensing data shows that the current QLs are not working as intended. The QL for Journavx was changed to allow for a maximum of 30 tablets in 6 months, to reduce dispensing of excessive supply. See Appendix D.

C. Line Extensions

The P&T Committee clarified the formulary status for four product line extensions by the original manufacturer. Line extensions have the same FDA indication(s) as the “parent” drug and retain the same formulary and copayment status as the “parent” drug.

- 1. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors**—designating **zanubrutinib (Brukinsa) tablets** with the same formulary status (UF), PA, QL, and Specialty Drug List as the parent Brukinsa capsules.
- 2. Anticoagulants: Oral Anticoagulants**—designating **apixaban (Eliquis) film-coated tablet for oral suspension** with the same formulary status (BCF) and TRICARE Maintenance Drug List status as the Eliquis tablets.
- 3. TIBs: IL-23s**—designating **ustekinumab-aauz (Otulfi) vials** with the same formulary status (UF), non step-preferred, PA, QL, Specialty and TRICARE Maintenance Drug Lists as Otulfi syringes.
- 4. Hematological Agents: Platelets**—designating **avatrombopag (Doptelet Sprinkle) capsules** with the same formulary status (UF), PA, QL, and Specialty Drug List status as Doptelet tablets. Note that the PA for Doptelet was updated to allow the new pediatric age range. See page 26. The same PA will apply for both the tablets and sprinkle formulation.

COMMITTEE ACTION: LINE EXTENSION AND

IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, MN,

Specialty and TRICARE Maintenance Drug Lists status for the four products listed above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

D. TRICARE Maintenance Drug List Updates

At the February 2025 P&T meeting, QLs were recommended for two estradiol vaginal rings used to treat menopausal symptoms, Estring and Femring. A review of MHS prescribing patterns showed higher than recommended quantities dispensed. The QL for Estring and Femring previously allowed for 1 ring dispensed per 90 days. After implementation, it was identified that this posed a problem at the retail point of service due to the TRICARE Maintenance Drug List limitation of two 30-day supply fills at retail. This led to QL rejects and processing issues at the retail point of service.

The pricing of Estring and Femring were evaluated at the MHS different points of service. It was cost advantageous to remove Estring from the TRICARE Maintenance Drug List. Femring is more costly at retail, but overall utilization of Femring is relatively low. The committee recommended removing both Estring and Femring from the TRICARE Maintenance Drug List. See Appendix F.

COMMITTEE ACTION: TRICARE Maintenance Drug List IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) removing Estring and Femring from the TRICARE Maintenance Drug List. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION

A. Brand over Generic Additions

Oncological Agents: Chronic Myelogenous Leukemia—nilotinib (Tasigna) is designated as UF without a PA. A generic is now marketed, however, this product is less cost-effective compared to the branded agent. Therefore, the branded Tasigna capsules will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization. Accordingly, the Tier 1 (generic) copay for brand Tasigna is recommended.

B. Brand over Generic Removals

- 1. Anticoagulants: Oral Anticoagulants—dabigatran capsules (Pradaxa)** were recommended for brand over generic status at the August 2023 P&T meeting. Generic dabigatran capsules are now more cost effective than the branded agent. The brand over generic criteria for the Pradaxa capsules will be removed, and the Tier 2 copay will apply.
- 2. Attention Deficit Hyperactivity Disorder (ADHD) Agents: Stimulants—lisdexamfetamine capsules (Vyvanse)** At the May 2024 P&T meeting, brand over generic criteria was recommended for lisdexamfetamine (Vyvanse) capsules and chewable tablets in all new users at all points of service. Lisdexamfetamine capsules are now more cost-effective than the brand; however, the Vyvanse

chewable tablets remain more cost-effective than the generic. The brand over generic criteria and Tier 1 copay for Vyvanse capsules will be removed and Vyvanse capsules will have a Tier 2 copay. There are no changes to the brand over generic preference and Tier 1 copay for the Vyvanse chewable tablets.

3. **Renin-Angiotensin Antihypertensives: Combinations—sacubitril/valsartan tablets (Entresto)** were recommended for brand over generic criteria at the May 2025 P&T meeting. At this time, generic sacubitril/valsartan is more cost effective than Entresto, and the brand over generic preference will be removed and the Tier 2 copay will apply for Entresto.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT

AND PA CRITERIA IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) requiring brand Tasigna capsules over the generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. Brand Tasigna will be available at a Tier 1 copay. In addition, the brand over generic criteria for Pradaxa capsules, Vyvanse capsules, and Entresto tablets will be removed and the branded agents will return to a Tier 2 copay. The effective date will be the first Wednesday 60 days after signing of the minutes. The “brand over generic” requirement for Tasigna will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

VIII. DoD P&T COMMITTEE ADMINISTRATIVE AUTHORITIES

Background—The Administrative Authorities document outlines which P&T Committee functions can be performed administratively prior to the quarterly meeting, and subsequently presented to the P&T Committee for formal recommendation; those functions which require both Uniform Formulary Beneficiary Advisory Panel (UF BAP) and Director, DHA review, and those which solely require Director, DHA review and do not fall under the purview of the UF BAP panel. Prior to this meeting, the most recent updates to the Administrative Authorities document occurred at the February and May 2025 P&T Committee meetings.

Recommendation—The P&T Committee recommended updating the document in the following sections:

Approval by the Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments: In situations where the BAP meeting is delayed past the quarterly DoD P&T Committee meeting, the DoD P&T Committee recommended PA criteria may be applied, including automation and beneficiary notification for affected users. DoD P&T Committee recommended PA criteria will be presented to the UF BAP for review and comment at the next scheduled UF BAP meeting and ultimately presented to the Director, DHA for consideration and final decision.

Approval by the Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to the UF BAP for comments): In

situations when the BAP meeting is delayed past the quarterly DoD P&T Committee meeting, DoD P&T Committee recommended MN criteria and/or QLs may be applied. The DoD P&T Committee recommended MN criteria and/or QLs will be presented to the Director, DHA for consideration and final decision.

Justification—The above additions to the Administrative Authorities’ document will allow temporary implementation of PA criteria, MN criteria and QLs prior to signing of the quarterly meeting minutes by the Director, DHA in situations where significant delays are occurring.

COMMITTEE ACTION: P&T COMMITTEE ADMINISTRATIVE

AUTHORITY UPDATE—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) to update the document as outlined above. See Appendix H, page 80

X. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

A. Bulk Chemicals: DHA identified claims for bulk chemicals typically intended for compound formulations which are adjudicated by the pharmacy contractor without any restrictions (e.g., Prior Authorizations). These items are not FDA-approved and are meant for compounding and not for direct dispensing to the patient. These bulk chemicals will no longer adjudicate through the TRICARE pharmacy benefit. These bulk chemicals still may be covered but must be submitted through a compound claim and coverage will be determined through the TRICARE compound claim adjudication process.

B. Mandatory Generic Dispensing at MTFs: Per 32 CFR 199.21 (j)(2) use of generic drugs under the TRICARE pharmacy benefits program generally requires mandatory substitution of generic drugs listed with an “A” rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA and generic equivalents of grandfathered or Drug Efficacy Study Implementation (DESI) category drugs for brand name drugs.

Historically, the Mandatory Generic Policy has not been enforced by the TPharm Contractor at the MTF point of service. Upon the signing of these minutes, the mandatory Generic Policy shall be enforced at the MTF point of service to align with both the TMOP and retail pharmacies points of service applying to new patients only (grandfathering) with a look back of 120 days. The P&T Committee may designate exceptions to the mandatory generic enforcement (e.g., narrow therapeutic index drugs allowed for patients stabilized on therapy).

C. Private Label Agents: Private label products are manufactured by one company but branded and sold by another, similar to a store brand. Pharmacy Benefit Managers (PBMs) or other companies use private labeling to create their own version of a biosimilar, which is preferred on their company's drug formulary and not available to other healthcare plans. These private label products are not intended for dispensing to TRICARE beneficiaries. Since these private label products are not available for TRICARE beneficiaries they will not be added to the TRICARE Formulary and are not part of the TRICARE pharmacy benefit.

- **Interleukin 23 Inhibitors:** As a result of the above recommendation, the following products status will no longer be part of the TRICARE Pharmacy benefit. DHA will send letters to patients affected by this decision.
 - May 2025: ustekinumab-ttwe unbranded private label Pyzchiva by Quallent
 - August 2025: ustekinumab-aekn unbranded Selardsi private label by Teva
 - November 2025: ustekinumab-ttwe unbranded private label Pyzchiva by Cordavis (this product was originally included as one of the innovator drugs for this meeting but is now not part of the TRICARE pharmacy benefit with no further action required).
- D. Copay Changes for 2026:** The Committee was briefed on the statutorily required copay changes that will be effective in January 2026.
- E. Self-Monitoring Blood Glucose System (SMBG) Test strips:** The Medtronic 780G insulin pump, which is compatible with the Accu-Chek Guide test strip was added to the SMBG test strip PA form.
- F. Gastrointestinal-2 Agents for Primary Biliary Cholangitis:** The PA for seladelpar (Livdelzi) and elafibranor (Iqirvo) requires patients to have a contraindication to, intolerance to, or a failed trial of obeticholic acid (Ocaliva). Recently, the FDA mandated the market removal of Ocaliva due to hepatotoxicity, effective November 2025; therefore, the Livdelzi and Iqirvo PAs were updated to remove the Ocaliva step. See Appendix C.
- G. Basal Insulins: insulin degludec (Tresiba):** The current Tresiba PA requires the provider to explain why the patient cannot use unbranded insulin degludec. Unbranded insulin degludec will be discontinued by the manufacturer by the end of December 2025; thus, the question on unbranded insulin degludec was removed from the Tresiba PA. See Appendix C.

XII. ADJOURNMENT

The meeting adjourned at 1230 hours on November 6th. The next meeting will be in February 2026.

Appendix A—Attendance: November 2025 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

**Appendix F—TRICARE Maintenance Drug List Status of Medications Designated
Formulary or Nonformulary during the November 2025 DoD P&T
Committee Meeting**

Appendix G—Implementation Dates

Appendix H—Drugs with Complete Exclusion Status and Formulary Alternatives

Appendix I—DoD P&T Committee Administrative Authority

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

☐ concurs with all recommendations.

Implementation for the recommendations for the Metabolic Dysfunction Agents: Injectable Weight Loss Agents and Injectable Diabetic Agents subclasses will occur on the first Wednesday two weeks after signing of the minutes.

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**Acting Assistant Director
Health Care Administration and
Operations**

Minutes & Recommendations of the DoD P&T Committee Meeting November 5-6, 2025

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.) USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
LTC Megan Donahue, MC	Army, Physician at Large
LTC Ryan Burkhardt, MC	Army, Internal Medicine Physician
COL James Masterson, MSC	Army, Pharmacy Consultant
CDR Derek Larson, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
MAJ Loraine Baraki, MC	Army, OBGYN
CAPT Peter Cole, MC	Navy, Physician at Large
CAPT Katie Jaudon, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Lt Col Sara DeSpain, MC	Air Force, Physician at Large
Col Soo Sohn, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
LCDR Shira Paul, MC	Navy, Oncology Physician
David Nowinski, PharmD, BCOP	DHA, Oncology Pharmacist
CDR Jackie Finocchio, USCG	Coast Guard, Pharmacy Consultant
COL Yang Xia, MC	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Peter Glassman, MD	Department of Veteran’s Affairs
Eric Dill, PharmD	Department of Veteran’s Affairs
Marsha Peterson	DHA Contracting Officer
Eric Parsons, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integration Branch
LCDR Siung Kang	Defense Logistics Agency
Guests	
Maj Callie Cheatham, MC	Endocrinology, Air Force
Hazel Richardson, PharmD	CDC World Trade Center Health Plan
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
Lt Col Pansy Uberoi	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
CPT Ji Yoon Kim	DHA POD Formulary Management Branch
MAJ Brandon Hardin	BAMC Pharmacy Resident
Jules Canaley	DHA Contracting
Kirk Heyen	DHA Contracting
Keith Marasigan	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity (MN) Criteria
Drug Class Reviews MN Criteria	
liraglutide (Saxenda) Metabolic Dysfunction Agents: Injectable Weight Loss Agents	Note there are no changes from the current MN criteria. - Use of all formulary agents is contraindicated for patients 18 years of age or older - Use of Qsymia and Wegovy is contraindicated for patients 12 years of age or older and younger than 17 years of age - Use of all formulary agents resulted in therapeutic failure Formulary alternatives: phentermine products (phentermine, benzphetamine, diethylpropion IR/SR, phendimetrazine IR/SR) Qsymia, Contrave, Wegovy, and Zepbound.
- exenatide twice daily (generic Byetta) - liraglutide (generic Victoza) Metabolic Dysfunction Agents: Injectable Diabetes Agents	Updates from the November 2025 meeting are in bold and strikethrough Patient has experienced significant adverse effects from all formulary agents dulaglutide (Trulicity) and the preferred non-formulary agent semaglutide (Ozempic) which is not expected with the non-preferred products. Formulary and non-formulary alternatives: dulaglutide (Trulicity), semaglutide (Ozempic) and tirzepatide (Mounjaro)
- glulisine (Apidra) - lispro (Admelog) Insulins: Rapid-Acting Agents	Updates from the November 2025 meeting are in bold and strikethrough Use of insulin aspart (Novolog), insulin lispro (Humalog or unbranded biologic ~~authorized generic insulin lispro~~) insulin lispro-aabc (Lyumjev) and Insulin aspart-szjj (Merilog) have resulted in therapeutic failure Formulary alternatives: insulin aspart (Novolog), insulin lispro (Humalog or authorized generic lispro), insulin lispro-abc (Lyumjev) and insulin aspart-szjj (Merilog)
- insulin aspart-xjhz (Kirsty) - Humalog TEMPO Insulins: Rapid-Acting Agents	Use of insulin aspart (Novolog), insulin lispro (Humalog or unbranded biologic insulin lispro) insulin lispro-aabc (Lyumjev and Insulin aspart-szjj (Merilog) have resulted in therapeutic failure Formulary alternatives: insulin aspart (Novolog), insulin lispro (Humalog or unbranded biologic lispro), insulin lispro-abc (Lyumjev and insulin aspart-szjj (Merilog)
Insulin lispro-aabc U-200 (Lyumjev U-200) Insulins: Rapid-Acting Agents	Use of insulin lispro U-200 (HumalogU-200) has resulted in therapeutic failure Formulary alternatives: insulin lispro U-200 (Humalog U-200)

Appendix B—Table of Medical Necessity Criteria

Humalog Kwikpen Junior Insulins: Rapid-Acting Agents	No alternative formulary agent: the patient is unable to access the formulary alternative due to shortages. Formulary alternatives: insulin lispro unbranded biologic Kwikpen Junior
New Drugs MN Criteria	
dasatinib (Phyrago) Oncological Agents	No alternative formulary agent: The patient requires dasatinib and is receiving concurrent H2 blockers or PPIs Formulary alternatives: dasatinib (Spyrce, generic), imatinib (Gleevec, generic)
dihydro-ergotamine mesylate injection (Brekia) Migraine Agents	No alternative formulary agent: The patient is unable to use dihydroergotamine nasal spray due to severe rhinitis, nasal congestion or nasal structural abnormalities or cannot use sumatriptan injection Formulary alternatives: sumatriptan SC injection, dihydroergotamine nasal spray
donidalorsen injection (Dawnzera) Corticosteroids-Immune-Modulator: Hereditary Angioedema Agents	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Formulary agents resulted in therapeutic failure Formulary alternatives: Haegarda, Cinryze, Takhzyro
gepirone (Exxua) Antidepressants and Non-Opioid Pain Syndrome Agents	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Formulary agents resulted in therapeutic failure Formulary alternatives: citalopram, escitalopram, fluoxetine, sertraline, fluvoxamine, paroxetine hydrochloride IR; SNRI: venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER; NDRI: bupropion (IR, SR, ER); TCA: amitriptyline, desipramine, imipramine, nortriptyline; SARI: trazodone, nefazodone; MAOIs: phenelzine, tranylcypromine
metoprolol tartrate 10 mg/mL oral solution (Lopressor) Beta Blockers and Hydrochlorothiazide Combination Agents	- No alternative formulary agent: The patient requires a liquid beta blocker formulation due to a documented medical condition and not due to convenience - Formulary alternatives: metoprolol tartrate tabs, metoprolol succinate tabs, atenolol, nebivolol
Other MN Criteria	
iptacopan (Fabhalta) Hematological Agents	Updates from the November 2025 meeting are in bold and strikethrough - Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Formulary agents resulted in therapeutic failure - No alternative formulary agent –patient is not able to access an infusion center or ~~patient has C3G glomerulopathy~~ Formulary alternatives for PNH: pegcetacoplan (Empaveli); formulary alternatives for IgAN: Filspari, Vanrafia, empagliflozin, dapagliflozin

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
- semaglutide (Wegovy) - tirzepatide (Zepbound) Metabolic Dysfunction Agents: Injectable Weight Loss Agents	Updates from November 2025 are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of Wegovy and Zepbound <u>Manual PA Criteria:</u> Coverage for Wegovy or Zepbound is approved if: - The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge” - Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan? - If yes, subject to verification, proceed to the next question - If no, coverage is not approved - What Tricare Plan is the patient enrolled in? - TRICARE Select – proceed to the next question - TRICARE Prime – proceed to the next questions - TRICARE For Life – Coverage not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives. If the diagnosis is Diabetes Mellitus and the patient meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives. - The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested. - The provider will document the major condition and comorbidities treated selecting all that apply: - Obesity - Diabetes or impaired glucose tolerance - Obstructive sleep apnea - Osteoarthritis - Metabolic syndrome - Dyslipidemia - Hypertension - Metabolic dysfunction-associated steatohepatitis (MASH) - Established cardiovascular disease with a history of stroke - Established cardiovascular disease with a history of myocardial infarction - Established cardiovascular disease with a history of peripheral artery disease For Wegovy and Zepbound for adults for obesity - Patient is 18 years of age or older - Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity - The provider will document the BMI

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ For BMI less than 27, coverage is not approved ▪ For BMI ranging between 27 and 29 with a comorbidity ▪ For BMI ranging between 30 to 34 ▪ For BMI ranging between 35 to 39 ▪ For BMI greater than or equal to 40 • Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response ▪ Phentermine: Date _____ Duration of therapy _____ - OR • Patient has achieved greater than equal to 5 percent weight loss from baseline while on phentermine, benzphetamine, diethylpropion IR/SR or phendimetrazine IR/SR but BMI and central adiposity remain high, and further reduction is needed to attain optimal outcomes • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension or a patient not meeting blood pressure goal on 2 or more antihypertensives) OR <i>(changes from the August 2025 meeting)</i> • The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) for obesity • Patient is 12 years of age or older and younger than 18 years of age • Patient has a BMI greater than or equal to 95th percentile standardized for age For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity: • Patient is 18 years of age or older • Patient has moderate to severe OSA (documented apnea-hypopnea index greater than 15 events per hour) and a BMI greater than 30 For all patients • Concomitant use of this medication with another GLP1-RA is not allowed (e.g., exenatide Bydureon, Trulicity, Byetta, Adlyxin, Victoza, liraglutide, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus PA expires in 12 months for initial therapy; annual renewal required <u>Renewal PA Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met. Renewal criteria will apply to all users when the prescription is due for renewal. • The provider will document the BMI for renewal: ▪ BMI less than 27 ▪ BMI ranging between 27 and 29 ▪ BMI ranging between 30 to 34 ▪ BMI ranging between 35 to 39 ▪ BMI greater than or equal to 40 For Obesity:
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Appendix C—Table of Prior Authorization (PA) Criteria

	- The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification. Medical record documentation will be made available to TRICARE for audit, if requested. - For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication with full dosage titration - For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication - The patient is not pregnant The patient does not have a history of or a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 For OSA: - The patient has shown improvement in OSA symptoms based on the improvement of apnea hypopnea index
liraglutide (Saxenda) Metabolic Dysfunction Agents: Injectable Weight Loss Agents	Updates from November 2025 are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of Saxenda <u>Manual PA Criteria:</u> Coverage for Saxenda is approved if: - No change to coverage: The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge” - Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan? - If yes, subject to verification, proceed to the next question - If no, coverage is not approved : What Tricare Plan is the patient enrolled in? - TRICARE Select – proceed to the next question - TRICARE Prime – proceed to the next questions - TRICARE for Life– Coverage not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives. If the diagnosis is Diabetes Mellitus and the patient meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives. - The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested. The provider will document the major condition and comorbidities treated selecting all that apply: Obesity Diabetes or impaired glucose tolerance

Appendix C—Table of Prior Authorization (PA) Criteria

	– Obstructive sleep apnea – Osteoarthritis – Metabolic syndrome – Dyslipidemia – Hypertension – Metabolic dysfunction-associated steatohepatitis (MASH) – Established cardiovascular disease with a history of stroke – Established cardiovascular disease with a history of myocardial infarction – Established cardiovascular disease with a history of peripheral artery disease Adults: • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity • ~~Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity (diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)~~ • The provider will document the BMI – For BMI less than 27, coverage is not approved – For BMI ranging between 27 and 29 with a comorbidity – For BMI ranging between 30 to 34 – For BMI ranging between 35 to 39 – For BMI greater than or equal to 40 • Patient has tried and failed all of the following (generic phentermine [or benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR], Qsymia, and Contrave) or has experienced an adverse reaction or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) – phentermine, benzphetamine, diethylpropion (IR/SR), or phendimetrazine (IR/SR: Date _____ Duration of therapy _____ CI _____ OR _____ • Patient has achieved greater than or equal to 5 percent weight loss from baseline on phentermine, benzphetamine, diethylpropion IR/SR or phendimetrazine IR/SR but BMI and central adiposity remain high, and further reduction is needed to attain optimal outcomes • Note that for phentermine, contraindications include, arrhythmias, coronary artery disease, heart failure, stroke, ~~uncontrolled hypertension~~ or a patient not
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Appendix C—Table of Prior Authorization (PA) Criteria

	meeting blood pressure goal on 2 or more antihypertensives) (changes from the August 2025 meeting) – Qsymia (or one of its individual generic components phentermine or topiramate): Date _____ Duration of therapy _____ CI _____ – Contrave (or one of its individual generic components bupropion or naltrexone): Date _____ Duration of therapy _____ CI _____ – Wegovy: Date _____ Duration of therapy _____ CI _____ – Zepbound: Date _____ Duration of therapy _____ CI _____ Adolescents: • Patient is 12 years of age or older and younger than 18 years of age with BMI greater than or equal to 95th percentile standardized for age • Patient has tried and failed Qsymia or its individual generic components OR • Patient has a contraindication or has had an adverse reaction to Qsymia or its individual generic components (Note: provider must include the date of use and duration of therapy or contraindication to the drug) and Wegovy – Qsymia (or one of its individual generic components, phentermine or topiramate): Date _____ Duration of therapy _____ CI _____ – Wegovy: Date _____ Duration of therapy _____ CI _____ For all patients: • Concomitant use of Saxenda with another GLP1-RA is not allowed (e.g., exenatide Bydureon, Trulicity, Byetta, Adlyxin, Victoza/liraglutide, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus PA expires in 12 months for initial therapy; annual renewal required <u>Renewal PA Criteria:</u> Note that initial TRICARE PA approval required for renewal. Saxenda will be approved for an additional 12 months if the following are met. Renewal criteria will apply to all users when the prescription is due for renewal. • The provider will document the BMI for renewal: – BMI less than 27 – BMI ranging between 27 and 29 – BMI ranging between 30 to 34 – BMI ranging between 35 to 39
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Appendix C—Table of Prior Authorization (PA) Criteria

	– BMI greater than or equal to 40 • The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification. Medical record documentation will be made available to TRICARE for audit, if requested. • Patient is older than 12 years of age and younger than 18 years of age: the patient has lost greater than or equal to 4% of baseline body weight since starting medication • Patient is older than 18 years of age: the patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2
• dulaglutide (Trulicity) Metabolic Dysfunction Agents: Injectable Diabetic Agents	Updates from the November 2025 meeting are in bold and strikethrough. <u>Automated PA criteria:</u> The patient has filled a prescription for metformin or any diabetic drug at any MHS Pharmacy point of service (MTFs, retail pharmacies or TRICARE mail order pharmacy) during the previous 720 days. ~~All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.~~ <u>Manual PA criteria:</u> Manual PA criteria apply to all new uses of Trulicity if automated criteria are not met, Trulicity is approved (i.e., ~~a trial of metformin is NOT required~~) if • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has had inadequate response to metformin (alone or in combination) OR • The patient has experienced any of the following issues on metformin: • ~~impaired renal function precluding treatment with metformin OR~~ • history of lactic acidosis OR • The patient has a contraindication to metformin (e.g., impaired renal function) Non-FDA-approved uses are not approved, including use for weight loss in patients who do not have diabetes PA does not expire.
• semaglutide (Ozempic) • tirzepatide (Mounjaro) Metabolic Dysfunction Agents: Injectable Weight Loss Agents	Updates from the November 2025 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Ozempic and Mounjaro. ~~All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.~~ <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Ozempic and Mounjaro Type 2 Diabetes Mellitus

Appendix C—Table of Prior Authorization (PA) Criteria

	~~• Provider acknowledges that Trulicity is available to TRICARE beneficiaries at a lower copay than Ozempic or Mounjaro. Trulicity also has an indication to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors, Mounjaro does not have this indication.~~ • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has had inadequate response to metformin (alone or in combination) OR • The patient has experienced any of the following issues on metformin: ~~• impaired renal function precluding treatment with metformin OR~~ • history of lactic acidosis OR • The patient has a contraindication to metformin (e.g., impaired renal function) Non-FDA approved uses are not approved, including for weight loss in patients who do not have diabetes Updates from the May 2025 meeting are in bold for Ozempic Ozempic For Type 2 diabetes mellitus with chronic kidney disease • The patient has a diagnosis of type 2 diabetes and chronic kidney disease • The patient's estimated glomerular filtration rate (eGFR) is between 50 – 70 mL/min/m² • The patient is currently receiving a renin angiotensin inhibitor (ACE inhibitor or ARB blocker) or has a contraindication, has had an adverse effect, or has failed therapy • The patient is currently receiving an SGLT-2 inhibitor or has a contraindication, has had an adverse effect or has failed therapy PA does not expire
• exenatide twice daily (generic Byetta) • liraglutide (generic Victoza) Metabolic Dysfunction Agents: Injectable Weight Loss Agents	Changes from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of exenatide or liraglutide (generic Victoza) ~~Manual PA criteria—Bydureon BCSic, Byetta, Victoza, or Adlyxin~~ Coverage is approved (~~i.e., a trial of metformin and Trulicity and Ozempic is NOT required~~) if ~~• Provider acknowledges that Trulicity is available to TRICARE beneficiaries at a lower copay than Ozempic or Mounjaro. Trulicity also has an indication to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors, Adlyxin, Byetta and Bydureon BCSic do not have this indication~~ • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has had inadequate response to metformin (alone or in combination) OR • The patient has experienced any of the following issues on metformin: ~~• impaired renal function precluding treatment with metformin OR~~ • history of lactic acidosis OR • The patient has a contraindication to metformin (e.g., impaired renal function)

Appendix C—Table of Prior Authorization (PA) Criteria

	The patient has had an adverse reaction, inadequate response or has a contraindication to all of the following: ~~with~~ Trulicity, Ozempic and Mounjaro Non-FDA approved uses are not approved, including for weight loss in patients who do not have diabetes PA does not expire
- insulin glulisine (Apidra) - insulin lispro (Admelog) - insulin aspart-xjhz (Kirsty) - insulin lispro TEMPO (Humalog TEMPO) Insulins: Rapid-Acting Agents	Changes from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Apidra Admelog, Kirsty and Humalog TEMPO <u>Automated PA Criteria:</u> ~~The patient has filled a prescription for insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days~~ <u>Manual PA criteria:</u> ~~if automated criteria are not met,~~ Apidra, Admelog, Kirsty or Humalog TEMPO is approved if all criteria are met: - Provider acknowledges that Novolog, Humalog ~~and the authorized generic insulin lispro~~ unbranded biologic, insulin lispro-aabc (Lyumjev) and insulin aspart szjj (Merilog) do not require prior authorization. ~~are the DoD's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, prior authorization is not required.~~ - The patient has diabetes AND - The patient has tried and failed insulin aspart (Novolog) AND - The patient has tried and failed insulin lispro (Humalog) or ~~authorized generic unbranded biologic~~ insulin lispro) OR - The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog). Note this does not apply to insulin aspart-xjhz (Kirsty) or Humalog TEMPO. Non-FDA-approved uses are not approved PA does not expire
Insulin lispro-aabc TEMPO (Lyumjev TEMPO) Insulins: Rapid-Acting Agents	Manual PA criteria apply to all new users <u>Manual PA criteria:</u> Lyumjev TEMPO is approved if all criteria are met: - Provider acknowledges that Lyumjev TEMPO will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA - Provider acknowledges that Novolog, Humalog insulin lispro unbranded biologic, insulin lispro-aabc (Lyumjev) and insulin aspart szjj (Merilog) do not require prior authorization - The patient has diabetes AND - The patient has tried and failed Novolog, Humalog insulin lispro unbranded biologic, insulin lispro-aabc (Lyumjev) and insulin aspart szjj (Merilog) Non-FDA-approved uses are not approved PA does not expire until after implementation of complete exclusion status

Appendix C—Table of Prior Authorization (PA) Criteria

insulin lispro-aabc U-200 (Lyumjev U-200) Insulins: Rapid-Acting Agents	Manual PA criteria apply to all new and current users of Lyumjev U-200 <u>Manual PA criteria:</u> Lyumjev U-200 is approved if all criteria are met: - Provider acknowledges that Humalog U-200 does not require prior authorization. - The patient has diabetes AND - The patient has tried and failed Humalog U-200 Non-FDA-approved uses are not approved PA does not expire
Newly Approved Drug PAs	
brensocatib (Brinsupri) Pulmonary I Agents: Non-cystic fibrosis bronchiectasis	Updates from the November 2025 meeting are in bold Manual PA criteria apply to all new users of brensocatib (Brinsupri) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by or in consultation with a pulmonologist, infectious disease specialist, or rheumatologist - Patient has clinical bronchiectasis confirmed by chest CT scan - For adults – the patient had at least 2 exacerbations in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit or hospitalization - For pediatric patients – the patient had at least 1 exacerbation in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit or hospitalization - The respiratory symptoms being treated with brensocatib are not primarily due to asthma or COPD - Patient does not have cystic fibrosis - Patient does not require oxygen for more than 12 hours per day - Patient is not currently smoking The patient has had an inadequate response, adverse reaction, or contraindication to azithromycin Non-FDA approved uses are not approved PA does not expire
bumetanide nasal spray (Enbumyst) Diuretics	Updates from the November 2025 meeting are in bold Manual PA criteria apply to all new and current users of bumetanide nasal spray (Enbumyst) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that Enbumyst will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA Provider acknowledges that other loop diuretics are available to TRICARE beneficiaries, including bumetanide tablets, furosemide tablets, and torsemide and do not require prior authorization - Patient is 18 years of age or older - Patient has edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome - Patient is experiencing an increase in signs and symptoms of fluid overload

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient has failed a trial of two oral loop diuretics including ▪ furosemide ▪ bumetanide ▪ torsemide ▪ ethacrynic acid • Patient does not have rhinitis, nasal congestion, or nasal structural abnormalities • Patient is stable and does not require emergency care or hospitalization for heart failure, acute pulmonary edema or other condition that could result in hospitalization Non-FDA approved uses are not approved PA does not expire until after implementation of complete exclusion status
• dasatinib (Phyrago) Oncological Agents: Chronic Myelogenous Leukemia and Acute Lymphocytic Leukemia	Manual PA criteria apply to all new users of dasatinib (Phyrago) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Phyrago tablets are prescribed by or in consultation with a hematologist/oncologist • The patient has one of the following diagnoses: ▪ Adults 18 years of age or older with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase ▪ Adults 18 years of age or older with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib ▪ Adults 18 years of age or older with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment ▪ Pediatric patients 1 year of age and older with Ph+ CML in chronic phase. ▪ Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy. • Patient is receiving concurrent H2 blockers (e.g., famotidine, ranitidine, cimetidine) or Proton Pump Inhibitors (PPIs) (e.g., omeprazole, esomeprazole, rabeprazole, lansoprazole). ▪ The provider must document the reason why the patient requires long-term concurrent H2 blockers or proton pump inhibitors. _____ OR ▪ The patient has been referred to GI for additional work up (e.g., endoscopy) • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guideline version and page number. Other non-FDA approved uses are not approved except as noted above PA expires yearly Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional year if all the criteria are met: • The patient has a documented reason to remain on concurrent H2 blockers or PPIs

Appendix C—Table of Prior Authorization (PA) Criteria

delgocitinib 2% cream (Anzupgo) Atopy Agents	Manual PA criteria apply to all new users of delgocitinib (Anzupgo) Manual PA criteria: Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Patient has moderate to severe chronic hand eczema - Prescribed by a dermatologist, allergist, or immunologist - The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: - High potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - The patient is not using other immuno-biologics (e.g., Humira, Stelara etc.), other JAK inhibitors (e.g., Xeljanz, Olumiant, Rinvoq), or potent immunosuppressants such as azathioprine or cyclosporine Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - The patient's disease severity has improved and stabilized to warrant continued therapy
dihydroergotamine mesylate injection (Brekiya) Migraine Agent	Manual PA criteria apply to all new and current users of dihydroergotamine mesylate subcutaneous injection (Brekiya) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years or older - Patient is using Brekiya for the following indications - acute treatment of migraines with or without aura OR - cluster headaches - Medication is prescribed by or in consultation with a neurologist - Patient has a contraindication to, intolerance to, or has failed a trial of ALL the following: - Two different triptans (one must be either nasal or injectable): sumatriptan, rizatriptan, zolmitriptan, eletriptan - Nasal dihydroergotamine spray Non-FDA approved uses are not approved PA does not expire
donidalorsen injection (Dawnzera) HAE: Prophylaxis Agents	Manual PA criteria apply to all new users of donidalorsen (Dawnzera) <u>Manual PA criteria:</u> Coverage is approved if all apply: - Patient is 12 years of age or older - The patient has a diagnosis of hereditary angioedema - Prescribed by an allergist, immunologist, rheumatologist, or HAE specialist - Medication is prescribed for prophylaxis to prevent attacks of hereditary angioedema - The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., greater than or equal to 2 HAE attacks/month, or laryngeal attacks) - The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly)

Appendix C—Table of Prior Authorization (PA) Criteria

	- The patient has had an inadequate response, adverse reaction, or contraindication to all the following: - One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest) - One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo) Non-FDA-approved uses not approved Prior Authorization does not expire
dordaviprone (Modeyso) Oncological Agents	Manual PA criteria apply to all new users of dordaviprone (Modeyso) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is one year of age or older - Prescribed by a hematologist or oncologist - Patient has diagnosis of diffuse midline glioma (DMG) - Patient has a histone 3 (H3) K27M mutation - Patient has progressive disease - Patient has received at least one prior therapy. Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine. - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number Other non-FDA approved uses are not approved as noted above PA does not expire
escitalopram oxalate 15 mg capsules (no brand name) Antidepressants and Non-Opioid Pain Syndrome Agents	Manual PA criteria apply to all new and current users of escitalopram oxalate 15 mg capsules <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges that escitalopram oxalate 15 mg capsules will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA - Provider acknowledges that other escitalopram formulations are available to TRICARE beneficiaries and do not require prior authorization - Patient has major depressive disorder and is 12 years of age or older and younger than 65 years of age - Patient has generalized anxiety disorder and is younger than 65 years of age - Provider must document why the patient cannot take formulary alternatives (blank write in) - Acceptable responses include that the patient has tried and failed escitalopram 5 mg tablets, escitalopram 10 mg tablets, and escitalopram 20 mg tablets Non-FDA approved uses are not approved PA does not expire until after implementation of complete exclusion status
gepirone (Exxua) Antidepressants and Non-Opioid Pain Syndrome Agents	Updates from November 2025 are in bold Manual PA criteria apply to all new users of gepirone (Exxua) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e., cognitive behavioral therapy (CBT), sleep hygiene) are encouraged to be used in conjunction with this medication. - Provider has complied with the safety and monitoring criteria (i.e., EKG to monitor for QT prolongation)

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient is being treated for major depressive disorder ~~depression~~ and: ▪ The patient has a contraindication to, intolerance to, or has failed a trial of THREE formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). ~~(formulary antidepressants include SSRI, SNRI, SARI, NDRI, TCA, A2RA, MAOI).~~ For example, – SSRIs (selective serotonin reuptake inhibitors, for example, citalopram, escitalopram, fluoxetine, paroxetine, sertraline) – SNRIs (serotonin/norepinephrine reuptake inhibitors, for example, venlafaxine, desvenlafaxine, duloxetine) – TCAs (tricyclic antidepressants, for example, amitriptyline, desipramine, imipramine, nortriptyline) – mirtazapine – bupropion – trazodone immediate release – nefazodone and – monoamine oxidase inhibitors – Note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated doses Non-FDA approved uses are not approved PA expires does not expire
• gepotidacin (Blujepa) Antibiotics	Manual PA criteria apply to all new users of gepotidacin (Blujepa) <u>Automated PA Criteria:</u> When prescribed by a urologist, urogynecologist, or infectious disease provider specialist to a patient 12 years or age or older, prior authorization is not required OR <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved if all criteria are met: • Patient is 12 years of age or older • Patient weighs 40 kilograms or more • Patient has an uncomplicated urinary tract infection (uUTI) (i.e., afebrile, infection that is limited to the bladder, and non-catheter associated infection) • Patient has a urine culture indicating the organism is <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Citrobacter freundii</i> complex, <i>Staphylococcus saprophyticus</i>, or <i>Enterococcus faecalis</i> • Patient has a contraindication to or has culture proven resistance to ALL alternative oral antibiotic treatment options (i.e. nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin, fluoroquinolones, penicillins, and cephalosporins) Non-FDA approved uses are not approved PA expires after each course of therapy. PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA
• imlunestrant (Inluriyo) Oncological Agents	Manual PA criteria apply to all new users of imlunestrant (Inluriyo) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist or oncologist • Patient has a diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer • Patient must have disease progression following at least one prior line of endocrine therapy (e.g., letrozole, fulvestrant)

Appendix C—Table of Prior Authorization (PA) Criteria

	The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number Other non-FDA approved uses are not approved except as noted above PA does not expire
lecanemab-irmb injection (Leqembi Iqlik) Alzheimer's Agents	Manual PA criteria apply to all new users of lecanemab-irmb (Leqembi IQLIK) Manual PA criteria: Coverage is approved if all criteria are met: - Medication is being prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine - Patient has a diagnosis of Alzheimer's disease - Patient is being treated for mild cognitive impairment or mild dementia - Patient has completed 18 months of intravenous lecanemab (Leqembi) treatment and achieved maintenance dosing - Prescriber must submit medical documentation to confirm completion of 18 months of initial treatment with intravenous lecanemab (Leqembi) Non-FDA approved uses are not approved Prior authorization does not expire
metoprolol tartrate 10 mg/mL oral solution (Lopressor) Beta Blockers and HCTZ Combination Agents	Manual PA criteria apply to all new users of metoprolol tartrate oral solution (Lopressor) <u>Age edit:</u> PA not required for patients 12 years of age and younger <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient has hypertension or angina - Provider must write in why the patient requires Lopressor oral solution and cannot crush metoprolol tablets - Acceptable responses: Patient requires a liquid formulation due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis) and not due to convenience Non-FDA-approved uses are not approved PA does not expire
nitisinone (Harliku) Miscellaneous Replacement Enzymes	Updates from the November 2025 meeting are in bold Manual PA criteria apply to all new and current users of nitisinone (Harliku) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges that Harliku will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA Provider acknowledges that other formulations of nitisinone are available to TRICARE beneficiaries and do not require prior authorization - Patient is 18 years of age or older - Patient has a diagnosis of alkaptonuria (AKU) - The provider must document why the patient cannot take formulary alternatives, including generic nitisinone 2 mg capsules (blank write-in) - Acceptable responses include that the patient has experienced a serious allergic reaction (i.e., hives, anaphylaxis) to an excipient in nitisinone 2 mg capsules Non-FDA approved uses are not approved PA does not expire until after implementation of complete exclusion status

Appendix C—Table of Prior Authorization (PA) Criteria

rilzabrutinib (Wayrilz) Hematological Agents: Platelets	Manual PA criteria apply to all new users of rilzabrutinib (Wayrilz) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Medication is prescribed by a hematologist or oncologist - Patient has had primary Immune Thrombocytopenic Purpura (ITP) for at least 3 months - Patient had two platelet counts of less than $30 \times 10^9/L$ at least 5 days apart - Patient has documented intolerance, insufficient response, or any contraindication to all the following: corticosteroids, IVIG, and a thrombopoietin receptor agonist (eltrombopag or avatrombopag) Non-FDA approved uses are not approved PA does not expire
sebetralstat (Ekterly) HAE: Acute treatment	Updates from the November 2025 meeting are in bold Manual PA criteria apply to all new users of sebetralstat (Ekterly) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by an allergist, immunologist, rheumatologist, OR in consultation with an HAE specialist - Patient has a diagnosis of hereditary angioedema (HAE) - Ekterly will be used for the acute treatment of HAE attacks - Patient is not currently receiving another drug for the acute treatment of HAE attacks The patient has had an inadequate response, adverse reaction, or contraindication to generic icatibant Non-FDA approved uses are not approved. PA does not expire
sepiapterin oral powder (Sephience) Miscellaneous Metabolic Agents	Updates from the November 2025 meeting are in bold Manual PA criteria apply to all new users of Sephience. Manual PA criteria: Coverage is approved if all criteria are met: - Patient is 1 month of age or older - Prescribed by or in consultation with a metabolic disease specialist - Patient has a diagnosis of phenylketonuria with hyperphenylalaninemia - Patient has uncontrolled blood phenylalanine concentrations >360 micromol/L while on at least one existing treatment modality (e.g., restriction of dietary phenylalanine) - Patient is not receiving concomitant pharmacologic treatment for PKU (e.g. sapropterin, pegvaliase) - Requested medication must be used in conjunction with a phenylalanine restricted diet Patient has had an inadequate response, adverse reaction, or contraindication to generic sapropterin up to maximally tolerated dose Non-FDA-approved uses are not approved PA expires in 6 months <u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - The patient's disease severity has improved and stabilized to warrant continued therapy

Appendix C—Table of Prior Authorization (PA) Criteria

• sitagliptin 25 mg/mL oral solution (Brynovin) Non-Insulin Diabetes Drugs: DPP-4 Inhibitors	Manual PA criteria apply to all new users of sitagliptin oral solution (Brynovin) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that Januvia and its combination products are TRICARE's preferred dipeptidyl peptidase-4 inhibitors and are available to TRICARE beneficiaries without requiring prior authorization. • Patient is 18 years or older • Patient has Type 2 Diabetes Mellitus (T2DM) • Provider must explain why the patient requires Brynovin oral solution and cannot take Januvia tablets ▪ Acceptable responses: Patient needs a liquid formulation due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis) and not due to convenience Non-FDA approved uses are not approved PA does not expire
• sulopenem etzadroxil/probenecid (Orlynvah) Beta Lactam Antibiotic	Manual PA criteria apply to all new users of sulopenem etzadroxil and probenecid (Orlynvah) <u>Automated PA Criteria:</u> When prescribed by a urologist, urogynecologist, or infectious disease provider specialist to a patient 18 years of age or older, prior authorization is not required. OR <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved if all criteria are met: • The provider acknowledges that all generic antibiotics for the treatment of UTI do not require prior authorization • Patient is 18 years of age or older • Patient has a diagnosis of uncomplicated urinary tract infection (i.e., afebrile, infection that is limited to the bladder, and non-catheter associated infection) • Patient has a culture proven infection from the Enterobacterales family (e.g. <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus mirabilis</i>). Note: This drug does not cover <i>Pseudomonas aeruginosa</i> • Patient has a contraindication to or has culture proven resistance to all alternative oral antibacterial treatment options (i.e., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin, fluoroquinolone, or beta-lactam) Non-FDA approved uses are not approved PA expires after each course of therapy. PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA
• zongertinib (Hernexeos) Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents	Manual PA criteria apply to all new users of zongertinib (Hernexeos) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist or oncologist • Patient has a diagnosis of unresectable or metastatic NSCLC with confirmed HER2 (ERBB2) tyrosine kinase domain activating mutations • Patient has received prior systemic therapy • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number Other non-FDA approved uses are not approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management PAs	
• clemastine (Clemsza) • clemastine (Clemasz) Antihistamine-1: First Generation and Combos	Updates from the November 2025 Meeting are in bold Manual PA criteria apply to all new users of clemastine (Clemasz) or clemastine (Clemsza). <u>Manual PA criteria:</u> clemastine (Clemasz) or clemastine (Clemsza). is approved if all criteria are met: • Provider acknowledges other formulations of clemastine are available without prior authorization. • Provider must explain why the patient requires clemastine (Clemasz) or clemastine (Clemsza) and cannot take the cost-effective generic clemastine formulations ▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available clemastine formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• dicyclomine 40 mg tablet Anticholinergic Antispasmodics	Manual PA criteria apply to all new users of dicyclomine 40 mg tablets. <u>Manual PA criteria:</u> dicyclomine 40 mg tablet is approved if all criteria are met: • Provider acknowledges other formulations of dicyclomine are available without prior authorization. • Provider must explain why the patient requires dicyclomine 40 mg and cannot take the cost-effective generic dicyclomine 10 mg or 20 mg formulations ▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available dicyclomine formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• flurbiprofen (Lurbiro) • flurbiprofen Lurbipr Pain Agents: NSAIDs	Updates from the November 2025 meeting are in bold Manual PA criteria apply to all new users of flurbiprofen (Lurbipr) or flurbiprofen (Lurbiro). <u>Manual PA criteria:</u> flurbiprofen (Lurbipr) or flurbiprofen (Lurbiro) is approved if all criteria are met: • Provider acknowledges other formulations of flurbiprofen are available without prior authorization. • Provider must explain why the patient requires flurbiprofen (Lurbipr) or flurbiprofen (Lurbiro) and cannot take the cost-effective generic flurbiprofen formulations ▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available flurbiprofen formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• concizumab-mtci (Alhemo) Antihemophilic Agents: Non-Factor Agents	Updates from the November 2025 meeting are in bold. Manual PA criteria apply to all new users of Alhemo <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 12 years of age or older • Prescribed by or in consultation with a hematologist • Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient is not concurrently receiving factor VIII or factor IX therapy unless for the treatment of breakthrough bleeding Non-FDA approved uses are not approved PA does not expire
• avatrombopag (Doptelet) tablets and sprinkles Hematological Agents: Platelets	Updates from the November 2025 meeting are in bold. Manual PA is required for new users of Doptelet. <u>Manual PA Criteria:</u> Doptelet is approved if all criteria are met: • Drug is prescribed by or in consultation with a gastroenterologist or hematologist/oncologist Liver Disease Indication • Patient is 18 years of age or older • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 10⁹/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis OR ITP Indication • Patient is 18 years of age or older with a diagnosis of chronic immune thrombocytopenia (ITP) and has failed to adequately respond to previous therapy OR patient is a pediatric patient with persistent or chronic ITP and has had an insufficient response to a previous treatment • Patient has tried and failed Nplate or Promacta OR has a contraindication to both Nplate and Promacta OR Is expected to have an adverse effect to both Nplate and Promacta that would not be anticipated by Avatrombopag • Doptelet is not being used concomitantly with other chronic ITP therapy Non-FDA-approved uses are not approved For thrombocytopenia associated with liver disease: PA expires in 60 days. New PA required per prescription fill For ITP: PA does not expire.
• fremanezumab (Ajovy) Migraine Agents: CGRP Preventative	Updates from November 2025 are in bold and strikethrough. Manual PA criteria applies to all new users of Ajovy <u>Manual PA Criteria:</u> Ajovy is approved if all criteria are met: • Patient is ~~18~~ six years of age or older and weighs 45 kg or more • The drug is prescribed by or in consultation with a neurologist • The patient also meets one of the following: ▪ Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR ▪ Patient has episodic migraine at a rate a migraine diagnosis with of at least 8 migraine days per month for 3 months OR ▪ Applicable to adults only: Patient has a diagnosis of chronic migraine • Patient has a contraindication to, intolerance to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: ▪ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate ▪ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol

Appendix C—Table of Prior Authorization (PA) Criteria

	- Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine Applicable to adults only: Provider acknowledges that Emgality 120 mg is TRICARE's preferred injectable CGRP inhibitor and is available without a PA. - Patient has tried and failed OR experienced an adverse event that is not expected to occur with Ajovy OR has a contraindication to Emgality 120 mg - Patient is not pregnant - Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed Non-FDA-approved uses are not approved PA expires after 6 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if one of the following apply: - The patient has had a reduction in mean monthly headache days of $\geq 50\%$ relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR - The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: - Migraine Disability Assessment (MIDAS) - Reduction of ≥ 5 points when baseline score is 11–20 - Reduction of $\geq 30\%$ when baseline score is > 20 - Headache Impact Test (HIT-6) - Reduction of ≥ 5 points - Migraine Physical Functional Impact Diary (MPFID) - Reduction of ≥ 5 points
ruxolitinib 1.5% cream (Opzelura) Atopy	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Opzelura. <u>Manual PA criteria:</u> Opzelura is approved if all criteria are met: - Patient is 12 two years of age and older - Opzelura is prescribed by a dermatologist, allergist, or immunologist - The patient has mild to moderate uncontrolled atopic dermatitis - The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: - Topical Corticosteroids: - For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) - For patients 12 two to 17 years of age: any topical corticosteroid AND - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - The patient is not using other immuno-biologics (e.g., Humira, Stelara etc), other JAK inhibitors (e.g., Xeljanz, Olumiant, Rinvoq), or potent immunosuppressants such as azathioprine or cyclosporine Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely. PA expires in 12 months for initial therapy; annual renewal required

Appendix C—Table of Prior Authorization (PA) Criteria

	<u>Renewal PA Criteria:</u> Note that initial TRICARE PA approval required for renewal. Opzelura will be approved for an additional 12 months if the following are met: • The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear • The patient's disease severity has improved and stabilized to warrant continued therapy
• ruxolitinib 1.5% cream (Opzelura) Atopy	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Opzelura. <u>Manual PA criteria:</u> Opzelura is approved if all criteria are met: • Patient is 42 two years of age and older • Opzelura is prescribed by a dermatologist, allergist, or immunologist • The patient has mild to moderate uncontrolled atopic dermatitis • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 42 two to 17 years of age: any topical corticosteroid AND ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient is not using other immuno-biologics (e.g.; Humira, Stelara etc.), other JAK inhibitors (e.g., Xeljanz, Olumiant, Rinvoq), or potent immunosuppressants such as azathioprine or cyclosporine Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear • The patient's disease severity has improved and stabilized to warrant continued therapy
• apremilast (Otezla) Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitors	Updates from the November 2025 meeting are in bold and strikethrough. <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. Manual PA criteria apply to new users of apremilast (Otezla) <u>Manual PA Criteria:</u> Coverage approved for patients: • Coverage approved for patients 18 years of age or older with a diagnosis of: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ▪ Oral ulcers associated with Behçet's disease (Note: Humira not required for Behçet's disease) ▪ Mild plaque psoriasis in patients who are candidates for systemic therapy or phototherapy if the following criteria are met: (Note: Humira not required for mild plaque psoriasis) – The patient has a contraindication to, intolerance to, or has failed treatment with medications from at least TWO of these THREE categories:

Appendix C—Table of Prior Authorization (PA) Criteria

	- Moderate to High Potency Topical Corticosteroids (class 1 – class 5) e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream, betamethasone dipropionate 0.05% cream/lotion/ointment, etc. - Steroid Sparing Agents: Vitamin D analogs (e.g. calcipotriene and calcitriol), tazarotene, or topical calcineurin inhibitors (e.g. tacrolimus and pimecrolimus) - Other Topicals: emollients, salicylic acid, anthralin, or coal tar AND - The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with phototherapy - Coverage approved for patients ages 6 to 17 years with: - Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and who also weigh at least 20 kg Moderate to severe psoriatic arthritis and who also weigh at least 20 kg - The criteria below apply to all patients unless noted: - The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira (Note: Does not apply to mild plaque psoriasis or Behçet's disease) - Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Behçet's disease) - Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR? - If yes: Fill in the blank write-in referencing literature to support combination, and attest patient will be monitored closely for adverse effects. Non-FDA-approved uses are not approved. PA does not expire
niraparib (Zejula) Oncological Agents: Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors	Updates from November 2025 are in bold and strikethrough Manual PA criteria apply to all new users of Zejula. <u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met: - Zejula is prescribed by or in consultation with a hematologist/oncologist - Patient is 18 years of age or older - Niraparib will be prescribed as a maintenance therapy for one of the following diagnoses: ~~Platinum sensitive, relapsed, high-grade, ovarian cancers: OR~~ Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either A deleterious or suspected deleterious BRCA mutation OR Genetic instability ~~Recurrent epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer AND~~

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer • Patient has received 2 or more lines of platinum-based chemotherapy AND • Patient was in objective response (either complete or partial) to ~~most recent treatment regimen AND~~ first-line platinum-based chemotherapy • ~~Zejula will not be combined with bevacizumab (Avastin)~~ OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis~~ To facilitate approval, please list the diagnosis, guideline version, and page number: _____. • ~~Female patients are not pregnant or planning to become pregnant and will take highly effective contraception while taking Zejula and for 6 months after the last dose.~~ Other non-FDA-approved uses are not approved PA does not expire.
• semaglutide (Rybelsus) Diabetes Non-Insulin: Oral Glucagon-Like Peptide-1 Receptor Agonists	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Rybelsus. <u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met: • Patient is 18 years of age or older • Patient has a confirmed diagnosis of type 2 diabetes • Patient has tried and had an inadequate response to metformin, or has a contraindication to metformin • Patient must be able to adhere to the administration requirements (take on an empty stomach with no more than 4 oz. of water at least 30 min before the first meal of day) • Patient does not have a history of pancreatitis • Patient does not have a personal or family history of medullary thyroid carcinoma (MTC) • Patient does not have multiple endocrine neoplasia syndrome type 2 (MEN2) • ~~Patient and provider acknowledge that Rybelsus has not been shown to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease~~ • Not approved for use in children or pregnant patients. Non-FDA approved uses are not approved including weight loss (obesity) or type 1 diabetes mellitus. PA does not expire.
• pegcetacoplan (Empaveli) Hematological Agents	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Empaveli. <u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met: • All indications ▪ Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements ▪ Patient is not receiving C3 or C5 inhibitors with Empaveli, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or iptacopan (Fabhalta)

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Patient has been vaccinated against certain encapsulated bacteria (for example, <i>Streptococcus pneumoniae</i>, <i>Neisseria meningitidis</i> types A, C, W, Y, and B, and <i>Haemophilus influenzae</i> type B) • Paroxysmal Nocturnal Hemoglobinuria (PNH) ▪ Patient is 18 years of age or older ▪ Patient has a documented diagnosis of PNH ▪ Patient has been counseled on the appropriate administration of the drug via infusion pump • Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) ▪ Patient is 12 years of age or older ▪ Prescribed by a nephrologist ▪ The patient has a diagnosis of C3G or IC-MPGN confirmed by biopsy ▪ Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gr ▪ Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m² ▪ Patient is on maximally tolerated RAS inhibitor (ACE/ARB) <u>doses</u> Non-FDA approved uses are not approved For PNH, PA does not expire; for C3G or IC-MPGN, PA expires in 9 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal for C3G and IC-MPGN. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • For Complement 3 glomerulopathy (C3G) & primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) Patient has had a response to Empaveli defined by: ▪ Reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR ▪ Reduction in proteinuria from baseline OR ▪ Patient's eGFR rate ≥30 mL/min/1.73 m²
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Appendix C—Table of Prior Authorization (PA) Criteria

darolutamide (Nubeqa) Oncological Agents: 2nd Generation Antiandrogens	Updates from the November 2025 meeting are in bold and strikethrough. ~~Note: For metastatic castration-sensitive prostate cancer (mCSPC) abiraterone acetate is listed as a category 1 recommendation for either doublet or triplet therapy. Abiraterone acetate is available as part of the Tricare benefit as a Tier 4 agent and available without a PA for hematologists, oncologists and urologists.~~ Manual PA is required for all new users of Nubeqa <u>Manual PA Criteria:</u> Nubeqa is approved if all criteria are met: - Drug is prescribed by or in consultation with a hematologist/oncologist or urologist AND - Patient is 18 years of age or older AND For non-metastatic castration-resistant prostate cancer (nmCRPC) - Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. The patient is required to try Xtandi first. OR. Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Nubeqa For metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel Note that for mCSPC, abiraterone acetate is listed as a National Comprehensive Cancer Care Network (NCCN) category 1 recommendation for either doublet or triplet therapy. Abiraterone acetate 250 mg is available as part of the Tricare benefit as a Tier 1 agent (generic copay) and available without a PA for hematologists, oncologists and urologists. Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. Not approved for low volume metastases unless patient has a contraindication to Xtandi and abiraterone that is not expected to occur with Nubeqa High volume metastases, approve AND - Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number Other non-FDA approved uses are not approved, except as noted above PA does not expire
sotatercept (Winrevair) Pulmonary Arterial Hypertension	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of sotatercept-csrk (Winrevair). <u>Manual PA criteria:</u> Coverage is approved if - Patient is 18 years of age or older - Prescribed by or in consultation with cardiologist or pulmonologist - Patient has documented diagnosis of WHO group 1 PAH - Patient has WHO functional class II or III PAH - Patient has had right heart catheterization - Documentation provided to confirm that patient has had right heart catheterization and confirms diagnosis of WHO Group 1 PAH - Documentation is provided to confirm the patient is on stable background therapy for PAH (i.e., monotherapy, double therapy, triple therapy)

Appendix C—Table of Prior Authorization (PA) Criteria

	~~Documentation is provided to confirm patient has been on stable doses of diuretics for more than 90 days. A stable dose of diuretic is defined as no addition of a new diuretic and no switching of an oral diuretic to parenteral administration. Dose adjustments for oral diuretics are acceptable.~~ - Females of childbearing potential must use contraception up to 4 months after the last dose Non-FDA approved uses are NOT approved PA does not expire
nilotinib (Tasigna) Oncological Agents: Chronic Myelogenous Leukemia	Manual PA criteria applies to new and current users of nilotinib generic at all points of service <u>Manual PA criteria:</u> nilotinib generics are approved if all criteria are met: - Provider acknowledges that the brand Tasigna capsule is the preferred product over generic nilotinib and is covered at the lowest copayment, which is the generic formulary copayment for non-Active-Duty patients, and at no cost share for Active-Duty patients. (Although Tasigna is a branded product, it will be covered at the generic formulary copayment or cost share) - Please provide a patient-specific justification as to why the brand Tasigna cannot be used in this patient. _____ (fill-in the blank). - Reasons to allow the generic nilotinib would be that the patient has had an adverse reaction to an excipient in brand Tasigna that would not be likely to occur with the generic nilotinib
- seladelpar (Livdelzi) - elafibranor (Iqirvo) Gastrointestinal-2 Agents	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of seladelpar (Livdelzi) or elafibranor (Iqirvo) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed or in consultation with a gastroenterologist, hepatologist or liver transplant physician - Patient has a diagnosis of primary biliary cholangitis (PBC) - Diagnosis has been confirmed by at least TWO of the following - Alkaline phosphatase elevated above the upper limit of normal as defined by normal laboratory reference values - Positive anti-mitochondrial antibodies - Histologic evidence of PBC from a liver biopsy - Patient does not have decompensated cirrhosis - Patient has been receiving ursodiol therapy for one year or greater and has had an inadequate response OR - Patient has been unable to tolerate ursodiol therapy ~~Patient has a contraindication to, intolerability to, or has failed a trial of obeticholic acid (Ocaliva)~~ Non-FDA approved uses are not approved PA expires after 6 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - Patient has responded to therapy as determined by the prescribing physician (for example, improved biochemical markers of PBC: alkaline phosphatase, bilirubin, gamma-glutamyl transpeptidase, aspartate aminotransferase, alanine aminotransferase)

Appendix C—Table of Prior Authorization (PA) Criteria

Insulin degludec (Tresiba) Insulins: Basal	Updates from the November 2025 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of insulin degludec (Tresiba) <u>Manual PA criteria:</u> Coverage for insulin degludec (Tresiba) is approved if - The provider acknowledges that insulin glargine (Lantus) is TRICARE's preferred basal insulin and is available without a PA at the lowest Tier 1 copay - The patient has tried and had an inadequate response to insulin glargine (Lantus) - The patient is one year of age or older - The provider must explain why the patient cannot use Lantus (fill in the blank) - The provider must explain why the patient cannot use Toujeo (fill in the blank) ~~The provider must explain why the patient cannot use unbranded insulin degludec (fill in the blank)~~ Non-FDA-approved uses are not approved Prior authorization does not expire
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Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
- liraglutide (Saxenda) - semaglutide (Wegovy) - tirzepatide (Zepbound) Weight Loss Agents	- Retail: 30-day supply - MTF/TMOP: 60-day supply
brensocatib (Brinsupri) Pulmonary-1 Agent	- Retail: 30-day supply - MTF/TMOP: 60-day supply
dasatinib (Phyrago) Oncological Agent	MTF/TMOP/Retail: 60-day supply
delgocitinib 2% cream (Anzupgo) Atopy	MTF/TMOP/Retail: 60 grams/30 days
dihydro-ergotamine mesylate injection (Brekiya) Migraine Agents	- Retail: 12 autoinjectors/30 days (4 autoinjectors per box) - MTF/TMOP: 36 autoinjectors/90 days (4 autoinjectors per box)
donidalorsen injection (Dawnzera) Corticosteroids-Immune-Modulator: Hereditary Angioedema Agents	MTF/TMOP/Retail: 30-day supply
dordaviprone (Modeyso) Anti-depressants and Non-opioid Pain Syndrome Agents: Selective Serotonin Reuptake Inhibitors	MTF/TMOP/Retail: 20 capsules/fill
gepotidacin (Blujepa) Antibiotics	MTF/TMOP/Retail: 20 tablets/prescription fill with no refills
imlunestrant (Inluriyo) Breast Cancer Agents: Estrogen Receptor Antagonist	MTF/TMOP/Retail: 60-day supply
lecanemab-irmb (Legembi IQLIK) Alzheimer's Agents	- Retail: 30-day supply - MTF/TMOP: 60-day supply

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
nalmeffene injection (Zurnai) Deterrents-narcotic Antagonists: Narcotic Antagonists	MTF/TMOP/Retail: 60-day supply
rilzabrutinib (Wayrilz) Hematological Agents: Platelets	MTF/TMOP/Retail: 60-day supply
sebetralstat (Ekterly) Corticosteroids-Immune-Modulator: Hereditary Angioedema Agents	MTF/TMOP/Retail: 30-day supply
sepiapterin oral powder (Sephience) Metabolic Agents - Miscellaneous	MTF/TMOP/Retail: 30-day supply
sulopenem etzadroxil and probenecid (Orlynvah) Antibiotics: Beta-lactams	MTF/TMOP/Retail: 10 tablets per fill
zongertinib (Hernexeos) Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents	MTF/TMOP/Retail: 60 day supply
suzetrigine (Journavx) Pain Agents	Updates from the November meeting are in bold and strikethrough - MTF/TMOP/Retail: ~~30 tablets/30 days supply with no refills~~ - MTF/TMOP/Retail Max limit of 30 tablets in 6 months

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
brensocatib (Brinsupri) Pulmonary-1 Agent	azithromycin 250 mg tablets	10 mg, 25 mg tablets given once daily	Non-cystic fibrosis bronchiectasis (NCFB)	- upper respiratory tract infection - headache - rash - dry skin - hyperkeratosis - hypertension	- Brinsupri is indicated for the treatment of (NCFB) in adult and pediatric patients 12 years of age and older - Phase-3 study showed statistically significant decrease in the annualized rate of pulmonary exacerbation (PEX) and increased the time to first PEX compared to placebo - Safety: overall well tolerated with low rates of adverse events - Azithromycin is currently accepted for symptom management and supported by MHS providers - Brinsupri provides an additional treatment option for NCFB	- UF - PA - QL - Specialty Drug List
bumetanide nasal spray (Enbumyst) Diuretics	- furosemide - bumetanide - torsemide - Soaanz - Furoscix kit	unit dose nasal spray: 0.5 mg per 0.1 mL	Treatment of adults with edema associated with CHF, hepatic and renal disease, including nephrotic syndrome	- hypovolemia - headache - muscle cramps - dizziness - hypotension - nausea - encephalopathy	- First intranasal formulation of a loop diuretic - No new clinical efficacy studies; approved via 505(b)(2) using data from Bumex - One pharmacokinetic study available - Enbumyst nasal 2 mg was equal to Bumex 2 mg tabs and IV for diuresis, natriuresis, and potassium excretion - Potentially slightly faster onset of action by about 20 min but did not translate into improved diuresis or natriuresis - Not for chronic use; must transition to oral diuretics “as soon as practical” - Device is well-accepted - used with several other nasally administered drugs – naloxone, epinephrine (Neffy) - Not an option for patients with sinusitis, nasal congestion or structural abnormalities - There is no data available with Enbumyst (or with Furoscix on body infusor) that this treatment approach reduces the need for hospitalization - Provides no compelling clinical advantage over existing agents	Complete Exclusion

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
dasatinib (Phyrago) Oncological	- dasatinib - Spyrcel	Tablet: 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg	- Adults with newly diagnosed Ph+ CML in chronic phase - Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib - Adults with Ph+ ALL with resistance or intolerance to prior therapy 1 year of age and older with Ph+ CML in chronic phase 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy	- myelosuppression - fluid retention - diarrhea - headache - skin rash - hemorrhage - dyspnea - fatigue - nausea - musculoskeletal pain	- New tablet formulation of dasatinib that can be used with H2 blockers and proton pump inhibitors (PPIs) because absorption is “independent of gastric pH”; however, the mechanism by which this is accomplished is redacted in the FDA review - No new clinical efficacy studies; approved via 505(b)(2) application from Spyrcel and is bioequivalent to Spyrcel - Other than allowing use with PPIs/H2 blockers, provides no compelling clinical advantage over existing agents	- NF - PA - MN - QL - Specialty Drug List - TRICARE Maintenance Drug List
delgocitinib 2% cream(Anzupgo) Atopy	- Dupixent - Opzelura	Cream: 20 mg of delgocitinib per gram (2%)	Topical treatment of moderate to severe chronic hand eczema in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable	- pain - paresthesia - pruritus - erythema - skin infection - leukopenia - neutropenia	- Topical agent limited to treatment of chronic hand eczema - Two phase 3 studies demonstrated larger proportions of patients achieving IGA-CHE treatment success compared with vehicle - It is currently unknown whether Anzupgo may be associated with potential risks related to JAK inhibition (e.g., higher rates of mortality, malignancy); use with other JAK inhibitors or immunosuppressants is not recommended - Provides an additional option for adults with chronic hand eczema who have failed topical corticosteroid treatment	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• dihydro-ergotamine mesylate injection (Brekiya) Migraine Agents	• sumatriptan • Migranal Nasal	• autoinjector: 1mg/ml	• Acute treatment of migraine with or without aura and the acute treatment of cluster headaches in adults	• serious cardiac events	• Published guidelines for both episodic migraine and cluster headache recommend DHE in acute management only as a third-line agent after NSAIDs and several triptans, in refractory cases, or when GI factors limit oral product use • Both ergot alkaloids and triptans have similar warnings and contraindications for patients with significant cardiovascular abnormalities • No prospective clinical trials • Nasal DHE (available in generic formulations) is a preferred alternative to injectable DHE in terms of onset of pain relief and duration, and should be used in most situations unless the patient has nasal irritation or septal deviation • Brekiya may only benefit a small subset of patients with severe, recalcitrant migraine symptoms who cannot use nasal route of administration	• NF • PA • MN • QL • Rapid Response program
• donidalorsen (Dawnzera) Corticosteroids-Immune-Modulator: Hereditary Angioedema Agents	• Orladeyo • Takhzyro	• Autoinjector: 80mg/0.8 mL	• Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥12 years	• injection reactions • URI • UTI • abdominal discomfort	• Dawnzera is indicated for prophylaxis of attacks of HAE≥12 years • A single phase 3 trial demonstrated a statistically significant reduction in the number of attacks per month compared to placebo • A network meta-analysis for other prophylactic HAE treatments involving other targeted pathways (Andembry, Haegarda, Takhzyro) demonstrates a similar and statistically significant reduction in monthly attacks compared to placebo • Offers an additional pharmacologic option for prophylaxis of this condition	• NF • PA • MN • QL • Specialty Drug List • TRICARE Maintenance Drug List • Rapid Response program

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
dordaviprone (Modeyso) Oncological Agents	None (radiation standard of care)	- Capsule; Oral 125 mg capsules 625 mg PO weekly	Treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy	- fatigue - headache - vomiting - nausea - musculoskeletal pain	- FDA-approved for diffuse midline glioma with a H3 K27M mutation in adult and pediatric patients ≥ 1 year of age - Ultra-rare and aggressive brain tumor primarily affecting children and young adults with very limited treatment options - Open label study demonstrated overall response rate (ORR) of 22% with a median duration of response of 10.3 months - Open label study demonstrated ORR of 22% with a median duration of response of 10.3 months - Continued approval of Modeyso is contingent on results of the Phase III confirmatory trial - Modeyso is recommended for H3 K27M-mutant glioblastoma per NCCN - Provides an option for recurrent H3 K27M-mutant diffuse midline glioma for adult and pediatric patients	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List contingent
escitalopram 15 mg capsules (no brand name) Anti-depressants and Non-opioid Pain Syndrome Agents: Selective Serotonin Reuptake Inhibitors	- escitalopram tablets - escitalopram 1mg/ml oral solution	- Capsule; oral 15 mg capsule 1 capsule daily	- Major depressive disorder in adults younger than 65 years of age and pediatric patients 12 years of age and older. - Generalized anxiety disorder in adults younger than 65 years of age	- insomnia - ejaculation disorder - nausea - increased sweating - fatigue - somnolence - decreased libido	- Capsule formulation of escitalopram - No new clinical efficacy studies; approved via 505(b)(2) - Not indicated in geriatric patients (> 65yo) or patients with hepatic impairment (tablets can be used in these populations) - Provides no clinical advantage over existing agents	Complete Exclusion

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
gepirone (Exxua) Anti-depressants and Non-opioid Pain Syndrome Agents	- venlafaxine - sertraline - Trintellix	- Tablets; oral 18.2 mg, 36.3 mg, 54.5 mg, 72.6 mg	Treatment of major depressive disorder (MDD) in adults	- dizziness - nausea - insomnia - abdominal pain - dyspepsia	- Gepirone was approved following FDA review for over two decades - Two phase 3 studies demonstrated clinical efficacy in the treatment of major depressive disorder in two small, short-term (8-week), placebo-controlled pivotal trials - The two pivotal studies were completed more than 20 years ago but the primary efficacy endpoint of change from baseline in HAM-D-17 total score remains an acceptable measure of efficacy - Prolonged QTc included as a contraindication, where ECG monitoring is required before treatment and during dose titration - Exxua is a therapeutic alternative to other antidepressants, including the SSRIs, SNRIs, TCAs, bupropion, mirtazapine, vortioxetine (Trintellix), levomilnacipran, vilazodone, nefazodone, and trazodone	- NF - PA - MN - TRICARE Maintenance Drug List
gepotidacin (Blujepa) Antibiotics	- Orlynvah 1 tablet BID x 5 days - nitrofurantoin (Macrobid) 100 mg BID x 5 days - trimethoprim-sulfamethoxazole 160 mg/800 mg BID x 3 days - fosfomycin 3 g x 1 dose	750 mg tablets 1500 mg BID x 5 days	Treatment of female adult & pediatric patients ≥12 years of age weighing at least 40 kg with uncomplicated UTI (uUTI) caused by the following susceptible microorganisms: E. coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis	diarrhea	- Triazaacenaphthylene bacterial topoisomerase inhibitor indicated in the treatment of uUTI in female patients 12 years of age and older, weighing at least 40 kilograms - Two phase 3 studies demonstrated non-inferiority to nitrofurantoin, one of the studies demonstrated superiority to nitrofurantoin - Should be restricted to patients with uUTIs that have proven or strongly suspected susceptibility to E. coli, K. pneumoniae, C. freundii, S. saprophyticus, and E. faecalis to reduce the development of drug-resistant bacteria - Blujepa is a therapeutic alternative for the treatment of uUTI when patients are unable to use other established oral antibacterial agents	- UF - PA - QL - Rapid Response program

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• imlunestrant (Inluriyo) Breast Cancer Agents: Estrogen Receptor Antagonist	• fulvestrant • elacestrant (Orserdu)	• 200 mg tablets given 400 mg PO QD on an empty stomach until disease progression or toxicity	• Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	• hemoglobin ↓ • musculoskeletal pain • calcium ↓ • neutrophils ↓ • AST ↑ • fatigue • diarrhea • ALT ↑ • triglycerides ↑ • nausea • platelets ↓ • constipation • cholesterol ↑ • abdominal pain	• Second oral selective estrogen receptor degrader approved for ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer • Phase 3 study demonstrated improved progression free survival (PFS) in patients with ESR1-mutations, reducing the risk of progression or death by 38% compared to standard endocrine therapy (fulvestrant or exemestane) • Combination of Inluriyo with Verzenio further enhanced PFS across all patient groups, regardless of mutation status • NCCN guidelines place Inluriyo and Orserdu on equal footing as category 2A recommendations, other recommended regimen first-line or subsequent-line therapy for HR-positive, HER2-negative, ESR1-mutated recurrent unresectable or metastatic breast cancer • Therapeutic option for patients with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List
• lecanemab-irmb (Leqembi IQLIK) Alzheimer's Agents	• lecanemab IV	• Prefilled syringe: 360mg/1.8 mL, start after 18 months of lecanemab IV therapy	• Treatment of Alzheimer's disease; should be initiated in patients with mild cognitive impairment or mild dementia stage of disease	• induration • pain • pruritic • rash • ecchymosis • hematoma • headache • fever • fatigue	• Amyloid beta-directed antibody indicated for the maintenance treatment of Alzheimer's disease (AD) after initial treatment with Leqembi IV • No new clinical efficacy studies • Common adverse events associated with Leqembi IQLIK include mild to moderate localized and systemic injection-related reactions • The decision to use Leqembi IQLIK, as well as other biologic treatments, must be individualized with careful consideration for benefits outweighing the risks of therapy • Leqembi IQLIK provides an additional treatment option for early AD management	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
metoprolol tartrate oral solution (Lopressor) Beta Blockers and Hydro-chlorothiazide Combinations	- Lopressor tab - Bystolic tab - Carospir suspension - Norliqva solution	Oral solution: 10 mg/mL	- Adults with hypertension - Adults for long-term treatment of angina pectoris - Adults for treatment of hemodynamically stable patients with definite/suspected MI, to reduce risk of CV mortality, when used in conjunction with IV metoprolol	- tiredness - dizziness - depression - shortness of breath - bradycardia - hypotension - diarrhea - pruritus - rash	- New oral suspension formulation of metoprolol - No new clinical efficacy studies; approved via 505(b)(2) using the data for Lopressor tablets - Same indications as Lopressor tablets; not approved in children - Metoprolol tablets can be crushed and mixed into an oral suspension - Numerous other cardioselective beta blockers are on the formulary - Although this is the first commercially available beta blocker in an alternative formulation, it provides no compelling clinical advantage over existing agents	- NF - PA - MN - TRICARE Maintenance Drug List
nalmefene injection (Zurnai) Alcohol Deterrents-narcotic Antagonists: Narcotic Antagonist	- nalmefene nasal (Opvee) - nalmefene vial - naloxone (various intranasal and injectable)	1.5 mg/0.5 mL prefilled, single-use autoinjector - Inject outer thigh through clothing if necessary I.M. or S.C. - Additional doses every 2 to 5 minutes	Emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients ≥ 12 years as manifested by respiratory and/or CNS depression	- nausea - headache - dizziness chills - vomiting - allodynia - palpitations - tinnitus - burning sensation - hot flush - irritability	- Nalmefene auto-injector for emergency treatment of known or suspected opioid overdose - Approved via 505(b)(2); No new clinical studies were completed - Zurnai has a long half-life of 9 hours with an onset of action between 2.5 to 5 minutes - Provides an alternative to intranasal and injectable nalmefene and naloxone products	- UF - QL
nitisinone tablets (Harliku) Metabolic Agents-Miscellaneous: Replacement Enzymes	- nitisinone capsules/suspension (Orfadin) - nitisinone tablets (Nityr)	2 mg tablets given once daily	Reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU)	- tyrosine levels increased - keratitis - thrombocytopenia	- Indicated to reduce urine HGA in adults with a rare disease, alkaptonuria (AKU) - Open label study did not meet primary endpoint of change in total hip range of motion - Harliku demonstrated a reduction in the urine HGA - Harliku shares the same active ingredient and strengths as Orfadin and Nityr - Although Orfadin and Nityr are not FDA approved for this indication, they have long been used off label for AKU - Orfadin is approved in Europe for the treatment of AKU - Provides no compelling advantage over existing nitisinone products	Complete Exclusion

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
rilzabrutinib (Wayrilz) Hematological Agents: Platelets	- eltrombopag 50mg daily - romiplostim 1 mcg/kg weekly - assume 50kg person	- Tablet 400 mg 400 mg BID	Treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment	- diarrhea - nausea - headache - abdominal pain	- BTK inhibitor approved for adults with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment - Phase 3 study demonstrated durable platelet response of 23% vs. 0% for placebo - Wayrilz is only approved for use in adults - Promacta can be used in pediatrics and comes in an oral suspension formulation - Provides another option for the treatment of persistent or chronic ITP in adults in those who have experienced an insufficient response to previous modalities	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List contingent
sebetralstat (Ekterly) Corticosteroids-Immune-Modulator: Hereditary Angioedema Agents	- Firazyr - Berinerit - Ruconest - Kalbitor	Tablet: 300 mg	Treatment of acute attacks of hereditary angioedema (HAE) in ≥12 years	headache	- Ekterly is approved for the treatment of acute HAE attacks - A phase 3 study demonstrated statistically significant faster time to the beginning of symptom relief with Ekterly compared with placebo - Carries an overall minimal adverse event profile with and is well tolerated - Provides an additional abortive treatment option for this condition	- UF - PA - QL - Specialty Drug List
sepiapterin oral powder (Sephience) Metabolic Agents - Miscellaneous	- Kuvan - Palynziq	Oral powder: 250 mg or 1,000 mg	Treatment of hyperphenylalaninemia in ≥1 month of age with sepiapterin-responsive phenylketonuria (PKU), in conjunction with phenylalanine restricted diet	- diarrhea - headache - abdominal pain - hypo-phenylalaninemia - feces discoloration - oropharyngeal pain	- Approved for treatment of hyperphenylalaninemia in patients ≥1 month of age with sepiapterin-responsive PKU - Phase 3 study demonstrated significant reductions in blood Phe levels vs. placebo after 6 weeks of therapy - Overall well tolerated, however carries an increased for increased bleeding - Provides an additional pharmacologic treatment option for this condition	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
sitagliptin 25 mg/mL oral solution (Brynovin) Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) inhibitors	sitagliptin tablets	- Solution; oral 25mg/ml	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	- upper respiratory tract infection - nasopharyngitis - headache	- Oral solution formulation of sitagliptin - No new clinical efficacy studies; approved via 505(b)(2) - Sitagliptin tablets cannot be split, crushed or chewed - Provides an option for those who cannot swallow	- UF - PA - TRICARE Maintenance Drug List
sulopenem etzadroxil and probenecid (Orlynvah) Antibiotics: Beta-lactams	- ciprofloxacin - amoxicillin/clavulanate - nitrofurantoin - sulfamethoxazole/trimethoprim - fosfomycin - Blujepa	- sulopenem etzadroxil 500 mg/probenecid 500 mg in a tablet - One tablet BID for 5 days	Uncomplicated urinary tract infections (uUTI) caused by <i>E. coli</i>, <i>K. pneumoniae</i>, or <i>P. mirabilis</i> in adult women ≥ 18 who have limited or no alternative oral antibacterial treatment options	- diarrhea - nausea - vulvovaginal mycotic infections - headache - vomiting	- Orlynvah is effective for uUTI caused by the microorganisms <i>E. coli</i>, <i>K. pneumoniae</i>, or <i>P. mirabilis</i> in adult women who have limited or no alternative oral antibacterial treatment options based on statistical superiority in the micro-MITTR population of SURE-1 trial and noninferiority/superiority in the micro-MITTS population of REASSURE - Was not studied in pregnancy, limiting its utilization - Data from both trials combined showed diarrhea occurred in 194 (10%) patients versus 45 (4%) and 21 (3%) of patients in the Augmentin and Cipro arms, respectively - Contraindicated in patients with known blood dyscrasias, known uric acid kidney stones, and those concomitantly taking ketorolac - Given that Orlynvah is the first oral penem antibacterial drug on the U.S. market, effective antimicrobial stewardship and appropriate positioning of the drug in the hierarchy of uUTI treatment options is critical to mitigate risk of increased carbapenem resistance associated with its use - There are several FDA-approved antibiotics for treatment of uUTI and Orlynvah is not considered as first-line empiric therapy	- UF - PA - QL - Rapid Response

Appendix E—Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
zongertinib (Hernexeos) Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents	Enhertu	60 mg tablets - For patients < 90 kg: 120 mg PO QD; - for patients ≥ 90 kg: 180 mg PO QD - Take until disease progression or unacceptable toxicity	Treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have prior systemic therapy	- diarrhea - hepatotoxicity - rash - fatigue - nausea	- Oral agent approved for treatment of NSCLC with HER2 (ERBB2) activating mutations after prior systemic therapy - Single-arm, open-label study demonstrated overall response ratio (ORR) of 75% in patients previously treated with prior platinum chemotherapy - Hernexeos demonstrated efficacy with an ORR of 44% in patients previously treated with an antibody-drug conjugate (e.g., Enhertu) - NCCN guidelines recommend Hernexeos and Enhertu as “Preferred” subsequent therapy options for HER2-mutation positive NSCLC. Kadcylla is another agent used off-label and recommended by NCCN for this indication - Ongoing phase III study comparing Hernexeos with current standard of care regimen containing a checkpoint inhibitor + platinum chemotherapy + pemetrexed in the first-line setting - Safety profile of Hernexeos appears to be manageable with a low drug discontinuation rate - Hernexeos is an alternative to Enhertu for its FDA-approved indication	- UF - PA - QL - Specialty Drug List - TRICARE Maintenance Drug List

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes*

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
November 2025	Drug Class Reviews Rapid Acting Insulins Designated UF <i>Retain current status on the list</i> - All other rapid-acting insulin products not listed as “remove from/do not add” Designated NF <i>Retain current status on the list</i> - insulin aspart U-100 (Admelog) - insulin glulisine U-100 (Apidra) - insulin lispro U-100 (Humalog TEMPO, Humalog Kwikpen Jr) - insulin lispro U-200 (Humalog Kwikpen) - insulin lispro-aabc U-200 (Lyumjev Kwikpen) <i>Add to the TMDL</i> - insulin aspart-xjhz (Kirsty), subject to feasibility Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF - sitagliptin 25 mg/mL oral solution (Bynovin) Designated NF <i>Add – no reason to exempt from NF TMOP requirement</i> - gepirone (Exxua) - metoprolol 10 mg/mL oral solution (Lopressor) Other Items <i>Add to the list</i> - sotatercept (Winrevair)	Drug Class Reviews Rapid Acting Insulins Designated UF <i>Remove from/Do not add</i> - insulin lispro U-100 (Humalog Kwikpen) - insulin aspart U-100 (Novolog Flexpen and vial) - insulin aspart-szjj U-100 (Merilog pen and vial) Metabolic Dysfunction: Injectable Weight Loss Agents Subclass Designated UF <i>Do not add—not cost advantageous to government</i> - semaglutide (Wegovy) - tirzepatide (Zepbound) Designated NF <i>Exempt from NF TMOP requirement—not cost advantageous to government</i> - liraglutide (Saxenda, generics) Metabolic Dysfunction: Injectable Diabetic Agents Subclass Designated UF <i>Remove from/do not add to the list –not cost advantageous to government</i> - dulaglutide (Trulicity) - semaglutide (Ozempic) - tirzepatide (Mounjaro) Designated NF <i>Exempt from NF TMOP requirement—not cost advantageous to government</i> - liraglutide (Victoza, generics) - exenatide (Byetta generics)

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
		Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Do not add—acute use</i> • gepotidacin (Blujepa) • nalmeferene 1.5 mg/0.5 mL autoinjector (Zurnai) • sebetralstat (Ekterly) • sulopenem etzadrozil/probenecid (Orlynvah) <i>Exempt from NF TMOP requirement—acute use</i> • dihydroergotamine mesylate 1 mg/mL (Brekiya) Other Items <i>Remove from list no longer cost advantageous/technical limitations</i> • estradiol acetate vaginal ring (Femring) • estradiol vaginal system (Estring)

*Legal/Regulatory Authorities

- 10 USC 1074g(a)(9) requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to these requirements are listed on the TRICARE Maintenance Drug List (TMDL).
- 32 CFR 199.21(r) implements 10 USC 1074g(a)(9) and sets out operation of the TMDL in detail.
- 32 CFR 199.21(h)(2)(ii) requires that non-formulary pharmaceutical agents be “generally not available in military treatment facilities or in the retail point of service.” As a result, NF/Tier 3 agents (including generics) must be on the TMDL unless a reason exists to exempt the agent from the NF TMOP requirement (e.g., acute use, clinical considerations, not available at TMOP, cost effectiveness).
- 32 CFR 199.21(g)(5) covers formulary status and review of newly approved drugs (other than generics), which are added to the UF unless the P&T Committee recommends NF/Tier 3 status within 120 days of approval. In the meantime, newly approved drugs are considered to be in a classification pending status and available under the same terms as NF/Tier 3 medications.

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement)
November 2025	Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) <i>Designated UF</i> • brensocatib (Brinsupri) • delgocitinib 2% cream (Anzupgo) • dordaviprone (Modeyso) • imlunestrant (Inluriyo) • lecanemab-irmb (Legembi Iqlik auto-injector) • rilzabrutinib (Wayrilz) • sepiatpterin oral powder (Sephience) • zongertinib (Hernexeos) <i>Designated NF</i> <i>No reason to exempt from TMOP requirement</i> • dasatinib (Phyrago) • donidalorsen (Dawnzera)	

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Due to the volume of recommendations requiring implementation due to the UF Beneficiary Advisory Panel pause, one week was added to implementation, which is reflected in the dates below.

Upon signing: July 20, 2026

Two weeks after signing: August 12, 2026

30 days after Signing: August 26, 2026

60 days after signing: September 29, 2026

90 days after signing: October 28, 2026

120 days after signing: December 2, 2026, due to the Thanksgiving Day holiday

* Note that implementation occurs the first Wednesday following “X” days after signing of the minutes in all points of service.

† P&T Committee Administrative Authorities were used to implement some recommendations not requiring UF BAP comment. See the November 2023 Table of Administrative Authorities.

Appendix H—Complete Exclusion Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
November 2025	Diuretics	• bumetanide nasal spray (Enbumyst)	• bumetanide tabs • furosemide tabs • torsemide tabs	• 120 days
November 2025	Migraine Agents	• escitalopram 15 mg capsules (no brand name)	• citalopram • escitalopram • fluoxetine • sertraline	• 120 days
November 2025	Miscellaneous Enzyme Replacement Agents	• nitisinone (Harliku)	• nitisinone capsules (Orfadin) • nitisinone tabs (Nityr, generic)	• 120 days
November 2025	Rapid Acting Insulins U-100	• U-100: insulin lispro-aabc TEMPO (Lyumjev TEMPO)	• insulin aspart (Novolog) • insulin lispro (Humalog) • insulin lispro unbranded biologic • insulin lispro-aabc (Lyumjev) • insulin aspart (Merilog)	• 120 days

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3).

Drugs recommended for complete exclusion will not be available at the MTFs or TMOP points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the complete exclusion agents at the Retail points of service.

For a cumulative listing of all completely excluded agents to date, refer to previous versions of the P&T Committee quarterly meeting minutes, found on the health.mil website.

Appendix I—DoD P&T Committee Administrative Authority Document

DoD P&T Committee Updates to Approval Authorities

Note that updates are in bold font

**Table 1. Processes and Recommendation/Approval Authorities
For the November 2025 DoD P&T Committee Meeting
Also includes changes from February and May 2025**

Process	Function
Administrative (not part of DoD P&T Committee process; Uniform Formulary Beneficiary Advisory Panel (UF BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm5 (Mail Order Pharmacy and Retail Pharmacies Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; P&T Committee Chair and others as needed	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing PA requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non-step-preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to PA forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Implementing temporary PA requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting) and to institute and/or change

	existing PAs, as necessary, to comply with governing federal law and policy. (From the February 2025 DoD P&T Committee meeting) ▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator” drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be “grandfathered” when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the ~~Expanded MTF/Mail Order Pharmacy Initiative~~ TRICARE Maintenance Drug List. (From the May 2025 meeting) ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the ~~Expanded MTF/Mail Order Pharmacy Initiative~~ TRICARE Maintenance Drug List. from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). (From the May 2025 meeting) ▪ After consultation with the Chair of the DoD P&T Committee, implementing “brand over generic” authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon PA. The branded product will adjudicate at the Tier 1 co-pay at ~~the Retail Pharmacies Pharmacy Network and the Mail Order Pharmacy.~~ The “brand over generic” authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. (From the May 2025 meeting)
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Appendix I—DoD P&T Committee Administrative Authority Document

	▪ Designating “line extension” products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTs coding for TPharm5, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA “health.mil” website. ▪ ~~Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. (From the May 2025 meeting)~~ ▪ Adding or deleting drugs or drug classes from the Clinical Services TRICARE Specialty Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List. Addition or deletion of drugs or drug classes from the Clinical Services TRICARE Specialty Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. <i>(From the May 2025 meeting)</i> ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying or revising manual PA criteria, MN criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs, MNs and/or QLs implemented in these situations will be removed when the situation has resolved.
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	- FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA-approved devices or supplies and determination as to whether a new FDA-approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination is made to consider the device for coverage, then the timeline for review by DoD P&T Committee will be established. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. <i>(From the May 2025 meeting)</i> - Designating “line extension” devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments	- Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). - Classification of a medication with Tier 4 (not covered) Complete Exclusion status (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and formulation of an implementation plan (including effective date). <i>(From the May 2025 meeting)</i> - Establishment of PA requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). - Changes to existing PA (e.g., due to the availability of new efficacy or safety data). - Discontinuation of PA requirements for a drug. - Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). - Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. - Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. - Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). - Designating individual generic drugs as nonformulary (Tier 3 co-pay). - The Director may approve devices or supplies as recommended by the P&T Committee and the UF BAP; however, approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. - Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with PA criteria and implementation plans as recommended by the DoD P&T Committee and UF BAP. In situations where the UF BAP meeting is delayed past the quarterly DoD P&T Committee meeting, the DoD P&T Committee recommended PA criteria may be applied, including automation and beneficiary notification for affected users. The DoD P&T Committee recommended PA criteria will be presented to the UF BAP for review and comment at the next

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	scheduled UF BAP meeting, and ultimately presented to the Director, DHA for consideration and final decision (<i>From the November 2025 meeting</i>).
Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to UF BAP for comments)	▪ Establishment of quantity limits for a medication, device or supply or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs, devices or supplies. ▪ Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes, devices or supplies on the Expanded MTF/Mail Order Pharmacy Initiative TRICARE Maintenance Drug List (<i>From the May 2025 meeting</i>) ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services TRICARE Specialty Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. ~~The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.~~ The list is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List. (<i>From the May 2025 meeting</i>) ▪ In situations where the UF BAP meeting is delayed past the quarterly DoD P&T Committee meeting, the DoD P&T Committee recommended MN criteria and or QLs may be applied. The DoD P&T Committee recommended MN criteria and/or QLs presented to the Director, DHA for consideration and final decision (<i>From the November 2025 meeting</i>).