DEPARTMENT OF WAR
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE FEBRUARY 2026 MEETING

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

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. UF DRUG CLASS REVIEW—TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN-23 (IL-23) INHIBITORS SUBCLASS: USTEKINUMAB AGENTS

P&T Comments

A. TIBs: IL-23 Inhibitors: Ustekinumab Agents—Relative Clinical Effectiveness Conclusion

Background— The IL-23 inhibitor subclass review for formulary status was completed in November 2024. New ustekinumab biosimilar products were reviewed as innovator drugs in February, May, and August 2025, however implementation is delayed due to the UF BAP pause. Two products, ustekinumab-aauz (unbranded Otulfi) and ustekinumab-hmny (Starjemza) are reviewed here as part of this subclass review. Previous P&T Committee conclusions regarding biosimilars are found in the August 2024 and November 2022 P&T Committee meeting minutes. In summary:

- FDA approved biosimilar products, whether officially designated as interchangeable or not, are equally safe and efficacious when compared to the reference product.
- Similar to the U.S. FDA, European Medicines Agency, and the United Kingdom Medicines and Healthcare Regulatory Agency guidance, the P&T Committee will consider all approved biosimilars as highly interchangeable to the reference product for both efficacy and safety.

- The IL-23 inhibitor subclass, which included the originator ustekinumab (Stelara), was reviewed at the November 2024 P&T Committee meeting. At the February, May and August 2025 P&T Committee meetings, newly approved ustekinumab biosimilars were reviewed for formulary placement and considered therapeutically equivalent to the reference product and each other. A trial of the step-preferred ustekinumab will be required before use of the other UF non-step-preferred and NF non-step-preferred products once selected.
- In joint federal collaboration with the VA, DoW elected to participate in a Joint National Contract (JNC) for ustekinumab. The JNC ustekinumab biosimilar (pending selection) was chosen as the Uniform Formulary (UF) step-preferred IL-23 agent during the November 2024 subclass review. The expected 2025 solicitation was postponed until 2026, with an expected award date in March 2026.
- At this meeting, formulary recommendations are made for the formulary status, step-therapy and Prior Authorization (PA) criteria, and implementation period for JNC.
- The ustekinumab products evaluated include ustekinumab (Stelara), ustekinumab (unbranded Stelara), ustekinumab-auub (Wezlana), ustekinumab-kfce (Yesintek), ustekinumab-ttwe (Pyzchiva), ustekinumab-stba (Steqeyma), ustekinumab-aekn (Selarsdi), ustekinumab-aauz (Otulfi), ustekinumab-aauz (unbranded Otulfi), ustekinumab-hmny (Starjemza), and ustekinumab-srlf (Imuldosa). These products are all equally safe and efficacious. Private label products that are not intended for TRICARE patients are excluded from the TRICARE pharmacy benefit, as outlined in the November 2025 P&T Committee meeting minutes.

Relative Clinical Effectiveness Conclusion— The clinical review focused on the similarity and interchangeability of the available ustekinumab products. Additional discussion occurred for the evidence supporting ustekinumab in the pediatric population.

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

Special Populations

- The FDA is currently evaluating the literature for expanded ages and indications for pediatric patients. Supplemental Biologic License Applications have been submitted for the indications of ulcerative colitis and Crohn's disease in patients aged two and older.
- Ustekinumab is currently approved by the European Medicines Association for use in pediatric patients with plaque psoriasis and Crohn's disease with no age limitations.
- Use of ustekinumab in pediatric patients for psoriatic arthritis, plaque psoriasis, ulcerative colitis, and Crohn's disease is supported by clinical evidence.

Other Factors

- Trade Agreements Act (TAA) Compliance: Two agents, ustekinumab-hmny (Starjemza) and ustekinumab-kfce (Yesintek) are not TAA compliant and are therefore not available for purchase for the MTF or TMOP points of service. These products are available in the retail ~~network~~ pharmacies.
- Latex Content: All products are latex-free, with the exception of ustekinumab (Stelara and unbranded Stelara) and ustekinumab-hmny (Starjemza).
- Formulations: All products are available in both 45 mg/0.5mL and 90 mg/mL prefilled syringes or prefilled pens. A 45mg/0.5mL single dose vial is available for all the products except ustekinumab-stba (Steqeyma).
- FDA Interchangeability: Ustekinumab-srlf (Imuldosa) is the only ustekinumab biosimilar that does not have FDA-labeled interchangeable status. As per the previous conclusions regarding biosimilars summarized above, for purposes of the TRICARE Pharmacy benefit, all biosimilars are interchangeable to one another and the reference product.

Overall Clinical Conclusion

- In terms of relative clinical effectiveness and safety, all ustekinumab products are interchangeable with each other.
- Only one ustekinumab product is needed to meet the needs of MHS beneficiaries.
- A trial of the ustekinumab product that will be selected for UF and step-preferred status will be required in all new and current users of the non-step-preferred products (e.g., "no grandfathering").
- Due to clinical literature supporting use in children, ustekinumab may be used to treat pediatric patients with diseases including plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease, regardless of FDA-labeling.

B. TIBs: IL-23 Inhibitors: Ustekinumab Agents—Relative Cost Effectiveness Conclusion

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

- CMA results showed that the formulary placement of a JNC-awarded ustekinumab product as the UF step-preferred agent would be cost effective.
- The BIA demonstrated that a JNC-awarded ustekinumab product will generate cost avoidance.

C. TIBs: IL-23 Inhibitors: Ustekinumab Agents——UF Recommendation

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

Per the November 2024 IL-23 inhibitor subclass review recommendations:

- The JNC-awarded ustekinumab product will move to the UF step-preferred position

Per the virtual meeting held on January 16, 2026 recommendations:

- Reaffirms the JNC-awarded ustekinumab product will move to the UF step-preferred position.
- Reaffirms implementation of the step therapy requiring a trial of the JNC-awarded ustekinumab product for all non-step-preferred IL-23 agents.

Per this meeting:

- Reaffirms the JNC-awarded ustekinumab product will move to the UF step-preferred position as stated above.
- Defines which products are designated as UF and non-step-preferred and which are designated as NF and non-step-preferred.

Note that the previous formulary recommendations for the ustekinumab biosimilars when they were reviewed as newly approved drugs at the February, May, and August 2025 P&T Committee meetings were not implemented, due to the UF BAP Pause. Accordingly, the formulary recommendations below supersede any previous formulary decisions.

JNC-Awarded Scenario

- UF and step-preferred
  - JNC-awarded ustekinumab product moves to UF and step-preferred status
- UF and non-step-preferred
  - ustekinumab-aauz (unbranded Otulfi)
  - ustekinumab-hmny (Starjemza)
  - ustekinumab-srlf (Imuldosa) *moves from NF non-step-preferred to UF non-step-preferred (August 2025 meeting)*
- NF
  - ustekinumab-aauz (branded Otulfi) *moves from UF non-step-preferred to NF non-step-preferred (recommended from the May 2025 meeting)*
  - ustekinumab-ttwe (Pyzchiva)
  - ustekinumab-aekn (Selarsdi)

- ustekinumab (unbranded Stelara)
- ustekinumab-stba (Steqeyma) *moves from UF non-step-preferred to NF non-step-preferred (recommended from the May 2025 meeting)*
- ustekinumab (Stelara) *moves from UF non-step-preferred to NF non-step-preferred (November 2024 meeting)*
- ustekinumab-auub (Wezlana) *moves from UF non-step-preferred to NF non-step preferred (recommended from the February 2025 meeting)*
- ustekinumab-kfce (Yesintek)

- Complete Exclusion: None
- Note as part of the step therapy recommendation, a trial of the JNC selected product is required first in all new and current users of another ustekinumab product.
- As per the November 2025 P&T Committee meeting, any private label ustekinumab biosimilars are not part of the TRICARE Pharmacy benefit.

D. TIBs: IL-23 Inhibitors: Ustekinumab Agents——Manual PA Criteria

At the November 2024 P&T Committee meeting, several updates were made to the PA criteria for the IL-23 inhibitors. Additional updates recommended in subsequent P&T Committee meetings are summarized below, although implementation for some of these changes is delayed, due to the UF BAP pause.

- February 2025: Updated the requirement for previous use of Humira to allow previous use of Humira or infliximab; and removed the requirement for failure of non-biologic therapy for ulcerative colitis.
- February, May, August 2025: Ustekinumab biosimilar products were reviewed as innovator drugs, with PAs added.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria as discussed below in new and current users.

- For the UF step-preferred ustekinumab product, if the prescribing physician specialist is identified as a rheumatologist, dermatologist or gastroenterologist during adjudication, no PA will be required ("automated specialist bypass.") An automated drug-lookback will apply for adalimumab and ustekinumab to allow for PA approval if the patient has received either of these two drugs in the last 720 days. The current age restrictions will be removed, allowing utilization in patients of any age for the treatment of plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease.

- For the UF non-step-preferred agents, a trial of the UF step-preferred agent will be required in all new and current users. No changes will be made to automation or age restrictions.
- For the NF non-step-preferred agents, a trial of all UF agents will be required in all new and current users. No change will be made to the automation or age restrictions.

The Manual PA criteria are as follows

UF Step-Preferred ustekinumab

1. ustekinumab-aauz (Otulfi)

Automated PA Criteria: When prescribed by a dermatologist or gastroenterologist a prior authorization is not required. Once therapy is initiated by a dermatologist or gastroenterologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.

Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) or another ustekinumab product at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE mail order pharmacy) during the previous 180 days.

Manual PA criteria apply to all **new** users of **ustekinumab-aauz (Otulfi)**

Manual PA Criteria: If automated PA criteria are not met, coverage is approved if all criteria are met:

- The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira
- Patients may have used infliximab in lieu of Humira for UC and CD
- Coverage is approved for patients with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Moderately to severely active Crohn's Disease (CD)
  - Moderately to severely active ulcerative colitis (UC)
- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)

- **Coverage is not provided for concomitant use with other TIBs including, but not limited to, TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors**

Non-FDA approved uses are not approved

PA does not expire

2. UF non-step-preferred ustekinumab

- **ustekinumab-aauz (unbranded Otulfi)**
- **ustekinumab-hmny (Starjemza)**
- **ustekinumab-srlf (Imuldosa)**

Updates from the February 2026 meeting are in bold

Manual PA criteria apply to all **new and current** users of **ustekinumab-aauz (unbranded Otulfi), ustekinumab-hmny (Starjemza) and ustekinumab-srlf (Imuldosa)**

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

- **The provider acknowledges that the step-preferred product Otulfi is TRICARE's preferred ustekinumab product**
- The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira AND
- **Please provide patient-specific justification as to why the step-preferred ustekinumab aauz (Otulfi) cannot be used in this patient._____**
  - **Acceptable reasons include: the patient has an allergy to an inactive ingredient found in the step-preferred product that is not in the non-step-preferred product**
- Patients may have used infliximab in lieu of Humira for UC and CD
- Coverage is approved for patients with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Moderately to severely active Crohn's Disease (CD)
  - Moderately to severely active ulcerative colitis (UC)
- Coverage is approved for patients ages 6 to 17 years of age with:
  - Active psoriatic arthritis

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
  - Coverage is not provided for concomitant use with other TIBs including, but not limited to, TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors

Non-FDA approved uses are not approved

PA does not expire

3. NF non-step-preferred

- **ustekinumab-ttwe (Pyzchiva)**
- **ustekinumab-aekn (Selarsdi)**
- **ustekinumab (Stelara)**
- **ustekinumab (unbranded Stelara)**
- **ustekinumab-stba (Steqeyma)**
- **ustekinumab-auub (Wezlana)**
- **ustekinumab-kfce (Yesintek)**

Updates from the February 2026 meeting are in bold and Strikethrough

Manual PA criteria apply to all **new and current** users of **ustekinumab-aauz (Otulfi), ustekinumab-ttwe (Pyzchiva), ustekinumab-aekn (Selarsdi), ustekinumab (Stelara), ustekinumab (unbranded Stelara), ustekinumab-stba (Steqeyma), ustekinumab-auub (Wezlana), ustekinumab-kfce (Yesintek)**

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

- ~~The provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira~~
- The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira AND

- **Please provide a patient-specific justification as to why the step-preferred ustekinumab-aauz (Otulfi) and the UF non-step-preferred products unbranded Otulfi, Starjemza, Imuldosa cannot be used in this patient _____**
  - **Acceptable reasons include: the patient has an allergy to an inactive ingredient found in the step-preferred product that is not in the NF non-step-preferred product**
- Patients may have used infliximab in lieu of Humira for UC and CD
- Coverage is approved for patients with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Moderately to severely active Crohn's Disease (CD)
  - Moderately to severely active ulcerative colitis (UC)
- Coverage is approved for patients ages 6 to 17 years of age with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
  - Coverage is not provided for concomitant use with other TIBs including, but not limited to, TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors

Non-FDA approved uses are not approved

PA does not expire

E. TIBs: IL-23 Inhibitors: Ustekinumab Agents—UF recommendation, PA and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes.

- The JNC-awarded ustekinumab product will be designated UF and step-preferred no later than two weeks after the JNC award date, as recommended at the November 2024 P&T Committee meeting.

- Step therapy will require trial of the JNC preferred product in all new users for all non-step-preferred IL-23 inhibitors (ustekinumab, risankizumab, guselkumab, tildrakizumab, mirikizumab), and the PAs will be updated to implement this step therapy requirement two weeks after the JNC award date, as voted on at the November 2024 P&T meeting.
- The formulary status of the non-step-preferred agents will not change unless reviewed by the UF BAP and Director's signature.
- The formulary status of the ustekinumab products not selected by the JNC will have their formulary status change the first Wednesday 30 days after the date the P&T Committee meeting minutes are signed.
    - For current users of a non-step-preferred ustekinumab product, the required trial of the JNC step-preferred agent will be implemented the first Wednesday 30 days after the JNC effective date. There will be no-grandfathering between ustekinumab products. New and current users of a non-step-preferred ustekinumab product will be subject to the step at this implementation.
    - This timeline allows time to update the PA forms and for DHA to mail letters to beneficiaries affected by the NF copay change and PA step therapy requirements.
- For current users of a non-ustekinumab IL-23 inhibitor (Skyrizi, Tremfya, Ilumya, Omvoh), grandfathering will be allowed and only new patients will be affected
- ~~The MTFs will optimize utilization of the therapeutic interchange to the UF Step-Preferred ustekinumab product.~~

III. UF DRUG CLASS REVIEW—TIBS: IL-23 INHIBITORS SUBCLASS: USTEKINUMAB AGENTS

UF BAP Comments

A. TIBs: IL-23 Inhibitors: Ustekinumab Agents—UF Recommendation

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

- UF and step-preferred
    - Otulfi
- UF and non-step-preferred
    - unbranded Otulfi
    - Starjemza
    - Imuldosa
- NF

- Pyzchiva
- Selarsdi
- unbranded Stelara
- Steqeyma
- Stelara
- Wezlana
- Yesintek

- Complete Exclusion: None
- Note as part of the step therapy recommendation, a trial of the JNC selected product is required first in all new and current users of another ustekinumab product.
- As per the November 2025 P&T Committee meeting, any private label ustekinumab biosimilars are not part of the TRICARE Pharmacy benefit.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. TIBs: IL-23 Inhibitors: Ustekinumab Agents—Manual PA Criteria

The P&T Committee recommended PA criteria in new and current users, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. TIBs: IL-23 Inhibitors: Ustekinumab Agents—UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended the effective dates, timelines and beneficiary communication, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—ONCOLOGICAL AGENTS: MYELOFIBROSIS SUBCLASS

P&T Comments

A. Oncological Agents: Myelofibrosis Subclass—Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the janus kinase (JAK) inhibitors in the myelofibrosis subclass. Two drugs, ruxolitinib (Jakafi) and fedratinib (Inrebic) were part of the original drug class review at the February 2022 P&T Committee meeting. Since then, two additional agents, pacritinib (Vonjo) and momelotinib (Ojjaara), were reviewed during new drug presentations at the May 2022 and February 2024 meetings, respectively.

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

Efficacy

- All four agents are FDA-approved for the treatment of myelofibrosis.
- A 2024 network meta-analysis for the JAK inhibitors supported continued first-line use of Jakafi for efficacy in spleen reduction volume (SVR) and total symptoms score reduction (TSSR).
    - Ojjaara was identified as a significant alternative option for SVR and TSSR.
- There are no high-quality head-to-head trials available directly comparing one JAK inhibitor with another to demonstrate superiority of any agent.
- No benefits in overall survival have been seen with the newer agents (Inrebic, Vonjo and Ojjaara) when compared to Jakafi.

Professional Treatment Guidelines

- The National Comprehensive Cancer Network (NCCN) guidelines recommend all four agents, ruxolitinib (Jakafi), fedratinib (Inrebic), pacritinib (Vonjo), and momelotinib (Ojjaara), for treating myelofibrosis.
    - Jakafi and Inrebic have a Category 1 recommendation for higher risk patients in non-transplant candidates with platelets above 50 x 10^9/L.
    - Vonjo has a Category 1 recommendation for higher-risk myelofibrosis in non-transplant candidates with low platelet counts (<50 x 10^9/L).
    - Ojjaara has a Category 1 recommendation for patients with myelofibrosis-associated anemia with ongoing symptomatic splenomegaly and/or constitutional symptoms.

Safety

- The safety profiles of the agents overlap, with anemia and gastrointestinal (GI) toxicity the most commonly reported class-related adverse events.
- Inrebic carries a unique Black Box Warning for Wernicke's encephalopathy and has the highest rate of Grade 3-4 anemia (43%) based on the JAKARTA trials when indirectly compared to the individual clinical trial data with the other drugs.
- Vonjo showed a significantly higher rate of other serious adverse events (47%) in the PERSIST-2 clinical trial. It has a significantly decreased risk Grade 3-4 anemia when compared to ruxolitinib (Jakafi).
- Ojjaara demonstrated a decreased risk of Grade 3-4 anemia (5.6%) when compared to Jakafi (23.1%), in the SIMPLIFY-1 trial.
- When compared to Jakafi, Ojjaara and Vonjo did not show a reduced risk of thrombocytopenia.

Individual Product Characteristics

- Jakafi remains the standard first-line JAK inhibitor for myelofibrosis due to its mature efficacy and safety data and its long-standing NCCN Category 1 recommendation. It has additional indications for treating polycythemia vera, essential thrombocytopenia and graft versus host disease. Dose titration guidelines and NCCN recommendations are available to manage patients with thrombocytopenia and anemia. Provider feedback also indicated that ruxolitinib (Jakafi) is an appropriate first-line treatment choice.
- Vonjo is an option for patients with low platelets.
- Ojjaara is preferred for patients with anemia and has been shown noninferior for efficacy when compared to Jakafi.
- Inrebic is a reasonable alternative for patients who have failed prior JAK inhibitor therapy (refractory disease) but has a black box warning for Wernicke's encephalopathy.

Overall Conclusions

- In terms of clinical effectiveness for myelofibrosis, all four products are highly therapeutically interchangeable.
- In terms of safety, there is a moderate degree of therapeutic interchangeability among the four products
- To meet the needs of the beneficiaries, all four products should remain on the formulary.

B. Oncological Agents: Myelofibrosis Subclass—Relative Cost Effectiveness Analysis and Conclusion

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

- Jakafi was the most cost-effective JAK inhibitor, while Ojjaara was the least cost-effective agent.
- 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 was the most cost-effective course of action for the Military Health System (MHS).

C. Oncological Agents: Myelofibrosis Subclass—UF Recommendation

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

- UF
  - fedratinib (Inrebic)
  - momelotinib (Ojjaara)
  - pacritinib (Vonjo)
  - ruxolitinib (Jakafi)
- NF– None
- Complete Exclusion – None

D. Oncological Agents: Myelofibrosis Subclass—Manual PA Criteria

PA criteria currently apply only to Inrebic and Ojjaara. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for the myelofibrosis drugs as outlined below

- PA is not required for Jakafi, due to its long marketing history for efficacy and safety, provider feedback and low risk of inappropriate use. A trial of Jakafi is now required first in all new users of Inrebic, Vonjo, and Ojjaara
- The current Inrebic PA now includes the Jakafi step preference.
- For Ojjaara, a trial of Jakafi is not required for patients with anemia who have been considered for treatment with Jakafi and erythropoietin-stimulating agents (e.g., Epoetin).
- New PA criteria for Vonjo in new users includes the Jakafi step, however a trial of Jakafi is not required in patients with thrombocytopenia.

The Manual PA criteria are as follows:

1. fedratinib (Inrebic)

Updates from the February 2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Inrebic

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

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with a hematologist/oncologist
- **Provider is aware that ruxolitinib (Jakafi) is the preferred agent for myelofibrosis and that it is available without a PA**
- **Patient has tried and progressed on ruxolitinib (Jakafi) or had an inadequate response to, experienced an adverse reaction to, or has a contraindication to ruxolitinib (Jakafi) that is not expected to occur with fedratinib**
- Fedratinib will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
- 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. **Note that the presence of the NCCN recommendation does not allow a trial of fedratinib without first trying ruxolitinib if ruxolitinib is also recommended. 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. momelotinib (Ojjaara)

Updates from the February 2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Ojjaara

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

- The patient is 18 years of age or older
- The drug is prescribed by or in consultation with a hematologist/oncologist
- **Provider is aware that ruxolitinib (Jakafi) is the preferred agent for myelofibrosis and that it is available without a PA**
- **Patient has tried and progressed on ruxolitinib (Jakafi) or had an inadequate response to, experienced an adverse reaction to, or has a contraindication to ruxolitinib (Jakafi) that is not expected to occur with momelotinib**
- Patient has diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
- ~~Provider is aware of the warnings, screenings, and monitoring precautions of Ojjaara~~

- ~~If female of reproductive potential patient is not pregnant and not planning to become pregnant~~
- ~~If female of reproductive potential patient will avoid breast feeding for at least 1 week after discontinuation~~
- **A trial of Jakafi is not required if the patient has anemia with a Hg<8 g/dL and has been considered for Jakafi and erythropoiesis stimulating agents (e.g., Procrit, Epogen, Aranesp)**
- 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**. Note that the presence of the NCCN recommendation does not allow a trial of momelotinib without first trying ruxolitinib if ruxolitinib is also recommended**. 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. pacritinib (Vonjo)

New criteria from the February 2026 meeting

Manual PA criteria apply to all new users of Vonjo

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

- The patient is 18 years of age or older
- The drug is prescribed by or in consultation with a hematologist/oncologist
- Provider is aware that ruxolitinib (Jakafi) is the preferred agent for myelofibrosis and that it is available without a PA
- Patient has tried and progressed on ruxolitinib (Jakafi) or had an inadequate response to, experienced an adverse reaction to, or has a contraindication to ruxolitinib (Jakafi) that is not expected to occur with Vonjo OR
- A trial of Jakafi is not required if Vonjo will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 109 /L.

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

PA does not expire

E. Oncological Agents: Myelofibrosis Subclass——UF recommendation, PA criteria, and Implementation Period

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

V. UF DRUG CLASS REVIEW—ONCOLOGICAL AGENTS: MYELOFIBROSIS SUBCLASS

UF BAP Comments

A. Oncological Agents: Myelofibrosis Subclass—UF Recommendation

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

- UF
  - Inrebic
  - Ojjaara
  - Vonjo
  - Jakafi
- NF
- Complete Exclusion – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Oncological Agents: Myelofibrosis Subclass—Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Inrebic, Vonjo and Ojjaara, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Oncological Agents: Myelofibrosis Subclass—UF Recommendation, PA Criteria, and Implementation Period

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VI. 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
  - elinzanetant (Lynkuet) – Miscellaneous Gynecological Agent for menopause
  - mitapivat (Aqvesme) – Miscellaneous Metabolic Agents for Alpha or Beta Thalassemia
  - nerandomilast (Jascayd) – Pulmonary I Agents: Idiopathic Pulmonary Fibrosis
  - plozasiran injection (Redemplo) – Antilipidemic 2 Agent for Familial Chylomicronemia Syndrome (FCS)
  - sevabertinib (Hyrnuo) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents
  - ziftomenib (Komzifti) – Acute Myelogenous Leukemia (AML)
- NF
  - elamipretide injection (Forzinity) – Miscellaneous Metabolic Agent for Barth Syndrome
  - omidenepag isopropyl 0.002% ophthalmic solution (Omlonti) – Glaucoma Agents
  - paltusotine (Palsonify) – Miscellaneous Endocrine Agent for Acromegaly
  - remibrutinib (Rhapsido) – Atopy Agent for Chronic Spontaneous Urticaria
  - sibeprenlimab injection (Voyxact) – Miscellaneous Nephrology Agent for Immunoglobulin A (IgA) Nephropathy
- Complete Exclusion

- celecoxib 10 mg/mL oral suspension (Vyscoxa) – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - Vyscoxa oral suspension was recommended for complete exclusion status as it has little to no clinical benefit relative to the other NSAIDs, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include celecoxib capsules, naproxen oral suspension and meloxicam oral suspension.
- clonidine HCl oral solution 0.02 mg/mL (Javadin) – Anti-Hypertensive Agents
  - Javadin was recommended for complete exclusion status as it has little to no clinical benefit relative to other clonidine formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include clonidine tablets and clonidine transdermal systems.
- cyclobenzaprine 2.8 mg SL tab (Tonmya) – Skeletal Muscle Relaxants
  - Tonmya was recommended for complete exclusion status as it has little to no clinical benefit relative to other cyclobenzaprine formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include cyclobenzaprine tablets, pregabalin caps, and duloxetine caps.
- furosemide 80 mg/mL SC injection (Lasix ONYU) – Diuretics
  - Lasix ONYOU was recommended for complete exclusion status as it has little to no clinical benefit relative to the other loop diuretics, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include furosemide tablets, bumetanide tablets, and torsemide tablets.

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) for all the drugs except Jascayd, and for Jascayd (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- Applying manual PA criteria to new users of Redemplo. Note that updates were also made to the PA for olezarsen (Tryngolza), the other drug approved for FCS, to require a trial of Redemplo first. See the utilization management section on page 24.
- Applying temporary PA criteria to new and current users of the Vyscoxa, Javadin, Lasix ONYU, and Tonmya, until implementation of the recommended Compete Exclusion status.
- Applying manual PA criteria to use users of Lynkuet, requiring a trial of other non-hormonal drugs first.

- Applying manual PA criteria to new and current users of Forzinity. FDA accelerated approval was based on an intermediate clinical endpoint and continued approval may be contingent on confirmatory trials. As a result, manual PA criteria will require specialist prescribing with required renewal criteria for clinical reassessment of ongoing treatment response.
- Applying manual criteria to new users of Rhapsido, requiring specialist prescribing, and a trial of second-generation antihistamines, Xolair and Dupixent first.
- Applying manual PA criteria to new users of the oncology drugs and specialty drugs Aqvesme, Jascayd, Palsonify, Hyrnuo, Voyxact, and Komzifti.
- Applying manual PA criteria to new users of Omlonti, requiring a trial of generic latanoprost first.

The Manual PA criteria are as follows:

1. **celecoxib 10 mg/mL oral suspension (Vyscoxa)**

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

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

   - Provider acknowledges that Vyscoxa will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA
   - Provider acknowledges that other celecoxib formulations are available to TRICARE beneficiaries, including celecoxib capsules and do not require prior authorization
   - Provider must document why the patient cannot take celecoxib capsules
     - Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in celecoxib capsules.

   Non-FDA approved uses are not approved

   PA does not expire until after implementation of complete exclusion status

2. **clonidine HCl 0.02 mg/mL oral solution (Javadin)**

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

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

   - Provider acknowledges that Javadin will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA

- Provider acknowledges that other clonidine formulations are available to TRICARE beneficiaries, including clonidine tablets and clonidine transdermal system and do not require prior authorization
- Patient is 18 years of age or older
- Patient has hypertension
- Provider must document why the patient cannot take clonidine tablets and clonidine transdermal system
    - Acceptable responses include: the patient cannot swallow tablets due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience, and has had significant skin irritation with clonidine transdermal system

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

3. cyclobenzaprine 2.8 mg SL tabs (Tonmya)

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

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

- Provider acknowledges that Tonmya will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA
- Provider acknowledges that other cyclobenzaprine formulations are available to TRICARE beneficiaries, including generic cyclobenzaprine tablets and do not require prior authorization
- Patient is 18 years of age or older
- Patient has a diagnosis of fibromyalgia based on American College of Rheumatology (ACR) diagnostic criteria
- Patient has had a trial and failed or had intolerance to one or more generic medications used to treat fibromyalgia, such as cyclobenzaprine, pregabalin, and duloxetine
- Provider must document why the patient is unable to use cyclobenzaprine tablets
    - Acceptable responses include: the patient cannot swallow tablets due to documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience, and has had significant skin irritation with clonidine transdermal system

Non-FDA approved uses are not approved

PA expires in 6 months. A new PA must be submitted until implementation of complete exclusion status

4. elamipretide injection (Forzinity)

Manual PA criteria apply to all new users of Forzinity

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

- Patient is 12 years of age or older
- Patient weighs at least 30 kg
- Medication is prescribed by a physician with expertise in mitochondrial medicine or genetic disorders
- Patient has genetically confirmed Barth syndrome
- Patient is ambulatory, yet impaired as assessed by the 6-minute walk test
- Patient must not have any of the following: undergoing a pubertal growth spurt, uncontrolled hypertension, history of heart transplant, implantation of cardiac defibrillator, receiving chemotherapeutic or immunosuppressant agents, or prior radiation therapy to the chest
- Provider acknowledges FDA-accelerated approval is based on improvement in knee extensor muscle strength and continued FDA approval may be contingent upon verification of clinical benefit in confirmatory trials

Non-FDA approved uses are not approved

PA expires in 6 months. Provider must fill out a new PA form

5. elinzanetant (Lynkuet)

Manual PA criteria apply to all new users of Lynkuet

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

- Patient has moderate to severe vasomotor symptoms due to menopause
- Patient has a contraindication to menopausal hormone therapy (estrogens with or without progestins) OR
- Patient has an intolerance to menopausal hormone therapy OR
- Based on individual patient characteristics and risk factors, the provider has determined that the patient is not a candidate for menopausal hormone therapy
- Patient has tried and failed or had an adverse reaction to at least one of the following non-hormonal treatments for vasomotor symptoms: an SSRI (for example, paroxetine, escitalopram, or citalopram), an SNRI (for example, venlafaxine, desvenlafaxine, or duloxetine), OR gabapentin

Non-FDA approved uses are not approved

PA expires in 6 months.

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

- Patient had a positive response to therapy as noted by a decrease in the number of moderate to severe hot flashes

6. furosemide 80 mg/mL SC injection (Lasix ONYOU)

Manual PA criteria apply to all new and current users of Lasix ONYOU

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

- Provider acknowledges that Lasix ONYOU will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA
- Provider acknowledges that other loop diuretics are available to TRICARE beneficiaries, including bumetanide tablets, furosemide tablets, and torsemide tablets and do not require prior authorization
- Patient is 18 years of age or older
- Patient has edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome
- Patient is experiencing an increase in signs and symptoms of fluid overload
- Patient has failed a trial of two oral loop diuretics including
  - furosemide
  - bumetanide
  - torsemide
  - ethacrynic acid
- Patient is stable and does not require emergency care or hospitalization for heart failure, acute pulmonary edema or other condition that could result in hospitalization

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

7. mitapivat (Aqvesme)

Manual PA criteria apply to all new users of Aqvesme

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

- Patient is 18 years of age or older
- Medication is prescribed by or in consultation with a hematologist or oncologist
- Patient has a diagnosis of anemia associated with transfusion dependent or non-transfusion dependent alpha-thalassemia or beta-thalassemia

Off-label uses are not approved unless supporting documentation is provided

PA expires in 6 months

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all the criteria are met:

- Patient had a positive response to therapy as noted by a decrease in the number of RBC units transfused or an increase in hemoglobin

8. nerandomilast (Jascayd)

Manual PA criteria apply to all new users of Jascayd

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

- Provider acknowledges pirfenidone (Esbriet generic) is the Department of Defense's preferred drug for Idiopathic Pulmonary Fibrosis (IPF)
- Patient is 18 years of age or older
- Prescribed by a pulmonologist
- Patient is non-smoking
- Patient has documented diagnosis of idiopathic pulmonary fibrosis (IPF) AND
    - Patient requires add-on therapy with nerandomilast (Jascayd) and:
        - Patient tried and failed pirfenidone (Esbriet generic) due to progression of disease as defined as greater than 10% decline of forced vital capacity (FVC) OR
        - Patient tried and failed nintedanib (Ofev) due to progression of disease as defined as greater than 10% decline of forced vital capacity (FVC)

OR

- Patient requires monotherapy with nerandomilast (Jascayd) and:
    - Patient tried and failed pirfenidone (Esbriet generic) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with pirfenidone (Esbriet generic) OR
    - Patient tried and failed nintedanib (Ofev) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with nintedanib (Ofev)
- Patient is not receiving triple therapy with nerandomilast (Jascayd), pirfenidone (Esbriet, generics), and nintedanib (Ofev)

Non-FDA approved uses are not approved; usage for progressive pulmonary fibrosis is not approved at this time

PA expires in 12 months

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all the criteria are met

- Prescribed by a pulmonologist
- Patient has shown clinical benefit with therapy

9. omidenepag isopropyl 0.002% ophthalmic solution (Omlonti)

Manual PA criteria apply to all new users of Omlonti

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

- Patient is 18 years of age or older
- Patient has elevated intraocular pressure (IOP) due to open-angle glaucoma or ocular hypertension
- Patient has tried and failed or had an adverse reaction or contraindication to generic latanoprost 0.005%

Non-FDA-approved uses are not approved.

PA does not expire.

10. paltusotine (Palsonify)

Manual PA criteria apply to all new users of Palsonify

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

- Patient is 18 years or older
- Prescribed by or in consultation with an endocrinologist
- Patient has a diagnosis of acromegaly
- The patient has had inadequate response to surgery or is not a candidate for surgery
- The patient has had an inadequate response to, intolerability to, or has a contraindication to one injectable somatostatin analog (for example, octreotide, lanreotide, pasireotide)

Non-FDA approved uses are not approved

PA does not expire

11. plozasiran (Redemplo)

Manual PA criteria apply to all new users of Redemplo

Manual PA criteria: Coverage is approved if all apply:

- Patient is 18 years of age or older
- Prescribed by cardiologist, an endocrinologist, or an internal medicine physician experienced in disorders related to severe hypertriglyceridemia

- Patient has undergone genetic testing to confirm the diagnosis of familial chylomicronemia syndrome OR
- Patient has evidence of symptomatic persistent chylomicronemia with recurrent pancreatitis
- Patient has a fasting triglyceride level of 880 mg/dL or greater
- Patient will adhere to a low fat-diet (less than or equal to 20 g fat per day) while receiving Redemplo

Non-FDA-approved uses not approved

Prior Authorization does not expire

12. remibrutinib (Rhapsido)

Manual PA criteria apply to all new users of Rhapsido

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

- Patient is 18 years of age or older
- Prescribed by an allergist, immunologist or dermatologist
- Patient has chronic spontaneous urticaria with symptoms lasting greater than 6 weeks
- The patient remains symptomatic despite trial of at least 4 weeks with recommended second generation H1 antihistamine (e.g., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine)
- The patient has had an inadequate response to, intolerability to, or has a contraindication to both Xolair and Dupixent

Non-FDA approved uses are not approved

PA expires in 12 months

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all the criteria are met

- The patient's disease severity has improved and stabilized to warrant continued therapy

13. sevabertinib (Hyrnuo)

Manual PA criteria apply to all new users of Hyrnuo

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist

- Patient has locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC)
- Patient's tumor has human epidermal growth factor receptor 2 (HER2) (ERBB2) tyrosine kinase domain activating mutations
- Patient has received prior systemic therapy
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number:

Other non-FDA approved uses are not approved except as noted above

PA does not expire

14. sibeprenlimab injection (Voyxact)

Manual PA criteria apply to all new users of Voyxact

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

- Patient is 18 years of age or older
- Prescribed by a nephrologist
- Patient has biopsy verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli
- Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73m2
- Patient has urinary protein excretion greater than or equal to 1.0 g/day or urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.75
- Patient continues to have proteinuria despite maximal Angiotensin-Converting Enzyme (ACE) inhibitor or Angiotensin II receptor blockers (ARB) therapy and an SGLT-2 inhibitor (for example, empagliflozin, dapagliflozin) and is at high risk for disease progression
- Patient will not use Voyxact concomitantly with Filspari or Vanrafia or Fabhalta

Non-FDA approved uses are not approved

PA expires in 9 months

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

- The patient experienced a reduction in urine protein-to-creatinine ratio (UPCR) from baseline or reduction in proteinuria from baseline

15. ziftomenib (Komzifti)

Manual PA criteria apply to all new users of Komzifti

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Patient has relapsed or refractory acute myeloid leukemia
- Patient has a susceptible NPM1-mutation with no satisfactory alternative treatment options
- Patient does not have concomitant KMT2A gene translocation
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number_____

Other non-FDA approved uses are not approved except as noted above

PA does not expire

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF recommendation, PA, and Implementation Period

The P&T Committee recommended (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
  - elinzanetant (Lynkuet) – Miscellaneous Gynecological Agent for menopause

- mitapivat (Aqvesme) – Miscellaneous Metabolic Agents for Alpha or Beta Thalassemia
- nerandomilast (Jascayd) – Pulmonary I Agents: Idiopathic Pulmonary Fibrosis
- plozasiran injection (Redemplo) – Antilipidemic 2 Agent for Familial Chylomicronemia Syndrome (FCS)
- sevabertinib (Hyrnuo) – Lung Cancer: Human Epidermal Growth Factor Receptor 2 (HER2) Agents
- ziftomenib (Komzifti) – Acute Myelogenous Leukemia (AML)

- NF
  - elamipretide injection (Forzinity) – Miscellaneous Metabolic Agent for Barth Syndrome
  - omidenepag isopropyl 0.002% ophthalmic solution (Omlonti) – Glaucoma Agents
  - paltusotine (Palsonify) – Miscellaneous Endocrine Agent for Acromegaly
  - remibrutinib (Rhapsido) – Atopy Agent for Chronic Spontaneous Urticaria
  - sibeprenlimab injection (Voyxact) – Miscellaneous Nephrology Agent for Immunoglobulin A (IgA) Nephropathy
- Complete Exclusion
  - celecoxib 10 mg/mL oral suspension (Vyscoxa) – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - clonidine HCl oral solution 0.02 mg/mL (Javadin) – Anti-Hypertensive Agents
  - cyclobenzaprine 2.8 SL tab (Tonmya) – Skeletal Muscle Relaxants
  - furosemide 80 mg/mL SC injection (Lasix ONYU) – Diuretics

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 PLAN

P&T Comments

A. Manual PA Criteria

a) Anticonvulsants-Antimania Agents—lamotrigine 10 mg/mL oral suspension (Subvenite)— This suspension formulation of lamotrigine is less cost-effective than lamotrigine tablets. The addition of a PA, similar to the existing PA for topiramate oral solution (Eprontia), was recommended to encourage use of the lamotrigine tablet formulation. An automated age edit will allow patients younger than 12 years of age to bypass the PA. Additionally, both Subvenite suspension and Eprontia oral solution will be added to the Rapid Response/Safety Net Program managed by the TPharm5 pharmacy contractor.

b) Antipsychotic Agents: Atypical cariprazine (Vraylar) — Vraylar is currently designated as NF without a PA. Based upon a review of guidelines, provider feedback and cost, PA criteria were recommended for Vraylar. The PA criteria were modeled off existing PA criteria for other nonformulary psychiatric medications and include the FDA-approved indication, requiring prescribing by or in consultation with a specialist, and requiring a trial of other generic agents first.

The PA criteria are as follows:

The Manual PA criteria are as follows:

1. lamotrigine 10 mg/mL suspension (Subvenite)

Manual PA criteria apply to all new users of Subvenite

PA does not apply to patients younger than 12 years of age (age edit)

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

- Drug is prescribed by or in consultation with an adult or pediatric neurologist or psychiatrist
- Patient requires a liquid formulation due to swallowing difficulty or has a feeding tube

PA does not expire

2. cariprazine (Vraylar)

Manual PA criteria apply to all new users of Vraylar

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

- Drug is prescribed by or in consultation with a psychiatrist
- Major Depressive Disorder
  - Patient is 18 years of age or older
  - Patient has had treatment failure of at least two other formulary antidepressants, for example:
    - SSRI (e.g. citalopram, escitalopram, fluoxetine)
    - SNRl (e.g. venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER)
    - TCA (e.g. amitriptyline, desipramine, imipramine, nortriptyline)
    - mirtazapine
    - bupropion
    - trazodone immediate-release
    - nefazodone
    - MAOI
  - Patient has had an inadequate response, intolerance to, or contraindication to aripiprazole
  - Patient has concurrent use of an antidepressant

- Schizophrenia
  - Patient is 13 years of age or older
  - Patient has tried and failed at least two formulary atypical antipsychotics (e.g., risperidone, aripiprazole, lurasidone, quetiapine)
- Manic or mixed episodes associated with Bipolar I
  - Patient is 10 years of age or older
  - Patient has tried and failed at least two formulary atypical antipsychotics
- Depressive episodes associated with Bipolar I
  - Patient is 18 years of age or older

- Patient has tried and failed at least two formulary atypical antipsychotics (e.g., risperidone, aripiprazole, lurasidone, quetiapine)

Non-FDA approved uses are not approved

PA does not expire

B. New PA Criteria and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for cariprazine (Vraylar) and lamotrigine suspension (Subvenite) in new users, due to the significant cost differences compared with other available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended manual PA for Subvenite and Vraylar, 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—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) **Antipsychotic Agents: Atypical—lumateperone (Caplyta)—**The manual PA criteria for Caplyta were updated to include its use as adjunctive therapy for major depressive disorder in adults. The PA criteria were modeled off existing PA criteria for other nonformulary psychiatric medications and include FDA-approved indication, requiring prescribing by or in consultation with a specialist, and requiring a trial of other generic agents first, similar to what was done with Vraylar above.

b) **Atopy—tezepelumab (Tezspire)—**Tezspire is now indicated for add-on maintenance therapy in patients 12 years of age and older for inadequately controlled chronic rhinosinusitis with nasal polyps. The PA was updated mirroring Dupixent's criteria for this indication.

c) **Corticosteroids-Immune Modulators: Hereditary Angioedema (HAE) Agents berotralstat (Orladeyo)—**The manual PA criteria were updated to expand use in pediatric patients 2 to 11 years of age for HAE prophylaxis.

d) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKIs)—pirtobrutinib (Jaypirca)—**The manual PA criteria for Jaypirca were updated to allow use for relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) in patients who have previously been treated with a covalent BTK inhibitor.

e) **Oncological Agents—revumenib (Revuforj)—**The manual PA criteria for Revuforj were updated to allow for the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 mutation.

f) **Psoriasis Agents—roflumilast 0.05% cream (Zoryve)—**The manual PA for Zoryve was updated to allow for the expanded age indication for atopic dermatitis to include pediatric patients 2 to 5 years of age.

g) **TIBs: Tumor Necrosis Factor Inhibitors (TNFs)—golimumab (Simponi)—** Simponi received an expanded indication to include pediatric patients weighing 15 kg or more with ulcerative colitis. The updated PA criteria for this pediatric indication mirror the existing requirements for adults with ulcerative colitis.

h) **TIBs: Interleukin 23 (IL-23) inhibitors—guselkumab (Tremfya)—**The PA criteria for Tremfya were updated to allow for use in pediatric patients 6 years of age and older weighing 40 kg or more with moderate-to-severe plaque psoriasis or active psoriatic arthritis. A trial of adalimumab and a non-biologic systemic therapy will be required for both indications.

i) **TIBs: Miscellaneous—tofacitinib (Xeljanz)—**Xeljanz is now indicated in psoriatic arthritis patients 2 years and older. The manual PA was updated to include this expanded age indication and also incorporate the TIBs PA standardization updates, which included removing the automated lookback for Humira and removal of safety monitoring information.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) implementation for updates to the manual PA criteria for Caplyta, Tezspire, Orladeyo, Jaypirca, Revuforj, Zoryve, Simponi, Tremfya and Xeljanz in new users. Implementation of the PA criteria updates will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

A. Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria for Caplyta, Tezspire, Orladeyo, Jaypirca, Revuforj, Zoryve, Simponi, Tremfya and Xeljanz in new users. Implementation of the PA criteria updates will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

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

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

P&T Comments

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs. The updated PA criteria outlined below will apply to new users.

a) **Antilipidemic 2 Agents: olezarsen (Tryngolza)—**The manual PA criteria for Tryngolza was updated to require a trial of Redemplo first, in new users, due to cost effectiveness. Refer to the new drug section on page 17.

b) **Antipsychotic Agents: Atypical—brexpiprazole (Rexulti)—**The Rexulti PA was updated to require prescribing by or in consultation with a psychiatrist for the major depressive disorder and schizophrenia indications, plus require a trial of two generic antidepressants. Additionally, the Alzheimer's disease indication was updated to allow prescribing by or in consultation with a neurologist, psychiatrist, or specialist in geriatric medicine. Rexulti will be added to the Rapid Response/Safety Net program.

c) **Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablet—**At the August 2025 P&T meeting, the P&T Committee recommended PA criteria for bisoprolol 2.5 mg tablets. Other bisoprolol formulations, including generic bisoprolol 5 mg tablets (scored), are more cost-effective than the 2.5 mg strength. A provider requested access to this lower strength for patients who require very low dose titration for heart failure or post myocardial infarction. In these instances, splitting the 2.5 mg tablet to attain even smaller doses may be desirable. As a result, this rationale will be added to the acceptable write-in PA criteria for approval.

d) **Hematological Agents—avacopan (Tavneos)—**The Tavneos manual PA was updated to allow for nephrologist prescribing, based on MTF feedback.

e) **Nephrology Agents Miscellaneous—sparsentan (Filspari)—**The Filspari PA criteria were updated to lower the baseline qualifying urine-protein creatinine ratio from at least 1.5 g/grams to at least 1.0 g/grams, based on a recent update to the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines.

f) **Oncological Agents—**Efforts to standardize and streamline the PAs for oncology drugs are ongoing. Edits were made to the PA criteria for nine oncology drugs. As part of this standardization effort, the following actions were taken: editing the NCCN guideline question to cite specific guideline version and page number to ease approvals for new indications, updating indications to more closely match FDA label language, and removing lengthy clinical monitoring and counseling questions based on provider feedback. Other required updates identified at this time are detailed below.

- **Leukemia and Lymphoma Agents: Acute Myeloid Leukemia (AML)—azacitidine (Onureg)—**The PA was updated to include t-cell lymphoma indications that are in the NCCN guidelines and in other commercial health plan PAs.
- **Multiple Myeloma—ixazomib (Ninlaro)—**The PA was updated for the indications and limitations of use language, to better align with FDA labeling for Ninlaro.
- **Oncological Agents—avapritinib (Ayvakit)—**The PA was updated to allow allergists to write for Ayvakit. This update was based on MTF oncologist feedback that stated that allergist prescribing for mastocytosis is appropriate.
- **Oncological Agents: Lung Cancer—pralsetinib (Gavreto)—**The PA was updated to include an FDA-approved thyroid cancer indication that was not on the current PA.
- **Oncological Agents: Lung Cancer—crizotinib (Xalkori)—**The PA was updated for oncology standardization only.
- **Oncological Agents: Melanoma—cobimetinib (Cotellic)—**The Cotellic PA did not have the NCCN question that is present in all other oncology PAs; therefore, this question was added.
- **Oncological Agents: Non-BTKIs—duvelisib (Copiktra)—**The marginal zone lymphoma indication was removed, and limitations of use language was added to the PA. This aligns the Copiktra PA with current FDA labeling.
- **Oncological Agents: Non-BTKIs—idelalisib (Zydelig)—**The indications for small lymphocytic lymphoma and follicular lymphoma were withdrawn by the manufacturer and were removed from the PA.

g) **TIBs: TNFs—adalimumab (Humira, biosimilars)—**An MTF provider requested that the adalimumab PA be updated to allow use for refractory sarcoidosis and to allow prescribing by pulmonologists. These updates were made along with TIBs standardization updates

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Tryngolza, Rexulti, bisoprolol 2.5 mg, Tavneos, Filspari, Onureg, Ninlaro, Ayvakit, Tazverik, Gavreto, Xalkori, Cotellic, Copiktra, Zydelig and adalimumab in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes

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

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for the new drugs listed above in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

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

XIV. BRAND OVER GENERIC AUTHORIZATIONS AND TIER 1 COPAY AND IMPLEMENTATION PLAN: MENOPAUSAL HORMONE THERAPY: ORAL SINGLE AGENTS—CONJUGATED ESTROGEN TABLETS (PREMARIN)

P&T Comments

- **Menopausal Hormone Therapy: Oral Single Agents—conjugated estrogen tablets (Premarin):** Premarin tablets are designated as UF with a PA required for certain populations (e.g., males). A generic formulation is now marketed; however, this product is less cost-effective compared to the branded agent. Therefore, the branded Premarin tablets will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization. Accordingly, the Tier 1 (generic) copay for brand Premarin tablets is recommended.

  The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) requiring brand Premarin tablets over the generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to

why the brand cannot be used. Brand Premarin will be available at a Tier 1 copay. The effective date will be no later than the first Wednesday 60 days after signing of the minutes. The "brand over generic" requirement for Premarin tablets will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XV. BRAND OVER GENERIC AUTHORIZATIONS AND TIER 1 COPAY AND IMPLEMENTATION PLAN: MENOPAUSAL HORMONE THERAPY: ORAL SINGLE AGENTS—CONJUGATED ESTROGEN TABLETS (PREMARIN

UF BAP Comments

The P&T Committee recommended the addition of brand over generic criteria for Premarin tablets, as outlined above, with an implementation of the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

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