DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

November 2025

I. CONVENING

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

II. ATTENDANCE

The attendance roster is listed in Appendix A.

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

B. Clarification of previous meeting minutes

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

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

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

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass

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

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

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

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

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

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

Clinical Practice Guidelines for Weight Loss

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

Weight Loss

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

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

Major Adverse Cardiovascular Events (MACE)

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

Obstructive Sleep Apnea (OSA)

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

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

Metabolic dysfunction–associated steatohepatitis (MASH)

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

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

Safety

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

Individual Product Characteristics

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

Overall Clinical Conclusion

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

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

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

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

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:
    - UF
        - semaglutide (Wegovy)
        - tirzepatide (Zepbound)
    - NF
        - liraglutide (Saxenda)
    - Complete Exclusion: Note that tirzepatide vials (Zepbound vials) will continue to remain designated with complete exclusion status, as this

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

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

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

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

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

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

- For the nonformulary drug Saxenda, the requirement for a trial of phentermine, phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), Wegovy and Zepbound remains.
- Continuation of GLP1-RA therapy will be allowed for patients who have successfully lost weight with phentermine, but who require additional pharmacotherapy to reach a lower weight loss goal.
- PA will expire annually, with yearly renewal required.
- The Saxenda PA will have the BMI categories added, in order to align with the Wegovy and Zepbound PAs.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current MN criteria for Saxenda. For Saxenda a trial of all the formulary alternatives is required, including generic phentermine, phentermine/topiramate (Qsymia), naltrexone/bupropion (Contrave), Wegovy and Zepbound. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QL of a 30-day supply at Retail pharmacies and a 60-day supply at MTFs and TMOP for Saxenda, Wegovy and Zepbound. See Appendix D.

5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST***— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) that Saxenda, Wegovy and Zepbound will not be subject to the TRICARE Maintenance Drug List. See Appendix F.

6. ***COMMITTEE ACTION: UF, PA, MN, QLs, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD—*** The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes. See Appendix G.

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass

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

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

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

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

T2DM and Glycemic Control

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

T2DM and MACE Reduction

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

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

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

T2DM and Chronic Kidney Disease (CKD)

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

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

Safety

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

Individual Product Characteristics

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

Overall Conclusions

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

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

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

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

- dulaglutide (Trulicity)
- semaglutide (Ozempic) *moves from NF to UF*
- tirzepatide (Mounjaro) *moves from NF to UF*

- NF
  - exenatide twice daily (generic Byetta)
  - liraglutide (generic Victoza)
- Complete Exclusion – None
- Note that if generic or branded formulations of lixisenatide (Adlyxin), exenatide once weekly (Bydureon BCise) or Victoza return to the market they will be designated as NF.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***— PA criteria apply to all agents within the class, requiring a trial of metformin first. Additionally, exenatide and liraglutide require a trial of both Trulicity and Ozempic. Trulicity currently has an automated look back allowing coverage if the patient has received any diabetic drug in the past 720 days.

   The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the subclass for new users. An initial trial of metformin is still required first. For exenatide and liraglutide, Trulicity, Ozempic and now Mounjaro are required first. The automated lookback for any diabetic drug will remain for dulaglutide. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) minor updates to the current MN criteria for generic exenatide and generic liraglutide. Mounjaro was added to the list of formulary alternatives. See Appendix B for the full criteria.
4. ***COMMITTEE ACTION: QLs***—QLs currently apply to liraglutide, but not the remainder of the class. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) removing the QL for liraglutide, for consistency with the class.
5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST***— The injectable diabetic drugs are currently included on the TRICARE Maintenance Drug list. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) removing Trulicity, Ozempic and Mounjaro from the list; generic exenatide and liraglutide will not be subject to the TRICARE Maintenance Drug List requirements. See Appendix F.
6. ***COMMITTEE ACTION: UF, MN, PA, QL TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD—***

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

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

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

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

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

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

Efficacy and Safety

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

Individual Product Characteristics

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

Therapeutic Interchangeability and Clinical Coverage

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

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

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

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

   <u>U-100 Insulins</u>

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

- insulin lispro TEMPO (Humalog TEMPO) – *moves from UF to NF*
- insulin aspart–xjhz (Kirsty)
- insulin aspart (Admelog)
- insulin glulisine (Apidra)

- Complete Exclusion
  - insulin aspart/niacinamide (Fiasp)
  - insulin lispro-aabc TEMPO (Lyumjev TEMPO) – *moves from NF to complete exclusion status*

U-200 Insulins

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

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA currently applies to Apidra, Admelog and the Lyumjev TEMPO and Humalog TEMPO pens. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PAs as outlined below, in new users. See Appendix C.
   - PA is not required for the branded insulin lispro Humalog Junior Kwik pen, intended for pediatric patients.
   - PA will apply to the RAIs recommended for NF status (with the exception of branded Humalog Junior), as these products currently have or are expected to have low utilization in the MHS. PA will only apply to new users of Apidra, Admelog, Kirsty, Humalog TEMPO, Lyumjev TEMPO pens, and Lyumjev U-200.
   - For Apidra and Admelog, the current automated lookback will be removed, however patients are still required to try Novolog, Humalog or unbranded biologic insulin lispro.
   - For Kirsty and the Humalog TEMPO pen, a trial of Novolog, Humalog and insulin lispro unbranded biologic will be required in new users.

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

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The current MN criteria for Admelog and Apidra allow use if the patient has had an inadequate response to Novolog, Humalog or unbranded biologic insulin lispro. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updating the current MN criteria for Admelog an Apidra to also require a trial of Lyumjev U-100 and Merilog, which are added to the list of formulary alternatives. The new MN criteria for Kirsty and Lyumjev TEMPO will mirror the Apidra and Admelog MN criteria. See Appendix B for the full criteria.
4. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST***—The RAIs are currently on the TRICARE Maintenance Drug list. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) removing Humalog, Novolog and Merilog from the list. Admelog, Apidra, Humalog TEMPO, Humalog Junior and Lyumjev U-200 will be added to/maintained on the list, Kirsty will be added to the list, contingent on feasibility, as this product is currently non-Trade Agreement Act compliant. See Appendix F.
5. ***COMMITTEE ACTION***: ***RAPID RESPONSE PROGRAM***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding branded Humalog Kwikpen Junior to the rapid response program (safety net program) maintained by the TPharm 5 contractor.
6. ***COMMITTEE ACTION: UF, MN, PA, TRICARE MAINTENANCE DRUG LIST, RAPID RESPONSE and IMPLEMENTATION PERIOD—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) DHA send letters to patients affected by the recommendation for NF status for branded Humalog Kwikpen Junior, Humalog TEMPO pen and Lyumjev U-200 pen; and 3) DHA send letters at 60 and 30 days prior to implementation for the patients affected by the recommendation for Complete Exclusion status for Lyumjev TEMPO pen. See Appendix G.

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

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

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

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:
    - UF
        - brensocatib (Brinsupri) – Pulmonary I Agent for non-cystic fibrosis bronchiectasis
        - delgocitinib 2% cream (Anzupgo) – Atopy Agent for chronic hand eczema
        - dordaviprone (Modeyso) – Oncological Agent for glioma
        - gepotidacin (Blujepa) – Antibiotic for urinary tract injections (UTI)
        - imlunestrant (Inluriyo) – Oncological Agent for breast cancer
        - lecanemab-irmb injection (Leqembi Iqlik) – Alzheimer's Agent
        - nalmefene injection (Zurnai) – Alcohol Deterrents-Narcotic Antagonists
        - rilzabrutinib (Wayrilz) – Hematological Agents: Platelets, for thrombocytopenia
        - sebetralstat (Ekterly) – Hereditary Angioedema (HAE)– Acute treatment
        - sepiapterin oral powder (Sephience) – Miscellaneous Metabolic Agents for hyperphenylalaninemia in phenylketonuria
        - sitagliptin 25 mg/mL oral solution (Brynovin) – Non-Inulin Diabetes Drugs – Dipeptidyl Peptidase-4 (DPP-4) inhibitor
        - sulopenem etzadroxil /probenecid (Orlynvah) – Beta lactam Antibiotic for UTI
        - zongertinib (Hernexeos) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2)
    - NF
        - dasatinib (Phyrago) – Oncological Agent for Chronic Myelogenous Leukemia and Acute Lymphocytic Leukemia
        - dihydroergotamine mesylate injection (Brekiya) – Migraine Agent
        - donidalorsen injection (Dawnzera) – HAE - prophylaxis Agent

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

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

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria. See Appendix C for the full criteria.
    - Applying manual PA criteria to new users of Brinsupri, requiring specialist prescribing and a trial of azithromycin.

- Applying manual PA criteria to new users of Orlynvah, and Blujepa, requiring culture-proven bacterial UTI, and contraindications to or antibiotic resistance to standard UTI antimicrobials. Automated specialist bypass was added to allow PA approval if the prescriber is a urologist, urogynecologist or infectious disease specialist.
- Applying manual PA criteria to new users of Leqembi, requiring specialist prescribing and medical documentation that the patient has completed 18 months of initial treatment with intravenous lecanemab-irmb (Leqembi).
- Applying manual PA criteria to new users of Exxua, requiring a trial of three formulary antidepressants first.
- Applying manual PA criteria to new users of Anzupgo, requiring a trial of topical corticosteroids, and topical calcineurin inhibitors, consistent with the PA criteria for other products used to treat eczema.
- Applying manual PA criteria to the hematology/oncology drugs Modeyso, Inluriyo, Wayrilz, Hernexeos, and Phyrago.
- Applying manual PA criteria to new and current users of Brekiya, requiring a trial of two triptans and nasal dihydroergotamine spray first.
- Applying manual PA criteria to new users of Ekterly, Brynovin, Dawnzera, Sephience and Lopressor oral solution.
- Applying temporary manual PA criteria to new and current users of Enbumyst nasal spray, escitalopram 15 mg capsules and Harliku until implementation of complete exclusion status.

4. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) QLs for Anzupgo, Blujepa, Brekiya, Brinsupri, Dawnzera, Ekterly, Hernexeos, Inluriyo, Leqembi, Modeyso, Phyrago, Orlynvah, Sephience, Wayrilz and Zurnai. See Appendix D for the QLs.
5. ***COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding, Dawnzera, Blujepa, Ekterly, and Orlynvah to Rapid Response program managed by the TRICARE pharmacy benefits contractor. The program identifies beneficiaries who have not received a prescription fill after the initial reject.
6. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS*** —The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List which includes the NF medications subject to the TMOP requirement.

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

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

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

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

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

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

a) **Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tabs (Clemsza)—**This clemastine tablet formulation is less cost-effective than other clemastine tablets that are available in the same strength.

b) **Anticholinergics-Antispasmodics—dicyclomine 40 mg tablet—**This dicyclomine tablet formulation is less cost-effective than currently available dicyclomine tablets and capsules. The 40 mg dose can be achieved using other available formulations.

c) **Pain Agents: NSAIDs—flurbiprofen 100 mg tabs (Lurbiro)—**There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

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

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

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

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

a) **Antihemophilic Agents: Non-Factor Agents—concizumab-mtci (Alhemo)—**The PA for Alhemo was updated to allow for the new indication for hemophilia A or B without inhibitors. Previously, Alhemo was only indicated in hemophilia A or B with inhibitors.

b) **Hematological Agents: Platelets—avatrombopag (Doptelet)**—Doptelet received an expanded age indication for thrombocytopenia in pediatric patients one year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. The Doptelet manual PA criteria were updated to remove a minimum age for ITP. (Note that Doptelet sprinkles were addressed as a line extension at this meeting. See page 28.)

c) **Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Preventative—fremanezumab (Ajovy)—**The manual PA was updated to allow for an expanded age indication for episodic migraine prevention to include pediatric patients 6-17 years old and weighing greater than or equal to 45 kg.

d) **Atopy—ruxolitinib 1.5% cream (Opzelura)**—Opzelura is now indicated in children as young as 2 years old with atopic dermatitis. The PA criteria were updated accordingly.

e) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors—apremilast (Otezla)—**The manual PA for Otezla was updated to allow for an expanded age indication for psoriatic arthritis to include pediatric patients 6-17 years old.

f) **Oncological Agents: Poly ADP-Ribose Polymerase (PARP) Inhibitors—niraparib (Zejula)**—The FDA narrowed Zejula's indication for first-line maintenance treatment of advanced ovarian cancer to those with homologous recombination deficiency (HRD)-positive tumors only. Additional edits were made to the Zejula PA to align with ongoing oncology standardization efforts. For more information on oncology standardization, please refer to the November 2024 P&T meeting minutes.

g) **Diabetes Non-Insulin: Oral Glucagon-Like Peptide-1 Receptor Agonists—semaglutide (Rybelsus)—**Rybelsus is now indicated to reduce the risk of MACE in type 2 diabetic adults. The current PA states that Rybelsus has not been proven for MACE. This line will be removed due to this new indication and supporting data.

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

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

3. Updated PA Criteria for Reasons other than New Indications

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

a) **Oncological Agents: 2nd Generation Antiandrogens—darolutamide (Nubeqa)**—The Nubeqa PA was updated based on provider feedback and National Comprehensive Cancer Network (NCCN) guideline updates. The PA now aligns with NCCN guidelines on Nubeqa use with docetaxel and on high vs. low volume metastases.

b) **Pulmonary Arterial Hypertension Agents—sotatercept (Winrevair)—** The manual PA was updated to remove the current diuretic requirement. In the STELLAR trial used to gain FDA approval, not all the participants were receiving diuretics. The P&T Committee also reviewed an analysis of background medications for patient dispensed Winrevair. Winrevair will also now be available for dispensing through the specialty mail pharmacy and will be added to the TRICARE Maintenance Drug List. See Appendix F.

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

4. Removal of PAs

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

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

B. Quantity Limits (QLs)

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

C. Line Extensions

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

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

COMMITTEE ACTION: LINE EXTENSION AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, MN,

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

D. TRICARE Maintenance Drug List Updates

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

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

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

VII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION

A. Brand over Generic Additions

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

B. Brand over Generic Removals

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

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

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

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

VIII. DoD P&T COMMITTEE ADMINISTRATIVE AUTHORITIES

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

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

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

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

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

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

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

X. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

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

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

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

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

- **Interleukin 23 Inhibitors**: As a result of the above recommendation, the following products status will no longer be part of the TRICARE Pharmacy benefit. DHA will send letters to patients affected by this decision.
  - May 2025: ustekinumab-ttwe unbranded private label Pyzchiva by Quallent
  - August 2025: ustekinumab-aekn unbranded Selardsi private label by Teva
  - November 2025: ustekinumab-ttwe unbranded private label Pyzchiva by Cordavis (this product was originally included as one of the innovator drugs for this meeting but is now not part of the TRICARE pharmacy benefit with no further action required).

D. Copay Changes for 2026: The Committee was briefed on the statutorily required copay changes that will be effective in January 2026.

E. Self-Monitoring Blood Glucose System (SMBG) Test strips: The Medtronic 780G insulin pump, which is compatible with the Accu-Chek Guide test strip was added to the SMBG test strip PA form.

F. Gastrointestinal-2 Agents for Primary Biliary Cholangitis: The PA for seladelpar (Livdelzi) and elafibranor (Iqirvo) requires patients to have a contraindication to, intolerability to, or a failed trial of obeticholic acid (Ocaliva). Recently, the FDA mandated the market removal of Ocaliva due to hepatoxicity, effective November 2025; therefore, the Livdelzi and Iqirvo PAs were updated to remove the Ocaliva step. See Appendix C.

G. Basal Insulins: insulin degludec (Tresiba): The current Tresiba PA requires the provider to explain why the patient cannot use unbranded insulin degludec. Unbranded insulin degludec will be discontinued by the manufacturer by the end of December 2025; thus, the question on unbranded insulin degludec was removed from the Tresiba PA. See Appendix C.

XII. ADJOURNMENT

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

Appendix A—Attendance: November 2025 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

\Signed\Signature on file

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

The Director, DHA:

☐ concurs with all recommendations.

☒ concurs with the recommendations, with the following modifications:

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

☐ concurs with the recommendations, except for the following:

\Signed\Signature on file
Acting Assistant Director
Health Care Administration and Operations

20 July 2026

Date 20 July 2026

Appendix A—Attendance

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

Appendix A—Attendance

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

Appendix B—Table of Medical Necessity Criteria

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

Appendix B—Table of Medical Necessity Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

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

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

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

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

	• The patient has had an inadequate response, adverse reaction, or contraindication to all the following:
	  ▪ One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest)
	  ▪ One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo)
	Non-FDA-approved uses not approved
	Prior Authorization does not expire

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix D—Table of Quantity Limits (QL)

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

Appendix D—Table of Quantity Limits (QL)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Legal/Regulatory Authorities**

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

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

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

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

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*
Due to the volume of recommendations requiring implementation due to the UF Beneficiary Advisory Panel pause, one week was added to implementation, which is reflected in the dates below.

Upon signing: July 20, 2026

Two weeks after signing: August 12, 2026

30 days after Signing: August 26, 2026

60 days after signing: September 29, 2026

90 days after signing: October 28, 2026

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

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

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

Appendix H—Complete Exclusion Drugs and Therapeutic Alternatives*

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

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

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

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

Appendix I—DoD P&T Committee Administrative Authority Document

DoD P&T Committee Updates to Approval Authorities

Note that updates are in bold font

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

Also includes changes from February and May 2025

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

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

	▪ Designating "line extension" products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm5, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA "health.mil" website. ▪ ~~**Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting.**~~ (***From the May 2025 meeting)*** ▪ Adding or deleting drugs or drug classes from the ~~**Clinical Services**~~ **TRICARE Specialty** Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list ~~**also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies**~~ **is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List**. Addition or deletion of drugs or drug classes from the ~~**Clinical Services**~~ **TRICARE Specialty** Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. (***From the May 2025 meeting)*** ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying or revising manual PA criteria, MN criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs, MNs and/or QLs implemented in these situations will be removed when the situation has resolved.

	▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA-approved devices or supplies and determination as to whether a new FDA-approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination **is** made to consider **the device** for coverage, **then the** timeline for review by DoD P&T Committee **will be established**. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. (***From the May 2025 meeting)*** ▪ Designating "line extension" devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication **with Tier 4 (not covered**) **Complete Exclusion status (not covered**) on the Uniform Formulary, for products ~~**selected for complete exclusion**~~ that provide very little or no clinical effectiveness relative to similar agents, and **formulation of an** implementation plan (including effective date). (***From the May 2025 meeting)*** ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing PA (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as nonformulary (Tier 3 co-pay). ▪ The Director may approve devices or supplies as recommended by the P&T Committee and the UF BAP; however, approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. ▪ Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with PA criteria and implementation plans as recommended by the DoD P&T Committee and UF BAP. ▪ **In situations where the UF BAP meeting is delayed past the quarterly DoD P&T Committee meeting, the DoD P&T Committee recommended PA criteria may be applied, including automation and beneficiary notification for affected users. The DoD P&T Committee recommended PA criteria will be presented to the UF BAP for review and comment at the next**

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