DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE MAY 2026 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING Day #3 AM - 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—ANTIHEMOPHILIC AGENTS: NON-FACTOR AGENTS SUBCLASS

P&T Comments

A. Antihemophilic Agents: Non-Factor Agents Subclass—Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the Antihemophilic Agents class, Non-Factor Agents subclass. This subclass has not previously been reviewed and consists of four drugs that were previously reviewed as innovators and designated as UF: emicizumab-kxwh (Hemlibra) marstacimab-hncq (Hympavzi), concizumab-mtci (Alhemo), and fitusiran (Qfitlia).

Relative Clinical Effectiveness Conclusion— The following clinical review focuses on non-factor agents for hemophilia A or hemophilia B, with or without inhibitors. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Indications and Mechanisms of Action

- **emicizumab-kxwh (Hemlibra)** is only indicated for hemophilia A with or without inhibitors. It is the only non-factor agent currently approved for use in newborns and young children. As a factor VIIIa mimetic, it mimics the action of factor VIIIa while retaining efficacy even in the presence of factor VIII inhibitors.

- **marstacimab-hncq (Hympavzi)** is indicated for patients 12 years and older with hemophilia A and B without inhibitors. The manufacturer is seeking approval for an expanded indication in patients as young as six years old and in patients with hemophilia A and B with inhibitors. Hympavzi is a monoclonal antibody that antagonizes tissue factor pathway inhibitor (TFPI), which is a primary inhibitor of the extrinsic coagulation cascade.
- **concizumab-mtci (Alhemo)** is indicated for patients 12 years and older with hemophilia A and B with or without inhibitors. Like Hympavzi, it is a TFPI antagonist.
- **fitusiran (Qfitlia)** is also indicated for patients 12 years and older with hemophilia A and B with or without inhibitors, like Alhemo. Unlike the others, it is a non-biologic. Qfitlia is a small interfering RNA molecule that targets and lowers antithrombin.

Efficacy

- There are no published head-to-head trials that directly compare the non-factor agents against each other. Available data analyzed for the clinical review included pivotal trials, systematic reviews, and meta-analyses.
- The Annualized Bleeding Rate (ABR) for treated bleeds was the primary efficacy measure evaluated. The lower the ABR score, the better the outcome, and the optimal ABR is zero, representing zero bleeds. Additionally, quality of life measures including the total Health-related Quality of Life of Adults with Hemophilia questionnaire (Haem-A-QoL) score were evaluated.
- Although indirect efficacy comparisons are difficult due to differences in study design, the FDA-approved dosing of Qfitlia appears to result in slightly higher ABRs than the other non-factor agents in patients with or without inhibitors. More long-term data is needed to confirm if Qfitlia is less efficacious than the other agents.
- One meta-analysis included six trials for Hemlibra, Alhemo, and Qfitlia. Compared to on-demand therapy with factor agents, non-factor prophylaxis significantly decreased ABR and increased quality of life in patients. No significant differences in ABR were noted between Hemlibra, Alhemo, or Qfitlia; however, this analysis was exploratory and included a Qfitlia dose that was higher than the FDA-approved dose.
- Data on Hympavzi was not included in any of the meta-analyses reviewed, but the pivotal Hympavzi trial for patients without inhibitors showed non-inferiority when compared to factor prophylaxis in terms of ABR.

Safety

- Injection site reactions are the most common adverse reaction for all four non-factor agents.

- All four non-factor agents have concerns with hypercoagulability when used concomitantly with clotting factor concentrates or bypassing agents in situations of active bleeds or surgical management.
- Thrombotic events were reported with all four non-factor products in clinical trials. Studies with Alhemo and Qfitlia were paused, and dose modification strategies were required to mitigate this risk.
- Hemlibra has a black box warning for thrombotic microangiopathy and thromboembolism. These complications were observed in patients who received on average a cumulative amount of >100 U/kg/24 hours of activated prothrombin complex concentrate (aPCC) while receiving Hemlibra prophylaxis. Qfitlia has a black box warning for thrombotic events and for acute and recurrent gallbladder disease, with some patients requiring cholecystectomy.
- Hemlibra interferes with partial thromboplastin time (PTT) and PTT-based clinical coagulation assays, artificially normalizing results. Alhemo can increase lab values of fibrin D-dimer and prothrombin fragment 1.2.
- There is more long-term safety data for Hemlibra than there is for Hympavzi, Alhemo, and Qfitlia. Additional long-term safety data is needed to clarify thromboembolic risk with these newer agents.

Other Factors

- Hemlibra is administered every one to four weeks, Hympavzi once weekly, Alhemo once daily, and Qfitlia once every one to two months.
- Hemlibra and Hympavzi do not require routine lab monitoring, while Alhemo requires drug plasma-level lab monitoring and Qfitlia requires regular monitoring of antithrombin activity and liver enzymes.
- Unlike the other non-factor agents which have a pen formulation, Hemlibra is only available in a vial.
- Qfitlia is the only non-factor agent that has an antidote, antithrombin infusion.
- For Hemlibra and Alhemo, there were rare instances of anti-drug antibodies that decreased drug efficacy. In clinical trials, Hympavzi and Qfitlia did not have any anti-drug antibodies that had clinically significant effect on efficacy or safety.
- There is limited data on using Hemlibra concurrently with immune tolerance induction (ITI) therapy and no data for concomitant use of Hympavzi, Alhemo, and Qfitlia with ITI.

Overall Clinical Conclusion

- In terms of efficacy, all four agents have a high degree of therapeutic interchangeability for their approved indications; however, Hemlibra is required on the formulary for the youngest hemophilia patients.

- Based on available safety data, all agents have a moderate degree of therapeutic interchangeability; some uncertainty remains with the rebalancing agents (Hympavzi, Alhemo, and Qfitlia) concerning long-term safety, given lack of data.
- At least one agent is required for each clinical indication (e.g., Hemophilia A with inhibitors, Hemophilia B without inhibitors, etc.) to meet the vast majority of Military Health System (MHS) beneficiary treatment needs.

B. Antihemophilic Agents: Non-Factor Agents Subclass—Relative Cost Effectiveness Conclusion

The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA) and budget impact analysis (BIA). The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) that 1) Hemlibra represents 99% of current use and is the least costly agent overall; 2) given current utilization, it is difficult to predict future use of Hympavzi, Alhemo, and Qfitlia; and 3) for the Hemophilia B without inhibitors indication, Alhemo and Hympavzi are less costly than Qfitlia.

C. Antihemophilic Agents: Non-Factor Agents Subclass—UF Recommendation

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - emicizumab-kxwh (Hemlibra)
  - marstacimab-hncq (Hympavzi)
  - concizumab-mtci (Alhemo)
- NF
  - fitusiran (Qfitlia)
- Complete Exclusion - None

D. Antihemophilic Agents: Non-Factor Agents Subclass—Manual PA Criteria

PA currently applies to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria as discussed below in new users.

- Removing the PA for emicizumab-kxwh (Hemlibra), based on provider input and cost-effectiveness.
- For Alhemo, Hympavzi and Qfitlia, criteria were added to prevent use with immune tolerance induction, due to the lack of supporting data for combination therapy.

- Qfitlia will require step-therapy with Hemlibra for patients with Hemophilia A, and with either Hympavzi or Alhemo for patients with hemophilia B, based on specialist feedback. The step-therapy will apply to new users.

The Manual PA criteria are as follows.

1. concizumab-mtci (Alhemo)

Updates from the May2026 meeting are in bold

Manual PA criteria apply to all new users of Alhemo

Manual PA Criteria: Coverage for Alhemo is approved if:

- Patient is 12 years of age or older
- Prescribed by or in consultation with a hematologist
- Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors
- Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding
- **Medication is not being used in combination with Immune Tolerance Induction (ITI)**

Non-FDA approved uses are not approved

PA does not expire

2. fitusiran (Qfitlia)

Updates from the May2026 meeting are in bold

Manual PA criteria apply to all new users of Qfitlia

Manual PA Criteria: Coverage for Qfitlia is approved if:

- Patient is 12 years of age or older
- Prescribed by or in consultation with a hematologist
- Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors
- Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding
- For hemophilia A, the patient has had an inadequate response, intolerance, or contraindication to emicizumab-kxwh (Hemlibra)

- **For hemophilia B, the patient has had an inadequate response, intolerance, or contraindication to marstacimab-hncq (Hympavzi) or concizumab-mtci (Alhemo)**
- **Medication is not being used in combination with Immune Tolerance Induction (ITI)**

Non-FDA approved uses are not approved

PA does not expire

3. marstacimab-hncq (Hympavzi)

Updates from the May2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Hympavzi

Manual PA Criteria: Coverage for Hympavzi is approved if:

- Patient is 12 years of age or older
- Prescribed by or in consultation with a hematologist
- Patient has ~~**moderate to severe**~~ hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors
- Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding
- **Medication is not being used in combination with Immune Tolerance Induction (ITI)**

Non-FDA approved uses are not approved

PA does not expire

E. Antihemophilic Agents: Non-Factors Agents Subclass—UF recommendation, PA and Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service and 2) DHA send letters to patients affected by the formulary change for Qfitlia.

III. UF DRUG CLASS REVIEW—ANTIHEMOPHILIC AGENTS: NON-FACTOR AGENTS SUBCLASS AGENTS SUBCLASS

UF BAP Comments

A. Antihemophilic Agents: Non-Factor Agents Subclass —UF Recommendation

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

- UF
  - emicizumab-kxwh (Hemlibra)
  - marstacimab-hncq (Hympavzi)
  - concizumab-mtci (Alhemo)
- NF
  - fitusiran (Qfitlia)

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Antihemophilic Agents: Non-Factor Agents Subclass—Manual PA Criteria

The P&T Committee recommended removing the PA criteria for Hemlibra, and updating the PA criteria for Alhemo, Hympavzi and Qfitlia, as outlined above, including the step requirements for Qfitlia.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Antihemophilic Agents: Non-Factor Agents Subclass—Manual PA Criteria —UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 60 days after signing of the minutes in all points of service and DHA send letters to patients affected by the formulary change for Qfitlia.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—LEUKEMIA AND LYMPHOMA AGENTS: BREAKPOINT CLUSTER (BCR)-ABLESON (ABL) TYROSINE KINASE INHIBITORS (TKIS) SUBCLASS

P&T Comments

A. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass—Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the Leukemia and Lymphoma class, BCR-ABL Tyrosine Kinase Inhibitors (TKI) subclass. The class was last reviewed in August 2015 and included the following drugs: imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna), bosutinib tablet (Bosulif), and ponatinib (Iclusig). Since the last class review, new entrants include asciminib (Scemblix), and alternative formulations for nilotinib, dasatinib and imatinib. Imatinib is considered a first generation BCR-ABL TKI; while dasatinib, nilotinib, and bosutinib are considered second generation; asciminib and ponatinib are third generation products. Generic formulations are available for imatinib, bosutinib and nilotinib. The clinical review focused on frontline treatment with these agents for Chronic Myeloid Leukemia.

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

Professional Treatment Guidelines

- The BCR-ABL TKIs are all recommended for the treatment of Chronic Myeloid Leukemia (CML) in the National Comprehensive Cancer Network (NCCN) guidelines.
    - The following agents are preferred with Category 1 recommendation for low-risk Chronic Phase-CML: imatinib, dasatinib, nilotinib, bosutinib, and asciminib.
    - The following agents are preferred with Category 1 recommendation for intermediate or high-risk Chronic Phase-CML: dasatinib, nilotinib, bosutinib, and asciminib. Imatinib is considered an "other recommended treatment" for these risk categories.
    - Ponatinib is a later line therapy for CML, which is recommended after use of two other TKIs or for accelerated or blast phase disease.

Efficacy

- For low, intermediate, and high-risk chronic phase-CML, NCCN categorizes imatinib and asciminib with an efficacy level 4 or "very effective." Dasatinib, nilotinib, bosutinib are ranked with an efficacy level 5 or "highly effective."
- Indirect comparison between agents is challenging due to the varying treatment arms, study designs, and inclusion criteria in the clinical trial data.
- Where available, comparative studies demonstrate that second generation TKIs (dasatinib, nilotinib, bosutinib) and the third generation TKI (asciminib)

demonstrate a more rapid and deeper molecular response for newly diagnosed CML patients, compared to imatinib.

- To date, the newer generation TKIs, compared to imatinib, do not improve overall survival or maintenance of treatment-free remission for frontline treatment of chronic phase-CML.

Safety

- Adverse events that are commonly associated with these agents include gastrointestinal (GI) symptoms, myelosuppression, rash, edema, musculoskeletal pain, and fatigue.
- Similar warnings for all the products include cardiovascular concerns, hepatic toxicity, fetal toxicity, growth failure, and fatigue.
    - Imatinib has fewer cardiovascular warnings compared to other agents.
    - Dasatinib carries a higher risk of pleural effusion.
    - Nilotinib has a black box warning for QT interval prolongation and sudden death.
    - Bosutinib carries a high risk for GI toxicity.
    - Asciminib carries a warning for hypersensitivity reactions.

Other Factors

- Imatinib (Gleevec) is administered once daily. The tablets may be dispersed in water or apple juice for patients with swallowing difficulties. Generic formulations are available. It is approved in children as young as one year of age.
- Imatinib oral solution (Imkeldi) provides an alternative dosage formulation with the same indications as Gleevec. It was approved using bioavailability data, and clinical trials are not available. The labeling includes children as young as 10 months of age.
- Dasatinib is available in two different tablet formulations and is administered once daily without regard to food intake. Both formulations are approved for children.
    - Sprycel was the original dasatinib product and now has generic availability. Drug levels are highly dependent on gastric pH.
    - Phyrago is a branded dasatinib formulation that can be administered with H2 blockers and proton pump inhibitors. It was approved via the 505(b)(2) pathway using data from Sprycel. Absorption is independent of pH, however the mechanism by which this is accomplished is not publicly available.
- Nilotinib monohydrochloride monohydrate (Tasigna) is formulated as a sprinkle cap and is available as a generic. It was the first TKI to include information in the package insert regarding eligibility of certain patients to discontinue treatment after

three years of therapy. Another advantage is approval in the pediatric population. It requires administration on an empty stomach to limit cardiotoxicity.

- Nilotinib tartrate (Danziten) is a branded product that can be administered without mealtime restrictions. No new clinical trials were conducted and it lacks pediatric approval. Danziten has improved bioavailability allowing for a lower dose while achieving similar blood levels as Tasigna.
- Nilotinib d-tartrate (Nilceya) contains the dextro isomer of tartaric acid. It was approved via the 505(b)(2) pathway using data from Tasigna; clinical efficacy trials were not conducted. It does not provide compelling clinical advantages over Tasigna.
- Bosutinib is available under the brand name Bosulif. The tablets must be swallowed whole and are now generic. The capsules may be opened and sprinkled or mixed with applesauce or yogurt. Both formulations are approved for the pediatric population.
- Asciminib (Scemblix) is only available as a tablet administered once daily. It provides a treatment option for later stage CML.
- Ponatinib (Iclusig) is an option for more aggressive (e.g., accelerated phase) CML disease or for those who have failed treatment with two or more TKIs.

Overall Clinical Conclusion

- In terms of clinical effectiveness for reviewed indication, all agents have a high degree of therapeutic interchangeability.
- In terms of safety for reviewed indication, there is a moderate degree of therapeutic interchangeability.
- To meet the needs of the beneficiaries, at least one agent should remain on the formulary.

B. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- Generic imatinib and dasatinib were the most cost-effective TKIs.
- A BIA was performed to evaluate the potential impact of designating selected agents as formulary or non-formulary. BIA results showed that designating all agents as UF except for Danziten and nilotinib d-tartrate capsules (Nilceya) generated cost avoidance for the Military Health System (MHS).

C. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass—UF Recommendation

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

- UF
  - asciminib (Scemblix)
  - bosutinib tablets (Bosulif)
  - bosutinib capsules (Bosulif), *moves from NF to UF*
  - dasatinib (Sprycel, generic)
  - dasatinib (Phyrago), *moves from NF to UF*
  - imatinib (Gleevec, generic)
  - imatinib solution (Imkeldi), *moves from NF to UF*
  - nilotinib monohydrate monochloride (Tasigna, generic)
  - ponatinib (Iclusig)
- NF
  - nilotinib tartrate (Danziten)
- Complete Exclusion – None
  - nilotinib d-tartrate 50, 150, 200 mg capsules (Nilceya new brand name)

D. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass—Manual PA Criteria

PA criteria currently apply to the newer agents, Scemblix, Bosulif capsule, Phyrago, Imkeldi, Danziten, and Nilceya. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria as outlined below, including standardizing the wording regarding labeling, safety and NCCN guideline references. The PA updates will only apply to new users.

- No PA is required for the generic imatinib tablets (Gleevec, generic), dasatinib (Sprycel generic), and nilotinib monohydrate monochloride (Tasigna).
- The current PA for Imkeldi oral solution was updated to include the full list of FDA-approved indications.
- A trial of one generic TKI will now be required for new users of Phyrago, Danziten, Bosulif caps, and Scemblix. Iclusig will now require a PA and will include a trial of two TKIs. An automated lookback for generic imatinib or dasatinib will apply for Phyrago, Bosulif tablets and capsules and Scemblix.
- Although generic formulations of Tasigna are available, they are not cost-effective, and currently the branded Tasigna formulations are required instead of

the generics. The brand over generic PA for Tasigna will be maintained. Tasigna will also be maintained at the Tier 1 copay.

The Manual PA criteria are as follows:

1. **asciminib (Scemblix)**

   Updates from the May 2026 meeting are in bold and strikethrough

   Automated PA Criteria: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days

   Manual PA criteria apply to all new users

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

   - Patient is 18 years of age or older
   - Prescribed by or in consultation with an ~~hematologist/~~oncologist
   - The patient is being treated for the following:
     - Philadelphia chromosome-positive chronic myeloid leukemia ~~in chronic phase~~ and
       - **has tried and failed OR**
       - **had an intolerance to OR**
       - **has a risk stratification (i.e. low, advanced) OR**
       - **has a contraindication (e.g. comorbidity, mutation, concomitant PPI) to at least one generic TKI (i.e. imatinib, dasatinib)**
   - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.

   Non-FDA-approved uses are not approved except as noted above

   Prior authorization does not expire

2. **bosutinib tablets and capsules (Bosulif)**

   Updates from the May 2026 meeting are in bold and strikethrough

   Automated PA Criteria: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days

   Manual PA criteria apply to all new users

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with an ~~hematologist~~/oncologist
- **Patient has Philadelphia chromosome-positive chronic myeloid leukemia and**
  - **has tried and failed OR**
  - **had an intolerance to OR**
  - **has a risk stratification (i.e. low, advanced) OR**
  - **has a contraindication (e.g. comorbidity, mutation, concomitant PPI) to at least one generic TKI (i.e. imatinib, dasatinib)**
- ~~Patient is 1 years of age or older with chronic phase Ph+ chronic myelogenous leukemia, that is either newly diagnosed or resistant or intolerant to prior therapy OR~~
- ~~Patient is 18 years of age or older with accelerated or blast phase Ph+ chronic myeloid leukemia with resistance or intolerance to prior therapy~~
- ~~Patient cannot swallow tablets due to a documented medical condition (e.g. dysphagia)~~
- ~~The provider is aware of all warnings, screening, and monitoring precautions for Bosulif~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.

Non-FDA-approved uses are not approved except as noted above

Prior authorization does not expire

3. dasatinib (Phyrago)

Updates from the May 2026 meeting are in bold and strikethrough

Automated PA Criteria: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days

Manual PA criteria apply to all new users

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with an oncologist
- **Patient is being treated for one of the following:**
  - **Acute lymphoblastic leukemia**

- **Philadelphia chromosome-positive chronic myeloid leukemia and**
  - **has tried and failed OR**
  - **had an intolerance to OR**
  - **has a risk stratification (i.e. low, advanced) OR**
  - **has a contraindication (e.g., comorbidity, mutation, concomitant proton pump inhibitor use) to at least one generic TKI (i.e., imatinib, dasatinib)**

- ~~The patient has one of the following diagnoses:~~
  - ~~Adults 18 years or older with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase~~
  - ~~Adults 18 years or older with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib~~
  - ~~Adults 18 years or older with Ph+ acute lymphoblastic leukemia 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 PPI (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 _____.

Non-FDA-approved uses are not approved except as noted above

Prior authorization does not expire

- ~~PA expires yearly. PA will be renewed for an additional year if : patient has a documented reason to remain on concurrent H2 blockers or PPIs~~

4. Imatinib oral solution (Imkeldi)

Age edit: PA not required if patient is 6 years of age or younger

Manual PA criteria apply to all new users of Imkeldi solution

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

- Provider acknowledges that generic imatinib tablets can be dissolved in water or juice and are available to **TRICARE** beneficiaries without requiring prior authorization
- **Prescribed by or in consultation with an oncologist**
- **The patient is being treated for the following:**
  - **Philadelphia chromosome-positive chronic myeloid leukemia**
  - **Acute Lymphoblastic Leukemia**
  - **Myeloproliferative Disease**
  - **Mastocytosis**
  - **Hypereosinophilic Syndrome**
  - **Chronic Eosinophilic Leukemia**
  - **Dermatofibrosarcoma Protuberans**
  - **Gastrointestinal Stromal Tumor**
- Patient has had an adverse reaction to an excipient in imatinib tablets that is unlikely to occur with Imkeldi **or patient has documented swallowing dysfunction requiring an alternative formulation for treatment**
- ~~Patient has tried and failed treatment with dissolving imatinib tablets in liquid~~
- **The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.**

Non-FDA-approved uses are not approved except as noted above

Prior authorization does not expire

5. nilotinib tartrate (Danziten)

Updates from the May 2026 meeting are in bold and strikethrough

<u>Automated PA Criteria</u>: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days

Manual PA criteria apply to all new users

<u>Manual PA criteria:</u> Coverage is approved if all criteria are met:

- Provider acknowledges there is no PA required with Tasigna
- Prescribed by or in consultation with an ~~**hematologist**~~/oncologist
- Patient is 18 years of age or older
- **Patient has Philadelphia chromosome-positive chronic myeloid leukemia and**
  - **has tried and failed OR**

        - **had an intolerance to OR**
        - **has a risk stratification (i.e. low, advanced) OR**
        - **has a contraindication (e.g., comorbidity, mutation, concomitant proton pump inhibitor use) to at least one generic TKI (i.e., imatinib, dasatinib)**
    - ~~Patient has a diagnosis of:~~
        - ~~Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase~~
        - ~~Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib~~
    - ~~Patient has tried Tasigna and had an adverse reaction not expected to occur with Danziten OR~~
    - ~~Patient cannot avoid food 2 hours before and one hour after taking Tasigna~~
    - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.

    Non-FDA-approved uses are not approved except as noted above

    Prior authorization does not expire

6. **ponatinib (Iclusig)**

    Manual PA criteria apply to all new users

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

    - Prescribed by or in consultation an oncologist
    - The patient is being treated for the following:
        - Acute lymphoblastic leukemia
        - Philadelphia chromosome-positive chronic myeloid leukemia and
            - has tried and failed OR
            - had an intolerance to OR
            - has a risk stratification (i.e. low, advanced) OR
            - has a contraindication (e.g. comorbidity, mutation, concomitant PPI) to at least one generic TKI (i.e. imatinib, dasatinib)
    - The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.

    Non-FDA-approved uses are not approved except as noted above

    Prior authorization does not expire

E. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass —UF recommendation, PA, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service for the products moving to UF, the NF change for Danziten and the PA changes, 2) an effective date of the first Wednesday 120 days after signing of the minutes for the nilotinib d-tartrate (Nilceya) complete exclusion change, and 3) DHA mail letters to patients affected by the NF change for Danziten and the complete exclusion change for Nilceya

V. UF DRUG CLASS REVIEW——LEUKEMIA AND LYMPHOMA AGENTS: BREAKPOINT CLUSTER (BCR)-ABLESON (ABL) TYROSINE KINASE INHIBITORS (TKIS) SUBCLASS

UF BAP Comments

A. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass—UF Recommendation

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

- UF
  - asciminib (Scemblix)
  - bosutinib tablets (Bosulif)
  - bosutinib capsules (Bosulif), *moves from NF to UF*
  - dasatinib (Sprycel, generic)
  - dasatinib (Phyrago), *moves from NF to UF*
  - imatinib (Gleevec, generic)
  - imatinib solution (Imkeldi), *moves from NF to UF*
  - nilotinib monohydrate monochloride (Tasigna, generic)
  - ponatinib (Iclusig)
- NF
  - nilotinib tartrate (Danziten)
- Complete Exclusion – None
  - nilotinib d-tartrate 50, 150, 200 mg capsules (Nilceya new brand name)

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for TKIs as detailed above.

UF BAP Comments

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

C. Leukemia and Lymphoma Agents: BCR-ABL Tyrosine Kinase Inhibitors Subclass —UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended the implementation plan outlined above for the formulary and PA changes, and that DHA will mail letters to the patients affected by the NF change for Danziten and the complete exclusion status change for Nilceya..

UF BAP Comments

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

VI. 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 (18 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - aficamten (Myqorzo) – Miscellaneous Cardiovascular Agent for obstructive hypertrophic cardiomyopathy (HCM)

- copper histidinate injection (Zycubo) – Electrolyte-Mineral-Trace Element for Menkes Disease
- doxecitine /doxribtimine 2 gram packet for oral solution (Kygevvi) – Miscellaneous Metabolic Agent replacement enzyme for thymidine kinase 2 deficiency
- navepegritide powder for injection (Yuviwel) – Growth Stimulating Agent for achondroplasia
- orforglipron (Foundayo) – Metabolic Dysfunction Agents: Weight Loss
- pegzilarginase-nbln injection (Loargys) – Miscellaneous Metabolic Agent for hyperargininemia
- pivmecillinam (Pivya)– Beta Lactam Antibiotic for urinary tract infections

- NF
  - desmopressin acetate 0.05 mg/mL oral solution (Desmoda) – Miscellaneous Endocrine Agent for Diabetes Insipidus
  - etripamil nasal spray (Cardamyst) – Calcium Channel Blocker
  - icotrokinra (Icotyde) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitor for plaque psoriasis
  - lerodalcibep-liga injection (Lerochol) – Antilipidemic-1 Agent; Protein convertase subtilisin/kexin type 9 (PCSK9) inhibitor
  - lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta) – Attention Deficit Hyperactivity Disorder (ADHD) Agent Stimulant
  - methocarbamol 750 mg/5 mL oral suspension (Atmeksi) – Skeletal Muscle Relaxants and Combinations
  - tizanidine 2 mg/5 mL oral solution (Ontralfy) – Skeletal Muscle Relaxants and Combinations
  - tocilizumab-anoh injection syringe (Avtozma) – Targeted Immunomodulatory Biologics (TIBs), Interleukin-6 (IL-6) inhibitor; Actemra biosimilar (Note that the vials are available under the TRICARE Medical benefit)
- Complete Exclusion
  - amlodipine powder for oral solution (Sdamlo) – Calcium Channel Blocking Agents
    - Sdamlo powder for oral solution was recommended for complete exclusion status as it has little to no clinical benefit relative to the other amlodipine formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include amlodipine tablets, amlodipine 1

mg/mL oral suspension (Katerzia) and amlodipine 1 mg/mL oral solution (Norliqva).

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria:

- Applying manual PA criteria to new users of Foundayo, requiring a trial of generic phentermine first, similar to what is in place for the weight loss agents Wegovy and Zepbound.
- Applying manual PA criteria to new and current users of Icotyde, as is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira), ustekinumab-aauz (Otulfi) and ixekizumab (Taltz).
- Applying manual PA criteria to new and current users of Avtozma requiring a trial of the tocilizumab biosimilar Tyenne first, as is currently in place for Actemra.
- Applying temporary PA criteria to new and current users of Sdamlo until implementation of Complete Exclusion status.
- Applying manual PA criteria to new users of Myqorzo. Accordingly, updates were made to the other drug used for HCM, mavacamten (Camzyos); (see the utilization management section).
- Applying manual PA criteria to new users of Arynta, Cardamyst, Lerochol and the specialty drugs Zycubo, Kygevvi, Yuviwel, and Loargys.
- Applying manual PA criteria to Atmeksi, Desmoda, and Ontralfy, requiring a trial of other formulary agents first.
- Applying manual PA criteria to Pivya, similar to what is required for the other antibiotics used to treat urinary tract infections, Orlynvah, and Blujepa.

The Manual PA criteria are as follows:

1. aficamten (Myqorzo)

Manual PA criteria apply to all new users of Myqorzo

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

- Patient is 18 years of age or older
- Drug is prescribed by a cardiologist
- The patient has documented evidence of obstructive hypertrophic cardiomyopathy (HCM)

- Left ventricular outflow tract (LVOT) pressure gradient is greater than or equal to 30 mmHg at rest or greater than or equal to 50 mmHg after the Valsalva maneuver
- The patient has NYHA Class II to III obstructive HCM that is symptomatic (e.g., dyspnea, chest pain, lightheadedness, syncope, fatigue, reduced exercise capacity)
- The patient's left ventricular ejection fraction (LVEF) is greater than or equal to 55%
- Patient has failed therapy with at least one agent from both of the following classes:
  - Beta blockers (non-vasodilating) – propranolol, metoprolol AND
  - Calcium channel blockers (non-dihydropyridine) – verapamil, diltiazem
- Myqorzo will not be used concomitantly with Camzyos

Non-FDA approved uses are not approved

PA expires in 1 year

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be renewed indefinitely if the following applies:

- The patient has responded to therapy, as evidenced by improvement in obstructive hypertrophic cardiomyopathy symptoms

2. amlodipine powder for oral solution (Sdamlo)

Updates from the May 2026 meeting are in bold

Manual PA criteria apply to all new users of Sdamlo

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

- **Provider acknowledges that Sdamlo 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 must document why the patient cannot take amlodipine tablets, amlodipine suspension (Katerzia), or amlodipine solution (Norliqva)
  - Acceptable responses include that the patient requires a long-acting calcium channel blocker and cannot swallow amlodipine tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience AND that they have failed and tried Katerzia AND Norliqva

Non-FDA approved uses are not approved

PA does not expire **until after implementation of complete exclusion status**

3. copper histidinate injection (Zycubo)

Manual PA criteria apply to all new users of Zycubo

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

- Patient is 17 years of age or younger
- Prescribed by a physician who specializes in Menkes Disease treatment
- Patient has a confirmed diagnosis of Menkes Disease with a severe pathogenic variant of the ATP7A gene
- Patient does not have any of the following: mild phenotype, liver or kidney disease, participation in other investigational treatment, any disease which impacts gastrointestinal absorption

Non-FDA approved uses are not approved

PA does not expire

4. desmopressin acetate 0.05 mg/mL oral solution (Desmoda)

Age edit: PA does not apply to patients 6 years of age and younger

Manual PA criteria apply to all new users of Desmoda

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

- Patient has a diagnosis of diabetes insipidus
- Prescription is written by an endocrinologist
- Provider must explain why patient requires desmopressin oral solution and cannot take desmopressin tablets and the DDAVP nasal spray. Acceptable responses include:
  - The patient requires desmopressin oral solution (Desmoda) and cannot swallow desmopressin tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience OR
  - The patient can't administer nasal spray due to severe nasal obstruction or prior nasal surgery

Non-FDA approved uses are not approved

PA does not expire

5. doxecitine / doxribtimine 2 gram packet for oral solution (Kygevvi)

Manual PA criteria apply to all new users of Kygevvi

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

- Prescribed by or in consultation with a neurologist, geneticist, or physician who specializes in metabolic and/or neuromuscular disorders
- Patient has had a genetic test confirming the diagnosis of Thymidine Kinase 2 Deficiency (TK2d) with biallelic pathogenic or likely pathogenic variants in the TK2 gene
- Patient had symptom onset consistent with Thymidine Kinase 2 Deficiency (TK2d) at 12 years of age or less

Non-FDA-approved uses are not approved.

Prior authorization does not expire

6. etripamil nasal spray (Cardamyst)

Manual PA criteria apply to all new users of Cardamyst

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 cardiologist or electrophysiologist.
- Patient has ECG documentation of previous episodes of paroxysmal supraventricular tachycardia (PSVT)
- Previous PSVT episodes have lasted 20 minutes or longer
- Patient has experienced at least one episode of PSVT that required hospitalization or ER visit in the past 12 months
- Patient is currently receiving oral pharmacological therapy for prevention of PSVT
- Patient has declined ablation or is not a candidate for ablation based on disease or other medical considerations OR
  - Patient has post-ablation PSVT
  - The patient is aware of the safety and effectiveness of ablation as the preferred therapy
- The patient has been educated on the use of vagal maneuvers in PSVT and self-administration of etripamil (Cardamyst)

Non-FDA approved uses are not approved as noted above

PA expires in 1 year

Renewal criteria: Note that initial TRICARE coverage is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- The patient has responded to therapy and is complying with the administration instructions.

7. icotrokinra (Icotyde)

Manual PA criteria apply to all new users of Icotyde

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

- Provider acknowledges that adalimumab is TRICARE's preferred biologic product
  - Patient had an inadequate response to adalimumab or the patient experienced an adverse reaction to adalimumab that is not expected to occur with icotrokinra or the patient has a contraindication to adalimumab
- Provider acknowledges that ustekinumab-aauz (Otulfi) is TRICARE's preferred IL-23 product
  - Patient had an inadequate response to ustekinumab or the patient experienced an adverse reaction to ustekinumab that is not expected to occur with icotrokinra or the patient has a contraindication to ustekinumab
- Provider acknowledges that a trial of ixekizumab (Taltz) is required
  - Patient had an inadequate response to ixekizumab or the patient experienced an adverse reaction to ixekizumab that is not expected to occur with icotrokinra (Icotyde) or the patient has a contraindication to ixekizumab
- Patient is 12 years of age or older
- Patient has moderate to severe plaque psoriasis and is a candidate for phototherapy or systemic therapy
- Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL_36, JAK inhibitors

Non-FDA approved uses are not approved

PA expires in 1 year

Renewal criteria: Note initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:

- The patient has responded to therapy and
- Patient will not be receiving any other targeted immunomodulatory biologics concurrently

8. lerodalcibep-liga injection (Lerochol)

Manual PA criteria apply to all new users of Lerochol

Manual PA criteria: Coverage is approved if all criteria are not met

- Patient tried and failed therapy or experienced a significant adverse reaction with evolocumab (Repatha)
- Patient is 18 years of age or older

For HeFH

- The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses
- Patient experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms while on statin therapy OR
- Patient has undergone at least 2 trials of statin rechallenges with reappearance of muscle symptoms OR
- Patient has had a creatine kinase level greater than 10 times the upper limit of normal OR rhabdomyolysis with CK greater than 10,000 international units per liter (IU/L) that is unrelated to statin use OR
- Patient has a contraindication to a statin
- Prescribed dosage is documented as 300 mg once monthly

For ASCVD

- Patient will be on concurrent statin therapy at maximal tolerated dose while on the requested medication OR
- Patient experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms while on statin therapy OR
- Patient has undergone at least 2 trials of statin rechallenges with reappearance of muscle symptoms OR
- Patient has had a creatine kinase level greater than 10 times the upper limit of normal OR rhabdomyolysis with CK greater than 10,000 international units per liter (IU/L) that is unrelated to statin use OR
- Patient has contraindication to a statin
- Patient is at very high risk for future ASCVD events AND patient has LDL level greater than 55 mg/dL despite statin at maximal tolerated doses OR
- Patient is not very high risk for future ASCVD events AND has an LDL greater than 70 mg/dL despite statin at maximal tolerated doses
- Patient tried EITHER atorvastatin (Lipitor) at a dose of 40 mg to 80 mg OR rosuvastatin (Crestor) at a dose of 20 mg to 40 mg for at least 4 to 6 weeks each OR
- Patient tried any statin at a maximally tolerated dose in combination with ezetimibe (Zetia) for at least 4 to 6 weeks OR
- Patient tried ezetimibe (Zetia) as monotherapy (alone) for at least 4 to 6 weeks
- Prescribed dosage is documented as 300 mg once monthly

For patients at high risk for ASCVD

- Patient has LDL level greater than 190 mg/dL OR
- Patient has diabetes and LDL level less than 190 mg/dL OR
- Patient has LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD greater than 7.5% OR
- Patient has LDL level less than 190 mg/dL and evidence of significant subclinical atherosclerosis defined as: Significant atherosclerotic plaque observed in an asymptomatic patient on any of the following diagnostic studies: coronary artery calcification noted on computed tomography (CT) studies, including calcium scoring, cardiac CT coronary angiography, chest CT for ruling out pulmonary embolism, chest CT for lung cancer screening, or diagnostic chest CT; carotid plaque noted on carotid ultrasound or angiography; or abnormal ankle-brachial index or plaque noted on peripheral arterial angiography
- Patient tried EITHER atorvastatin (Lipitor) at a dose of 40 mg to 80 mg OR rosuvastatin (Crestor) at a dose of 20 mg to 40 mg for at least 4 to 6 weeks each OR
- Patient tried any statin at a maximally tolerated dose in combination with ezetimibe (Zetia) for at least 4 to 6 weeks OR
- If patient statin intolerant has tried ezetimibe (Zetia) as monotherapy (alone) for at least 4 to 6 weeks
- Prescribed dosage is documented as 300 mg once monthly

For all indications

- Patient is not pregnant or breastfeeding— applies to all indications

Non-FDA approved uses are not approved

PA does not expire

9. lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)

Manual PA criteria apply to all new users of Arynta

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

- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient is 6 years of age or older
- Patient tried and failed mixed amphetamine salts ER (Adderall XR, generics) or another long-acting amphetamine or amphetamine derivative type drug
- Patient tried and failed methylphenidate OROS (Concerta, generics) or another long-acting methylphenidate or methylphenidate derivative type drug
- Provider must document why the patient cannot take lisdexamfetamine dimesylate capsules or chewable tablets

- Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in lisdexamfetamine dimesylate capsules; OR the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

OR

- Patient has a diagnosis of moderate to severe Binge Eating Disorder (BED)
- Patient is 18 years of age or older
- Patient tried and failed OR has a contraindication to an SSRI (for example, citalopram, fluoxetine, sertraline)
- Patient tried and failed OR has a contraindication to topiramate or zonisamide
- Provider must document why the patient cannot take lisdexamfetamine dimesylate capsules or chewable tablets.
  - Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in lisdexamfetamine dimesylate capsules; OR the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

10. methocarbamol 750 mg/5 mL oral suspension (Atmeksi)

Manual PA criteria apply to all new users of Atmeksi

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

- Patient is 16 years of age or older
- Provider must document why the patient cannot take methocarbamol tablets.
  - Acceptable responses include: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

11. navepegritide powder for injection (Yuviwel)

Manual PA criteria apply to all new users of Yuviwel

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

- Patient is 2 years of age or older
- Prescribed by or in consultation with a pediatric endocrinologist

- Patient has a documented diagnosis of achondroplasia with open epiphyses
- Provider acknowledges that Yuviwel was FDA approved in accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials AND provider acknowledges that a clinical benefit with Yuviwel has not been proven
- Patient/caregiver has been instructed on how to properly use, store, and administer Yuviwel
- Provider agrees to monitor growth and adjust dose according to body weight
- Provider agrees to permanently discontinue Yuviwel upon closure of epiphyses

Non-FDA-approved uses are not approved

PA expires in 1 year

12. orforglipron (Foundayo)

Manual PA criteria apply to all new users of Foundayo

Manual PA Criteria: Coverage for is approved if:

- The provider will acknowledge that "Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge"
- Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan?
  - If yes, subject to verification, proceed to the next question
  - If no, coverage is not approved
- What TRICARE Plan is the patient enrolled in?
  - TRICARE Select – proceed to the next question
  - TRICARE Prime – proceed to the next questions
  - TRICARE For Life- Coverage is not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.
- If the diagnosis is Diabetes Mellitus and the patient meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.
- The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged

throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested.

- The provider will document the major condition and comorbidities treated selecting all that apply:
  - Obesity
  - Diabetes or impaired glucose tolerance
  - Obstructive sleep apnea
  - Osteoarthritis
  - Metabolic syndrome
  - Dyslipidemia
  - Hypertension
  - Metabolic dysfunction-associated steatohepatitis (MASH)
  - Established cardiovascular disease with a history of stroke
  - Established cardiovascular disease with a history of myocardial infarction
  - Established cardiovascular disease with a history of peripheral artery disease
- Patient is 18 years of age or older
- Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity
- The provider will document the BMI
  - For BMI less than 27, coverage is not approved
  - For BMI ranging between 27 and 29 with a comorbidity
  - For BMI ranging between 30 to 34
  - For BMI ranging between 35 to 39
  - For BMI greater than or equal to 40
- Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response
  - Phentermine: Date_____ Duration of therapy _____
  OR
- Patient has achieved greater than equal to 5 percent weight loss from baseline while on phentermine, benzphetamine, diethylpropion IR/SR or phendimetrazine IR/SR but BMI and central adiposity remain high, and further reduction is needed to attain optimal outcomes

- The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, ~~uncontrolled hypertension~~ or a patient not meeting blood pressure goal on 2 or more antihypertensives) OR
- The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Foundayo

For all patients

- Concomitant use of this medication with another GLP1-RA is not allowed (e.g., exenatide, Trulicity, 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. Foundayo 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.
- 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

13. pegzilarginase-nbln injection (Loargys)

Manual PA criteria apply to all new users of Loargys

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

- Patient is 2 years of age or older
- Medication is prescribed by or in consultation with a neurologist or metabolic disease specialist
- Patient has a confirmed diagnosis of Arginase 1 Deficiency (ARG1-D)
- Patient has a plasma arginine level greater than or equal to 250 µmol/L
- Patient will continue a protein-restricted diet in conjunction with Loargys
- Provider has educated the patient or caregiver to recognize and treat anaphylaxis appropriately
- Patient will receive Loargys administration at home under the supervision of a healthcare provider

Non-FDA approved uses are not approved

PA does not expire

14. pivmecillinam (Pivya)

Manual PA criteria apply to all new users of Pivya

Automated PA Criteria: When prescribed by a urologist, urogynecologist, or infectious disease physician, 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 a female 18 years of age or older
- Patient has an uncomplicated urinary tract infection (uUTI) due to *Escherichia coli, Proteus mirabilis, Klebsiella spp, Enterobacter spp, Citrobacter spp or Staphylococcus saprophyticus*
- Patient has a contraindication to or has a culture-proven resistance to all routine oral antibiotic treatment options (i.e., nitrofurantoin, sulfamethoxazole/trimethoprim, amoxicillin/clavulanate, cephalexin, fosfomycin, or fluoroquinolone)
- Patient has no known history of carnitine deficiency or porphyria

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

15. tizanidine 2 mg/5 mL oral solution (Ontralfy)

Manual PA criteria apply to all new users of Ontralfy

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

- Provider acknowledges that tizanidine tablets and other formulary muscle relaxants are available without the need of a prior authorization
- Provider must explain why the patient requires tizanidine oral solution and cannot take tizanidine tablets or one of the other cost-effective formulary alternatives.
  - Acceptable responses include: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

16. tocilizumab-anoh injection (Avtozma)

Manual PA criteria apply to all new and current users of tocilizumab (Actemra) and Avtozma

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

- Provider acknowledges the TRICARE benefit requires a trial of Humira. Has the patient tried Humira? (Note: Applies to RA and pJIA)
  - Patient had inadequate response OR experienced an adverse reaction OR has a contraindication to Humira
- Provider acknowledges the TRICARE's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. Has the patient tried Tyenne? (Note: Applies to all indications)
  - Patient had inadequate response OR experienced an adverse reaction OR has a contraindication to Tyenne
- Patient has:
  - Moderate to severely active RA and has had an inadequate response to at least 1 or more DMARDs
  - Active polyarticular Juvenile Idiopathic Arthritis (pJIA)
  - Giant cell arteritis
  - Systemic sclerosis-associated lung disease
  - Systemic Juvenile Idiopathic Arthritis (sJIA)
- Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL_36, JAK inhibitors

Non-FDA approved uses are not approved

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 (18 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:

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

VII. 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
  - aficamten (Myqorzo)
  - copper histidinate injection (Zycubo)
  - doxecitine /doxribtimine 2 gram packet for oral solution (Kygevvi)
  - navepegritide powder for injection (Yuviwel)
  - orforglipron (Foundayo)
  - pegzilarginase-nbln injection (Loargys)
  - pivmecillinam (Pivya)
- NF
  - desmopressin acetate 0.05 mg/mL oral solution (Desmoda)
  - etripamil nasal spray (Cardamyst)
  - icotrokinra (Icotyde)
  - lerodalcibep-liga injection (Lerochol)
  - lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)
  - methocarbamol 750 mg/5 mL oral suspension (Atmeksi)
  - tizanidine 2 mg/5 mL oral solution (Ontralfy)
  - tocilizumab-anoh injection syringe (Avtozma)
- Complete Exclusion

- amlodipine powder for oral solution (Sdamlo)

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:

VIII. 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 seven 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. All of the below PAs will require a provider to write-in clinical rationale explaining the need for the medication.

a) **Antihistamine-1: Second Generation and Combinations—desloratadine solution**—Desloratadine solution was previously available on the market before it was

discontinued by its manufacturer for business reasons. It has now been brought back to the market and is NF. Compared to other antihistamines, including alternate dosage forms, this desloratadine solution is not cost-effective.

b) **Corticosteroids-Immune Modulators: Low Potency—hydrocortisone rectal suppository (Anusol HC, Proctocort)—**These hydrocortisone rectal suppositories are much less cost-effective than other hydrocortisone rectal suppositories available in the same strengths.

c) **Diabetes Non-Insulin: Biguanides—metformin 625 mg IR tablet**—Numerous other metformin IR (500 mg and 850 mg) and ER (750 mg and 1000 mg) formulations are more cost-effective than this 625 mg IR formulation. This drug will be added to the same PA as other non-cost-effective metformin 625 mg formulations.

d) **Histamine 2 (H2) Blockers and Other Antiulcer Agents—ranitidine—**In April 2020, the FDA requested removal of all ranitidine products from the market due to N-nitrosodimethylamine (NDMA) contamination. In November 2025, the FDA approved a reformulated ranitidine tablet that addressed the previous NDMA concern. This reformulated ranitidine is much less cost-effective than all other H2-blockers.

e) **Pain: Non-Steroidal Anti-inflammatory Drugs (NSAIDs)**

   i. **ibuprofen 300 mg tablet**—Ibuprofen is available in a variety of strengths and formulations including 200 mg and 400 mg tablets. There are numerous other more cost-effective NSAIDs on the formulary that can meet the needs of the beneficiaries.

   ii. **ketoprofen (Orudis) 75 mg capsule**—Numerous other more cost effective NSAIDs are available including ketoprofen 50 mg capsule

f) **Skeletal Muscle Relaxants and Combinations—tizanidine 8 mg capsule—**This tizanidine 8 mg capsule made by a sole manufacturer is less cost-effective than tizanidine 2 mg and 4 mg tablets. This drug will be added to the same PA as other non-cost-effective tizanidine capsule formulations.

The Manual PA criteria are as follows:

1. desloratadine solution

Manual PA criteria apply to all new and current users of desloratadine

Manual PA criteria: desloratadine solution is approved if all criteria are met:

- Provider is aware and acknowledges that other formulations of antihistamines are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.
- Provider must explain why the patient requires desloratadine solution and cannot take the cost-effective 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 desloratadine tablet, loratadine solution, and levocetirizine solution

Non-FDA approved uses are not approved

PA does not expire

2. hydrocortisone rectal suppository (Anusol HC, Proctocort)

Manual PA criteria apply to all new and current users of hydrocortisone rectal suppositories

Manual PA criteria: hydrocortisone rectal suppository is approved if all criteria are met:

- Provider is aware and acknowledges that other formulations are hydrocortisone rectal suppository are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.
- Provider must explain why the patient requires hydrocortisone rectal suppository and cannot take the cost-effective alternatives
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available hydrocortisone rectal suppositories

Non-FDA approved uses are not approved

PA does not expire

3. metformin 625 mg IR tablet

Manual PA criteria apply to all new and current users of metformin 625 mg IR tablets

Manual PA criteria: metformin 625 mg IR tablet is approved if all criteria are met:

- Provider acknowledges other metformin formulations, including the 500 mg and 850 mg immediate release tablets, and 750 mg and 1000 mg extended release tablets are available without requiring prior authorization.
- The provider must explain why the patient can't take a different metformin formulation. (blank write-in)
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin tablets

Non-FDA approved uses are not approved

PA does not expire

4. ranitidine

Manual PA criteria apply to all new and current users of ranitidine

Manual PA criteria: ranitidine approved if all criteria are met:

- Provider acknowledges other formulations of H2 blockers are available to TRICARE beneficiaries without prior authorization. Providers are encouraged to consider changing the prescription to one of these products.
- Provider must explain why the patient requires ranitidine and cannot take the cost-effective H2 blocker 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 cimetidine, famotidine, and nizatidine

Non-FDA approved uses are not approved

PA does not expire

5. ibuprofen 300 mg

Manual PA criteria apply to all new and current users of ibuprofen 300 mg tablets

Manual PA criteria: ibuprofen 300 mg tablet is approved if all criteria are met:

- Provider acknowledges other formulations of ibuprofen and other NSAIDs are available to TRICARE beneficiaries without prior authorization. Providers are encouraged to consider changing the prescription to one of these products.
- Provider must explain why the patient requires ibuprofen 300 mg tablets and cannot take the cost-effective alternatives
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available ibuprofen tablets

Non-FDA approved uses are not approved

PA does not expire

6. ketoprofen 75 mg (Orudis) capsules

Manual PA criteria apply to all new and current users of ketoprofen 75 mg capsules

Manual PA criteria: ketoprofen 75 mg capsules are approved if all criteria are met:

- Provider acknowledges other formulations of ketoprofen and other NSAIDs are available to TRICARE beneficiaries without prior authorization. Providers are encouraged to consider changing the prescription to one of these products.
- Provider must explain why the patient requires ketoprofen 75 mg capsules and cannot take the cost-effective alternatives
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available ketoprofen capsules

Non-FDA approved uses are not approved

PA does not expire

7. tizanidine 8 mg capsule

Manual PA criteria apply to all new and current users of tizanidine 8 mg capsules

Manual PA criteria: tizanidine 8 mg capsules are approved if all criteria are met:

- Provider acknowledges that tizanidine tablets and other formulary muscle relaxants are available to TRICARE beneficiaries without prior authorization. Providers are encouraged to consider changing the prescription to another formulary muscle relaxant.
- Provider must explain why the patient requires tizanidine 8 mg capsules and cannot take the cost-effective alternatives
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tizanidine tablets

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 (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for ibuprofen 300 mg, metformin IR 625 mg, tizanidine 8 mg, ketoprofen 75 mg, ranitidine, desloratadine 0.5 mg/mL solution, and hydrocortisone rectal suppositories in new and current users, due to the significant cost differences compared with other available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

IX. 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 criteria for ibuprofen 300 mg, metformin IR 625 mg, tizanidine 8 mg, ketoprofen 75 mg, ranitidine, desloratadine 0.5 mg/mL solution, and hydrocortisone rectal suppositories 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:

X. UTILIZATION MANAGEMENT—NEW PA CRITERIA

P&T Comments

A. New PA Criteria

The P&T Committee recommended new PA criteria for several drugs.

a) **New PA criteria for drugs approved under New Drug Applications (NDA) pathways:** The P&T Committee reviewed two medications that contain active ingredients widely found in cost-effective generic formulations. These two products were approved via the NDA pathway, but do not have proprietary names. The drugs will default to UF status, with the PA criteria detailed below. New and current users will be affected.

   i. **Skeletal Muscle Relaxants and Combinations—metaxalone 640 mg tablet—**This formulation of metaxalone is less cost-effective than alternatives including metaxalone 400 mg and 800 mg. Additionally, there are many other more cost-effective muscle relaxants on the formulary. The P&T committee recommended a write-in PA for new and current users of metaxalone 640 mg tablets. Providers must explain why the patient requires this drug and cannot take cost effective alternatives.

   ii. **Beta Blockers and hydrochlorothiazide (HCTZ) Combinations—metoprolol tartrate 12.5 mg IR tablet—**This formulation of metoprolol is less cost-effective than other versions of metoprolol. Of note, metoprolol tartrate 25 mg IR tablets can be split, and many are available pre-scored. Cardiologist feedback supported addition of a write-in PA for new and current

users of metoprolol tartrate 12.5 mg IR tablets. Providers must explain why the patient requires this drug and cannot take cost effective alternatives.

b) **Gastrointestinal-2 Agents—sodium phenylbutyrate packets for oral suspension (Olpruva), sodium phenylbutyrate oral pellets (Pheburane), and glycerol phenylbutyrate oral liquid (Ravicti)**—Olpruva, Pheburane, Ravicti, and generic sodium phenylbutyrate powder and tablets are approved for treating urea cycle disorders in combination with dietary management. They are all designated as UF.

Olpruva recently gained an expanded age indication, which prompted a review of whether PA should apply to these drugs. Generic sodium phenylbutyrate is the most cost-effective agent but has been associated with poor palatability. Olpruva, Pheburane, and Ravicti are formulated to either mask the unpleasant taste or are tasteless or odorless. In addition, Ravicti is available as a preparation without sodium content for those who require sodium restriction.

Many commercial plans require PA for these products. Provider outreach determined it was reasonable to require a trial of generic sodium phenylbutyrate first in most patients. The P&T committee recommended PA criteria in new users for Olpruva, Pheburane, and Ravicti, restricting use to the FDA-approved indication, requiring specialist prescribing, and a trial of generic sodium phenylbutyrate. Additionally, the PA allows patients with dietary sodium restrictions access to Ravicti. Generic sodium phenylbutyrate will continue to be available without a PA. Olpruva, Pheburane, and Ravicti will be added to the Rapid Response/Safety Net Program.

The Manual PA criteria are as follows:

1. **sodium phenylbutyrate (Olpruva, Pheburane)**

Manual PA criteria apply to all new users of sodium phenylbutyrate packets for oral suspension (Olpruva) and sodium phenylbutyrate oral pellets (Pheburane).

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

- Provider acknowledges that generic sodium phenylbutyrate powder is available at the lowest copay and doesn't require a PA and can be mixed with liquids and/or specialized formula and common soft foods to improve taste
- Patient has a diagnosis of urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) confirmed through genetic, biochemical or enzymatic test
- Patient has inadequate response to dietary interventions AND will continue to manage the urea cycle disorder with dietary measures, including protein restriction and/or amino acid supplementation
- Provider acknowledges Olpruva and Pheburane can’t be administered through a feeding tube
- Prescription is written by a specialist in diagnosing and treating urea cycle disorders

- The patient has tried and failed or has a contraindication to sodium phenylbutyrate powder OR
- Patient is unable to tolerate sodium phenylbutyrate powder due to excessive nausea/vomiting or allergy to its inactive ingredients OR
- Patient is under 18 and cannot tolerate it due to palatability despite mixing with other foods to mask its taste

Non-FDA approved uses are not approved

PA does not expire

2. glycerol phenylbutyrate oral liquid (Ravicti)

Manual PA criteria apply to all new users of glycerol phenylbutyrate oral solution (Ravicti)

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

- Provider acknowledges that generic sodium phenylbutyrate powder is available at the lowest copay and doesn't require a PA and can be mixed with liquids and/or specialized formula and common soft foods to improve taste
- Patient has a diagnosis of urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) confirmed through genetic, biochemical or enzymatic test
- Patient has inadequate response to dietary interventions AND will continue to manage the urea cycle disorder with dietary measures, including protein restriction and/or amino acid supplementation
- Ravicti will not be used concomitantly with any sodium phenylbutyrate products (i.e. powders, tablets, or pellets)
- Prescription is written by a specialist in diagnosing and treating urea cycle disorders
- The patient has tried and failed or has a contraindication to generic sodium phenylbutyrate Pheburane or Olpruva OR
- Patient has experienced one or more of the following adverse effects: intolerance to inactive ingredients in generic sodium phenylbutyrate, Pheburane and Olpruva, vomiting or severe nausea limiting adherence, edema due to sodium content, or worsening CHF or kidney function OR
- Patient has a diagnosis of CHF, severe renal insufficiency, or sodium retention accompanied by edema, requiring low sodium version product

Non-FDA approved uses are not approved

PA does not expire

c) **Pulmonary-1 Agents: Short-acting Beta Agonists—budesonide/albuterol (Airsupra)**—Airsupra is a metered dose inhaler containing budesonide, an inhaled corticosteroid (ICS), and albuterol, a short-acting beta agonist (SABA). It is approved as an as-needed rescue inhaler to treat or prevent asthma symptoms. At the November 2023 P&T meeting, the committee reviewed Airsupra as an innovator drug and it was designated with NF status at the November 2023 P&T Committee meeting. Increasing utilization and spend have been noted, prompting a rereview for addition of a PA.

In the 2025 Global Initiative for Asthma guidelines, ICS-formoterol is listed as the preferred reliever therapy, and ICS-SABA or SABA alone are listed as alternative options. MHS specialist feedback relayed that generic budesonide/formoterol (Symbicort) is used first-line, and Airsupra has a limited role. The VA and several commercial health plans require a PA for Airsupra. Airsupra is significantly less cost-effective than budesonide and albuterol taken as separate inhalers and generic ICS-formoterol combination product Symbicort.

For the reasons above, PA criteria were recommended, restricting Airsupra use to the FDA-approved indication and requiring a trial of or contraindication to other inhalers.

The Manual PA criteria are as follows:

budesonide/albuterol (Airsupra)

Manual PA criteria apply to all new users of Airsupra

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

- Provider acknowledges that generic budesonide/formoterol is available at the lowest copay and does not require a PA
- Patient is 18 years of age or older
- Patient has a diagnosis of asthma
- Patient has tried and failed rescue use of ICS/formoterol or albuterol plus a separate ICS OR
- Patient has been receiving a medium to high-dose inhaled ICS/LABA or ICS with LAMA for at least 3 months using spacer and appropriate technique and has demonstrated inadequate symptom control with frequent exacerbations and/or night-time awakenings OR
- Patient has a documented allergic reaction (e.g., anaphylaxis) to formoterol

Non-FDA approved uses are not approved

PA does not expire

B. New PA Criteria Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for metaxalone 640 mg and metoprolol tartrate 12.5 mg IR tablet in new and

current users, and Airsupra, Olpruva, Pheburane, and Ravicti in new users, due to provider feedback, clinical guidelines, and the significant cost differences compared with generic alternatives. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes. DHA will mail letters to the patients affected by the new PA requirements for metaxalone 640 mg and metoprolol tartrate 12.5 mg IR.

XI. UTILIZATION MANAGEMENT—NEW PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria metaxalone 640 mg and metoprolol tartrate 12.5 mg IR tablet in new and current users, and Airsupra, Olpruva, Pheburane, and Ravicti in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. DHA will mail letters to the patients affected by the new PA requirements for metaxalone 640 mg and metoprolol tartrate 12.5 mg IR.

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 (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Antibiotics—gepotidacin (Blujepa)--**The manual PA criteria for Blujepa were updated to include its use in the treatment of *Neisseria gonorrhoeae* in patients 12 years of age or older who have limited or no alternative options.

b) **Atopy: IL-13, IL-31—dupilumab (Dupixent)—**The manual PA criteria for Dupixent were updated to allow for the new indication of allergic fungal rhinosinusitis in patients six years of age or older. The updated PA criteria require specialist prescribing and a trial of other therapies.

c) **Breast Cancer Agents: PARP Inhibitors—rucaparib (Rubraca)—**The P&T committee recommended updates to the Rubraca PA to allow for earlier treatment of prostate cancer based on the latest FDA label. Rubraca is now indicated for the

treatment of metastatic castration-resistant prostate cancer (mCRPC) associated with a deleterious BRCA mutation (germline and/or somatic) in adults who have been treated with androgen receptor-directed therapy. Additionally, oncology standardization edits were incorporated.

d) **Electrolyte-Mineral-Trace Element Replacement—ferric maltol (Accrufer)—** The manual PA criteria for Accrufer were updated to allow use in patients 10 years of age and older. Previously, Accrufer had only been approved for use in adults.

e) **Gynecological Agents Miscellaneous—flibanserin (Addyi)—**The FDA updated the Addyi label to include postmenopausal women less than 65 years old. Previously, Addyi was only approved in premenopausal women for hypoactive sexual desire disorder. The manual PA criteria were updated accordingly.

f) **Lung Cancer: HER2+—zongertinib (Hernexeos)—**Hernexeos is now indicated for treatment naïve patients who have non-squamous metastatic non-small cell lung cancer (mNSCLC) with a HER2 (ERBB2) mutation in the tyrosine kinase domain. The P&T committee recommended updates to the manual PA criteria to remove the requirement for prior systemic therapy.

g) **Metabolic Agents Miscellaneous—pegvaliase-pqpz (Palynziq)—**The manual PA criteria for Palynziq were updated to allow for the expanded age indication for phenylketonuria to include pediatric patients 12 to 17 years of age. Additionally, the renewal criteria were updated to align with other agents in the class.

h) **Oncological Agents—niraparib/abiraterone acetate (Akeega)—**The manual PA criteria for Akeega were updated to include a new indication for the treatment of deleterious or suspected deleterious BRCA2-mutated (BRCA2m) metastatic castration-sensitive prostate cancer (mCSPC) in adults. In addition, oncology standardization edits were incorporated (i.e., revising the NCCN question and removing safety questions).

i) **Targeted Immunomodulatory Biologics (TIBs)—deucravacitinib (Sotyktu)—** Sotyktu received a new indication for the treatment of adults with active psoriatic arthritis. This new indication was added to the PA, and step-therapy for all indications were edited to require a trial of ustekinumab and to require Taltz instead of Cosentyx. The MN criteria were also updated.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the PA updates for Blujepa, Dupixent, Rubraca, Accufer, Addyi, Hernexeos, Palynziq, Akeega and Sotyktu. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after 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 the PA updates for Blujepa, Dupixent, Rubraca, Accufer, Addyi, Hernexeos, Palynziq, Akeega and Sotyktu. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—UPDATED PA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes, while the PA removal for pirfenidone will be effective the first Wednesday 2 weeks after signing of the minutes.

a) **Endocrine Agents Miscellaneous—octreotide (Mycapssa)—**Mycapssa is an oral formulation of octreotide that is currently designated as NF with a PA. An MTF endocrinologist requested an update to the Mycapssa PA which currently requires a trial and failure of injectable octreotide. This requirement does not match the FDA labeling or available clinical trials and guidelines which state that oral octreotide should only be considered if a patient has had an adequate response to injectable octreotide. This question on the PA was updated, and an additional blank write in question was added requiring the provider to document the clinical rational for why the patient could not remain on injectable octreotide.

b) **Hematological Agents—avacopan (Tavneos)—**The FDA released a safety alert on Tavneos due to concerns regarding serious drug-induced liver injuries, some fatal, and vanishing bile duct syndrome. This warning language was added to the Tavneos PA. The P&T committee will continue to follow for any future FDA actions.

c) **Miscellaneous Cardiovascular Agents for obstructive hypertrophic cardiomyopathy (HCM)—mavacamten (Camzyos)—**The manual PA criteria was updated due to the recent approval of aficamten (Myqorzo), (see new drugs

section). The PA was updated to include the prohibition of concomitant use with Myqorzo, and to remove some of the safety criteria.

d) Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis and Progressive Pulmonary Fibrosis

Several changes were made to the PAs for the drugs approved for treating idiopathic pulmonary fibrosis, including pirfenidone (Esbriet), nintedanib (Ofev) and nerandomilast (Jascayd). There is step-therapy in the class, where a trial of generic Esbriet is required first. The details are discussed below, with new users affected.

1) **PA update for nerandomilast (Jascayd)—**Jascayd received a new indication for progressive pulmonary fibrosis (PPF) in adults. The P&T committee recommended allowing this indication and requiring step therapy with nintedanib (Ofev) first, based on current guidelines.

2) **PA update for nintedanib (Ofev)—**Ofev is approved for treating idiopathic pulmonary fibrosis, along with Esbriet and Jascayd. The renewal criteria for Ofev were updated to align with the renewal criteria for Jascayd. Additionally, concurrent use of Esbriet and Ofev will now be allowed, based on clinical trial data.

3) **PA removal for pirfenidone (Esbriet)—**Currently, pirfenidone is designated as UF requiring a PA. It is available as a generic and is more cost effective than other agents used for idiopathic pulmonary fibrosis. For these reasons, it was recommended for PA removal.

e) TIBs: Tumor Necrosis Factor Inhibitors—etanercept (Enbrel)—The current step-therapy requirements for Enbrel were adjusted to include the preferred formulary alternatives (i.e., Humira, ustekinumab and Taltz) for all adult and pediatric indications, as appropriate. Currently Enbrel only requires step-therapy with Humira in adults and with ustekinumab for pediatric plaque psoriasis.

f) TIBs: IL-1, IL-6, CTLA-4—anakinra (Kineret)—An MTF rheumatologist requested that the P&T committee consider adding the off-label indications of gout and pseudogout to the Kineret PA. This recommendation was supported by the American College of Rheumatology 2020 Gout guidelines, which list an IL-1 inhibitor as an option for gout patients who cannot tolerate or have a contraindication to anti-inflammatory therapies. Additionally, Kineret is more cost-effective than some TRICARE medical benefit medications used for these indications. The off-label uses for gout and pseudogout are approved if Kineret is prescribed by or in consultation with a rheumatologist and the patient has had an inadequate response, intolerance, or contraindication to other therapies.

g) Updating Automated Specialist Bypass Implementation— Automated specialist bypass is a process where physicians of certain specialties are allowed to bypass selected PAs if their National Provider Identifier (NPI) number corresponds with the preferred specialist taxonomy designated in the P&T Committee minutes.

Automated specialist bypass was first recommended for Humira in May 2023, allowing rheumatologists to bypass the PA. Since that time, automation has been

recommended for over 20 drugs. An audit of these drugs revealed that these PAs were not operationalized as intended; providers without the approved taxonomy were inappropriately bypassing the PA criteria.

To clarify, the P&T Committee will explicitly identify who may bypass the PA utilizing an automated specialist lookback. The P&T Committee will clearly identify which provider specialty types are allowed to bypass. The self-attestation question allowing providers to manually bypass the PA will be removed to ensure compliance, and only the providers identified through the automated lookup will be allowed to bypass the PA.

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

UF BAP Comments

The P&T Committee recommended updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes, while the PA removal for pirfenidone will be effective the first Wednesday 2 weeks after signing of the minutes.

UF BAP Comments

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