DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE NOVEMBER 2025 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING Day #2 PM - refer to the posted Agenda for meetings dates and times at https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with Section 1074g of Title 10, United States Code (USC), as implemented by Section 199.21 of Title 32, Code of Federal Regulations (CFR), the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA) or their designee, on formulary or complete exclusion status, prior authorizations (PAs), pre-authorizations, and the effective date for a pharmaceutical agent's change from formulary to nonformulary (NF) or to complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEW—METABOLIC DYSFUNCTION AGENTS: INJECTABLE WEIGHT LOSS AGENTS SUBCLASS

P&T Comments

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—Relative Clinical Effectiveness Conclusion

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), 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 Clinical 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 (Ozempic").

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.

B. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass— Relative Cost Effectiveness Conclusion

The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (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 requirement 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).

C. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—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).

D. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—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 BAP pause.

- Feb 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

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.

The Manual PA criteria are as follows.

1. semaglutide (Wegovy) and tirzepatide (Zepbound)

Updates from the November 2025 meeting 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:

- **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

<u>For Wegovy and Zepbound for adults for obesity</u>

- 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., arrhythmia, 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

<u>For Wegovy for adolescents</u> (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

<u>For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity</u>

- 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

<u>For all patients</u>

- 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 up 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

2. liraglutide (Saxenda)

Updates from the November 2025 meeting are in bold and ~~strikethrough~~

Manual PA criteria apply to all new users of Saxenda

Manual PA Criteria: Coverage for Saxenda is approved if:

- **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.
- **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 30to 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 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**
- **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 _____

<u>Adolescents</u>

- 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 _____

<u>For all patients</u>

- 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

Renewal PA Criteria: 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 up 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 a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2**

E. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF recommendation, PA and Implementation Plan

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.

III. UF DRUG CLASS REVIEW—METABOLIC DYSFUNCTION AGENTS: INJECTABLE WEIGHT LOSS AGENTS SUBCLASS

UF BAP Comments

A. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF Recommendation

The P&T Committee recommended the formulary status as discussed above.

- 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.
- There were no changes to the formulary status for phentermine and derivatives, bupropion/naltrexone (Contrave) phentermine/topiramate (Qsymia) or orlistat (Xenical).

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—Manual PA Criteria

The P&T Committee recommended PA criteria in new users of Wegovy, Zepbound and Saxenda, with renewal criteria applying to new and current users, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Metabolic Dysfunction Agents: Injectable Weight Loss Agents Subclass—UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 30 days after signing of the minutes in all points of service.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—METABOLIC DYSFUNCTION AGENTS: INJECTABLE DIABETIC AGENTS SUBCLASS

P&T Comments

A. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Clinical Effectiveness Conclusion

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 Rybelsus was not reviewed here 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.

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. 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 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)

C. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—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.

D. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—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.

The Manual PA criteria are as follows:

1. dulaglutide (Trulicity)

Updates from the November 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Trulicity

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**

Prior authorization does not expire

2. semaglutide (Ozempic) and tirzepatide (Mounjaro)

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:

- ~~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:
  - Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience
  - ~~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**

Prior authorization does not expire

3. exenatide twice daily (generic Byetta) and liraglutide (generic Victoza)

Updates from the November 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of exenatide or liraglutide

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. Adlixyn, Byetta, and Bydureon B-Cise 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)**
- The patient has had **an adverse reaction,** inadequate **response or has a contraindication to all of the following**: Trulicity, Ozempic **and Mounjaro**

Non-FDA approved uses are not approved**, including use for weight loss in patients who do not have diabetes**

PA does not expire

E. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF recommendation, PA, 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.

V. UF DRUG CLASS REVIEW——METABOLIC DYSFUNCTION AGENTS: INJECTABLE DIABETIC AGENTS SUBCLASS

UF BAP Comments

A. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF Recommendation

The P&T Committee recommended formulary status as discussed above.

- 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.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

B. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Trulicity, Ozempic, Mounjaro, generic Byetta and generic Victoza as detailed above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

C. Metabolic Dysfunction Agents: Injectable Diabetic Agents Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended an effective date the first Wednesday 60 days after signing of the minutes in all points of service.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

VI. UF DRUG CLASS REVIEW—INSULINS: RAPID -ACTING INSULINS (RAIS) ANALOGS SUBCLASS

P&T Comments

A. Insulins: RAIs Subclass—Clinical Effectiveness Conclusion

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 use. 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.
- *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 lispro/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.

B. Insulins: RAIs Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. 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.

C. Insulins: RAIs Subclass—UF Recommendation

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following.

U-100 Insulins

- UF
  - insulin aspart (Novolog Flexpen and vial)
  - insulin lispro (Humalog Kwikpen and vial)
  - insulin lispro (Humalog Kwikpen unbranded biologic)
  - Insulin lispro Junior (Humalog Kwikpen Junior unbranded biologic)
  - insulin lispro – aabc (Lyumjev Kwikpen and vial)
  - insulin aspart–szjj (Merilog)
- NF
  - insulin lispro Junior Kwikpen branded (Humalog Kwikpen Junior) – *moves from UF to NF*
  - insulin lispro TEMPO (Humalog TEMPO) – *moves from UF to NF*
  - insulin aspart–xjhz (Kirsty)
  - insulin aspart (Admelog)
  - insulin glulisine (Apidra)
- Complete Exclusion
  - insulin aspart/niacinamide (Fiasp)
  - insulin lispro-aabc TEMPO (Lyumjev TEMPO) – *moves from NF to complete exclusion status*

U-200 Insulins

- UF
  - insulin lispro U-200 (Humalog Kwikpen)

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

D. Insulins: RAIs Subclass—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.

- 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.

The Manual PA criteria are as follows:

1. insulin glulisine (Apidra)
insulin lispro (Admelog)
insulin aspart-xjhz (Kirsty)
insulin lispro TEMPO (Humalog TEMPO)

Updates 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** are approved if all criteria are met:

- Provider acknowledges that Novolog, Humalog ~~and the authorized generic~~ insulin lispro **unbranded biologic, insulin lispro-aabc (Lyumjev) and insulin aspart szjj (Merilog) do not require prior authorization.** ~~are the DoD's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, prior authorization is not required.~~
- The patient has diabetes AND
  - The patient has tried and failed insulin aspart (Novolog) AND
  - The patient has tried and failed insulin lispro (Humalog) or authorized generic unbranded biologic insulin lispro)

  OR
- The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog). **Note this does not apply to insulin aspart-xjhz (Kirsty) or Humalog TEMPO.**

Non-FDA-approved uses are not approved

PA does not expire

2. insulin lispro-aabc U-200 (Lyumjev U-200)

Manual PA criteria apply to all new users of Lyumjev U-200

Manual PA Criteria: Coverage 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

Prior authorization does not expire

3. Lyumjev TEMPO

Manual PA criteria apply to all new users of Lyumjev TEMPO Pen

Manual PA Criteria: Coverage is approved if all criteria are met:

- Provider acknowledges that Lyumjev TEMPO pen will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T Committee 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 insulin aspart (Novolog) AND
  - The patient has tried and failed insulin lispro (Humalog) or authorized generic unbranded biologic insulin lispro)

Non FDA-approved uses are not approved

PA does not expire until implementation of Complete Exclusion status

E. Insulins: RAIs Subclass—UF recommendation, PA, 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.

VII. UF DRUG CLASS REVIEW—RAPID -ACTING INSULINS (RAIS) ANALOGS S SUBCLASS

UF BAP Comments

A. Insulins: RAIs Subclass—UF Recommendation

The P&T Committee recommended formulary status as discussed above.

U-100 Insulins

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

- insulin aspart (Admelog)
- insulin glulisine (Apidra)

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

U-200 Insulins

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Insulins: RAIs Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Apidra, Admelog, Kirsty, Humalog TEMPO, Lyumjev TEMPO, and Lyumjev U-200 as detailed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Insulins: RAIs Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended 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.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

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

P&T Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

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).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—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) – Oncological Agents for Non-small Cell Lung Cancer (NSCLC)

- 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
  - 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.

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA 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 manual PA criteria to new and current users of Enbumyst nasal spray, escitalopram 15 mg capsules and Harliku until implementation of complete exclusion status.

The Manual PA criteria are as follows:

1. brensocatib (Brinsupri)

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

2. bumetanide nasal spray (Enbumyst)

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 DoD 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
- 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

3. dasatinib (Phyrago)

Manual PA criteria apply to all new users of dasatinib (Phyrago)

Manual PA criteria: 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 of PPIs

4. delgocitinib 2% cream (Anzupgo)

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

5. dihydroergotamine mesylate injection (Brekiya)

Manual PA criteria apply to all new and current users of dihydroergotamine mesylate subcutaneous injection (Brekiya)

Manual PA criteria: 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

6. donidalorsen injection (Dawnzera)

Manual PA criteria apply to all new users of donidalorsen (Dawnzera)

Manual PA criteria: 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)
- 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

7. dordaviprone (Modeyso)

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

8. escitalopram oxalate 15 mg capsules (no brand name)

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 DoD 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

9. gepirone (Exxua)

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., 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)
- Patient is being treated for major depressive disorder and:
  - The patient has a contraindication to, intolerability to, or has failed a trial of THREE formulary antidepressant medications. For example,
    - SSRIs (selective serotonin reuptake inhibitors, for example, citalopram, escitalopram, fluoxetine, paroxetine, sertraline)
    - SNRIs (serotonin/norepinephrine reuptake inhibitors, 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

10. gepotidacin (Blujepa)

Manual PA criteria apply to all new users of gepotidacin (Blujepa)

Automated PA Criteria: 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

Manual PA criteria: 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

11. imlunestrant (Inluriyo)

Manual PA criteria apply to all new users of imlunestrant (Inluriyo)

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 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)
- 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

12. lecanemab-irmb injection (Leqembi Iqlik)

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

13. metoprolol tartrate 10 mg/mL oral solution (Lopressor)

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

14. nitisinone (Harliku)

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 DoD 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

15. rilzabrutinib (Wayrilz)

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 × 109/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

16. sebetralstat (Ekterly)

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

17. sepiapterin oral powder (Sephience)

Manual PA criteria apply to all new users of Sephience

Manual PA criteria: Coverage is approved for initial therapy 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

18. sitagliptin 25 mg/mL oral solution (Brynovin)

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 DoD'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)
- Please 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

19. sulopenem etzadroxil/probenecid (Orlynvah)

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

20. zongertinib (Hernexeos)

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

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF recommendation, PA, 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.
- **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.

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

UF BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended the formulary status for the newly approved drugs as discussed above.

- 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) – Oncological Agents for Non-small Cell Lung Cancer (NSCLC)

- 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
- Completely Excluded
  - bumetanide nasal spray (Enbumyst) – Diuretics
  - escitalopram 15 mg caps (no brand name) – Antidepressants and Non-Opioid Pain Syndrome Agents
  - nitisinone (Harliku) – Miscellaneous Replacement Enzymes for alkaptonuria-associated urine homogentisic acid

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended the PA criteria for the new drugs as stated previously.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended implementation periods as noted above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

P&T Comments

A. 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 produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators 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 tablets (Clemasza)—**This clemastine tablet is less cost-effective than other clemastine tablets that are available in the same strength.

b) **Anticholinergics Antispasmodics—dicyclomine 40 mg tablets—**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 tablets (Lurbiro)—**There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

The Manual PA criteria are as follows:

1. **clemastine 2.68 mg tablets (Clemasza)**

   Manual PA criteria apply to all new users of Clemasza

   Manual PA criteria: Clemasza 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 Clemasza and cannot take the cost-effective 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

PA does not expire

2. dicyclomine 40 mg tablet

The PA criteria are as follows:

Manual PA criteria apply to all new users of dicyclomine 40 mg tabs

Manual PA criteria: dicyclomine 40 mg tablets are 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 tablet sand 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 bisoprolol formulations

Non-FDA approved uses are not approved

PA does not expire

3. flurbiprofen (Lurbiro)

Manual PA criteria apply to all new users of Lurbiro

Manual PA criteria: 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 Lurbiro and cannot take the cost-effective 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 buspirone formulations

Non-FDA approved uses are not approved

PA does not expire

B. New PA Criteria for Drugs Not Subject to 32 CFR 199.21(G)(5) and Implementation Plan

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for clemastine (Clemsza), dicyclomine 40 mg tablet, and flurbiprofen (Lurbiro) in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first

Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

XI. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended manual PA for clemastine (Clemsza), dicyclomine 40 mg tablet, and flurbiprofen (Lurbiro) as stated above; and an effective date the first Wednesday 60 days after signing of the minutes and DHA will send letters to the affected beneficiaries.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

A. Updated PA 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.

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.

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 45kg.

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 GLP-1RAs—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.

B. Updated PA Criteria for New FDA Approved Indications Implementation Plan

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) implementation for the updates to the PA criteria for Alhemo, Doptelet, Ajovy, Opzelura, Otezla, Zejula, Rybelsus, and Empaveli in new users in new users will be effective the first Wednesday 60 days after the signing of the minutes.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria Alhemo, Doptelet, Ajovy, Opzelura, Otezla, Zejula, Rybelsus, and Empaveli in new users due to FDA-approved indications and expanded age ranges. Implementation of the new PA criteria will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

A. Updated PA Criteria for Reasons other than New FDA Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for two drugs. 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.

A. Updated Manual PA Criteria and Implementation Period for Reasons other than New FDA Approved Indications

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.

XV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR REASONS OTHER THAN NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended 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.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

XVI. UTILIZATION MANAGEMENT—REMOVAL OF PA AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (12 for, 6 opposed, 2 abstained, 0 absent) removing the PA for one drug with implementation effective the first Wednesday 2 weeks after signing of the minutes.

Anti-infectives: Anti-Helminthics—ivermectin (Stromectol, generics)—In 2021, PA criteria were added to ivermectin due to increased utilization during the COVID-19 pandemic. MTF providers are now requesting easier access to ivermectin to treat scabies. The PA will be removed for ivermectin to decrease provider administrative burden and delays in therapy.

XVII. UTILIZATION MANAGEMENT—REMOVAL OF PA and IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended removing the PA criteria for ivermectin as outlined above, with implementation effective the first Wednesday two weeks after signing of the minutes.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

XVIII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATIONS ADDITIONS AND REMOVALS AND IMPLEMENTATION PLAN

P&T Comments

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 PA. Accordingly, the Tier 1 (generic) copay for brand Tasigna is recommended.

Removals

- **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.
- **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.
- **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.

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.

XIX. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended the addition of brand over authorized generic criteria for Tasigna, and the removals for Pradaxa capsules, Vyvanse capsules, and Entresto tablets as outlined above, with an implementation of the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***