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 overdosage 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 to80 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 interluekin-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 lubriprostone (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 Burkhart, 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) Manual PA criteria: 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: o modafinil or armodafinil • **Treatment for cataplexy does not require trial of modafinil or armodafinil** o stimulant-based therapy (amphetamine-based therapy or methylphenidate) o **sodium oxybate (Xywav)** o **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) Manual PA criteria: 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: o **modafinil or armodafinil** • **Treatment for cataplexy does not require trial of modafinil or armodafinil.** o stimulant-based therapy (amphetamine-based therapy or methylphenidate). o **sodium oxybate (Xywav)** o **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) Manual PA Criteria: 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:

	– 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

	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** Manual PA Criteria: 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 of 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.

Appendix C—Table of Prior Authorization (PA) Criteria

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 levacetylleucine (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 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 • 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 (Hympavzi) **Antihemophilic Factors**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of Hympavzi. Manual PA criteria: Hympavzi 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

Appendix C—Table of Prior Authorization (PA) Criteria

• nilotinib tartrate tablets (Danziten) **Oncological Agents**	Manual PA criteria apply to all new users of Danziten Manual PA criteria: 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 Manual PA criteria: 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 Manual PA criteria: 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 Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met:

Appendix C—Table of Prior Authorization (PA) Criteria

	• 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 Manual PA criteria: 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-aaub (Wezlana) Automated PA criteria: 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: If automated PA criteria are note 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, aminosalicylates (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 Manual PA criteria: 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**	*Note that the PA was not implemented, as Tridacaine XL was determined not to be part of the TRICARE Pharmacy benefit*. **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**). Manual PA criteria: 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 Manual PA criteria: 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

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• 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

Appendix C—Table of Prior Authorization (PA) Criteria

• 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). Manual PA criteria: 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, intolerability 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, intolerability 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.** **Renewal criteria: 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) Manual PA criteria: 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, intolerability 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, intolerability 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, intolerability 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, intolerability 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) Manual PA criteria: 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 of 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

Appendix C—Table of Prior Authorization (PA) Criteria

	Renewal PA Criteria: **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. **Automated PA Criteria: 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 Manual PA criteria: 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, intolerability 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 ▪ trazadone IR ▪ nefazodone ▪ MAOI Non-FDA-approved uses are not approved Prior Authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• 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 **<u>Automated PA Criteria</u>: 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) *(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)* • 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

	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, intolerability 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, intolerability 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, aminosalicylates (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 intolerability 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 intolerability 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 Renewal criteria: 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) Manual PA criteria: 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

Appendix C—Table of Prior Authorization (PA) Criteria

• 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 Manual PA criteria: 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), Onpattro (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. Manual PA criteria: 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), Onpattro (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 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 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 Manual PA criteria: Braftovi is approved if all criteria are met: • Patient is greater than or equal to 18 years or 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

	▪ Unresectable or metastatic colorectal cancer ▪ Metastatic non-small cell lung cancer • Braftovi 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 supratherapeutic**~~ 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) Manual PA Criteria: **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.

• 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 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.

Appendix C—Table of Prior Authorization (PA) Criteria

• 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). Automated PA Criteria: 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 Manual PA Criteria: 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 (Sotyku) **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). Manual PA Criteria: 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).

	• ~~**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**~~ 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: • **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**~~

	~~▪ 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, aminosalicylates (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, 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** ~~▪ 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, aminosalicylates (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

	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). Manual PA criteria: 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 of 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, aminosalicylates, 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). Manual PA Criteria: 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, aminosalicylates [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** Manual PA criteria: 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** **Automated PA Criteria: 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 Manual PA criteria: 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**

	• 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
	
	<u>Automated PA Criteria</u>: 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 (Hympavzi) **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 **Automated PA Criteria: When prescribed by an obstetrician/gynecologist specialist, the QL over-ride authorization form is not required. OR** **Automated PA Criteria: 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 (≥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 ≥ 13 years • Adjunctive to MDD in adults • Irritability in autistic ≥ 6 years • Tourette's ≥ 6 years	ADR (≥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 (≥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 (≥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 (≥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 Ibrance 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 Ibrance and fulvestrant resulted in higher incidences of adverse events compared with placebo in combination with Ibrance 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 (Hympavzi) Antihemophilic Factors	• Hemlibra • Altuviiio • 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 (≥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, Hympavzi 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 • Hympavzi 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 (≥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 (≥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 (≥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 ~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 andT2 DM 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 (≥3%): • nasopharyngitis • upper respiratory tract infection • headache • fatigue • N/VD • 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 (≥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*** *Retain current status on the TRICARE Maintenance Drug List* • solriamfetol (Sunosi)	**Drug Class Reviews** **Sleep Disorder: Wakefulness Promoting Agents subclass** ***Designated UF*** *Do not add* • sodium/calcium/magnesium/potassium oxybate packets for oral suspension (Xywav) ***Designated NF*** *Exempt from NF requirement (not available at TMOP)* • sodium oxybate ER (Lumryz) • sodium oxybate authorized generic (Xyrem authorized generics) • sodium oxybate (Xyrem) **Narcotic Analgesics and Combinations: Buprenorphine and Combinations** ***Designated UF*** *Do not add* • 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*** *Do not add – not cost advantageous to government* • acoramidis (Attruby) *Do not add – requires further evaluation* • Omnipod 5 Libre2/G6 • vanzacaftor/tezacaftor/deutivacaftor (Alyftrek) ***Designated NF – exempt from NF requirement*** *Acute or limited duration of use* • filgrastim-txid (Nypozi) *Established exemption for antipsychotics* • aripiprazole oral film (Opipza) *Not cost advantageous to government* • 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.

Appendix H—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 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.**

	▪ 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

	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.