DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
November 2024

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on November 6th and 7th, 2024.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of August 2024 Minutes—RDML Matthew Case, Acting Assistant Director, Health Care Administration DHA, approved the minutes from the August 2024 DoD P&T Committee meeting on October 28th, 2024.

B. Clarification of previous meeting minutes

- **May 2024**
  - **Implementation Plan for 60-days after signing recommendations:** The 60-days after signing implementation date occurred on October 2nd, 2024.
- **August 2024**
  - **Newly Approved Drug—Humira by Cordavis implementation plan:** The adalimumab (Humira) formulation by Cordavis was recommended for Complete Exclusion status. Due to the low numbers of patients currently receiving this formulation, the implementation will occur two weeks after signing of the August minutes, rather than the usual 120 days. Beneficiary notification will occur soon thereafter.
  - **Antilipidemic 1's—Statin and Non-Statins:** Fluvastatin ER (Lescol XL) is moving from nonformulary to uniform formulary status, so the current medical necessity criteria will be removed.

III. REQUIREMENTS

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

(MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g (a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, 10 USC 1074g (a)(9), added by Section 702(c)(2) of the NDAA for FY 2015 requires beneficiaries generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

A. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-17 and IL-23 Inhibitors Subclasses

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 class, 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 Bimzelx label was expanded for HS on November 19, 2024).* Limitations include

lack of approval for children and adverse effects of liver abnormalities, suicidal ideation (although no risk evaluation and mitigation strategy (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 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 or 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. *(Refer to the November 2022 and August 2024 DoD P&T Committee meeting minutes for the "Process for Evaluating Biosimilars and Biologics").*
- **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 patients with inflammatory bowel disease (IBD), 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 tied 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 clear reason to prefer one over another in terms of safety or efficacy for plaque psoriasis.

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 PASI100 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 ulcerative colitis treatment per most guidelines.
- The TNF inhibitors, Stelara, Entyvio, and JAK inhibitors are recommended per guidelines. Stelara is 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:
    - The most common adverse drug reactions across all therapies included infections, nasopharyngitis, and headaches.
    - 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 and 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 recommended 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.
- Biosimilars 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 one another, 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 additional choices for providers based on individual patient characteristics.

Relative Cost Effectiveness Analysis and 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 come on the market, 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 biosimilars to ustekinumab.
- The 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 judgement of the P&T Committee.

1. ***COMMITTEE ACTION: 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 agents, but Humira 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 products (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.

2. ***COMMITTEE ACTION: 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. See Appendix C for the full criteria.
   - *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 using 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 medications with which 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 first for the plaque psoriasis indication. A trial of Humira is required for the indications of psoriatic arthritis, ankylosing spondylitis, and non-radiographic ankylosing 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 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, since Stelara will move to UF, non-step-preferred status and the other IL-23 products do not have this criteria. 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 conditions set is open to allow the JNC selection to be placed as the step-preferred UF IL-23.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—*** The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) MN criteria for the NF IL-17s, Siliq and Bimzelx, and for the IL-23 product Omvoh. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QLs for all agents of a 60-day supply at all three points of service (POS). See Appendix D for the full QLs.

5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the IL-17 subclass and IL-23 subclass on the TRICARE Maintenance Drug List and on the non-formulary to mail requirement.

6. ***COMMITTEE ACTION: UF, PA, MN, QL, TRICARE MAINTENANCE DRUG LIST, and IMPLEMENTATION PERIOD—*** 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. See Appendix G for the actual implementation date.

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

Background—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)] which are solely indicated for prevention of migraine headache and were reviewed in November 2023, are not discussed here.

Relative Clinical Effectiveness Conclusion—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 regarding preventive treatment of episodic migraine management.

Efficacy

- *Acute treatment*: A 2024 British Medical Journal (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 network meta-analysis shows superior efficacy of the injectable CGRPs over the oral preventive medications.

Safety

- *Acute treatment*: A 2024 BMJ network meta-analysis concludes that Ubrelvy showed a statistically significantly increased risk of nausea compared with placebo; the risk of Nurtec ODT was not significant. For other adverse event outcomes 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 Nurtec ODT was not statistically 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 Cephalagia network meta-analysis.)

Other Factors

- *ubrogepant (Ubrelvy)* allows for multiple repeated doses in a 24-hour period. 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.

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 Ubrelvy was the most cost-effective oral CGRP antagonist, followed by Qulipta, and then 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 MHS.

1. ***COMMITTEE ACTION: 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

2. ***COMMITTEE ACTION: 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 step-preferred oral CGRPs (Ubrelvy for preventive use and Qulipta for acute use) 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. See Appendix C for the full criteria.

   - 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 a trial of 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 if a new PA is submitted. 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.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Nurtec ODT. See Appendix B for the full criteria.
4. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current quantity limits for Ubrelvy, Nurtec ODT, and Qulipta. See Appendix D for the full QLs.
5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) excluding all three oral CGRPs due to the acute use exception. See Appendix F.
6. ***COMMITTEE ACTION: UF, PA, MN, TRICARE MAINTENANCE DRUG LIST 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. See Appendix G for the implementation date.

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

Background—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 June 2025 with other Federal partners. The short-acting, intermediate-acting and combination insulins were also included in the review.

The DoD P&T Committee concluded in November 2022 and reaffirmed in 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.

Note that the inhaled insulin product Afrezza is now classified as a miscellaneous insulin and will not be reviewed here; it will remain NF with PA.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded for the RAIs (19 for, 0 opposed, 0 abstained, 1 absent) and for the short-acting, 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 Associate, 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 the 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 in 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 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. 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 were rarely used. Providers related that having an RAI that was compatible with insulin pumps 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-Acting, Intermediate-Acting and Combination Insulins

- For the short-acting products, Humulin R and Novolin N 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 neutral protamine Hagedorn (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-acting 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-acting, intermediate-acting and combinations space, the products are the same.
- Overall utilization of this subclass is much lower in the MHS than the RAIs.

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 accepts this review as the clinical review for rapid-acting insulins.
- The injectable short-acting, intermediate-acting and combination insulin reference products and their biosimilars are interchangeable. The MHS will continue to participate in the JNC process and will designate the JNC selected-product as the UF step-preferred product for all new patients.

Relative Cost Effectiveness Analysis and Conclusion—Given clinical interchangeability, cost can be the defining factor for selecting a 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 following:

- The cost analysis for the RAIs included the influence of shortages and 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 JNCs to secure optimal pricing for biosimilars.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following.
    - The JNC selected rapid-acting, short-acting, intermediate-acting, and combination insulins will be designated as UF and step-preferred on the JNC effective date.
    - The rapid-acting, short-acting, intermediate-acting, 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 and the Beneficiary Advisory Panel.
    - 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)

2. ***COMMITTEE ACTION: 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 of Apidra. (See Appendix C)

- 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 if the non-preferred product has an indication that is lacking with the JNC step-preferred product.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) maintaining the current MN criteria for Admelog an Apidra. See Appendix B for the full criteria. Upon the JNC effective date, the formulary alternatives will be the JNC selected preferred product and products designated as UF and step-preferred.
4. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) maintaining all rapid-acting, short-acting intermediate-acting and combination insulins on the list. See Appendix F.
5. ***COMMITTEE ACTION***: ***RAPID RESPONSE PROGRAM***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the RAIs on the rapid response (safety net program) maintained by Express Scripts. Upon the JNC effective date, the short-acting, intermediate-acting, and combination insulins will be added to the rapid response program.
6. ***COMMITTEE ACTION: UF, PA, MN, TRICARE MAINTENANCE DRUG LIST, RAPID RESPONSE PROGRAM 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.

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

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.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—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). See Appendix E for the complete list of newly approved drugs reviewed at the November 2024 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the TRICARE Mail Order Pharmacy.

1. ***COMMITTEE ACTION: 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

- Complete Exclusion
  - clobetasol 0.05% ophthalmic emulsion (no brand name) – Miscellaneous Ophthalmic
    - Clobetasol ophthalmic emulsion was recommended for complete exclusion status as it offers little to no additional clinical effectiveness compared to the other ophthalmic steroids, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include dexamethasone 0.01% ophthalmic suspension, loteprednol 0.5% ophthalmic suspension and prednisolone 1% ophthalmic suspension.
  - tirzepatide vials (Zepbound vials) – Weight Loss Agents; this formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vials to patient self-pay only. Formulary alternatives include liraglutide (Saxenda), semaglutide (Mounjaro) and tirzepatide pens (Zepbound pens).

2. ***COMMITTEE ACTION: MN 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) MN criteria for Tryvio, Onyda XR, Ohtuvayre, Femlyv, Sofdra, Vafseo, and Cobenfy. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: 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 (see Appendix C for the full 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.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—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) QLs for Ohtuvayre, Neffy, Lazcluze, Ebglyss, Aqneursa, Nemluvio, Yorvipath, Livdelzi, Vafseo, Vigafyde and Voranigo. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—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 or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List which includes the NF medications subject to the mail requirement.

6. ***COMMITTEE ACTION: UF, MN, PA, QL, TRICARE MAINTENANCE DRUG LIST 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; see Appendix G.
    - **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 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

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

   Manual PA criteria were recommended for three recently marketed drugs 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. Additionally, Torpenz will be added to the rapid response program.

   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.

   COMMITTEE ACTION: 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 everolimus tablet (Torpenz), methocarbamol 1,000 mg tablet (generic, Tanlor), 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. Everolimus (Torpenz) will be added to the Rapid Response Program. See Appendix C for the full criteria.

2. **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. See Appendix C for full criteria.

   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 criteria 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 of 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 50 kg or greater.

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.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 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. See Appendix C for the full criteria.

3. Updated PA and MN Criteria for Reasons other than New Indications

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 patients with 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 where the provider acknowledges there is limited data regarding the risk of osteosarcoma.

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 one case report. This updated 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 before Zenpep.

   COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the 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 signing of the minutes. See Appendix C for the full criteria.

B. 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 PCSK-9 inhibitor first, and to include the new FDA-approved indication for primary prevention in high-risk patients. Updates were also 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 clarifying information to the P&T Committee regarding Nexletol, Nexlizet 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.

> ***COMMITTEE ACTION: NEXLETOL, NEXLIZET and REPATHA UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—***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. Nexletol and Nexlizet will be removed from TRICARE Maintenance Drug List, due to flat-pricing across all POS. 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. See Appendix C for the full criteria.

C. Line Extensions

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

1. **Atopy—**designating **tralokinumab-ldrm (Adbry) autoinjector** with the same formulary status (NF), PA, QL, MN, Specialty and TRICARE Maintenance Drug List status as the parent Adbry prefilled syringe.
2. **Renin-Angiotensin Antihypertensives: Combinations—**designating **sacubitril/valsartan (Entresto Sprinkle)** with the same formulary status (UF) as the parent Entresto film-coated tablet.
3. **Self-Monitoring Blood Glucose Systems: Therapeutic Continuous Glucose Monitoring Systems—**designating **Freestyle Libre 3 Plus Sensor** with the same formulary status (UF) and PA as the parent FreeStyle Libre 3 Sensor. QLs will be updated from 28 to 30 days at retail, and from 84 to 90 days at MTF and Mail.

4. **Oncological Agents: Lung Cancer—**designating **selpercatinib (Retevmo) tablets** with the same formulary status (UF), PA, QL, Specialty, and TRICARE Maintenance Drug List status as the parent Retevmo capsules.
5. **TIBs: TNFs—**designating **adalimumab-ryvk (unbranded Simlandi) syringe kit** with the same formulary status (NF), non-step preferred, PA, QL, MN, Specialty and TRICARE Maintenance Drug List status as the parent Simlandi autoinjector.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) the formulary, QL, PA, MN, Specialty status, and TRICARE Maintenance Drug List status for Adbry, Entresto Sprinkle, FreeStyle Libre 3 Plus Sensor, Retevmo, and unbranded Simlandi. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. RE-EVALUATION OF NF GENERICS—ACNE AGENTS: TOPICAL ACNE AND ROSACEA

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/Tier 3 drugs that are now available in generic formulations needs to be readdressed. Refer to the November 2022 DoD P&T Committee minutes for additional information regarding established procedures for returning generic NF agents to formulary status.

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30 days supply, for NF/Tier 3 Topical Acne and Rosacea agents (adapalene or clindamycin gel and combinations.)

COMMITTEE ACTION: FORMULARY STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) the following changes to formulary status and prior authorization criteria, effective the first Wednesday 30 days after signing of the minutes. (See Appendix G for implementation dates):

- Returning the following to UF status: adapalene/benzoyl peroxide 0.1/2.5% gel pump (Epiduo generics; GCN 31775) and adapalene/benzoyl peroxide 0.3/2.5% gel pump (Epiduo Forte generics; GCN 39163); 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; GCN 31775), adapalene/BP 0.3/2.5% gel pump (Epiduo Forte generics; GCN 39163), and clindamycin/BP 1.2/2.5% gel (Acanya generics; GCN 29418); the latter is very little used compared to the three other current clindamycin/benzol peroxide gel products on the UF.

There are no changes to the PA or MN criteria for the remaining NF, non-step-preferred acne agents (e.g., Ziana, Veltin, Onexton, Neuac Kit).

IX. TRICARE MAINTENANCE DRUG LIST UPDATES

Nonformulary medications are generally restricted to TMOP pursuant to 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), added by Section 702(c)(2) of the NDAA for FY 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the TRICARE pharmacy contractor managed TMOP. Medications subject to either the nonformulary requirement or added to the EMMPI program are combined as the TRICARE Maintenance Drug List, formerly known as the Select Maintenance Drug List.

The P&T Committee reviewed a list of drugs previously added to the TRICARE Maintenance Drug List on a contingent basis that were implemented after the March 1, 2024 start date for specialty replenishment (see Appendix F, Table 2 for a list). The P&T Committee also noted that the LHRH agonist antagonist relugolix (Orgovyx), which is currently on the contingent list, is projected for addition in Jan 2025.

X. MHS GENESIS OVER-THE-COUNTER (OTC) LIST BORIC ACID VAGINAL SUPPOSITORIES AND DICLOFENAC 1% TOPICAL GEL

Background—The DoD P&T Committee reviewed an MTF request to add boric acid vaginal suppositories to the MHS GENESIS (MHSG) OTC List. In addition, the P&T Committee considered addition of diclofenac 1% topical gel to the MHSG OTC list due to market changes from prescription to OTC versions of this product, which is widely used at MTFs. OTC drugs included on the MHSG OTC list allows dispensing of the product at MTFs, but not Retail network pharmacies or TMOP. The P&T Committee noted that:

boric acid vaginal suppositories

- Boric acid vaginal suppositories promote an acidic environment in the vagina to help balance normal vaginal flora and are typically used on a nightly basis for 2-3 weeks.
- The 2021 sexually-transmitted infection guidelines from the Centers for Disease Control and Prevention (CDC) support the use of boric acid suppositories as an option for treatment of recurrent non-albicans vulvovaginal candidiasis and recurrent bacterial vaginosis. For recurrent trichomoniasis the guidelines state alternative regimens might be effective but not have been systematically evaluated, therefore consultation with an infectious disease specialist or urogynecologist is recommended.
- Feedback from urogynecology supports availability on the MHSG OTC List.
- The product is commercially available as Azo Boric Acid 600-mg vaginal suppository [I-Health; national drug code (NDC) 87651-07-6030; generic code number (GCN) 54689]. It is both listed in First DataBank (a requirement for adjudication through the Pharmacy Data Transaction Service) and available to

MTFs through the national prime vendor. Compounded versions are not covered by TRICARE.

- Boric acid vaginal suppositories are a cost-effective alternative compared to other second- or third-line options for these conditions

diclofenac 1% topical gel

- Diclofenac 1% gel first became available as an OTC product in February 2020; prescription versions (e.g., Voltaren gel) are now leaving the market.
- The Joint National Contract (JNC) product for diclofenac 1% gel (Exelan Pharma) has a new NDC for an OTC version (NDC 76282-0103-39; GCN 45680).
- Diclofenac 1% gel is an effective and widely used topical pain agent, particularly at MTFs, which fill about 25,000 prescriptions for the product per month. It is considerably more cost-effective than alternative topical pain agents, including 1.5% topical solution (e.g., Pennsaid) and lidocaine 5% patches.
- ***COMMITTEE ACTION: MHS GENESIS OTC LIST AND IMPLEMENTATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) boric acid 600 mg vaginal suppositories (GCN) 54689) and diclofenac 1% gel (GCN 45680) to the MHS GENESIS OTC list, and any current BCF legend diclofenac 1% gel formulations that are now available OTC will be removed from the BCF. Implementation will occur on or before the first Wednesday two weeks after signing of the minutes.

XII. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

A. Explanation PA Expiration Dates—For PAs where the PA does not expire, coverage will continue unless or until there is an action by the P&T Committee, including re-review of the drug or drug class and a corresponding change in PA criteria.

B. Other Changes to the MHSG OTC List: CetaKlenz and Cetaphil Skin Cleansers—The NDCs for CetaKlenz skin cleanser (GCN 78090) are not adjudicating through PDTS. NDC 00904584416 is obsolete in First DataBank (FDB) and NDC 20555001100 is not listed in FDB. A similar product, under GCN 53704 (Cetaphil Gentle Skin Cleanser), has been added as an alternative and is now included on the MHSG OTC list.

XIII. ADJOURNMENT

The meeting adjourned at 1600 hours on November 7th. The next meeting will be in February 2025.

Appendix A—Attendance: November 2024 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

[redacted]

Matthew Case
RDML, USN
Acting Assistant Director, Health Care Administration
27 January 2025
Date

Appendix A—Attendance

Voting Members Present	
[redacted]	er)

Appendix A—Attendance

Nonvoting Members Present
[redacted]
Guests
[redacted]
Others Present
[redacted]

Appendix A—Attendance

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• brodalumab (Siliq) **TIBs: IL-17 Subclass**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure **Formulary Alternatives:** Humira, Taltz, Cosentyx
• bimekizumab (Bimzelx) **TIBs: IL-17 Subclass**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure **Formulary Alternatives:** Humira, Taltz, Cosentyx
• mirikizumab (Omvoh) **TIBs: IL-23 Subclass**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure **Formulary Alternatives:** Humira, Stelara, Tremfya, Skyrizi
• rimegepant (Nurtec ODT) **Migraine Agents: Oral CGRP Antagonists**	• Use of formulary agents are contraindicated • Formulary agents resulted in therapeutic failure **Formulary alternatives:** **For Acute migraine headache treatment:** ubrogepant (Ubrelvy), three formulary triptans (for example: rizatriptan, sumatriptan, zolmitriptan, eletriptan, naratriptan) **For Preventive migraine headache:** atogepant (Qulipta) AND one injectable CGRP (Aimovig, Emgality, Ajovy)
• insulin lispro (Admelog) • insulin glulisine (Apidra) **Insulins: Rapid Acting**	**Note: no changes from the Nov 2024 meeting** • Use of insulin aspart (Novolog) and insulin lispro (Humalog or authorized unbranded biologics) have resulted in therapeutic failure **Formulary Alternatives:** insulin aspart (Novolog) and insulin lispro (Humalog or authorized unbranded biologics
New Drugs MN Criteria	
• aprocitentan (Tryvio) **Antihypertensive Agent: Endothelin Receptor Antagonists**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** spironolactone, eplerenone, alpha blocker (ex. doxazosin), beta blocker (ex. metoprolol succinate, bisoprolol, carvedilol), amiloride, and hydralazine
• clonidine ER caps (Onyda XR) **ADHD Agents: Non-Stimulants**	• Use of formulary agents is contraindicated • Formulary agents resulted in therapeutic failure • No alternative formulary agent: cannot swallow tablets **Formulary alternatives**: atomoxetine (Strattera, generic), clonidine ER (Kapvay, generic), guanfacine ER (Intuniv

Appendix B—Table of Medical Necessity Criteria

• ensifentrine (Ohtuvayre **Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives**: Breztri, Trelegy
• norethindrone acetate/ ethinyl estradiol ODT (Femlyv) **Contraceptive Agents: Monophasics w/20 mcg Estrogen**	• No alternative formulary agent: patient requires Femlyv ODT due to established difficulties with chewing and swallowing, and inability to use non-oral dosage forms (e.g., ring, patch, injection). Submit documentation **Formulary alternatives:** norethindone/EE (generic Loestrin, Aurovela, Microgestin, Junel, Larin or equivalent); etonogestrel/EE ring (generic NuvaRing); norelgestromin/EE patch (Xulane, Zafemy); and medroxyprogesterone acetate injection (generic Depo-Provera)
• sofpironium topical gel (Sofdra) **Antiperspirants**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** topical 20% or higher aluminum salt solution (e.g., Drysol), glycopyrronium (Qbrexza cloth), Botox
• Vadadustat (Vafseo) **Hematological Agents: RBC Stimulants Erythropoietin**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure • **Formulary alternatives:** epoetin alfa (Procrit, Epogen, Retacrit), darbepoetin alfa (Aranesp)
• xanomeline/ trospium (Cobenfy) **Antipsychotic Agents: Atypical**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure • Patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk • No alternative formulary agent – patient has tried the 2 formulary alternatives AND has a history of schizophrenia with acute psychosis requiring hospitalization **Formulary alternatives:** one second generation antipsychotic (e.g., aripiprazole, lurasidone, olanzapine, ziprasidone), one first generation antipsychotic (e.g., haloperidol)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• ixekizumab (Taltz) **TIBs: IL-17 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough** **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 pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND** **Manual PA Criteria: If automated PA criteria are not** coverage is approved if all criteria are met: ~~• Humira, Cosentyx, AND, Stelara Step:~~ ~~○ Contraindication/inadequate response exists to Humira, Cosentyx, AND, Stelara~~ ~~○ Adverse reactions to Humira, Cosentyx, AND, Stelara not expected with requested non-step-preferred TIB~~ • Patients **~~≥ 18~~ 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 requirement 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 an inadequate response to Humira OR had an adverse reaction to Humira that is not expected to occur with Taltz ~~the requested agent~~ OR has a contraindication to Humira (Note: Applies to PsA, AS, nr-axSpA)** • ~~Has the p~~ **P**atient 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)** ~~• Negative TB test result in past 12 months (or TB adequately managed)~~ • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to: ~~adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade~~) **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

Appendix C—Table of Prior Authorization (PA) Criteria

• secukinumab (Cosentyx) **TIBs: IL-17 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough.** PA criteria apply to all new users of secukinumab (Cosentyx) ~~**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. AND**~~ Manual PA Criteria: ~~**If automated criteria are not met,**~~ Cosentyx is approved if all criteria are met. • ~~**Humira is the Department of Defense's preferred targeted biologic agent.**~~ **The provider acknowledges that Taltz is the Department of Defense's preferred interleukin-17 (IL-17) agent. A trial of Humira and Taltz are required before Cosentyx.** ~~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 Cosentyx OR ▪ The patient has a contraindication to Humira **and Taltz** ▪ **Note that a trial of Taltz is not required for patients with a diagnosis of generalized pustular psoriasis (GPP), enthesis-related arthritis (ERA), hidradenitis suppurative (HS) or for pediatric patients with 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 generalized pustular psoriasis 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) ▪ Moderate to severe hidradenitis suppurativa (HS) • OR Coverage approved for **pediatric patients with one of the following diagnosis/indications:** ▪ Moderate to severe plaque psoriasis in patients 6 years of age or older who are candidates for systemic therapy or phototherapy ▪ Enthesitis-related arthritis (ERA) in patients 4 years of age or older ▪ Active psoriatic arthritis in patients 2 years of age or older ▪ Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past in patients 12 years of age or older • The criteria below apply to all patients unless noted: ▪ **For plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa, and generalized pustular psoriasis:** 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: does not apply to AS, nr-axSpA, or ERA indications)

	▪ **For ankylosing spondylitis and non-radiographic axial spondyloarthritis**: Patient has had an inadequate response to at least two NSAIDs over a period of at least two months • Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya,, Kineret, Olumiant, Otezla, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ **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
• brodalumab (Siliq) **TIBs: IL-17 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough.** **PA criteria apply to all new users of brodalumab (Siliq)** 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 (IL-17) agent. A trial of Humira, Taltz and Cosentyx are required before Siliq** • ~~**The patient must have tried Humira, Cosentyx, Stelara, Tremfya, Ilumya AND Taltz first are** required steps:~~ ▪ Patient had an inadequate response to Humira, Cosentyx, ~~Stelara, Tremfya, Ilumya~~ AND Taltz OR ▪ Patient had an adverse reaction to Humira, Cosentyx, ~~Stelara, Tremfya, Ilumya~~ AND Taltz that is not expected to occur with the requested agent OR ▪ Patient has a contraindication to Humira, Cosentyx, ~~Stelara, Tremfya, Ilumya~~ 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 currently have or has not had a history of Crohn's disease~~ • Patient does not have suicidal ideation and behavior ~~**(SIB)**~~ • 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.) • ~~Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ • Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya,, Kineret, Olumiant, Otezla, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ **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

Appendix C—Table of Prior Authorization (PA) Criteria

• bimekizumab (Bimzelx) **TIBs: IL-17 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough.** **PA criteria apply to all new users of bimekizumab-bkzx (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**~~. Humira Taltz is the Department of Defense's preferred targeted biologic where patient must try Taltz Humira.~~ **The patient must have tried Taltz, Humira and Cosentyx.** ▪ The patient had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with Bimzelx OR ▪ The patient has a contraindication to Humira and • Patient had inadequate response to ~~**Stelara**~~ **Taltz** OR had adverse reaction to ~~**Stelara**~~ **Taltz** that is not expected to occur Bimzelx OR has a contraindication to ~~**Stelara**~~ **Taltz** AND • Patient had an inadequate response to Cosentyx OR had an adverse reaction to Cosentyx that is not expected to occur with Bimzelx OR patient has a contraindication to Cosentyx 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** • **For plaque psoriasis and psoriatic arthritis:** Patient had an 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 evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ • **For ankylosing spondylitis and non-radiographic axial spondyloarthritis: Patient has had an inadequate response to at least two NSAIDs over a period of at least two months** • Patient will not be receiving any other targeted immunomodulatory biologics with bimekizumab, including but not limited to the following: ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ **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
• ustekinumab (Stelara) **TIBs: IL-23 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough.** **PA criteria apply to all new users of ustekinumab (Stelara)** ~~Note that Humira is the Department of Defense's preferred targeted biologic agent.~~ Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. Manual PA criteria: **If automated PA criteria are note met, c**overage 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 Stelar OR ▪ The patient has a contraindication to Humira • Coverage approved for patients ~~≥ 18~~ **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 ~~who have failed or intolerant to immunomodulators, corticosteroids, or Humira.~~ ▪ Moderately to severely ulcerative colitis (UC)~~; infliximab may be used first in lieu of Humira~~ • 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 evidence of a negative TB test result in past 12 months (or TB is adequately managed~~ ▪ 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 ~~adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade~~) **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
• guselkumab (Tremfya) **TIBs: IL-23 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough** **PA criteria apply to all new users of guselkumab (Tremfya)** <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: ~~• Humira is the Department of Defense's preferred targeted biologic agent where patient must try Humira~~ • **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 adverse reaction to Humira that is not expected to occur with Tremfya OR ▪ Patient has a contraindication to Humira ~~AND~~ ~~• Patient had inadequate response to Stelara OR had adverse reaction to Stelara that is not expected to occur with the requested agent OR has a contraindication to Stelara AND~~ ~~• Patient had inadequate response to Cosentyx OR had adverse reaction to Cosentyx that is not expected to occur with the requested agent OR has a contraindication to Cosentyx AND~~ • Patient is 18 years of age of older with the following diagnoses/indications:

	▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy ▪ ~~Moderate to severely active ulcerative colitis (UC) (Note: Cosentyx step not required)~~ • Patient had inadequate response, **intolerance, or contraindication** to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, (e.g. sulfasalazine, mesalamine), corticosteroids, immunosuppressants e.g., azathioprine). Note does not apply to Chron's disease) • ~~Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ • 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, S1p, JAK inhibitors** ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ Non-FDA approved uses are not approved PA does not expire
• tildrakizumab (Ilumya) **TIBs: IL-23 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough** **PA criteria apply to all new users of tildrakizumab (Ilumya)** **<u>Automated PA Criteria</u>: 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 pharmacies, or mail order) during the previous 180 days.** <u>Manual PA criteria</u>: **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** • ~~Humira is the Department of Defense's preferred targeted biologic agent where patient must 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 had inadequate response to Stelara OR had adverse reaction to Stelara that is not expected to occur with the requested agent OR has a contraindication to Stelara AND~~ • ~~Patient had inadequate response to Cosentyx OR had adverse reaction to Cosentyx that is not expected to occur with the requested agent OR has a contraindication to Cosentyx AND~~ • Patient is 18 years of age of older with the following diagnoses/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 has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ • 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 ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ Non-FDA approved uses are not approved PA does not expire
• risankizumab (Skyrizi) pens, syringes **TIBs: IL-23 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough** **PA criteria apply to all new users of risankizumab (Skyrizi) pens and syringes** **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 has had an inadequate response to Humira ~~Cosentyx, AND Stelara~~ OR ▪ The patient has had an adverse reaction to Humira ~~Cosentyx, AND Stelara~~ that is not expected with **Skyrizi** ~~the requested non-step-preferred~~ TIB AND ▪ The patient has a contraindication to Humira, ~~**Cosentyx AND Stelara**~~ AND • Patient is 18 years or older with the following diagnosis/indication: ▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis 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** • ~~The patient has had a negative TB test result in past 12 months (or TB is adequately managed)~~ • **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

Appendix C—Table of Prior Authorization (PA) Criteria

• risankizumab (Skyrizi OBI), on-body injector **TIBs: IL-23 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough** **PA criteria apply to all new users of risankizumab (Skyrizi) On-Body Injector (Skyrizi OBI).** Manual PA Criteria: Coverage is approved if all criteria are met: • **Provider acknowledges a trial of Humira is required before Skyrizi OBI** ▪ The patient has had an inadequate response to Humira ~~AND Stelara~~ OR ▪ The patient has had an adverse reaction to Humira~~, AND Stelara~~ that is not expected with **Skyrizi** ~~the requested non-step preferred TIB~~ OR ▪ The patient has a contraindication or has had an inadequate response to Humira ~~AND Stelara~~ AND • Patient **is 18 years of age or older** ~~≥ 18~~ years old with the following diagnoses: ▪ 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** • ~~The patient has had a negative TB test result in past 12 months (or TB is adequately managed)~~ **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
• mirikizumab (Omvoh) **TIBs: IL-23 Subclass**	**Updates from the November 2024 meeting are in bold and strikethrough** **PA criteria apply to all new users of Omvoh** Manual PA criteria: Coverage is approved if all criteria are met: • ~~Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis~~ • **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 a diagnosis of: ▪ Moderate to severely active ulcerative colitis • 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), etc.

	~~• Patient has negative TB test result in past 12 months (or TB is adequately managed)~~ • Patient will not be receiving any other targeted immunomodulatory biologics with mirikizumab including but not limited to the following: **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors** ~~certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), upadacitinib (Rinvoq ER), or vedolizumab (Entyvio)~~ Non-FDA approved uses are not approved PA does not expire
• atogepant (Qulipta) **Migraine Agents: Oral CGRP Antagonists**	**Updates from the November 2024 meeting are in bold.** PA criteria apply to all 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 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-aooe (Aimovig) ▪ fremanezumab-vfrm (Ajovy) ▪ galcanezumab-gnlm (Emgality) Non-FDA-approved uses are not approved PA expires after 6 months

Appendix C—Table of Prior Authorization (PA) Criteria

	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
• rimegepant (Nurtec ODT) **Migraine Agents: Oral CGRP Antagonists**	**Changes from the November 2024 meeting are in bold and strikethrough** **PA apply to all new and current users of Nurtec ODT** Manual PA Criteria**:** Nurtec ODT 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-aooe (Aimovig) ▪ fremanezumab-vfrm (Ajovy)

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ galcanezumab-gnlm (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 for prevention of episodic migraine, then a trial of Qulipta is not required if a new PA is submitted** • 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 approved. PA expires after 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
• ubrogepant (Ubrelvy) **Migraine Agents: Oral CGRP Antagonists**	**Updates from the November 2024 meeting are in bold** PA criteria apply to all new users of ubrogepant (Ubrelvy). **Automated PA criteria: The patient has filled a prescription for rimegepant (Nurtec ODT) or any formulation of a triptan at any MHS point of service (MTFs, Retail pharmacies, or TRICARE Mail Order Pharmacy during the previous 180 days.** Manual PA criteria: **If automated criteria are not met**, Ubrelvy is approved if all criteria are met: • 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., 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 approved. ~~PA expires after 6 months~~ **PA does not expire** ~~Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met (Note that initial TRICARE PA approval is required for renewal):~~ ~~Acute Treatment: Patient has a documented positive clinical response~~

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• insulin lispro (Admelog) • insulin glulisine (Apidra) **Insulins: Rapid-Acting**	**Note: No changes from the Nov 2024 meeting** Automated PA Criteria: The patient has filled a prescription for insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days Manual PA criteria: if automated criteria are not met, Apidra or Admelog is approved if all criteria are met: • Provider acknowledges Novolog, Humalog and the authorized generic insulin lispro are the DoD's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, prior authorization is not required. • The patient has diabetes AND ▪ The patient has tried and failed insulin aspart (Novolog AND ▪ The patient has tried and failed insulin lispro (Humalog or authorized generic insulin lispro) OR • The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog) Non-FDA-approved uses are not approved PA does not expire
Newly Approved Drug PAs	
• aprocitentan (Tryvio) **Antihypertensive Agents: Endothelin Receptor Agonists**	**Updates from the current PA criteria are in bold and strikethrough** Manual PA criteria apply to all new users of 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, **nephrologis**t, or prescriber with certification from the American Society of Hypertension) • Patient has systolic blood pressure of greater than 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) ~~• If patient is a female or child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation~~ ~~• If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation~~ • **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. ~~PA does not expire~~. **PA expires in one year**

Appendix C—Table of Prior Authorization (PA) Criteria

	<u>Renewal Criteria</u>: 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** • **Provider continues to be enrolled in the Risk Evaluation and Mitigation Strategies program**
• carbidopa-levodopa XR (Crexont) **Parkinson's Agents**	Manual PA criteria apply to all new users of Crexont <u>Manual PA criteria</u>: Crexont is approved if: • Patient has tried and failed generic controlled release formulation of carbidopa/levodopa Non-FDA-approved uses are not approved PA does not expire
• clonidine XR oral suspension (Onyda XR) **ADHD Agents: Non-stimulants**	Manual PA criteria apply to all new users of Onyda XR <u>Manual PA criteria:</u> 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 OR • A trial of a non-stimulant medication is not required if the patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, autism spectrum disorder, etc). Non-FDA approved uses are not approved PA does not expire
• ensifentrine nebulized inhalation suspension (Ohtuvayre) **Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease**	**Updates from the current PA criteria are in bold and strikethrough** **Manual PA criteria apply to all new users of ensifentrine (Ohtuvayre)** <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • The patient is 18 years of age or older • The drug is prescribed by or in consultation with pulmonologist • Patient has moderate to severe COPD ~~(i.e., GOLD 2 [moderate] or GOLD 3 [severe]~~ airflow obstruction as demonstrated by Forced Expiratory Volume 1 second (FEV1) ranging between 30% to 80% • ~~Prescriber affirms that ensifentrine is only to be used as add on therapy to one of the following inhaler: LAMA, LABA, LAMA/LABA, or LAMA/LABA/ICS~~ • **Patient has tried and failed, defined as uncontrolled symptoms, with either of the following treatments:** ▪ **LAMA/LABA (Bevespi Aerosphere, Stiolto Respimat, Anoro Ellipta) or** ▪ **LAMA/LABA/ICS (Breztri Aerosphere, Trelegy Ellipta) AND**

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	• **Ensifentrine will only be used as add on therapy to ~~LAMA, LABA~~ LAMA/LABA or LAMA/LABA/ICS** **Non-FDA approved uses are not approved** ~~PA does not expire.~~ **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**
• lazertinib (Lazcluze) **Epidermal Growth Factor Receptor (EGFR) plus Non-small Cell Lung Cancer (NSCLC)**	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
• lebrikizumab-lbkz (Ebglyss) **Atopy Agents**	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 • The drug is 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 - For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) or - For patients 12 to 17 years of age: any topical corticosteroid ▪ topical calcineurin inhibitors (i.e., tacrolimus, pimecrolimus) • 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. 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
• levacetylleucine (Aqneursa) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of levacetylleucine (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) • Concomitant use of this medication with arimoclomol (Miplyffa) is not allowed Non-FDA approved uses are not approved PA does not expire
• norethindrone acetate/ethinyl estradiol ODT (Femlyv) **Contraceptive Agents: Monophasics with 20mcg Estrogen**	Manual PA criteria apply to all new users of norethindrone acetate and ethinyl estradiol orally disintegrating tablets (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
• nemolizumab-ilto (Nemluvio) **TIBs: Miscellaneous Interleukins**	Manual PA criteria apply to all new users of nemolizumab (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

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	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.
• palopegteriparatide (Yorvipath) **Osteoporosis Agents**	Manual PA criteria apply to all new users of palopegteriparatide (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 a 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
• seladelpar (Livdelzi) **Gastrointestinal-2 Agents**	Manual PA criteria apply to all new users of seladelpar (Livdelzi) 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 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 expires after 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient has responded to the requested medication as determined by the prescribing physician (for example, improved biochemical markers of PBC: alkaline phosphatase, bilirubin, gamma-glutamyl

	transpeptidase, aspartate aminotransferase, alanine aminotransferase)
• sofpironium topical gel (Sofdra) **Antiperspirants**	**Updates from the current PA criteria are in bold and strikethrough** Manual PA criteria apply to all new users of sofpironium (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 ~~one~~ **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
• vadadustat (Vafseo) **Hematological Agents Red Blood Cell (RBC) Stimulants: Erythropoietin**	Manual PA criteria apply to all new users of vadadustat (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 is 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 expires 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.
• vorasidenib (Voranigo) **Oncological Agents**	Manual PA criteria apply to all new users of vorasidenib (Voanigo) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 12 years of age or older • Prescribed by or in consultation with an 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

Appendix C—Table of Prior Authorization (PA) Criteria

	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.
• xanomeline/trospium chloride (Cobenfy) **Antipsychotic Agents: Atypical**	**Updates from the current PA criteria are in bold and strikethroug**h Manual PA criteria apply to all new users of xanomeline/trospium chloride (Cobenfy) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • 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 • ~~Patient has Positive and Negative Syndrome Scale (PANSS) total score between 80 and 120~~ Non-FDA approved uses are not approved. PA does not expire
Utilization Management PAs	
• everolimus (Torpenz) **Oncological Agents: Renal Cell Carcinoma**	Manual PA criteria apply to all new & current users of everolimus tablets (Torpenz). Manual PA criteria: everolimus (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 PA does not expire
• methocarbamol 1,000 mg tablet **Skeletal Muscle Relaxants and Combinations**	**Updates from the November 2024 meeting are in bold and strikeout.** 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 tablet is 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. These agents are available without a PA. • The provider must explain why this agent is required and the patient cannot **use methocarbamol 500 mg or 750 mg** ~~take the formulary alternatives~~ ~~formulations of methocarbamol.~~ ▪ Acceptable responses include the patient has trialed and failed methocarbamol 500 mg or 750 mg AND cyclobenzaprine 5 mg or 10 mg

Appendix C—Table of Prior Authorization (PA) Criteria

	Non-FDA-approved uses are not approved. Prior authorization does not expire
• ondansetron 16 mg ODT **Antiemetic-Antivertigo Agents**	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 PA does not expire
• adagrasib (Krazati) **Oncological Agents: Lung Cancer**	**Updates from the November 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of adagrasib (Krazati) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a hematologist or oncologist • The patient has a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) ~~as determined by an FDA-approved test~~ **OR** • **To drug is used to treat KRAS G12C-mutated locally advanced or metastatic CRC in combination with cetuximab, in patients who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy** • ~~The patient will be monitored for QTC prolongation, gastrointestinal adverse reactions, hepatotoxicity, and interstitial lung disease~~ • ~~If patient is a female, the patient will avoid breastfeeding during treatment and for at least 1 week after cessation 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. ~~If so, please list the diagnosis:~~ **To facilitate approval, please list the diagnosis, guideline version and page number _____.** Other non-FDA approved uses are NOT approved, except as noted above PA does not expire
• olaparib (Lynparza) **Oncologic Agents: Ovarian Cancer**	**Updates from the November 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Lynparza Manual PA Criteria: Lynparza 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 or urologist • Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test (see prostate diagnosis with HRR mutation below for exception)

	• Lynparza will be prescribed as treatment for one of the following diagnoses: ▪ Recurrent or Stage IV Triple negative breast cancer ▪ Recurrent or Stage IV hormone receptor (+) (ER, PR, or both) HER2(-) breast cancer AND was either – Previously treated with prior endocrine therapy OR – Was not an appropriate candidate for endocrine therapy ▪ Recurrent advanced ovarian cancers (platinum-sensitive or platinum resistant), fallopian tube or primary peritoneal cancers & – Patient has received at least 3 prior lines of therapy AND – Lynparza will not be used as a single agent ▪ Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene (e.g., BRCA, ATM)-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior androgen receptor-directed therapy – Of note, a patient does not require both a BRCA mutation and another separate HRR mutation; any HRR mutation satisfies requirement – this is an exception to the initial requirement that a patient have a BRCA mutation specifically ▪ Deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) in combination with abiraterone and prednisone or prednisolone ▪ Deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy • OR Lynparza will be prescribed as maintenance therapy for one of the following diagnoses: ▪ Patients with deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or peritoneal cancer – Patient has received 2 or more lines of platinum-based chemotherapy – Patient was in objective response (either complete or partial) to most recent treatment regimen – Lynparza will not be combined with bevacizumab (Avastin) ▪ Newly diagnosed, advanced, high-grade, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND – Patient has had a complete or partial response to primary therapy with a platinum-based therapy ▪ Metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ **To facilitate approval, please list the diagnosis, guideline version and page number _____.** ~~• Female patients are not pregnant or planning to become pregnant and will use highly effective contraception while taking Lynparza and for 6 months after the last dose~~ ~~• Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment~~ ~~▪ Male patients will use effective contraception while taking Lynparza and for at least 3 months after cessation of therapy~~

	Other non-FDA approved uses are NOT approved except as noted above PA does not expire
• repotrectinib (Augtyro) **Oncological Agents**	**Updates from the November 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of repotrectinib (Augtyro) 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 hematologist or oncologist • Patient ~~has~~ **is an adult with** locally advanced or metastatic **ROS1-positive** non-small cell lung cancer (NSCLC) • **Patient is 12 years of age or older with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative** • ~~Patient has NSCLC that is ROS1-positive~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis: ~~**To facilitate approval, please list the diagnosis, guideline version and page number _____.** • ~~Provider is aware of all warnings, screening and monitoring precautions for Augtyro~~ Other non-FDA approved uses are NOT approved except as noted above PA does not expire

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• selpercatinib (Retevmo) **Oncological Agents: Lung Cancer**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA apply to all new users of Retevmo Manual PA Criteria: Retevmo is approved if all criteria are met: • Retevmo is prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following indications: ▪ Adult patients with **locally advanced or** metastatic ~~RET fusion-positive~~ non-small cell lung cancer (NSCLC) ▪ Patients ~~12~~ **two** years **of age** and older with advanced or metastatic ~~RET-mutant~~ medullary thyroid cancer (MTC) **with a RET mutation** who require systemic therapy ▪ Patients ~~12~~ **two** years **of age** and older with advanced or metastatic ~~RET fusion positive~~ thyroid cancer **with a RET gene fusion** who require systemic therapy and who are radioactive iodine refractory (if radioactive iodine is appropriate) ▪ ~~Adult patients~~ **Patients 2 years of age and older** with 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 • ~~Patient will be monitored for hepatotoxicity and QT prolongation~~ • ~~Patient does not have uncontrolled hypertension~~ • ~~Provider is aware and has counseled patient that Retevmo can cause life threatening hemorrhage and allergic reactions~~ • ~~Female patients of childbearing age are not pregnant confirmed by ( ) HCG~~ • ~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~ • ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis~~: **To facilitate approval, please list the diagnosis, guideline version and page number _____.** Other non-FDA approved uses are NOT approved except as noted above Prior authorization does not expire
• apremilast (Otezla) **TIBs: Non-TNFs**	**Updates from the November 2024 meeting are in bold and strikethrough.** Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria applies to new users of apremilast (Otezla) Manual PA Criteria: Coverage approved for patients: • **Coverage approved for patients 18 years of age or older with a diagnosis of:** ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ▪ Oral ulcers associated with Behçet's disease (Note: Humira not required for Behçet's disease)

	▪ Mild plaque psoriasis in patients who are candidates for systemic therapy or phototherapy if the following criteria are met: (Note: Humira not required for mild plaque psoriasis) – The patient has a contraindication to, intolerability to, or has failed treatment with medications from at least TWO of these THREE categories: • Moderate to High Potency Topical Corticosteroids (class 1 – class 5) e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream, betamethasone dipropionate 0.05% cream/lotion/ointment, etc. • Steroid Sparing Agents: Vitamin D analogs (e.g. calcipotriene and calcitriol), tazarotene, or topical calcineurin inhibitors (e.g. tacrolimus and pimecrolimus) • Other Topicals: emollients, salicylic acid, anthralin, or coal tar AND – The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy • **Coverage approved for patients ages 6 to 17 years with:** ▪ **Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and who also weigh at least 20 kg** • The below criteria apply to all patients unless noted: ▪ The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira (Note: Does not apply to mild plaque psoriasis or Behçet's disease) ▪ Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Behçet's disease ▪ Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR? – If yes: Fill in the blank write-in referencing literature to support combination, and attest patient will be monitored closely for adverse effects. Non-FDA-approved uses are not approved. PA does not expire
• benralizumab (Fasenra) **Atopy**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA is required for all new users of Fasenra Pen <u>Manual PA Criteria</u>: Fasenra Pen coverage will be approved for initial therapy for 12 months if all criteria are met: **For Eosinophilic Granulomatosis with Polyangiitis (EGPA)** • **The patient has a diagnosis of EGPA** • **The patient is 18 years of age or older** • **The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist, or hematologist**

	For severe persistent eosinophilic asthma • The patient has a diagnosis of severe persistent eosinophilic asthma • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist, or pulmonologist • The patient must have an eosinophilic phenotype asthma as defined as either ▪ Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR ▪ Eosinophils ≥ 300 cells/mcL • The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR ▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: ▪ Long-acting beta agonist LABA e.g., Serevent, Striverdi), ▪ Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) • The patient is not currently receiving another immunobiologic (e.g., mepolizumab [Nucala], dupilumab [Dupixent] or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely <u>Renewal Criteria</u>; (initial TRICARE PA approval is required for renewal) AND • **For EGPA: The patient's disease severity has improved and stabilized to warrant continued therapy** • **For severe persistent eosinophilic asthma**: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use

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• certolizumab (Cimzia) **TIBs: TNFs**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Cimzia Manual PA Criteria: Coverage is approved for Cimzia if: • **Coverage approved for patients 2- 17 years of age with:** ▪ **Moderate to severe active polyarticular juvenile idiopathic arthritis** • Coverage approved for patients 18 years of age and older with: ▪ Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. ▪ Moderately to severely active Crohn's disease (CD). ▪ Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation ~~with evidence of elevated CRP and/or MRI evidence of sacroiliitis and Ankylosing Spondylitis Disease Activity Score (ASDAS) ≥ 2.1~~ • The provider acknowledges Humira is the Department of Defense's preferred targeted biologic agent **in adults and children**. The patient has tried Humira. • The patient has a contraindication to Humira (adalimumab) OR • 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. • ~~Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Cimzia. Is the prescriber aware of this?~~ • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) **(Note: Does not apply to AS or nr-axSpA)** • AS and nr-axSpA only**:** Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? • ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed~~ • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: adalimumab (Humira), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).Non-FDA-approved uses are not approved. Non-FDA-approved uses are not approved. Prior authorization does not expire

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• dupilumab (Dupixent) **Atopy**	**Updates from the November 2024 meeting for chronic rhinosinusitis with nasal polyposis are in bold and strikethrough** **Note that there were no changes to the PA criteria for other indications** Manual PA criteria apply to all new users of dupilumab (Dupixent) Manual PA criteria: Coverage is approved if all criteria are met: For Chronic rhinosinusitis with nasal polyposis (CRSwNP): • The patient is **12** ~~18~~ years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: ▪ Presence of nasal polyposis is confirmed by imaging or direct visualization AND ▪ At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments: ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND ▪ The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength Non-FDA-approved uses are not approved Prior authorization expires after 12 months for CRSwNP Renewal criteria: (initial TRICARE PA approval is required for renewal). Dupixent will be approved indefinitely for CRSwNP if: • CRSwNP: There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score.
• lacosamide ER (Motpoly XR) **Anticonvulsant** **Antimania Agents**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of lacosamide ER capsules (Motpoly XR) Manual PA criteria: Coverage is approved if all criteria are met: • Patient has a diagnosis of partial-onset seizures **OR a diagnosis of primary generalized tonic-clonic seizures** • Patient weighs at least 50 kg • Medication is prescribed by or in consultation with a neurologist • Provider is aware of the warnings, screening and monitoring precautions for Motpoly XR Other non-FDA approved uses are NOT approved. PA does not expire.
• fezolinetant (Veozah) **Gynecological Agents Misc.**	**Updates from the November 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of fezolinetant (Veozah) Manual PA criteria: Coverage is approved if all criteria are met: • Patient has moderate to severe vasomotor symptoms due to menopause

	• Patient has a contraindication to menopausal hormone therapy (estrogens with or without progestins) OR • Patient has an intolerance to menopausal hormone therapy OR • Based on individual patient characteristics and risk factors, the provider has determined that the patient is not a candidate for menopausal hormone therapy • Patient has tried and failed or had an adverse reaction to at least one of the following non-hormonal treatments for vasomotor symptoms ▪ an SSRI (i.e. paroxetine, escitalopram, or citalopram) ▪ an SNRI (i.e. venlafaxine, desvenlafaxine, or duloxetine) ▪ gabapentin AND • Patient does not have severe renal impairment (eGFR of 15 to 30 mL/min/1.73m2) or end-stage renal disease (eGFR less than 15 mL/min/1.73m2) • Patient does not have cirrhosis • Provider acknowledges that patient's baseline hepatic function will be evaluated via bloodwork prior to therapy, ~~at~~ **monthly for the first** 3 months, at 6 months, at 9 months and when symptoms suggest hepatic injury • **Provider has advised patient to stop taking Veozah immediately and seek medical attention if they experience signs or symptoms that may suggest liver injury (new onset fatigue, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or right upper quadrant pain)** Non-FDA approved uses are not approved PA expires after 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if the following applies: • Patient has had a positive response to therapy as noted by a decrease in the number of moderate to severe hot flashes
• iptacopan (Fabhalta) **Hematological Agents**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Fabhalta Manual PA criteria: Coverage is approved if all criteria are met **All indications** • Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements • Patient is not receiving C3 or C5 inhibitors with Fabhalta, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or pegcetacoplan (Empaveli) • Patient is 18 years of age or older **Paroxysmal nocturnal hemoglobinuria (PNH) – no changes to current PA criteria except as noted above** **Immunoglobin A nephropathy (IgAN)** • **Prescribed by a nephrologist** • **The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli** • **Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gram** • **Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2**

	• **Patient is not currently receiving dialysis or has not undergone kidney transplant** • **Patient has not received immunosuppressants, including corticosteroids, or Filspari in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months** • **Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and an SGLT-2 inhibitor (e.g., empagliflozin, dapagliflozin) and is at high risk for disease progression** • **Patient has failed therapy with, or has a contraindication to, or has had intolerable adverse effects with Filspari** • **Patient will not use Fabhalta concomitantly with Filspari** Non-FDA approved uses are NOT approved including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires after 9 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all the following apply: • **Patient has had a response to Fabhalta defined by** ▪ **reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR** ▪ **reduction in proteinuria from baseline** • **Patient's eGFR rate ≥ 30 mL/min/1.73 m2**
• oteseconazole (Vivjoa) **Antifungals**	**Updates from the November 2024 meeting are in bold** Manual PA criteria apply to all new users of Vivjoa Manual PA Criteria: Coverage is approved if all criteria are met: • The prescription is written by a gynecologist **or an infectious diseases specialist** • Patient is post-menopausal OR post-menarchal and not of reproductive potential (i.e., history of tubal ligation, salpingo-oophorectomy, or hysterectomy) • Patient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC) confirmed by microscopy, nucleic acid amplification testing (NAAT) testing, or culture. RVVC is defined as greater than or equal to four acute episodes of symptomatic vulvovaginal candidiasis within a one year period • Patient has experienced therapeutic failure, contraindication, or intolerance to a six month maintenance course of oral fluconazole Non FDA-approved uses are not approved PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA
• peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia) **Immunological Agents Miscellaneous**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Palforzia Manual PA Criteria: Palforzia is approved if all criteria are met: • Palforzia is prescribed by an allergist or immunologist , or in consultation with an allergist or immunologist, and the provider has satisfied the requirements of the REMS program • The patient is between the ages of ~~**four**~~ **1** to 17 years • The patient has a documented history of peanut allergy • The patient has a history of diagnostic evidence of peanut allergy, including either serum IgE to peanut of ≥0.35 kUA/L (serum testing) and/or positive skin prick test (SPT) for peanut ≥ 3 mm greater than negative control

	• The patient does not have uncontrolled asthma; eosinophilic esophagitis or other eosinophilic gastrointestinal diseases • The patient has not had severe or life-threatening anaphylaxis within the previous 60 days prior to starting therapy • Provider acknowledges that the patient will be counseled on the following: ▪ Avoiding peanut ingestion ▪ The need for access to an epinephrine injector ▪ Palforzia is not intended to treat emergencies Non-FDA-approved uses are not approved PA does not expire
• pimavanserin (Nuplazid) **Antipsychotics: Atypicals**	**Updates from the November 2024 meeting are in strikethrough** Manual PA criteria apply to all new users of pimavanserin Manual PA Criteria: Nuplazid is approved if the following criteria are met: • Patient is age 18 years of age or older • Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis • Nuplazid is being prescribed by or in consultation with a neurologist, psychiatrist, or gerontologist (i.e., geriatric medicine specialist) • Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin • ~~**The patient's baseline Mini-Mental State Examination (MMSE) score ≥ 21.**~~ • Patient does NOT have history of known QT prolongation, cardiac arrhythmias, or other circumstances that would increase the risk of Torsades de Pointes and/or sudden death • Patient is NOT taking additional antipsychotics Non-FDA approved uses are NOT approved Prior authorization does not expire
• roflumilast 0.15% cream (Zoryve) **Psoriasis Agents**	**Changes from the November 2024 meeting are for the new indication for atopic dermatitis** **Note that there were no changes to the PA criteria for the 0.3% formulation for plaque psoriasis** Manual PA criteria apply to all new users of Zoryve 0.15% cream Manual PA criteria: Coverage is approved if all criteria are met: **Atopic Dermatitis** • **Patient is 6 years of age or older** • **The medication is being prescribed by or in consultation with a dermatologist, allergist, or immunologist** • **The patient has mild to moderate atopic dermatitis** • **The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following:** ▪ **For patients 18 years of age or older: high potency class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)** ▪ **For patients 6 to 17 years of age: any topical corticosteroid** ▪ **Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)** Non-FDA-approved uses are not approved

Appendix C—Table of Prior Authorization (PA) Criteria

	PA expires in 1 year for Atopic Dermatitis; PA does not expire for plaque psoriasis **<u>Renewal criteria</u>: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:** • **Atopic Dermatitis: The patient's disease severity has improved and stabilized to warrant continued therapy.**
• teriparatide 600 mcg (Forteo and generic) **Osteoporosis Agents: PTH Analogs**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Forteo <u>Manual PA criteria</u>: Coverage is approved if all criteria are met • The provider acknowledges that the brand Forteo formulation is the preferred product over generic teriparatide and is covered at the lowest copayment, which is the generic formulary copayment for non-Active-Duty patients, and at no cost share for Active-Duty patients. (Although Forteo is a branded product, it will be covered at the generic formulary copayment or cost share) • A patient-specific justification must be provided as to why the brand Forteo product cannot be used in this patient • Patient is greater than or equal to 18 years of age • Patient is a postmenopausal female with osteoporosis or is a male with primary or hypogonadal osteoporosis or is a male or female who has osteoporosis associated with sustained systemic glucocorticoid therapy (for example, greater than 6 months use of greater than 7.5 mg/day prednisone or equivalent • Patient has one of the following: ▪ The patient is at high risk for fracture, defined as one of the following: – history of osteoporotic fracture – multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) – documented bone mineral density (BMD) T-score of -2.5 or worse – has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • ~~Cumulative treatment with Forteo will not exceed 24 months during the patient's lifetime AND~~ • **Patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton)** Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. ~~Prior Authorization may not be renewed.~~ **Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply:** • **The patient has had a positive response to therapy**

	• **Provider acknowledges that there are limited data assessing the risk of osteosarcoma beyond 2 years of use with teriparatide**
• teriparatide 620 mcg (Bonsity) **Osteoporosis Agents: PTH Analogs**	**Updates from the November 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Bonsity. Manual PA criteria: Coverage is approved if all criteria are met • The provider acknowledges that Forteo is the Department of Defense's preferred osteoporosis parathyroid hormone (PTH) analog; the patient must try and fail Forteo prior to use of Bonsity • Patient is greater than or equal to 18 years of age • Patient is a postmenopausal female with osteoporosis or is a male with primary or hypogonadal osteoporosis or is a male or female who has osteoporosis associated with sustained systemic glucocorticoid therapy (for example, greater than 6 months use of greater than 7.5 mg/day prednisone or equivalent • Patient has one of the following: ▪ The patient is at high risk for fracture, defined as one of the following: – history of osteoporotic fracture – multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) – documented bone mineral density (BMD) T-score of -2.5 or worse – has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • ~~Cumulative treatment with Forteo will not exceed 24 months during the patient's lifetime AND~~ • **Patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton)** Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. ~~Prior Authorization may not be renewed.~~ **Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply:** • **The patient has had a positive response to therapy** • **Provider acknowledges that there are limited data assessing the risk of osteosarcoma beyond 2 years of use with teriparatide**

Appendix C—Table of Prior Authorization (PA) Criteria

• pancrelipase (Zenpep) **Pancreatic Enzyme Replacement Therapy (PERT)**	**Updates from the November 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Zenpep. Manual PA criteria: Zenpep is approved if ALL of the following criteria are met: • **Provider acknowledges that Creon is the DoD's preferred Pancreatic Enzyme Replacement product and that Prior Authorization is not required for Creon** • For patients 2 years of age or younger ▪ The patient has had a sufficient trial of Creon and treatment was unsuccessful • For patients older than 2 years of age ▪ The patient has failed an adequate trial of Creon, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ ~~AND~~ ~~▪ The patient has failed an adequate trial of Pancreaze, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND~~ ~~▪ The patient has failed an adequate trial of Pertzye, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND~~ ~~▪ The patient has failed an adequate trial of Viokace; defined as at least 2 dose adjustments done over a period of at least 4 week; document the dates tried _____. OR the patient is between 2 and 19 years of age and requires a dosage strength that is not available with Viokace.~~ Prior authorization does not expire.
• bempedoic acid (Nexletol) • bempedoic acid/ezetimibe (Nexlizet) **Antilipidemic-1s: Non-statins and combinations**	**Updates from the November 2024 meeting are in bold and strikethrough** PA criteria apply to new users of Nexletol and Nexlizet ~~**Automated PA criteria: The patient has filled a prescription for Repatha or Praluent at any MHS pharmacy point of service (MTFs, retail pharmacies, or network TRICARE Mail Order Pharmacy) during the previous 720 days**~~ Manual PA Criteria: ~~**If automated PA criteria are not met**~~ Nexletol or Nexlizet is approved if all criteria are met: • Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization) • Patient has one of the following diagnoses: ▪ Patient has established atherosclerotic cardiovascular disease (ASCVD) including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attach (TIA) or peripheral arterial disease (PAD), OR ▪ Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following: o type 1 or type 2 diabetes or o 10-year ASCVD risk score (Pooled Cohort Equation – PCE) >20% or Reynolds Risk score > 30% or SCORE risk score >7.5% over 10 yrs or o Coronary calcium score >400 Agatston units at any time in the past ▪ Patient has Heterozygous Familial Hypercholesterolemia (HeFH)

Appendix C—Table of Prior Authorization (PA) Criteria

	AND • For Nexletol: ▪ Patient is taking concurrent ezetimibe OR ▪ Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks AND ▪ Patient is on concurrent statin therapy at the maximum tolerated dose and dose hasn't reached LDL goals OR ▪ Patient is statin intolerant based on one of the following: o Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, muscle cramps), with at least 2 statins OR o History of creatine kinase (CK) levels greater than 10 x the upper limit of normal (ULN) unrelated to statin use OR o History of statin-associated rhabdomyolysis o Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) ~~**AND**~~ ~~▪ **Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR**~~ ~~▪ **Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCSK-9 inhibitor**~~ • For Nexlizet: ▪ Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) AND ▪ Patient is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal OR ▪ Patient is statin intolerant based on one of the following: o Patient has experienced intolerable (muscle pain, cramp) with at least 2 statins OR o History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR o History of statin-associated rhabdomyolysis OR o Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) AND ~~▪ **Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR**~~ ~~▪ **Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCSK-9 inhibitor**~~ Non-FDA-approved uses are not allowed Prior authorization does not expire
• evolocumab (Repatha) **PCSK-9 Inhibitors**	**Changes from November 2024 meeting are in BOLD** Manual PA criteria apply to all new users of Repatha **<u>Automated PA Criteria:</u> When prescribed by a cardiologist, endocrinologist or cardiac transplant specialist, prior authorization is not required. Once therapy is initiated by a specialist, an automated drug lookback will apply, allowing for continuation of coverage by any other prescriber if the patient has received the requested mediation in the past 180 days. OR**

	<u>Automated PA Criteria:</u> The patient has filled a prescription for atorvastatin, rosuvastatin, ezetimibe or ezetimibe/simvastatin at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days OR
	
	<u>Manual PA Criteria:</u> if automated criteria are not me, evolocumab (Repatha) is approved if all criteria are met
	
	• When prescribed by a cardiologist, endocrinologist or cardiac transplant specialist, prior authorization is not required.
	
	For HoFH and HeFH
	
	• For heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH), the patient is 10 years of age or older
	
	• The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol
	
	• The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses
	
	For ASCVD
	
	• The patient is at least 18 years of age for clinical atherosclerotic cardiovascular disease (ASCVD)
	
	• The patient has established ASCVD with the following LDLs, despite maximally tolerated statin doses:
	
	  • Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high risk conditions. *Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information*) OR
	
	  • Not at very high risk of events: LDL > 70 mg/dL AND
	
	  • The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR
	
	  • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR
	
	  • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND
	
	  • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy
	
	For patients at high risk for ASCVD
	
	  • The patient has LDL >190 mg/dL or
	
	  • Patient has diabetes and LDL <190 mg/dL or
	
	  • Patients with LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD >7.5% or
	
	  • Patients with LDL < 190 mg/dL and evidence of significant subclinical atherosclerosis defined as:
	
	  ▪ Significant atherosclerotic plaque observed in an asymptomatic patient on any of the following diagnostic studies: coronary artery calcification noted on computed tomography (CT) studies, including calcium scoring, cardiac CT coronary angiography, chest CT for ruling out pulmonary embolism, chest CT for lung cancer screening, or diagnostic chest CT; carotid plaque noted on carotid

	ultrasound or angiography; or abnormal ankle-brachial index or plaque noted on peripheral arterial angiography. AND • The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. *For all uses*: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: • Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. • Contraindication to statin ▪ The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) *For all indications* • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: • 140 mg every 2 weeks, or • 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. PA does not expire

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• TIBS (except Stelara)	No change to current QLs ▪ MTF/Mail/Retail 60 days supply
• Stelara	▪ Retail: This drug is covered for 1 syringe/vial Per fill at retail ▪ If available 3 syringes/vials Per fill at Home Delivery or MTFs
• ubrogepant (Ubrelvy) **Migraine Agents oral CGRPs**	▪ Retail: 16 tabs/30 days ▪ MTF/Mail:48 tabs/90 days
• rimegepant (Nurtec ODT) **Migraine Agents oral CGRPs**	**For Acute Migraine Indication:** ▪ Retail: 8 ODT/30 days ▪ MTF/Mail: 24 ODT/90 days **For Migraine Prevention Indication, approved through PA process:** ▪ Retail: 16 ODT/30 days ▪ MTF/Mail: 48 ODT/90 days Note that Nurtec ODT is only available as 8 ODT per pack
• atogepant (Qulipta) **Migraine Agents oral CGRPs**	▪ Retail: 30 tabs/30 days ▪ MTF/Mail: 90 tabs/90 days
• ensifentrine (Ohtuvayre) **Pulmonary 2 Agents: COPD**	▪ MTF/TMOP/Retail: 60-day supply
• epinephrine nasal spray (Neffy) **Respiratory Agents Miscellaneous**	▪ MTF/TMOP/Retail: 4 packages per fill
• Freestyle Libre 3 Plus **Self-Monitoring Blood Glucose Systems: Therapeutic Continuous Glucose Monitoring Systems**	▪ Retail: 30 days ▪ MTF/Mail: 90 days Note – The FreeStyle Libre 3 Plus sensor is replaced every 15 days, compared with the FreeStyle Libre 3 (November 2022) where the sensor is replaced every 14 days
• lazertinib (Lazcluze) **Oncological Agents: Epidermal Growth Factor Receptor (EGFR) plus Non-small Cell Lung Cancer (NSCLC)**	▪ MTF/TMOP/Retail: 60-day supply
• lebrikizumab-lbkz (Ebglyss) **Atopy Agents**	▪ Retail/MTF/TMOP: 60-day supply

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

Drug / Drug Class	Quantity Limits
• levacetylleucine (Aqneursa) **Neurological Agents Miscellaneous**	▪ MTF/TMOP/Retail: 60-day supply
• nemolizumab-ilto (Nemluvio) **TIBS: Miscellaneous Interleukins**	▪ MTF/TMOP/Retail: 60-day supply
• palopegteriparatide (Yorvipath) **Endocrine Agents Miscellaneous**	▪ MTF/TMOP/Retail: 60-day supply
• seladelpar (Livdelzi) **Gastrointestinal 2 Agents**	▪ MTF/TMOP/Retail: 60-day supply
• vadadustat (Vafseo) **Hematological Agents**	▪ MTF/TMOP/Retail: 60-day supply
• vigabatrin (Vigafyde) **Anticonvulsants-Antimania Agents**	▪ MTF/TMOP/Retail: 30-day supply
• vorasidenib (Voranigo) **Oncological Agent**	▪ Retail/MTF/TMOP: 60-day supply

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• aprocitentan (Tryvio) Anti-hypertensive Agents: Endothelin Receptor Agonist	• spironolactone (Aldactone) • metoprolol succinate (Toprol XL) • hydralazine (Apresoline) • macitentan (Opsumit)	• Tablet: 12.5 mg • Dosing: 12.5 mg orally once daily	• Treatment of hypertension (HTN) in combo with other antihypertensive drugs in adults who are not adequately controlled on other drugs	ADRs (≥ 2%): • edema/fluid retention • anemia	• Although Tryvio has a new MOA (endothelin receptor antagonist), current HTN guidelines recommend a mineralocorticoid receptor antagonist (spironolactone) for resistant HTN • Requires a REMS program due to increased LFTs, risk of hepatotoxicity, fluid retention, peripheral edema, fetal toxicity, and decreases in HCT/Hgb • The current place in therapy and long-term safety remains to be determined • More established therapies should be tried first as add-in therapy for resistant HTN	• NF • PA • MN
• carbidopa/ levodopa XR capsules (Crexont) Parkinson's Agents	• carbidopa/ levodopa XR cap (Rytary)	• XR Capsule: 35/140 mg 52.5/210 mg 70/280 mg 87.5/250 mg • Dosing: Treatment naïve: (C/L: 35/140 mg) cap BID x3d, then increase gradually up to max daily dose: (C/L: 525/2100 mg)	• Treatment of Parkinson's Disease • Post-encephalitic parkinsonism • Parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults.	ADRs (>3%): • nausea • Anxiety	• Approval based on single trial of Crexont demonstrating statistically significant improvement in mean change in daily "good on-time" from baseline, compared to IR carbidopa and levodopa • No head-to-head trials between Crexont and other extended or controlled release carbidopa levodopa • Crexont provides no compelling clinical advantage over existing agents	• UF • PA
• clobetasol 0.05% ophthalmic suspension (no brand name) Ophthalmic Miscellaneous	• dexamethasone ophth suspension • loteprednol ophth suspension • prednisolone ophth susp	• One drop into the affected eye BID beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period	• Treatment of post-operative inflammation and pain following ocular surgery	ADR (≥1%) • eye inflammation • corneal edema • anterior chamber inflammation • cystoid macular edema • intraocular pressure elevation • photophobia • vitreous detachment	• New formulation of ophthalmic corticosteroid • Phase 3 study demonstrated favorable efficacy over vehicle at reducing pain and anterior chamber cell count during the short-term study • Guidelines do not prefer one ophthalmic corticosteroid over another • Other than the fact it does not require tapering at the end of therapy, it provides no compelling clinical advantage over existing agents	• Completely Excluded

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• clonidine XR 0.1 mg/mL oral suspension (Onyda XR) ADHD Agents: Non-Stimulants	• clonidine XR tabs • guanfacine ER tabs • Intuniv tabs	• 0.1 mg/mL ER suspension Dosing: • 0.1 mg QHS • May increase 0.1 mg/ day at weekly intervals to max dose 0.4 mg per day	• Treatment of ADHD as monotherapy or as adjunctive therapy to CNS stimulant medications in patients ≥6 years of age	ADR (≥5%) • irritability • nightmare • insomnia • constipation • dry mouth	• New ER oral solution of clonidine • No new clinical data; FDA approved via 505(b)(2) pathway • Offers another formulation of extended-release clonidine for ADHD treatment, but has no compelling clinical advantages over other ADHD non-stimulants	• NF • PA • MN • TRICARE Maintenance Drug List
• ensifentrine nebulizer inhalation solution (Ohtuvayre) Pulmonary-2 Agents: COPD	• Daliresp • Spiriva • Anoro Ellpita • Trelegy • Breztri	• Inhalation suspension: 3 mg/2.5 mL aqueous suspension in unit-dose ampules • Dosing: 1 ampule BID	• The maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult s	ADR (1%) • back pain • Hypertension • urinary tract infection • diarrhea	• New selective, dual phosphodiesterase (PDE)3 and PDE4 inhibitor with bronchodilator and anti-inflammatory effects • Two phase III trials demonstrated significantly improved lung function when added on to maintenance COPD therapy; no data on whether this therapy will reduce COPD exacerbations • Generally well tolerated in both trials, with a similar incidence of AEs between ensifentrine and placebo • Has not been studied in all possible combinations of medications that could be used to currently treat COPD • Trials excluded patients receiving concurrent dual LAMA/LABA or triple therapy • Provides another alternative maintenance treatment for patients with COPD	• NF • PA • MN • QL • Specialty

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• epinephrine nasal spray (Neffy) Respiratory Agents	• EpiPen	• Nasal spray: 2 mg/0.1 mL • Dosing: 1 spray administered into one nostril	• Emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater	ADR (≥2%) • throat irritation • nasal discomfort • nasal pruritus • feeling jittery • rhinorrhea • sneezing • dizziness • nausea/vomiting	• First FDA-approved nasal epinephrine product • Limited use for pediatric patients due to weight (≥ 30 kg) • Approval based on pharmacokinetic data; limited clinical data • Neffy has a longer shelf life and can withstand greater temperature excursions than other epinephrine formulations • Offers an alternative to injectable epinephrine products	• UF • QL
• lazertinib (Lazcluze) Oncological Agents: Epidermal Growth Factor (EGFR) + Non-Small Cell Lung Cancer (NSCLC)	• Iressa	• Tablets: 80mg 240 mg • Dosing: 240mg QD	• Kinase inhibitor indicated in combination with amivantamab for 1st line treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations	ADR (≥20%) • rash • nail toxicity • infusion-related reaction • musculoskeletal pain • edema • stomatitis • VTE • paresthesia • fatigue • hemorrhage • pruritus • nausea	• Novel kinase inhibitor • Category 1 recommendation from the NCCN for treatment of this disease state • Shows increased clinical efficacy compared to its alternative, osimertinib • Associated with a higher side effect profile • Requires administered with prophylaxis during the first four months of administration to prevent venous thromboembolism (VTE) • The FDA is requiring a comprehensive safety analysis to further characterize the risk of VTE associated with treatment • lazertinib offers an additional treatment option for the treatment of locally advanced/metastatic NSCLC	• UF • PA • QL • Specialty • TRICARE Maintenance Drug List
• lebrikizumab-lbkz (Ebglyss) Atopy Agents	• Adbry • Dupixent	• 250 mg/2 mL single-dose prefilled pen or syringe • Dosing: 500 mg SC at week 0 and Week 2 followed by 250 mg SC Q2W; Maintenance Dose: 250 mg SQ Q4 W	• Treatment of adults and pediatrics ≥12 years weighing at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	ADRs (>1%) • conjunctivitis • Injection site • reactions • Herpes zoster	• Second IL-13 antagonist • Phase 3 study demonstrated significantly larger proportions of patients achieving an IGA response with Ebglyss vs. placebo • Ebglyss and Adbry both approved for children down to age 12, while Dupixent may be used in patients ≥ 6 months of age • Ebglyss therapy resulted in similar proportions of patients achieving a clinical response as were noted in the Dupixent pivotal studies and numerically slightly larger proportions than were observed with Adbry • Dupixent has several other indications including	• UF • PA • QL

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					asthma and chronic rhinosinusitis with nasal polyposis; conditions that are common among patients with atopic dermatitis • Ebglyss is an alternative to Adbry and Dupixent but provides no compelling clinical advantage over existing agents	
• levacetyl-leucine (Aqneursa) Neurological Agents	• Myplyffa (FDA-approved in Nov 2024)	• Capsule: 100 mg • Dosing: based on body weight PO daily	• Treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥ 15 kg	ADR (≥5%) • abdominal pain • dysphagia • upper respiratory tract infections • vomiting	• A Phase 3 study demonstrated a statistically significant impact on the Scale for the Assessment and Rating of Ataxia (SARA) score compared to placebo in patients, most of whom were on miglustat • Safety profile was overall well tolerated • Aqneursa is an option for the treatment of this rare condition	• UF • PA • QL • TRICARE Maintenance Drug List
• nemolizumab-ilto (Nemluvio) TIBS: Misc Interleukins	• Dupixent	• Single-dose prefilled dual chamber pen: 30 mg • Dosing: < 90 kg: loading dose 60 mg (two 30 mg injections) then 30 mg SUBQ Q4W ≥ 90 kg: loading dose 60 mg (two 30 mg injections) then 60 mg SUBQ Q4W	• Treatment of adults with prurigo nodularis	ADR (≥1%) • headache • dermatitis atopic • eczema • eczema nummular	• IL-31 receptor antagonist • Two randomized trials demonstrated statistically significantly achievement of improvement in Investigator's Global Assessment for disease severity and a reduction in Peak Pruritus Numeric Rating Scale compared with placebo • The safety profile is generally well tolerated with mild adverse events • Nemluvio offers an additional treatment option for this chronic, intractable disease	• UF • PA • QL • Specialty

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• norethindrone acetate/ ethinyl estradiol ODT (Femlyv) Contraceptive Agents: Monophasics with 20mcg estrogen	• norethindone/ EE (generic Loestrin, Aurovela, Microgestin, Junel, Larin or equivalent) • etonogestrel/EE ring (generic NuvaRing) • norelge-/EE patch (Xulane, Zafemy) • medroxyprogesterone acetate injection (generic Depo-Provera)	• 24 ODTs each with 1 mg norethindrone acetate and 20 mcg ethinyl estradiol and 4 inert ODTs • Dosing: Place 1 ODT on the tongue, allow to disintegrate, and then follow with 8 ounces of water	• Use by females of reproductive potential to prevent pregnancy	ADR (≥2%) • headache • vaginal candidiasis • nausea • menstrual cramps • breast tenderness • bacterial vaginitis • abnormal cervical smear • acne • mood swings • weight gain	• First orally disintegrating tablet (ODT) contraceptive formulation • No new clinical data • Femlyv is an alternative contraceptive for patients who have swallowing difficulties; however, there are numerous available contraceptives on the UF including multiple norethindrone 1 mg/ethinyl estradiol 0.02 mg tablets, chewable tablets, and alternative dosage forms (patch, ring, injection, etc.)	• NF • PA • MN
• palopeg-teriparatide (Yorvipath) Osteoporosis Agents	• parathyroid hormone • (Natpara)-**discontinued**	• Prefilled syringe: 60 mg 168 mcg/0.56 mL 294 mcg/0.98 mL 420 mcg/1.4 mL • Dosing: Starting dose is 18 mcg SC QD and titrated in 3 mcg increments/decrements	• Treatment of hypoparathyroidism in adults. Not for acute post surgical hypoparathyroidism.	ADRs (>5%) • injection site reactions • vasodilatory signs and symptoms • headache • diarrhea • back pain • hypercalcemia • oropharyngeal pain	• PTH analog • Phase 3 study demonstrated significantly more patients were able to achieve the composite efficacy endpoint vs. placebo in patients with chronic hypoparathyroidism who had not adequately responded to conventional therapy • Guidelines currently recommend conventional therapy with oral calcium supplementation and active vitamin D as first-line therapy • PTH replacement is recommended in patients who are not able to be adequately managed with conventional therapy • Natpara is similarly indicated in patients with chronic hypoparathyroidism. However, Natpara is associated with serious safety concerns regarding the risk of osteosarcoma and will no longer be available end of 2024; due to supply issues • Yorvipath provides an option for those who cannot be managed with conventional therapy	• UF • PA • QL • Specialty

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• seladelpar (Livdelzi) Gastro-intestinal-2 Agents	• Iqirvo • Ocaliva	• 10 mg Capsules: • Dosing: 10 mg PO QD	• Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA	ADRs (≥5%) • headache • abdominal pain • nausea • abdominal distension • dizziness	• Second PPAR agonist approved for the treatment of PBC • Phase 3 studies demonstrated Livdelzi improved biochemical markers of disease progression compared with placebo • Livdelzi demonstrated similar biochemical efficacy as Iqirvo and Ocaliva over 52 weeks; however, maintenance of biochemical response at Year 5 was demonstrated in an open-label extension study with Ocaliva • Over a 6-year period, Ocaliva-treated patients experienced a reduced risk of liver transplantation and death vs. comparable external controls • No head-to-head studies with Ocaliva or Iqirvo • Livdelzi is an alternative to Iqirvo and Ocaliva for PBC; however Ocaliva has real world outcomes data suggesting improvement in a clinical endpoint of transplant-free survival	• UF • PA • QL • Specialty
• sofpironium 12.45% topical gel pump (Sofdra) Antiperspirant	• Qbrexza	• topical gel: 12.45% (60 pumps/bottle) • Dosing: 1 pump per underarm QHS dose 0.7	• Treatment of primary axillary hyperhidrosis in patients 9 years of age and older	ADRs (≥2%) • dry mouth • blurred vision • site pain irritation • Mydriasis • urinary retention	• Two phase 3 studies achieved a ≥ 2-point improvement in the Hyperhidrosis Disease Severity Measure-Axilla score and reduced Gravimetric Sweat Production results compared to vehicle • No head to head trials vs other hyperhidrosis treatments • Adverse events were overall well tolerated and reversible, and mostly consistent with anticholinergic effects, as well as local site pain and skin irritation • Sofdra provides no compelling clinical advantage over existing agents	• NF • PA • MN • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• tirzepatide vial (Zepbound) Weight Loss Agents	• Zepbound pen • Wegovy • Saxenda	• Vial: 2.5mg/ml, 5mg/ml • Dosing: 2.5 mg injected subcutaneously once weekly	• Chronic weight management in adults •	ADRs (≥5%): • nausea • diarrhea • vomiting • constipation • abdominal pain • dyspepsia • injection site reactions • hypersensitivity reactions • eructation • hair loss, • gastroesophageal reflux	• The VIAL is another formulation of Zepbound, only available for cash paying patient • Only available through LillyDirect • Currently only available in 2.5 mg and 5 mg strength • No changes to the formulary placement and • PAs for the Zepbound autoinjectors	• Completely Excluded
• vadadustat (Vafseo) Hematological Agents: RBC Stimulants Erythropoietin Agents	• Jesduvroq • Procrit • Epogen • Retacrit	• Tablets: 150 mg 300 mg 450 mg • Dosing: 300 mg PO QD	• Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months	ADRs (≥10%): • hypertension • diarrhea	• Second approved oral HIF-PH inhibitor • Two phase 3 studies demonstrated noninferiority to ESA therapy regarding effects of hemoglobin levels and CV outcomes • Vafseo has a Boxed Warning like Jesduvroq and ESAs regarding increased risks of death, MI, stroke, VTE and thrombosis of vascular access • Vafseo should not be utilized in pediatrics or for treating of anemia in CKD among patients who are not on dialysis • Hepatotoxicity has been reported; and liver function testing is required • Provides no compelling clinical advantage over existing agents	• NF • PA • MN • Specialty • TRICARE Maintenance Drug List
• vigabatrin 100 mg/mL oral solution (Vigafyde) Anticonvulsant and Antimania Agents	• vigabatrin (Sabril) • vigabatrin (Viagadrone) • vigabatrin (Vigpoder) • vigabatrin generic	• Oral solution: 100 mg/ml • Dosing: Initiate 25 mg/kgBID; may increase every 3 days, max: 75 mg/kg BID	• Monotherapy for treatment of infantile spasms in patients 1 month to 2 years of age, for whom the benefits outweigh the potential risk of vision loss	ADRs (≥5%): • somnolence • bronchitis • ear infection • acute otitis media	• Another oral formulation of vigabatrin • Available in a concentrated solution that is ready to use, compared to alternative vigabatrin packets that require reconstitution • No new clinical data • Provides no compelling clinical advantage over existing agents	• UF • QL • Specialty • Add to Rapid Response (Safety net) program

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• vorasidenib (Voranigo) Oncological Agents	• N/A	• Tablet: 10 mg 40 mg • Dosing: ≥ 40 kg: 40 mg QD < 40 kg: 20 mg QD	• Treatment of patients ≥12 years Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection	ADRs (≥15%): • fatigue • headache • musculoskeletal pain • diarrhea • nausea • seizure	• A single phase 3 study demonstrated statistically significant improvement in progression-free survival as compared to placebo • The safety profile is overall well tolerated, however there is a notable warning for hepatotoxicity requiring regular monitoring of liver function tests • Voranigo provides an FDA approved option these rare, incurable CNS malignancies	• UF • PA • Specialty • TRICARE Maintenance Drug List
• xanomeline/ trospium (Cobenfy) Antipsychotic Agents: Atypical	• N/A	• Capsule: 50/20 mg 100/20 mg 125/30 mg • Dosing: Start: 50/20 mg BID x 2 days, then 100/20 mg BID x 5 days max: 125/30 BID	• Treatment of schizophrenia in adults	ADRs (≥5%): • rash • nausea • vomiting • diarrhea • abdominal pain • dyspepsia • constipation • hypertension • tachycardia • dizziness • gastrointestinal reflux disease	• Two identical phase 3 studies demonstrated a statistically significant reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo at 5 weeks • Long term extension data is lacking at this time • Adverse events were predominantly GI related and transient • Cobenfy provides an additional treatment option for patients with an established diagnosis of schizophrenia and a history of inadequate response to prior therapies	• NF • PA • MN

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

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

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from TMOP Requirement)
November 2024	**Drug Class Reviews** **Targeted Immunomodulatory Biologics: IL-17 and IL-23 subclasses** ***Designated UF*** *Retain current status for all agents on the TRICARE Maintenance Drug List* • guselkumab (Tremfya) • ixekizumab (Taltz) • risankizumab (Skyrizi) secukinumab (Cosentyx) • tildrakizumab (Ilumya) • ustekinumab (Stelara) ***Designated NF*** *Retain current status for all TIBs on the TRICARE Maintenance Drug List (no reason to exempt from NF requirement)* **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** *Designated NF (no reason to exempt from NF requirement)* • clonidine extended-release oral suspension (Onyda XR) • sofpironium gel (Sofdra) * 10 USC 1074g(a)(9) requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to these requirements are listed on the TRICARE Maintenance Drug List	**Drug Class Reviews** **(August 2024) Antilipidemics-1s – Non-statins and Combinations** *Do not add – not cost advantageous to Government* • nebivolol (Nexletol) • nebivolol/ezetimibe (Nexlizet) **Calcitonin Gene-Related Peptide (CGRP) Oral Agents** ***Designated UF*** *Do not add* • atogepant (Qulipta) • ubrogepant (Ubrelvy) ***Designated NF*** *Exempt from NF requirement (acute use)* • rimegepant (Nurtec) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** *Do not add– not cost advantageous to government* • carbidopa-levodopa extended release (Crexont) • lebrikizumab-lbkz (Ebglyss) • nemolizumab-ilto (Nemluvio) • palopeg teriparatide (Yorvipath) • seladelpar (Livdelzi) *Do not add– acute use* • epinephrine nasal spray (Neffy) *Do not add– REMS, limited duration of use* • vigabatrin oral solution (Vigafyde) ***Designated NF*** *Exempt from NF requirement (REMS and limited distribution requirements)* • aprocitentan (Tryvio) *Exempt from NF requirement (antipsychotic exception applies)* • xanomeline/trospium (Cobenfy) *Exempt from NF requirement (contraceptive exception applies)* • norethindrone acetate/ethinyl estradiol orally disintegrating tablet (Femlyv) *Exempt from NF requirement (not cost advantageous to government)* • ensifentrine (Ohtuvayre)

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

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

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from TMOP Requirement)
November 2024	**Drug Class Reviews** **Targeted Immunomodulatory Biologics: IL-17 and IL-23 subclasses –** maintain TIBs class as generally suitable for inclusion on the contingent list; retain/add any agent not already on the TRICARE Maintenance Drug list to the contingent list ***Designated NF*** *No reason to exempt from NF-2-Mail requirement* • bimekizumab (Bimzelx) • brodalumab (Siliq) • mirikizumab (Omvoh) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • lazertinib (Lazcluze) • levacetylleucine (Aqneursa) • vorasidenib (Voranigo) ***Designated NF*** *No reason to exempt from NF-2-Mail requirement* • vadadustat (Vafseo)	
Added April 2024–September 2024	**Medications previously on the contingent list that were added to the TRICARE Maintenance Drug List after March 24, by class and subclass (see May 2024 minutes, Appendix F, for medications added in March 24)**	

	• Antihemophilic Factors – emicizumab-kxwh (Hemlibra)
	• Antineoplastic and Premalignant Lung Cancer Lesion Agents – repotrectinib (Augtyro)
	• Endocrine agents Misc – pegvisomant (Somavert)
	• Neurological Agents: Movement Disorders – deutetrabenazine (Austedo XR), valbenazine tosylate (Ingrezza)
	• Oncological Agents
	  ○ No subclass – selpercatinib (Retevmo), alpelisib (Vijoice)
	  ○ PARP inhibitors – talazoparib tosylate (Talzenna)
	• Targeted Immunomodulatory Biologics
	  ○ Non-Tumor Necrosis Factor Inhibitors – vedolizumab (Entyvio Pen), ustekinumab (Stelara vial)
	  ○ Tumor Necrosis Factor Inhibitors – adalimumab-ryvk (Simlandi), infliximab-dyyb (Zymfentra)	

May 2023 – August 2024	**Drug Classes or Subclasses Designated by the P&T Committee at prior meetings as generally suitable for inclusion on the contingent list**	

	• Atopy
	• Breast Cancer: Cyclin Dependent Kinase Inhibitors
	• LHRH agonists/antagonists
	• Multiple Sclerosis agents
	• Oncological agents
	  ○ 2nd Generation Antiandrogens
	  ○ Acute Myelogenous Leukemia
	  ○ Breast Cancer	

	○ Chronic Myelogenous Leukemia ○ Colorectal Cancer ○ CYP-17 Inhibitors ○ EGFR+ Non-Small Cell Lung Cancer ○ Lung Cancer ○ Melanoma ○ Multiple Myeloma ○ Myelofibrosis ○ Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors ○ Renal Cell Carcinoma • Neurological Misc: Movement Disorders • Targeted Immunomodulatory Biologics (TIBs)

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: January 27, 2025

Repatha, Nexletol and Nexlizet: January 29, 2025

Two weeks after signing: February 12, 2025

30 days after Signing: February 26, 2025

60 days after signing: April 2, 2025

90 days after signing: April 30, 2025

120 days after signing: May 28, 2025

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

Appendix H—Completely Excluded Agents and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
November 2024	Ophthalmic Miscellaneous	• clobetasol 0.05% ophthalmic emulsion	• dexamethasone 0.01% ophthalmic suspension • loteprednol 0.5% ophthalmic suspension • prednisolone 1% ophthalmic suspension	• 120 days
November 2024	Weight Loss Agents	• tirzepatide vials (Zepbound)	• liraglutide (Saxenda) • semaglutide (Wegovy) • tirzepatide pens (Zepbound)	• 120 days

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

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

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