DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE NOVEMBER 2024 MEETING

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING DECEMBER 18, 2024

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, 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: INTERLEUKIN-17 AND INTERLEUKIN-23 INHIBITORS SUBCLASSES

P&T Comments

A. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-17 and IL-23 Inhibitors Subclasses—Relative Clinical Effectiveness Conclusion

Background—The Targeted Immunomodulatory Biologics (TIBs) class is comprised of several subclasses, including the tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab [Humira]) non-TNF inhibitors, and miscellaneous interleukin subclasses. The TIBs class was last reviewed at the August 2014 P&T Committee meeting and branded Humira is currently step-preferred for most indications. Since the original review, 17 new drugs with multiple new mechanisms of action have entered the market. These newer agents have strong clinical evidence in specific disease states.

Biosimilar entrants are on the horizon for ustekinumab (Stelara) and secukinumab (Cosentyx), with more products expected in the future. The advent of biosimilars is expected to reshape treatment options and create opportunities to participate in a Joint National Contract (JNC) with other federal partners to align formularies for continuity of care and produce cost avoidance. Therefore, to support the growing complexity of the TIBs, two additional subclasses were created based on mechanism of action, the Interleukin-17 inhibitors (IL-17s) and Interleukin-23 inhibitors (IL-23s).

The drugs in the subclass include the following:

- IL-17s bimekizumab (Bimzelx), brodalumab (Siliq), ixekizumab (Taltz) and secukinumab (Cosentyx)
- IL-23s guselkumab (Tremfya), mirikizumab (Omvoh), risankizumab (Skyrizi), tildrakizumab (Ilumya), and ustekinumab (Stelara)

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Interleukin-17 Agents

- **bimekizumab (Bimzelx)** is indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and non-radiographic ankylosing spondyloarthritis in adult patients. Approval for hidradenitis suppurativa (HS) is expected imminently. *(Note, following the meeting the FDA updated the Bimzelx label to include HS on November 19, 2024.)* Limitations include lack of approval for children and adverse effects of liver abnormalities, suicidal ideation (although no REMS program is required) and oral candidiasis.
- **brodalumab (Siliq)** is solely indicated for plaque psoriasis in adults who have failed other systemic therapy. Other limitations include the requirement for a risk evaluation and mitigation strategy (REMS) program due to risk of suicidal ideation and behavior.
- **ixekizumab (Taltz)** is indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and non-radiographic ankylosing spondyloarthritis. Advantages include approval for both adults and pediatric patients as young as six years old. Taltz is associated with a higher incidence of injection site reactions compared to other products.
- **secukinumab (Cosentyx)** is indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, non-radiographic ankylosing spondyloarthritis, enthesitis-related arthritis, and hidradenitis suppurativa. Advantages include approval for both adult and pediatric patients as young as two years old. Unique adverse reactions include risk of eczematous eruptions.
    - *Biosimilars:* Based on patent expiration, secukinumab will likely have the first IL-17 biosimilar.

Interleukin-23 Agents

- **ustekinumab (Stelara)** is indicated for plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease. It's mechanism of action includes both IL-23 and IL-12 inhibition. Advantages include approval for both adults and pediatric patients as young as six years old. Stelara is well accepted for use in pregnant women. Unique safety concerns include

risk of non-infectious pneumonia and posterior reversible encephalopathy syndrome (PRES) and infections related to inhibition of IL-12.

    - *Biosimilars:* There are five FDA-approved Stelara biosimilars (Wezlana, Selarsdi, Pyzchiva, Otulfi, and Imuldosa), but market launch will not occur until 2025. Current evidence shows that the biosimilars are therapeutically equivalent with their reference products, allowing for a high degree of therapeutic interchangeability.

- **guselkumab (Tremfya)** is indicated for plaque psoriasis, psoriatic arthritis, and ulcerative colitis in adults. The manufacturer of Tremfya is seeking approval for Crohn's disease.
- **tildrakizumab (Ilumya)** has only one indication, plaque psoriasis in adults.
- **risankizumab (Skyrizi)** is indicated for plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease in adult patients. It is available as a prefilled pen, prefilled syringe, and prefilled cartridge for use in an on-body injector (OBI). The OBI is only approved for Crohn's disease and ulcerative colitis. In IBD patients, there is an associated risk of hepatotoxicity.
- **mirikizumab (Omvoh)** is indicated for ulcerative colitis in adults. The manufacturer of Omvoh is seeking approval for Crohn's disease. For safety, hepatotoxicity is a concern.

Plaque Psoriasis (IL-17s and IL-23s)

- All agents approved for plaque psoriasis are equally recommended in the U.S. (American Academy of Dermatology) and European (European Dermatology Forum) guidelines.
- A 2023 Cochrane Review reported for efficacy the IL-17s provided the most robust class response, followed by the IL-23s, TNF inhibitors, and then oral small molecules (e.g., apremilast [Otezla]). In terms of reaching Psoriasis Area Sensitivity Index (PASI) 90 scores, Taltz, Skyrizi, Bimzelx and the TNF-inhibitor infliximab (Remicade) were similar for best response. For safety, there was no overall difference in serious adverse events. For any adverse event, there was a slight preference for IL-23s over IL-17s.
- In terms of clinical coverage, due to REMS requirements Siliq is not recommended as a step preferred agent due to safety concerns, and Ilumya and Siliq are limited by approval solely for plaque psoriasis. For the remaining Il-17 and IL-23 agents, there is no overarching reason to prefer one over another in terms of safety or efficacy.

Psoriatic Arthritis (IL-17s and IL-23s)

- Various guidelines for psoriatic arthritis recommend TNF-inhibitors, IL-23s and IL-17s as first-line.
- A 2024 Network Meta-analysis concluded Cosentyx and Taltz were the treatments with highest probability of reaching both PASI 100 and American College of Rheumatology Score (ACR) 70 for skin and peripheral arthritis.
- Overall, the drug choice is based on concurrent disease states. An IL-17 is recommended for disease manifestations that are difficult to treat (e.g., fingernails).

Spondyloarthritis (IL-17s)

- Guidelines from the European League Against Rheumatism (EULAR) recommend NSAIDs as first-line therapy. A biologic can be considered after failure of high-dose NSAIDs.
- A published matching-adjusted indirect comparison of the individual clinical trials for Cosentyx, Taltz and Bimzelx for ankylosing spondylitis did not show compelling differences in endpoints between these three drugs.

Inflammatory Bowel Disease – Crohn's Disease (IL-23s)

- Guidelines recommend considering use of biologics early in the disease course. Failure of non-biologics (e.g., 5-aminosalicylates, low-dose oral methotrexate) should not be required before a biologic.
- Guideline-recommend therapies include the TNF inhibitors, vedolizumab (Entyvio) which is an integrin receptor antagonist initiated as an IV infusion, IL-23s and Janus kinase (JAK) inhibitors (e.g., upadacitinib [Rinvoq]).
- When compared in a head-to-head, Skyrizi and Stelara were comparable for week 24 clinical remission although Skyrizi performed better at week 48 endoscopic remission. A head-to-head trial between Stelara and Humira did not show a statistically significant difference in clinical remission at 52 weeks.

Inflammatory Bowel Disease – Ulcerative Colitis (IL-23s)

- Non-biologics still maintain a role in UC treatment per most guidelines.
- The TNF inhibitors, Stelara, Entyvio, and JAK inhibitors are recommended per guidelines. Stelara is also currently recommended per the guidelines, other IL-23s are not discussed.
- Clinical trial data is available with Stelara, Skyrizi, Tremfya and Omvoh. No head-to-head trials are available to influence decision-making as to comparative efficacy and safety among the IL-23s.
- *Note that following the November P&T meeting updated ulcerative colitis guidelines were published and will be reviewed at a future meeting.*

Safety

- Published clinical practice guidelines do not make a distinction among individual IL-17 or IL-23 agents in terms of safety.
- Noted adverse events for all the products include hypersensitivity risk, increased risk of infections including tuberculosis, and warnings against concurrent use of live vaccines. Unique safety concerns were discussed above with the individual product summaries.
- A systematic review and meta-analysis of the adverse events with IL-17 and IL-23 inhibitors in plaque psoriasis and psoriatic arthritis found the following:
    - In long-term (52 week) treatment trials, Taltz and Skyrizi had the lowest frequency of serious adverse events.
    - The proportion of patients with any adverse event was lower with the IL-23 inhibitors compared with IL-17 inhibitors.
    - Overall, both classes appear well-tolerated with good safety profiles.

Other Factors

- Special populations:
    - Stelara has supported safety in the pregnancy population. There is no compelling evidence that alternative IL-17s or IL-23s should be preferred over another during pregnancy. TNF inhibitors are also considered safe and effective in pregnancy.
    - Pediatric patients are directed to secukinumab (Cosentyx), ixekizumab (Taltz), or ustekinumab (Stelara), based on FDA-labeling.
- Provider opinion:
    - Military Health System (MHS) dermatologists voiced that for plaque psoriasis the IL-17s and IL-23s are superior to Humira and have a quicker onset of action. They also stated a preference for Taltz or Skyrizi.
    - MHS gastroenterologists stated that for the IL-23s for Crohn's disease and ulcerative colitis Stelara is the first-choice due to current formulary status and cost, and that Skyrizi is reserved for cases of Stelara failure.
    - MHS rheumatologists relayed that Humira still has a place in the algorithm, and will have continued use, even if the step-preference is removed. They also requested adding Taltz to the formulary. However, they recommend that patients well controlled on Cosentyx should not be moved to Taltz.

Overall Conclusion

- Based on FDA indication and published guidelines it is reasonable to require a trial of Humira first for many immune-mediated diseases including plaque psoriasis. Network meta-analysis and provider preference recommend IL-17s or IL-23s as first-line treatment for plaque psoriasis.
- Biosimilar products are interchangeable to the reference product. Market launch of Stelara biosimilars in 2025 provides an opportunity for contracting initiatives with other Federal agencies via a JNC.
- Within the two subclasses, when the agents are compared to each other, there do not appear to be overall compelling differences in efficacy and safety. Individual patients may show differences in response to individual agents.
- Provider feedback overwhelmingly supported increasing accessibility to the IL-23 and IL-17 agents.
- For clinical coverage, at least one IL-17 and one IL-23 are needed on the formulary to meet the needs of MHS beneficiaries. Additional options should be considered to provide choices for providers based on individual patient characteristics.

B. TIBs: IL-17s and IL-23s Subclasses—Relative Cost Effectiveness Conclusion

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

Interleukin-17s

- CMA results showed that the formulary placement of ixekizumab (Taltz) as UF and step-preferred was cost-effective.
- BIA and sensitivity results showed that overall expenditures would increase, however, designating Taltz as step-preferred and all the other IL-17s as non-step-preferred would generate potential cost avoidance in the future as new patients transition over to Taltz.

Interleukin-23s

- CMA showed that leaving space open on the formulary to select a UF and step-preferred IL-23 via a future JNC could lead to increased long-term use of a cost-effective agent. Potential cost avoidance of anticipated biosimilar entrants to Stelara in 2025 were discussed.
- All BIA scenarios demonstrated elevated expenditures regardless of formulary status. However, as other biosimilars are marketed, designating cost effective agents as step-preferred may offer expenditure relief.

Additionally, for the IL-23s, a JNC opportunity in 2025 may provide cost effective biosimilar alternatives to Stelara.

- The DoD P&T Committee recognized that there is increasing expenditures for the class as new therapies emerge. While TNF inhibitors continue to remain a guideline-recommended therapy, improving the patient experience with increased access to drugs with multiple mechanisms of action, longer dosing intervals, and alternative side effect profiles over traditional TNF-inhibitors was supported by the collective professional judgment of the committee.

C. TIBs: IL-17s and IL-23s Subclasses—UF Recommendation

The P&T Committee recommended for the IL-17s (19 for, 0 opposed, 0 abstained, 1 absent) and for the IL-23s (18 for, 0 opposed, 1 abstained, 1 absent), the following.

IL-17s

- UF and step-preferred
  - ixekizumab (Taltz) *moves from NF non-step-preferred*
- UF and non-step-preferred
  - secukinumab (Cosentyx)
- NF and non-step-preferred
  - brodalumab (Siliq)
  - bimekizumab (Bimzelx)
- Completely Excluded – None
- Note, as part of this recommendation the requirement for a trial of Humira will be removed for the plaque psoriasis indication for the step-preferred agent but the Humira trial will remain for the other agents and indications.

IL-23s

- UF and step-preferred
  - No agent selected, leaving option open for a future JNC IL-23 originator/biosimilar (anticipated 2025)
- UF and non-step-preferred
  - ustekinumab (Stelara)
  - guselkumab (Tremfya) *moves from NF non-step-preferred*
  - risankizumab (Skyrizi) *moves from NF non-step-preferred*
  - tildrakizumab (Ilumya) *moves from NF non-step-preferred*
- NF and non-step-preferred
  - mirikizumab (Omvoh) *moves from UF non-step-preferred*

- Completely Excluded – None
- Note a trial of Humira is still preferred for some indications.

D. TIBs: IL-17s and IL-23s Subclasses—Manual PA Criteria

Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 1 absent) updated manual PA criteria for the IL-17 and IL-23 products in new users as outlined below.

General Changes

- Updating the step therapy requirements as outlined in the formulary recommendation and adding new indications as necessary.
- Refining the current statement regarding non-biologic systemic therapy for plaque psoriasis and ulcerative colitis to only include intolerance or contraindication and not inadequate response.
- Updating all ankylosing spondylitis and non-radiographic ankylosing spondyloarthritis criteria to remove the requirement for non-biologic systemic therapy and retaining the requirement for NSAIDs first, based on the EULAR guidelines.
- Removing the requirement to try non-biologic systemic therapy first for Crohn's disease.
- Removing the criteria regarding a negative tuberculosis test prior to starting therapy.
- Streamlining the list of medications to avoid concurrent use to classes rather than individual agents (new medications, biosimilars).

IL-17s: Current PA criteria for the IL-17s require a trial of Humira first for all indications. The recommended PA changes for the IL-17s include the following:

- For Taltz, which is now the step-preferred IL-17, removing the requirement for a trial of Humira for the plaque psoriasis indication. A trial of Humira is still required for the indications of psoriatic arthritis, ankylosing spondylitis, and non-radiographic spondylitis, unless the patient has had an inadequate response, contraindication or adverse reaction to Humira. Additionally, an automated look back for Cosentyx and Humira will allow bypass of the PA in new users. Automated specialist bypass will be added for dermatologists, so that no PA will be required.
- For Cosentyx, removing the current automation but maintaining the trial of Humira and adding a trial of Taltz first in new users, unless the patient has had an inadequate response, contraindication or cannot tolerate Humira and Taltz. A trial of Taltz is not required for the indications of generalized pustular psoriasis, enthesis-related arthritis, HS or pediatric psoriatic arthritis.

- For Siliq and Bimzelx, requiring a trial of Humira, Taltz and Cosentyx in new users, unless the patient has had an inadequate response, contraindication or cannot tolerate Humira, Taltz and Cosentyx.

IL-23s: For the IL-23 agents, currently Humira is required first for all indications. The recommended PA changes include the following:

- Maintaining the requirement for a trial of Humira for all the non-step preferred IL-23 products.
- For Stelara removing the requirement for a trial of Humira first if the patient is stable on IV therapy for infliximab for ulcerative colitis. Removing the requirement for other treatments (immunomodulators, corticosteroids, Humira) first for Crohn's disease.
- For Tremfya and Skyrizi, removing the previous step requirement for Cosentyx and Stelara; the Humira step will remain.
- For Ilumya, the Humira requirement will remain, but automated specialist bypass will be added for dermatologists.
- For Omvoh, requiring a trial of Humira, Stelara, Tremfya and Skyrizi in all new users, unless the patient has had an inadequate response, contraindication or cannot tolerate Humira, Stelara, Tremfya and Skyrizi.
- Biosimilars for the IL-23, ustekinumab are expected to launch in 2025. This provides a potential option for a JNC. This subclass condition set is open to allow the JNC selection to be placed as the step-preferred UF IL-23.

The Manual PA criteria is as follows.

IL-17s

1. ixekizumab (Taltz)

PA criteria apply to all new users of ixekizumab (Taltz)

Automated PA Criteria: When prescribed by a dermatologist prior authorization is not required. Once therapy is initiated by a dermatologist 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. OR

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

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

- Patients 18 years of age or older with:
  - Active psoriatic arthritis (PsA)
  - Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy (Note: Humira step does not apply)
  - Active ankylosing spondylitis (AS)
  - Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Pediatric patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy (6 years of age or older) (Note: Humira step does not apply)
- Patient had inadequate response to Humira OR had adverse reaction to Humira that is not expected to occur with the requested agent OR has a contraindication to Humira (Note: Applies to PsA, AS, nr-axSpA)
- Patient had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g. sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine], etc.) (Note: AS and nr-axSpA do not apply)
- Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS and nr-axSpA ONLY)
- Coverage 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, JAK inhibitors

Non-FDA-approved uses are not approved

Prior Authorization does not expire

2. secukinumab (Cosentyx)

Manual PA criteria apply to all new users of Cosentyx and coverage is approved if all criteria are met

- Provider acknowledges that Taltz is the Department of Defense's preferred IL-17. The patient must have tried Humira AND Taltz:
  - The patient had an inadequate response to Humira AND Taltz OR
  - The patient experienced an adverse reaction to Humira AND Taltz that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira AND Taltz (Note: Taltz trial not required for generalized pustular psoriasis, enthesis-related arthritis, hidradenitis suppurativa or pediatric psoriatic arthritis)

- Coverage is approved for patients 18 years of age or older with one of the following diagnosis/indications:
  - Active psoriatic arthritis (PsA)
  - Generalized pustular psoriasis (GPP) with a history of at least two GPP flares of moderate-to-severe intensity in the past
  - Moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy
  - Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
  - Active ankylosing spondylitis (AS, axSpA)
  - Moderate to severe hidradenitis suppurativa (HS)
- Coverage is approved for pediatric patients with one of the following diagnosis/indications:
  - Moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy (Age 6+)
  - Enthesis-related arthritis (ERA) (Age 4+)
  - Active psoriatic arthritis (PsA) (Age 2+)
  - Generalized pustular psoriasis (GPP) with a history of at least two GPP flares of moderate-to-severe intensity in the past (Age 12+)
- Criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], antibiotics, anti-androgens, etc.) (Note: AS, nr-axSpA, ERA do not apply)
  - Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS and nr-axSpA ONLY)
  - May not be used concomitantly with other TIBs agents, including but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors

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

Prior Authorization does not expire

3. brodalumab (Siliq)

Manual PA Criteria: PA criteria apply to all new users of brodalumab (Siliq) and coverage is approved if all criteria are met:

- The provider acknowledges that Taltz is the Department of Defense's preferred interleukin-17 (IL-17) agent. A trial of Humira, Taltz and Cosentyx are required before Siliq
  - Patient had inadequate response to Humira, Cosentyx, AND Taltz OR
  - Patient had adverse reaction to Humira, Cosentyx, AND Taltz that is not expected to occur with the requested agent OR
  - Patient has a contraindication to Humira, Cosentyx, AND Taltz AND
- Patient is 18 years of age of older
- Patient has moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy
- Patient does not have suicidal ideation and behavior
- Patient has had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g. sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine], etc.)
- Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, 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 6 months, then approved indefinitely.

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

- Patient has responded to therapy and has not had suicidal ideation

4. bimekizumab (Bimzelx)

PA criteria apply to all new users of bimekizumab (Bimzelx)

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

- The provider acknowledges that Taltz is the Department of Defense's preferred interleukin-17 agent. The patient must have tried Taltz, Humira and Cosentyx.
  - Patient had an inadequate response to Humira, Cosentyx, AND Taltz OR
  - Patient had adverse reaction to Humira, Cosentyx, AND Taltz that is not expected to occur with Bimzelx OR
  - Patient has a contraindication to Humira, Cosentyx, AND Taltz AND

- Patient is 18 years of age of older with:
  - Moderate to severe plaque psoriasis who is a candidate for systemic therapy or phototherapy
  - Active psoriatic arthritis
  - Active ankylosing spondylitis
  - Active non-radiographic axial spondyloarthritis with objective signs of inflammation
- Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) (Note: AS and nr-axSpA indications do not apply)
- Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies only to AS and nr-axSpA indication)
- Patient will not be receiving any other targeted immunomodulatory biologics with bimekizumab, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors

Non-FDA approved uses are not approved

PA does not expire

IL-23s

1. ustekinumab (Stelara)

PA criteria apply to all new users of Stelara

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

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

- Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira
  - The patient had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira
- Coverage approved for patients 18 years of age or older with:
  - Active psoriatic arthritis

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Moderately to severely active Crohn's disease
- Moderately to severely ulcerative colitis (UC)

- Coverage approved for patients ages 6 to 17 years with:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- The criteria below apply to all patients unless noted:
  - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Crohn's disease)
  - 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. guselkumab (Tremfya)

PA criteria apply to all new users of Tremfya

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

- Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira
  - The patient had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira
- Coverage approved for patients 18 years of age or older with the following diagnosis/indications:
  - Active psoriatic arthritis
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
  - Moderately to severely ulcerative colitis (UC)

- Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Crohn's disease)
- 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. tildrakizumab (Ilumya)

PA criteria apply to all new users of tildrakizumab (Ilumya)

Automated PA Criteria: When prescribed by a dermatologist prior authorization is not required. Once therapy is initiated by a dermatologist 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. OR

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

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

- Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira
  - Patient had an inadequate response to Humira OR
  - Patient had an adverse reaction to Humira that is not expected to occur with Ilumya OR
  - Patient has a contraindication to Humira AND
- Patient is 18 years of age of older with the following diagnosis/indications:
  - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants, etc.)

- 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

4. risankizumab (Skyrizi) pens and syringes

PA criteria apply to all new users of risankizumab (Skyrizi)

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

- Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira
  - Patient had an inadequate response to Humira OR
  - The patient has had an adverse reaction to Humira is not expected with Skyrizi the Skyrizi OR
  - Patient has a contraindication to Humira AND
- Patient is 18 years or older with the following diagnosis/indications:
  - Active psoriatic arthritis (PsA)
  - Moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
- Patient has tried and had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine])
- Coverage NOT provided for concomitant use with other TIBs, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors
- For treatment of plaque psoriasis or psoriatic arthritis providers should fill out the PA for Skyrizi pen and syringes. Use of the on-body injector is limited to Crohn's disease or ulcerative colitis.

Non-FDA approved uses are not approved

PA does not expire

5. risankizumab (Skyrizi OBI) on-body injector

Manual PA criteria apply to all new users of risankizumab On-Body Injector (Skyrizi OBI).

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

- Provider acknowledges that a trial of Humira is required before Skyrizi OBI
  - The patient has had an inadequate response to Humira OR
  - The patient has had an adverse reaction to Humira, that is not expected with Skyrizi OBI OR
  - The patient has a contraindication to Humira AND
- Patient is 18 years of age or older with the following diagnosis/indications
  - Moderately to severely active Crohn's disease
  - Moderately to severely active ulcerative colitis
- Patient has tried and had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) (Note: does not apply to CD)
- Coverage not provided for concomitant use with other TIBs, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors
- Use of the on-body injector for non-FDA-approved indications including plaque psoriasis, or psoriatic arthritis is not approved. Providers should fill out the PA for Skyrizi pen and syringes for indications other than Crohn's disease or ulcerative colitis.

Non-FDA approved uses are not approved

PA does not expire

6. mirikizumab (Omvoh)

Manual PA criteria apply to all new users of risankizumab mirikizumab (Omvoh)

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

- Provider acknowledges that a trial of Humira, Stelara, Tremfya and Skyrizi are required before Omvoh
  - Patient had inadequate response to Humira, Stelara, Tremfya, and Skyrizi OR
  - Patient had adverse reaction to Humira, Stelara, Tremfya, and Skyrizi that is not expected to occur with Omvoh the requested agent OR
  - Patient has a contraindication to Humira, Stelara, Tremfya, and Skyrizi
- Patient is 18 years of age or older with the following diagnosis/indications
  - Moderately to severely active ulcerative colitis

- Patient has tried and had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) (Note: does not apply to CD)
- Coverage not provided for concomitant use with other TIBs, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors

Non-FDA approved uses are not approved

PA does not expire

E. TIBs: IL-17s and IL-23s Subclasses—Implementation Plan

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

- ***IL-17s***: an effective date of the first Wednesday 90-days after signing of the minutes in all points of service, and
- ***IL-23s***: 1) an effective date of the first Wednesday 120-days after signing of the minutes in all points of service, and that 2) DHA send letters to the patients affected by the formulary change for Omvoh.

III. UF DRUG CLASS REVIEW—TIBS: IL-17s AND IL-23s SUBCLASSES

UF BAP Comments

A. TIBs: IL-17s and IL-23s Subclasses—UF Recommendation

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

IL-17s

- UF and step-preferred
  - Taltz *moves from NF non-step-preferred*
- UF and non-step-preferred
  - Cosentyx
- NF and non-step-preferred
  - Siliq
  - Bimzelx
- Completely Excluded – None

IL-23s

- UF and step-preferred
  - No agent selected at this time

- UF and non-step-preferred
    - Stelara
    - Tremfya *moves from NF non-step-preferred*
    - Skyrizi *moves from NF non-step-preferred*
    - Ilumya *moves from NF non-step-preferred*
- NF and non-step-preferred
    - Omvoh *moves from UF non-step-preferred*
- Completely Excluded – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. TIBs: IL-17s and IL-23s Subclasses—Manual PA Criteria

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. TIBs: IL-17s and IL-23s Subclasses—UF, PA and Implementation Plan

The P&T Committee recommended for the IL-17s an effective date of the first Wednesday 90 days after signing of the minutes in all points of service and for the IL-23s an effective date of the first Wednesday 120 days after signing of the minutes in all points of service and that DHA send letters to the patients affected by the formulary change for Omvoh.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—MIGRAINE AGENTS: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS ORAL AGENTS SUBCLASS

P&T Comments

A. Migraine Agents: CGRP Antagonists Oral Agents Subclass—Relative Clinical Effectiveness Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the oral CGRP antagonists. The subclass was previously reviewed in May 2022.

The drugs in the subclass differ in their FDA-approved indications. Ubrogepant (Ubrelvy) is approved for the acute treatment of migraine, rimegepant orally dissolving tablet (Nurtec ODT) is approved for both acute treatment of migraine and prevention of episodic migraine, and atogepant (Qulipta) is labeled for prevention of episodic and chronic migraine. The evidence review focused on new information published since 2022.

The injectable CGRP products [erenumab (Emgality), fremanezumab (Ajovy) and galcanezumab (Aimovig)] are solely indicated for prevention of migraine headache and were reviewed in November 2023.

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

Professional Treatment Recommendations

- *Acute migraine headache treatment*: According to the 2024 International Headache Society, medications with established efficacy for acute migraine treatment should be considered prior to initiating the oral CGRP agents. Specifically, oral CGRP agents may be considered after a trial of three or more triptans, or in patients with a contraindication to or intolerability to triptans.
- *Preventive migraine headache treatment*: The oral CGRP medications may be considered along with other standard treatment options, including antiepileptics (e.g., valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol), antidepressants (e.g., amitriptyline, nortriptyline) and injectable CGRP agents as first-line treatment options for episodic migraine prevention. This recommendation is supported by the 2024 American Headache Society.

Efficacy

- *Acute treatment*: A 2024 BMJ network meta-analysis concludes that the oral CGRP antagonists (Ubrelvy, Nurtec ODT) are less efficacious than triptans when assessing pain freedom at 2 hours and sustained pain freedom from 2 to 24 hours post-dose when compared to placebo.
- *Preventive treatment*: There are no head-to-head trials comparing Nurtec ODT and Qulipta to other standard migraine preventive treatments or to their injectable CGRPs counterparts.

  Recent NMA data shows superior efficacy of the injectable CGRPs over the oral preventive medications.

Safety

- *Acute treatment*: The 2024 BMJ network meta-analysis concludes that Ubrelvy showed a statistically significantly increased risk of nausea compared with placebo; the risk with Nurtec ODT was not significant. For other adverse events where comparative data was available (e.g., chest pain, dizziness, vomiting, paresthesia, and diarrhea), both Nurtec ODT and Ubrelvy were no different when compared to placebo.
- *Preventive treatment*: A 2023 Journal of Headache and Pain network meta-analysis concludes that based on moderate certainty evidence, the injectable CGRPs and oral CGRPs are not significantly different from placebo when assessing adverse events leading to discontinuation.

  When comparing the oral CGRPs, Qulipta was associated with a statistically significant higher odds of treatment-emergent adverse events when compared to placebo, while the Nurtec ODT was not different from placebo. Both Qulipta and Nurtec ODT were no different than placebo when assessing adverse events leading to discontinuation and serious adverse events. (2023 Cephalalgia network meta-analysis.)

Other Factors

- *ubrogepant (Ubrelvy)* allows for multiple repeated doses in a 24-hour period for acute migraine treatment. It is available in multiple strengths and can be dose-adjusted in patients with hepatic failure.
- *rimegepant (Nurtec ODT)* is available as a single strength. For acute treatment, a single dose may be used in a 24-hour period. For preventive treatment, the dosing regimen is taken every other day.
- *atogepant (Qulipta*) is indicated for preventive treatment for both chronic and episodic migraine types. It is available in multiple strengths and is dosed once daily.

Overall Conclusions

- In terms of efficacy and safety, there is a high degree of interchangeability between the oral CGRP agents, when compared across the same clinical indication.
- In order to meet the needs of MHS beneficiaries, at least one oral CGRP agent is required for treatment of each indication, acute migraine treatment and episodic migraine prevention.

B. Migraine Agents: CGRP Antagonists Oral Agents Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA, BIA, and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following

- CMA results showed that ubrogepant (Ubrelvy) was the most cost-effective oral CGRP antagonist, followed by atogepant (Qulipta), and then rimegepant (Nurtec ODT).
- BIA results found that designating Ubrelvy and Qulipta as UF step-preferred and Nurtec ODT as NF non-step-preferred demonstrated significant cost avoidance for the Military Health System (MHS).

C. Migraine Agents: CGRP Antagonists Oral Agents Subclass—UF Recommendation

The P&T Committee recommended (17 for, 2 opposed, 0 abstained, 1 absent) the following.

- UF step-preferred
  - atogepant (Qulipta) *moves from UF to UF step-preferred*
  - ubrogepant (Ubrelvy) moves *from UF to UF step-preferred*
- NF non-step-preferred
  - rimegepant (Nurtec ODT) *moves from UF to NF non-step-preferred*
- Complete exclusion – None
- Note that step-therapy will require a trial of Qulipta or Ubrelvy in new and current users of Nurtec ODT

D. Migraine Agents: CGRP Antagonists Oral Agents Subclass—Manual PA Criteria

PA criteria were originally recommended when the individual oral CGRP medications were first evaluated as new drugs in 2020. The PA criteria will follow the International Headache Society recommendations for first-line therapies. Additionally, use of the new step-preferred oral CGRPs will be required first before Nurtec ODT. The P&T Committee recommended (18 for, 1 opposed, 0 abstained, 1 absent) the following as outlined below.

- For Ubrelvy for acute use, in new users, an automated drug lookback for Nurtec ODT or a triptan in the previous 180 days will apply. If the patient has not previously received Nurtec ODT, then the current criteria for a trial of at least two triptans will be maintained. The current 6-month renewal criteria will be removed, therefore the PA won't expire.
- For Nurtec ODT, the manual PA criteria will apply to new and current users.
  - For acute use, a trial of Ubrelvy and two triptans (e.g., sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), or eletriptan (Relpax)) is required, unless the patient has a contraindication to, intolerability to or has failed treatment with triptans and Ubrelvy.

- For preventive use, a trial of Qulipta is required first in addition to the current requirements for one standard preventive drug (e.g. beta-blocker, anti-epileptic or antidepressant) and one injectable CGRP (Aimovig, Ajovy, Emgality)) unless the patient has a contraindication to, intolerability to or has failed these treatments.

  For patients currently using Nurtec ODT for migraine headache prevention who are stable on therapy, a trial of Qulipta is not required. Additionally, in patients who have an approved PA (identified as those currently using 16 tablets monthly), if a new prescription is written for Qulipta, a corresponding PA will be approved for Qulipta.

- For Qulipta, for preventive use in new users, an automated drug lookback for an injectable CGRP in the past 720 days will apply. If the patient has not previously received an injectable CGRP, then the current manual PA criteria will be maintained, requiring a trial of one standard preventive drug (e.g. beta-blocker) and one injectable CGRP.

The Manual PA criteria is as follows. Updates from the November 2024 meeting are in bold and strikethrough

1. atogepant (Qulipta)

PA criteria apply to new users of Qulipta

Automated PA criteria: The patient has filled a prescription for galcanezumab 120 mg (Emgality), erenumab (Aimovig), or fremanezumab (Ajovy) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 720 days.

Manual PA Criteria: **If automated PA criteria are not** met Qulipta is approved if all criteria are met:

- Patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed
- Patient has a diagnosis of chronic migraine OR
- Patient has Episodic Migraine as defined by the following:
  - 4 to 7 migraine days per month for 3 months AND has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR
  - 8 to 14 migraine days per month for 3 months

- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
  - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
  - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
  - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of one of these injectable CGRPs:
  - erenumab (Aimovig)
  - fremanezumab (Ajovy)
  - galcanezumab (Emgality)

Non-FDA-approved uses are not allowed

Prior authorization expires in 6 months

Renewal Criteria: (Initial TRICARE PA approval is required for renewal.) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

- The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
  - Migraine Disability Assessment (MIDAS)
    - Reduction of ≥ 5 points when baseline score is 11–20
    - Reduction of ≥ 30% when baseline score is > 20
  - Headache Impact Test (HIT-6)
    - Reduction of ≥ 5 points
  - Migraine Physical Functional Impact Diary (MPFID)
    - Reduction of ≥ 5 points

2. rimegepant (Nurtec ODT)

PA criteria apply to all new and current users of Nurtec ODT, and is approved if all criteria are met

For Both Acute Treatment and Prevention

- The patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist

- Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrelvy or another gepant) is not allowed

For Acute Treatment

- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
  - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) **AND**
- **Patient has a contraindication to, intolerability to, or has failed a trial of Ubrelvy**

For Prevention of Episodic Migraine

- The patient has episodic migraine as defined by one of the following:
  - Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR
  - Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
  - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
  - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
  - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents
  - erenumab (Aimovig)
  - fremanezumab (Ajovy)
  - galcanezumab (Emgality)
- **Patient has a contraindication to, intolerability to, or has failed a 2-month trial of Qulipta. OR**
- **It the patient is currently stable on Nurtec ODT, then a trial of Qulipta is not required and the patient may stay on Nurtec ODT therapy**
- If approved for prevention: authorized quantity limit is 16 ODT for 30 days or 48 ODT for 90 days

Non-FDA-approved uses are not allowed

Prior authorization expires in 6 months

Renewal Criteria: (Initial TRICARE PA approval is required for renewal.) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

Acute Treatment

- Patient has a documented positive clinical response to therapy

Preventive Treatment

- The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
  - Migraine Disability Assessment (MIDAS)
    - Reduction of ≥ 5 points when baseline score is 11–20
    - Reduction of ≥ 30% when baseline score is > 20
  - Headache Impact Test (HIT-6)
    - Reduction of ≥ 5 points
  - Migraine Physical Functional Impact Diary (MPFID)
    - Reduction of ≥ 5 points

3. ubrogepant (Ubrelvy)

PA criteria apply to new users of Qulipta

Automated PA criteria: The patient has filled a prescription for rimegepant (Nurtec ODT) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days.

Manual PA Criteria: **If automated PA criteria are not** met Ubrelvy or Nexlizet is approved if all criteria are met:

- Patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed
- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications

- sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)

Non-FDA-approved uses are not allowed

~~Prior authorization expires in 6 months~~ **PA does not expire**

~~Renewal Criteria: (Initial TRICARE PA approval is required for renewal.) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:~~

- ~~Acute Treatment: Patient has a documented positive clinical response~~

E. Migraine Agents: CGRP Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) that DHA will send letters to beneficiaries receiving Nurtec ODT who will be affected by the formulary status change and PA.

V. UF DRUG CLASS REVIEW—MIGRAINE AGENTS: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS ORAL AGENTS SUBCLASS

UF BAP Comments

A. Agents: CGRP Antagonists Oral Agents Subclass—UF Recommendation

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

- UF step-preferred
  - Qulipta
  - Ubrelvy
- NF non-step-preferred
  - Nurtec ODT
- Complete exclusion – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Migraine Agents: CGRP Antagonists Oral Agents Subclass—Manual PA Criteria

The P&T Committee recommended manual PA criteria as outlined above.

UF BAP Comments

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

C. Migraine Agents: CGRP Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

The P&T Committee recommended an effective date the first Wednesday 90 days after signing of the minutes in all points of service, and the DHA send letters to the patients affected by the formulary and PA changes for Nurtec ODT.

UF BAP Comments

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

VI. UF DRUG CLASS REVIEW—INSULINS: RAPID-ACTING INSULIN ANALOGS SUBCLASS AND SHORT-ACTING, INTERMEDIATE-ACTING AND COMBINATION INSULIN SUBCLASS

P&T Comments

A. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—Relative Clinical Effectiveness Conclusion

The Rapid Acting Insulin (RAI) subclass was last reviewed at the November 2019 DoD P&T Committee meeting, and branded insulin aspart (Novolog) and branded insulin lispro (Humalog) were designated as step-preferred. Since the last review, several biosimilars and unbranded biologics are now marketed. There are currently shortages in the class. Additionally, termination of pricing agreements along with other U.S. market forces, including the American Rescue Plan Act and Inflation Reduction Act, warranted a clinical effectiveness review in preparation for participation in a JNC in 2025 with other Federal partners. The short-, intermediate-acting and combination insulins were included in the review.

The DoD P&T Committee concluded in November 2022 and reaffirmed at the August 2024 meeting ("Process for Evaluating Biosimilars and Biologics") that by FDA approval and definition, biosimilars are equally safe and efficacious, which provides strong competition within products for drug classes with

biosimilars. Not all biosimilars are cost effective when compared to their reference product.

The P&T Committee concluded for the RAIs (19 for, 0 opposed, 0 abstained, 1 absent) and for the short-, intermediate-acting and combinations (18 for, 0 opposed, 0 abstained, 2 absent) the following:

RAIs

Professional Treatment Recommendations

- There were no major updates to the P&T Committee clinical conclusions from 2019 that showed there are no clinically relevant differences between the RAIs in lowering hemoglobin A1c. Since the last class review, biosimilar formulations of insulin lispro (Lyumjev and an unbranded lispro), and insulin aspart (unbranded) were reviewed as new drugs.
- Numerous clinical practice guidelines are available (e.g., American Diabetes Association, American Association of Clinical Endocrinologists, American College of Endocrinology) and none give preference to one RAI (insulin aspart, insulin lispro, and insulin glulisine) over another.
- For special populations, guidelines to include American College of Obstetrics and Gynecology and International Society for Pediatric and Adolescent Diabetes acknowledged that RAIs are safe in pregnancy and pediatrics and no preferences were given regarding use of one RAI over another.
- Although there are subtle differences between RAIs with regard to pharmacokinetic profiles in terms of onset and duration of action, there do not appear to be compelling clinically relevant difference between the products.

Safety

- With regard to adverse events, there was no new data to change the previous conclusion that there is no evidence suggesting a clinically relevant difference in the number, type or severity of adverse reactions between insulin aspart or insulin lispro.

Individual Product Characteristics

- *Insulin aspart (Novolog)* is approved for use in inulin pumps and is suitable for children as young as 2 years of age. Other advantages include availability in various dosage forms, including pens, vials, and cartridges.
- *Insulin lispro (Humalog)* advantages include approval for insulin pumps and in pediatric patients down to age 3 years, and availability in all dosage forms (pen, vials, and cartridges). It is also available in a U-200 formulation. The Humalog Junior KwikPen formulation allows half unit dosing for pediatrics.

- *Insulin glulisine (Apidra)* may be used in insulin pumps and in pediatric patients down to 4 years. Disadvantages of Apidra include a greater susceptibility to precipitation and catheter occlusions in insulin pumps, and the association with significantly elevated hypoglycemia rates.
- *Insulin lispro (Admelog)* is an insulin lispro formulation that does not show clinically relevant differences in hemoglobin A1c or post-prandial blood glucose versus Humalog. It is approved in pumps and in children as young as 3 years of age.
- *Fiasp* is a formulation of insulin aspart that contains niacinamide, a form of vitamin B3. There is no data to show that Fiasp is superior to other rapid-acting insulins, and it has been completely excluded from the formulary since November 2019.
- *Biosimilar RAIs:* Biosimilar RAI formulations include insulin lispro-aabc (Lyumjev) which is also available in a U-200 formulation, unbranded insulin lispro and unbranded insulin aspart. Currently, Lyumjev is not compatible in insulin pumps.

MHS Provider Feedback

- Provider feedback concluded that Humalog and Novolog are considered bioequivalent. The U-200 formulations are not routinely used clinically. Admelog and Apidra are rarely used. Providers related that having an RAI that was compatible with insulins was essential. Additionally, products with half-unit pens available with the Humalog Junior is preferred for pediatrics.

Therapeutic Interchangeability and Clinical overage

- Overall, there is a high degree of interchangeability among the RAIs, and one product is needed on the formulary to meet the needs of the majority of MHS patients.

Short-, Intermediate-Acting and Combination Insulins

- For the short-acting products, Humulin R and Novolin R provide the same active ingredient, onset, peak, and duration of action. Differences may exist in packaging or brand names, but the core function and effectiveness of regular insulin are consistent across brands.
- For the intermediate-acting products, Humulin N and Novolin N are both NPH insulin with the same active ingredient.
- Premixed insulins are beneficial for patients who have difficulty drawing insulin from two separate vials. The short acting/intermediate analog mix pens are therapeutically interchangeable with each other.
- American Diabetes Association guidelines do not state a preference for one product over another within the categories.

- During emergency conditions, the FDA allows substitution of one regular insulin (e.g., Humulin R, Novolin R) for another brand of regular insulin, and allows substitution of one intermediate-acting insulin (e.g., Humulin N, Novolin N) for another intermediate-acting insulin product on a unit-per-unit basis.
- MHS provider feedback stated that within the short-, intermediate-acting and combinations, the products are the same.

Overall Conclusions

- The RAI reference biologics and their biosimilars are interchangeable; the RAI analogs (e.g., lispro, aspart, and glulisine) are interchangeable; and the RAI analog reference products are interchangeable to other RAI analog biosimilars (e.g., lispro reference to aspart biosimilar). The DoD P&T Committee endorses this review as the clinical review for the rapid-acting insulins for JNC contracting purposes.
- The injectable short, intermediate, and combo insulin reference biologics and their biosimilars are interchangeable. The MHS will continue to participate in the JNC process and will select the JNC selected-product as the UF step-preferred product for all new patients.

B. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—Relative Cost Effectiveness Analysis and Conclusion

Given clinical interchangeability, cost can be the deciding factor for selecting a preferred rapid-acting, short-acting, intermediate-acting, and combination insulin product for inclusion on the UF, given the clinical conclusions above. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent):

- The cost analysis for the RAIs included the influence of shortages, termination of pricing agreement on current pricing.
- For both the RAIs and the short-acting, intermediate-acting and combination insulins, the JNC processes meet the requirements for determining the relative cost effectiveness for biosimilar agents.
- The P&T Committee supports participation in future JNC to secure optimal pricing for biosimilars.

C. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent)

- The JNC selected rapid acting, short, intermediate, and combination insulins will be designated as UF and step-preferred on the JNC effective date.
- The rapid-acting, short, intermediate, and combination insulins that are not selected for the JNC will be designated as non-step-preferred on the JNC effective date.
- The formulary status of the non-step-preferred/completely excluded RAIs will not change unless reviewed by the DoD P&T Committee.
- Step therapy will require a trial of the JNC preferred product in all new users for all the non-step-preferred products.
- The P&T Committee will recommend that MTFs should consider implementing an auto-substitution policy for the preferred agent.
- Until the JNC effective date for the RAIs, the current formulary status will apply.
    - UF and step-preferred
        - insulin aspart (Novolog Flex Pen)
        - insulin lispro (Humalog Kwikpen and authorized generic insulin lispro)
        - Lyumjev Kwikpen
    - UF and non-step-preferred
        - insulin aspart authorized generic
    - NF and non-step-preferred
        - insulin lispro (Admelog)
        - insulin glulisine (Apidra)
    - Completely Excluded
        - insulin aspart/niacinamide (Fiasp)

D. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—Manual PA Criteria

PA will not be required for the JNC preferred agent however, PA criteria have applied to the non-step-preferred products since the 2019 class review. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- Maintaining the current step therapy for Admelog and Apidra until the JNC effective date, requiring a trial of insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) in new users, unless the patient is on an insulin pump or if the patient is currently stabilized on Admelog or Apidra.

- A general PA form for future non-step-preferred products in new users was created and will launch on the JNC effective date. The general PA form will acknowledge the JNC step-preferred agent does not require a PA, will require a diabetes diagnosis, require a trial and failure of the JNC-selected step-preferred product unless there is a contraindication or adverse events, and allow for coverage is the non-preferred product has an indication that is lacking with the JNC step-preferred product.

E. Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass —UF, PA, and Implementation Period

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) the following:

- The implementation plan will be based on the JNC effective date, taking into consideration the implementation timeline for P&T Committee recommendations.
- Implementation of step-preferred agent for new and current patients will occur on the JNC effective date or no more than 2 weeks after JNC effective date.
- Implementation of non-step-preferred agents for new patients will occur 60 days after the JNC effective date to allow for updating the PA forms.

VII. UF DRUG CLASS REVIEW—INSULINS: RAPID-ACTING INSULIN ANALOGS SUBCLASS AND SHORT-ACTING, INTERMEDIATE-ACTING AND COMBINATION INSULIN SUBCLASS

UF BAP Comments

A. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass—UF Recommendation

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

- The JNC selected rapid acting, short, intermediate, and combination insulins will be designated as UF and step-preferred on the JNC effective date.
- The rapid-acting, short, intermediate, and combination insulins that are not selected for the JNC will be designated as non-step-preferred on the JNC effective date.
- The formulary status of the non-step-preferred/completely excluded RAIs will not change unless reviewed by the DoD P&T Committee.

- Step therapy will require a trial of the JNC preferred product in all new users for all the non-step-preferred products.
- The P&T Committee will recommend that MTFs should consider implementing an auto-substitution policy for the preferred agent.
- Until the JNC effective date for the RAIs, the current formulary status will apply.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass —Manual PA Criteria

The P&T Committee recommended manual PA criteria as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass —UF, PA, and Implementation Period

- The implementation plan will be based on the JNC effective date, taking into consideration the implementation timeline for P&T Committee recommendations.
- Implementation of step-preferred agent for new and current patients will occur on the JNC effective date or no more than 2 weeks after JNC effective date.
- Implementation of non-step-preferred agents for new patients will occur 60 days after the JNC effective date to allow for updating the PA forms.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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

The products were divided into two groups when presented at the DoD P&T Committee meeting. The generic names are presented below. Group 1 included Tryvio, Crexont, clobetasol ophthalmic, Onyda XR, Ebglyss, Nemluvio, Femlyv, Yorvipath, Livdelzi, Sofdra, Zepbound vials, Vafseo, Vigafyde, and Voranigo; Group 2 included Ohtuvayre, Neffy, Lazcluze, Aqneursa, and Cobenfy.

The P&T Committee agreed (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 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 (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF
  - carbidopa/levodopa extended release (ER) capsules (Crexont) – Parkinson's Agents
  - epinephrine 2 mg/0.1 mL nasal spray (Neffy) – Miscellaneous Respiratory Agents
  - lazertinib (Lazcluze) – Oncological Agents: Epidermal Growth Factor Receptor (EGFR) plus Non-Small Cell Lung Cancer (NSCLC)
  - lebrikizumab-lbkz injection (Ebglyss) – Atopy Agent for atopic dermatitis
  - levacetylleucine (Aqneursa) – Miscellaneous Neurological Agent for Niemann Pick disease
  - nemolizumab-ilto injection (Nemluvio) – TIBs: Miscellaneous Interleukins for prurigo nodularis
  - palopegteriparatide injection (Yorvipath) – Osteoporosis Agents
  - seladelpar (Livdelzi) – Gastrointestinal-2 Agent for primary biliary cholangitis
  - vigabatrin 100 mg/mL oral solution (Vigafyde) – Anticonvulsants – Antimania Agents
  - vorasidenib (Voranigo) – Oncological Agent
- NF

- aprocitentan (Tryvio) – Antihypertensive Agent – Endothelin Receptor Antagonists
- clonidine (ER) 0.1 mg/mL oral suspension (Onyda XR) – Attention Deficit Hyperactivity Disorder (ADHD) Agents: Non-Stimulants
- ensifentrine nebulized inhalation suspension (Ohtuvayre) – Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease
- norethindrone acetate/ ethinyl estradiol orally dissolving tablet (ODT) (Femlyv) – Contraceptive Agents: Monophasics with 20 mcg estrogen
- sofpironium 12.45% topical gel pump (Sofdra) – Antiperspirants
- vadadustat (Vafseo) – Hematological Agents: RBC Stimulants Erythropoietin Agents
- xanomeline/ trospium (Cobenfy) – Antipsychotic Agents: Atypical

- Completely Excluded
  - clobetasol 0.05% ophthalmic emulsion (no brand name) – Miscellaneous Ophthalmic
  - tirzepatide vials (Zepbound vials) – Weight Loss Agents; This formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vial to patient self-pay only.

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) the following PA criteria

- Applying manual PA criteria to new users of, Crexont, Lazcluze, Nemluvio, Aqneursa, Yorvipath, Vafseo, and Voranigo, consistent with the current PA requirements for the respective drug classes.
- Applying manual PA criteria to new users of Tryvio, requiring use of guideline-supported drugs for resistant hypertension first.
- Applying manual PA criteria to new users of Onyda XR, Ohtuvayre, Ebglyss, Femlyv, Livdelzi, and Sofdra, requiring a trial of other formulary alternatives first.
- Applying manual PA criteria to new users of Cobenfy requiring a trial of a first- and second-generation antipsychotic first.

The Manual PA criteria is as follows:

1. aprocitentan (Tryvio)

Manual PA criteria apply to all new users of the Tryvio.

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 a hypertension specialist (for example: internal medicine, cardiologist, nephrologist, or prescriber with certification from the American Society of Hypertension)
- Patient has systolic blood pressure of > 140 mmHg
- Patient has tried at least three antihypertensive medications from the following classes one of which must be a diuretic, taken at maximally tolerated doses
  - diuretic
  - renin-angiotensin system blockers (e.g., ACE inhibitor or ARB blocker)
  - calcium channel blockers
  - mineralocorticoid receptor blocker (e.g., spironolactone)
- Women of child-bearing age will be tested for pregnancy
- Provider is enrolled in the Risk Evaluation and Mitigation System (REMS) program
- Non-FDA approved uses are not approved, including for pulmonary arterial hypertension.
- Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met
  - Tryvio treatment has controlled blood pressure within goal range

2. carbidopa-levodopa XR (Crexont)

Manual PA criteria apply to all new users of Crexont

Manual PA criteria: Crexont is approved if:

- Patient has tried and failed generic controlled release formulation of carbidopa/levodopa

Non-FDA-approved uses are not approved

Prior Authorization does not expire

3. clonidine XR oral suspension (Onyda XR)

Manual PA criteria apply to all new users of Onyda XR

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

- Patient is 6 years of age or older
- Patient has diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient has tried and failed, had an inadequate response, OR contraindication to all of the following:
  - amphetamine salts XR (Adderall XR, generic) or other long-acting amphetamine or derivative drug
  - methylphenidate OROS (Concerta, generic) or other long-acting methylphenidate or derivative drug
  - non-stimulant ADHD medication (generic formulation of Strattera or Intuniv)
  - generic clonidine HCL extended-release tablet

Non-FDA-approved uses are not approved

Prior Authorization does not expire

4. ensifentrine (Ohtuvayre)

Manual PA criteria apply to all new users of ensifentrine

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

- Patient is 18 years of age or older
- The drug is prescribed or in consultation with pulmonologist
- Patient has moderate to severe COPD or airflow obstruction as demonstrated by Forced Expiratory Volume 1 second (FEV1) of 30%- 80%)
- Patient has tried and failed, defined as uncontrolled symptoms, with either of the following treatments:
  - LAMA/LABA (Duaklir Pressair, Bevespi Aerosphere, Stiolto Respimat, Anoro Ellipta) or
  - LAMA/LABA/ICS (Breztri Aerosphere, Trelegy Ellipta) AND
- Ensifentrine will only be used as add on therapy to LAMA/LABA or LAMA/LABA/ICS

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 for continuation of therapy if all the criteria are met:

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

5. lazertinib (Lazcluze)

Manual PA criteria apply to all new users of lazertinib (Lazcluze)

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
- Patient has a diagnosis of locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutation
- The medication will be prescribed in combination with amivantamab (Rybrevant)
- The patient will be given prophylaxis for the prevention of venous thromboembolism during the first four months of treatment
- 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

PA does not expire

6. lebrikizumab-lbkz (Ebglyss)

Manual PA criteria apply to all new users of lebrikizumab-lbkz (Ebglyss)

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

- Patient is 12 years of age or older
- Patient’s weight is 40 kg or greater
- Prescribed by a dermatologist, allergist or immunologist
- Patient has diagnosis of moderate to severe atopic dermatitis
- Patient has contraindication to, intolerability to, or has failed treatment with ONE medication in EACH of the following categories: topical corticosteroids and topical calcineurin inhibitors
- Patient has contraindication to, intolerability to, inability to access treatment, or patient failed treatment with Narrowband UVB phototherapy

- For all indications the patient is not currently receiving another immunobiologic therapy

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

PA expires after 12 months

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

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

7. levacetylleucine (Aqneursa)

Manual PA criteria apply to all new users of Aqneursa.

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

- Patient weighs 15 kilograms or greater
- Prescribed by a physician who specializes in the treatment of Niemann-Pick disease type C
- Patient has a genetically confirmed diagnosis of Niemann-Pick disease type C
- Patient has one or more neurologic symptoms (e.g., loss of motor function, difficulty swallowing, and speech and cognitive impairment)

Non-FDA approved uses are not approved

PA does not expire

8. norethindrone acetate/ethinyl estradiol ODT (Femlyv)

Manual PA criteria apply to all new users of Femlyv

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

- Provider acknowledges that other formulations of ethinyl estradiol (EE) 20 mcg/ norethindrone 1 mg (e.g., Loestrin, Aurovela, Microgestin, Junel, Larin or equivalent) are on the formulary and do not require prior authorization
- Provider acknowledges that there are chewable contraceptive tablets (norethindrone 1 mg/EE 20 mcg/iron (e.g., Charlotte 24 Fe, Finzala, Mibelas 24 Fe); norethindrone 0.8mg/EE 25 mcg (e.g., Kaitlib Fe, Layolis Fe); norethindrone 0.4mg/EE 35 mcg/iron (e.g., Wymzya Fe)) and alternate dosage forms (etonogestrel/EE ring (generic NuvaRing); norelgestromin/EE patch (Xulane, Zafemy); and medroxyprogesterone acetate injection (generic Depo-Provera) on the formulary that do not require prior authorization

- Patient has tried and failed or has a relative contraindication to a contraceptive from one of the following classes: chewable, patch, ring, injection, or IUD
- Patient requires oral disintegrating tablets and can neither chew nor swallow due to some documented medical condition (e.g., developmental disability, muscular weakness, etc.) and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

9. nemolizumab-ilto (Nemluvio)

Manual PA criteria apply to all new users of Nemluvio

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

- Patient is 18 years of age or older
- Nemluvio is prescribed by an allergist, immunologist, or dermatologist
- Patient has a diagnosis of prurigo nodularis
- Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk
- Patient has experienced pruritus for 6 weeks or longer
- Patient's prurigo nodularis is NOT medication-induced or secondary to a nondermatologic condition OR the patient has a secondary cause of prurigo nodularis that has been identified and adequately managed
- The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy

Non-FDA approved uses are not approved

PA does not expire

10. palopegteriparatide (Yorvipath)

Manual PA criteria apply to all new users of Yorvipath.

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

- Patient is 18 years of age or older
- Prescribed or in consultation with endocrinologist

- Patient has diagnosis of chronic hypoparathyroidism; based on hypocalcemia in the setting of inappropriately low serum PTH levels
- Patient cannot be well-controlled on calcium supplements and active forms of vitamin D
- Patient has an albumin-corrected serum calcium concentration greater than or equal to 7.8 mg/dL at baseline OR ionized serum calcium greater than or equal to 4.4 mg/dL at baseline
- Patient does not have acute post-surgical hypoparathyroidism

Non-FDA approved uses are not approved

PA does not expire

11. seladelpar (Livdelzi)

Manual PA criteria apply to all new users of Livdelzi.

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

- Patient is 18 years of age or older
- The drug is prescribed or in consultation with a gastroenterologist, hepatologist or liver transplant physician
- Patient has a diagnosis of primary biliary cholangitis (PBC)
- Diagnosis has been confirmed by at least TWO of the following
  - alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values
  - positive anti-mitochondrial antibodies (AMAs)
  - histologic evidence of PBC from a liver biopsy
- Patient does not have decompensated cirrhosis
- Patient has been receiving ursodiol therapy for one year or greater and has had an inadequate response OR has been unable to tolerate ursodiol therapy
- Patient has a contraindication to, intolerability to, or has failed a trial of obeticholic acid (Ocaliva)

Non-FDA approved uses are not approved

PA does expires in 6 months

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

- Patient meets initial criteria, has documentation of positive clinical response (e.g., improved biochemical markers of PBC such as ALP and bilirubin)

12. sofpironium topical gel (Sofdra)

Manual PA criteria apply to all new users of Sofdra

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

- Patient is 9 years of age or older
- Patient has diagnosis of primary axillary hyperhidrosis for greater than or equal to 6 months
- The drug is prescribed by a dermatologist
- Patient has tried and failed at least one topical 20% or higher aluminum salt antiperspirant (either OTC or prescription, e.g., Drysol)
- Patient has tried and failed at least two additional options (e.g. Botox, MiraDry, iontophoresis, oral anticholinergics [glycopyrrolate, oxybutynin, propantheline], propranolol, clonidine or diltiazem)

Non-FDA approved uses are not approved, including for palmar, plantar, facial, or other forms of hyperhidrosis

PA does not expire

13. vadadustat (Vafseo)

Manual PA criteria apply to all new users of Vafseo

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

- Provider acknowledges that epoetin alfa-epbx (Retacrit) is the preferred erythropoietin stimulating agents (ESA) for TRICARE and are available without prior authorization
- Patient is 18 years of age or older
- Prescribed by or in consultation with a nephrologist
- Patient has diagnosis of anemia due to chronic kidney disease
- Patient has experienced an inadequate response or adverse reaction to Retacrit
- Patient has been receiving dialysis for at least 3 months
- Provider is aware of the warnings, screening and monitoring precautions for Vafseo

Non-FDA approved uses are not approved

PA does expire in 6 months

Renewal Criteria: Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. Continued use of Vafseo will be approved indefinitely for the following:

- The patient has had a positive response to therapy (i.e., increase or stabilization in hemoglobin levels or a reduction or absence in red blood cell transfusions

14. vorasidenib (Voranigo)

Manual PA criteria apply to all new users of Voranigo

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

- Patient is 12 years of age or older
- The drug is prescribed by or in consultation with a hematologist/oncologist
- Patient has diagnosis of Grade 2 astrocytoma or oligodendroglioma and had surgery, including biopsy, sub-total resection, or gross total resection
- Patient has IDH1 or IDH2 mutations as demonstrated by an FDA-approved test
- 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

PA does not expire

15. xanomeline/trospium chloride (Cobenfy)

Manual PA criteria apply to all new users of Cobenfy

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

- Patient is 18 years of age or older
- The drug is prescribed by a psychiatrist
- Patient has an established, primary diagnosis of schizophrenia
- Patient has a history of acute exacerbations OR relapses of psychotic symptoms which have failed to respond to ONE SECOND generation antipsychotic at maximally tolerated doses
- Patient has a history of acute exacerbations OR relapses of psychotic symptoms which have failed to respond to ONE FIRST generation antipsychotic at maximally tolerated doses
- Patient is being treated for an acute exacerbation or relapse of psychotic symptoms

Non-FDA approved uses are not approved

PA does not expire

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) adding 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 Completely Excluded 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 recommendation at 30 day and 60 days prior to implementation.

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

UF BAP Comments

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

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

- UF
  - Crexont
  - Neffy
  - Lazcluze
  - Ebglyss
  - Aqneursa
  - Nemluvio
  - Yorvipath
  - Livdelzi
  - Vigafyde
  - Voranigo
- NF
  - Tryvio
  - Onyda XR

- Ohtuvayre
- Femlyv
- Sofdra
- Vafseo
- Cobenfy

- Completely Excluded
  - clobetasol 0.05% ophthalmic emulsion (no brand name)
  - Zepbound vials

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 and PA Implementation Period

The P&T Committee recommended implementation period of two weeks for the drugs recommended for UF and NF status, and 120 days for the drugs recommended as completely excluded as discussed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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

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

a) **Oncological Agents: Renal Cell Carcinoma—everolimus tablet (Torpenz)—**Other versions of everolimus tablets in the same strengths are available, including Afinitor and generics, that are more cost-effective than this version made by a sole manufacturer.

b) **Skeletal Muscle Relaxants and Combinations—methocarbamol 1,000 mg tablet (generic, Tanlor)—**Numerous other more cost-effective methocarbamol tablets are available including methocarbamol 500 mg and 750 mg.

c) **Antiemetic-Antivertigo Agents—ondansetron 16 mg ODT—**Numerous other more cost-effective ondansetron formulations are available including ondansetron tablets and ODTs in 4 mg and 8 mg strengths.

The Manual PA criteria is as follows:

1. everolimus tablet (Torpenz)

Manual PA criteria apply to all new and current users of everolimus (Torpenz)

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

- Provider acknowledges that this drug has been identified as having cost-effective alternatives and everolimus (Afinitor, generics) is available without prior authorization.
- Provider must explain why the patient cannot use everolimus (Afinitor, generics
  - Acceptable responses include if the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in everolimus (Afinitor, generics),

Non-FDA-approved uses are not approved

Prior authorization does not expire

2. **methocarbamol 1,000 mg tablets (generics, Tanlor)**

   Manual PA criteria apply to all new and current users of methocarbamol 1,000 mg tablets (generics, Tanlor)

   Manual PA criteria: methocarbamol 1,000 mg tablets (generics, Tanlor) are approved if all criteria are met:

   - Provider acknowledges that this drug has been identified as having cost-effective alternatives including methocarbamol 500 mg or 750 mg, which are available without prior authorization.
   - Provider must explain why the patient cannot use methocarbamol 500 mg or 750 mg
     - Acceptable responses include if the patient has trialed and failed methocarbamol 500 mg or 750 mg AND cyclobenzaprine 5 mg or 10 mg

   Non-FDA-approved uses are not approved

   Prior authorization does not expire

3. **ondansetron 16 mg ODT**

   Manual PA criteria apply to all new and current users of ondansetron 16 mg ODT

   Manual PA criteria: ondansetron 16 mg ODT is approved if all criteria are met:

   - Provider acknowledges that this drug has been identified as having cost-effective alternatives and ondansetron 4 mg and 8 mg tablets and ODTs are available without prior authorization.
   - Provider must explain why the patient cannot use preferred formulations of ondansetron
     - Acceptable responses include if the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in preferred formulations of ondansetron

   Non-FDA-approved uses are not approved

   Prior authorization 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 (17 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Torpenz, methocarbamol 1,000 mg and ondansetron 16 mg ODT in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first

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

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

UF BAP Comments

The P&T Committee recommended manual PA for Torpenz, methocarbamol 1,000 mg and ondansetron 16 mg ODT as stated above and an effective date the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 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) **Oncological Agents**—Efforts to standardize and streamline the PAs for oncology drugs are ongoing. Edits were made to four oncology PAs (Retevmo, Augtyro, Krazati, and Lynparza). 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.

- **Oncological Agents—repotrectinib (Augtyro)**—Augtyro is now approved for a subset of patients with solid tumors who have a neurotrophic receptor tyrosine kinase gene fusion. The manual PA criteria were also updated to reflect this new indication.

- **Oncological Agents: Lung Cancer—adagrasib (Krazati)—** The manual PA criteria were also updated to allow use of Krazati in combination with cetuximab for the treatment of KRAS G12C-mutated locally advanced or metastatic colorectal cancer in adults who have received prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.
- **Oncological Agents: Lung Cancer—selpercatinib (Retevmo)—**The manual PA were also expanded to include patients two years of age and older with one of the following cancers:
  - Advanced or metastatic medullary thyroid cancer with a rearranged during transfection (RET) mutation
  - Advanced or metastatic thyroid cancer with a RET gene fusion who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
  - Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
- **Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)—** The Lynparza PA was updated with the aforementioned oncology standardization edits.

b) Psoriasis Agents: roflumilast 0.15% cream (Zoryve)—Zoryve received a new indication for treating mild to moderate atopic dermatitis in patients six years of age or older. For this indication, Zoryve requirements include specialist prescribing or consultation with a specialist, and a trial of at least two weeks for both a topical corticosteroid and a topical calcineurin inhibitor, unless the patient has failed therapy, has a contraindication or has had an adverse reaction to the corticosteroid and calcineurin inhibitor.

c) Atopy: dupilumab (Dupixent)—The manual PA criteria were expanded to include patients 12 years of age or older with chronic rhinosinusitis with nasal polyposis.

d) Atopy: benralizumab (Fasenra Pen)—The manual PA criteria were updated to allow for treatment of adults with eosinophilic granulomatosis with polyangiitis.

e) TIBs: Non-TNFs—apremilast (Otezla)—Otezla received an expanded age indication for moderate to severe plaque psoriasis in children six years of age or older who weigh 20 kg or greater. The manual PA criteria were updated to require a trial of Humira and non-biologic systemic therapy for this indication.

f) **TIBs: TNFs—certolizumab (Cimzia)—**Cimzia received a new indication for active polyarticular juvenile idiopathic arthritis in patients two years of age or older. The manual PA criteria were updated and require a trial of Humira and non-biologic systemic therapy.

g) **Anticonvulsant Antimania Agents—lacosamide ER (Motpoly XR)—** The manual PA criteria were updated to allow for adjunctive use in treatment of primary generalized tonic-clonic seizures in patients weighing greater than or equal to 50 kg.

h) **Immunological Miscellaneous Agents—peanut (Arachis hypogaea) allergen powder-dnfp (Palforzia)—**The manual PA criteria were expanded to include patients one through three years of age with a confirmed diagnosis of peanut allergy.

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

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 4 absent) updates to the manual PA criteria for Retevmo, Augtyro, Krazati, Lynparza, Zoryve, Dupixent, Fasenra, Otezla, Cimzia, Motpoly XR, and Palforzia 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 NEW FDA APPROVED INDICATIONS

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Retevmo, Augtyro, Krazati, Lynparza, Zoryve, Dupixent, Fasenra, Otezla, Cimzia, Motpoly XR, and Palforzia in new users and an implementation effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria for several drugs, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

a) **Antipsychotic Agents: Atypical—pimavanserin (Nuplazid)—**The manual PA was edited to remove the requirement for a baseline Mini-Mental Status Examination score based on provider feedback.

b) **Antifungals—oteseconazole (Vivjoa)—**The Vivjoa PA criteria were updated to allow for prescribing by infectious disease specialists in addition to gynecologists, based on specialist feedback.

c) **Hematological Agents—iptacopan (Fabhalta)—**Fabhalta was reviewed as an innovator drug at the May 2024 P&T meeting and was designated NF with a PA, allowing use for paroxysmal nocturnal hemoglobinuria. In August 2024, the Fabhalta label was expanded to include the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. Currently, two other drugs are also approved for IgAN, sparsentan (Filspari), designated as UF, and budesonide delayed-release (Tarpeyo), which is completely excluded from the formulary. Filspari recently gained an expanded approval to slow the decline in kidney function in IgAN.

   A review of the clinical trial data for the three drugs, draft IgAN clinical practice guidelines, and cost effectiveness supported requiring a trial of Filspari before Fabhalta for IgAN. The updated PA criteria for Fabhalta also mirror the inclusion and exclusion criteria from the approval trial.

d) **Osteoporosis Agents: Parathyroid Hormone (PTH) Analogs—teriparatide (Forteo, Bonsity)—**The manual PA criteria for the teriparatide products were updated due to a change in the FDA label and provider feedback. Previous labeling did not recommend use beyond two years of therapy due to concerns for osteosarcoma, based on rodent studies. Subsequent human observational studies have not shown an increased osteosarcoma risk, and the FDA label now allows use beyond two years in patients at high risk for fracture. The PA criteria were updated to remove the two-year limitation and to add renewal criteria.

e) **Gynecological Agents Miscellaneous—fezolinetant (Veozah)—**Veozah was reviewed as an innovator drug at the August 2023 P&T meeting. In September of this year, the FDA released a drug safety communication stating that Veozah can cause rare but serious liver injury, based on one case report. This update in package labeling necessitated a change in the Veozah PA criteria for hepatic monitoring.

f) **Pancreatic Enzyme Replacement Therapy (PERT)—pancrelipase (Zenpep)—**For the PERT class, Creon is UF step-preferred, available without a PA, and available at the lowest (generic) co-pay. Viokace is UF non-step-preferred, while Pancreaze, Pertzye, and Zenpep are NF non-step-

preferred. For Zenpep, a trial of Creon, Viokace, Pancreaze and Pertzye are required first, based on cost effectiveness from the February 2019 review. Based on continual drug class surveillance, it was advantageous to the government to update the Zenpep PA and remove the additional requirements to trial Viokace, Pancreaze, and Pertzye.

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

The P&T Committee recommended (17 for, 0 opposed, 0 abstained and 3 absent) updated manual PA criteria for Nuplazid, Vivjoa, Fabhalta, Forteo, Bonsity, Veozah and Zenpep in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

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

BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Nuplazid, Vivjoa, Fabhalta, Forteo, Bonsity, Veozah and Zenpep, and an implementation effective 60-days after signing of the minutes.

UF BAP Comments

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

XVI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR ANTILIPIDEMIC-1S CLASS: NEXLETOL, NEXLIZET AND REPATHA

P&T Comments

A. Antilipidemic-1s Class: Non-statins and Combinations and proprotein convertase subtilisin/kexin type-9 (PCSK-9) Inhibitors Subclasses—Updated PA criteria

The non-statins and combinations subclasses, which included bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) were reviewed for formulary status at the August 2024 DoD P&T Committee meeting. Nexletol and Nexlizet were both recommended to move to UF status, and the PA criteria were revised to require a trial of a PCSK-9 inhibitor first, and to include the new FDA-approved indication for primary prevention in high-risk patients. Updates were made at that time to the PCSK-9 inhibitors PA criteria for alirocumab (Praluent) and evolocumab (Repatha) to expand

the allowable uses to the primary prevention population. Implementation of these changes is set to occur on January 29, 2025.

DHA contracting provided clarified information to the P&T Committee regarding Nexletol and Repatha, prompting the P&T Committee to recommend changes to the PA criteria. For Nexletol and Nexlizet, the requirement for a trial of PCSK-9 inhibitor and the automated lookback for a PCSK-9 inhibitor will not be implemented.

For Repatha, no PA will be required if the prescription is written by a cardiologist, endocrinologist or cardiac transplant physician (specialist bypass). Additionally, for prescriptions initially written by a specialist, an automated drug lookback for Repatha will allow PA approval if the patient has received the drug in the past 180 days, to allow continuation of therapy for prescriptions subsequently written by non-specialists. Lastly, an automated drug look back will apply for prescriptions filled for a high intensity statin, ezetimibe, or ezetimibe/simvastatin in the past 180 days to allow bypass of the PA.

B. Updated PA Criteria and Implementation Period for -1s Class: Non-statins and Combinations and proprotein convertase subtilisin/kexin type-9 (PCSK-9) Inhibitors Subclasses

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria in new users for Nexletol, Nexlizet and Repatha. The formulary status from the August 2024 P&T meeting (UF) will remain. The requirement for a PCSK-9 trial before Nexletol and Nexlizet from the August 2024 P&T meeting will not be implemented. Implementation of the changes noted above will be effective on signing of the minutes.

XVII. UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR ANTILIPIDEMIC-1S CLASS: NEXLETOL, NEXLIZET AND REPATHA

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Nexletol, Nexlizet and Repatha and an implementation effective on signing of the minutes.

UF BAP Comments

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

XVIII. RE-EVALUATION OF NF GENERICS—ACNE AGENTS TOPICAL ACNE AND ROSACEA: FORMULARY STATUS AND IMPLEMENTATION PLAN

P&T Comments

The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed.

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30 days, for NF Topical Acne and Rosacea agents (adapalene or clindamycin gel and combinations.)

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) the following changes to formulary status and prior authorization criteria, with an implementation of the first Wednesday 30 days after signing of the minutes at all points of service.

- Returning the following to UF status: adapalene/benzoyl peroxide 0.1/2.5% gel pump (Epiduo generics) and adapalene/benzoyl peroxide 0.3/2.5% gel pump (Epiduo Forte generics); these two agents are similar in terms of average cost per 30-day supply to the two current UF adapalene products.
- Removing the PA requirements for adapalene/benzoyl peroxide [BP] 0.1/2.5% gel pump (Epiduo generics), adapalene/BP 0.3/2.5% gel pump (Epiduo Forte generics), and clindamycin/BP 1.2/2.5% gel (Acanya generics); the latter is very little used compared to the three other current clindamycin/benzol peroxide gel products on the UF.

XIX. RE-EVALUATION OF NF GENERICS—ACNE AGENTS TOPICAL ACNE AND ROSACEA: FORMULARY STATUS AND IMPLEMENTATION PLAN

UF BAP Comments

Formulary and PA changes included returning Epiduo generic and Epiduo Forte generics to UF status, and removing the PA criteria for Epiduo generics, Epiduo Forte generics, and Acanya generics, with an implementation of the first Wednesday 30 days after signing of the minutes at all points of service.

UF BAP Comments

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