DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS
November 2022

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on November 2nd and 3rd, 2022.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of August 2022 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the August 2022 DoD P&T Committee meeting on October 26, 2022.

B. Clarification of Previous Minutes:

1. **August 2022 Meeting**

   - **Antidepressants and Non-Opioid Pain—Add to TPharm5 Rapid Response program:** Updated Prior Authorizations (PA) were recommended for the 9 branded products in the class. These drugs will be added to the TPharm5 Rapid Response/Safety Net program, which will provide additional outreach to beneficiaries who have not received a prescription after an initial PA reject.

   - **Sunset of the Medication Adherence Pilot—rosuvastatin copay:** Patients who have filled rosuvastatin prescriptions will receive an additional letter informing them of the co-pay increase from $0 to the generic Tier-1 copay when the pilot terminates on December 31, 2022.

2. **May 2022—Glucagon-Like Peptide 1-Receptor Agonists (GLP1-RA):** Corresponding updates were made to the PA criteria for the combination GLP1-RA/insulin products (Soliqua and Xultophy) to remove Bydureon as the step-preferred products and to add Trulicity and Ozempic as the formulary products.

3. **February 2022 Meeting—MHS GENESIS OTC Test List—benzocaine/menthol lozenges shortage:** Due to a shortage of Cepacol lozenges (GCNs 30354, 30355 on the list), Chloraseptic Max and Cloraseptic Sore Throat. (GCNs 31986, 97495) were added to the list, based on actual MTF purchasing patterns.

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 not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs 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), and TRICARE Tier 4/Not Covered 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. Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a nonformulary (NF) medication.

NF medications are generally restricted to the mail order program pursuant to 32 CFR 199.21(h)(3)(i) and (ii). Additionally, the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (9) and NDAA 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

IV. UF DRUG CLASS REVIEWS

A. Atopy Agents—Oral Janus Kinase Inhibitor (JAK-1) Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the oral JAK inhibitors approved for treating atopic dermatitis, commonly known as eczema. The drugs in the subclass include upadacitinib (Rinvoq), and abrocitinib (Cibinqo). This is the first time the oral JAK inhibitor subclass has been reviewed for formulary status.

The Atopy Class is a newly created drug class with a variety of agents indicated for atopic dermatitis (AD) and other disease states. It is comprised of products with differing mechanisms of action for treating eczema, including JAK inhibitors [Rinvoq, Cibinqo, and topical ruxolitinib (Opzelura)]; interleukin antagonists [dupilumab (Dupixent), benralizumab (Fasenra), mepolizumab (Nucala), and omalizumab (Xolair)]; calcineurin inhibitors [pimecrolimus (Elidel), tacrolimus (Protopic, generic)], and a phosphodiesterase-type 4 (PDE-4) inhibitor [crisaborole (Eucrisa)]. There is a mix of oral, injectable and topical formulations in the class. The oral JAK inhibitors, tofacitinib (Xeljanz) and baricitinib (Olumiant), will remain in the Targeted Immunomodulatory Biologics (TIBs) class, as they are not approved for treating atopic dermatitis.

Rinvoq and Cibinqo differ markedly in their FDA-approved indications. Rinvoq is approved for a variety of conditions, to include atopic dermatitis (moderate-severe), rheumatoid arthritis (moderate-severe), psoriatic arthritis, ulcerative colitis, and ankylosing spondylitis, while Cibinqo is solely approved for atopic dermatitis (moderate-severe). *(Note that the new Rinvoq indication for non-radiographic axial spondyloarthritis will be reviewed at the February 2023 P&T Committee meeting).*

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 1 abstained, 2 absent) the following:

Professional Treatment Guidelines

- Standard first-line treatments for atopic dermatitis include topical therapies (e.g., calcineurin inhibitors and topical corticosteroids) and consideration of phototherapy before initiating systemic therapies.

- The International Eczema Council 2017 guidelines summarize considerations for initiating systemic treatment options for treating atopic dermatitis. Patients with moderate-to-severe atopic dermatitis should be given appropriate topical therapies and disease management education. In patients with persistent symptoms, consideration for alternative diagnoses and phototherapy, if appropriate, is warranted. Patients who continue to have persistent moderate-to-severe atopic dermatitis symptoms despite the above measures are appropriate candidates for systemic therapy.

Efficacy

- There are no head-to-head trials comparing Rinvoq and Cibinqo. FDA approval was based on several randomized controlled trials (RCT) conducted for each medication.
- For both products, RCTs demonstrated statistically significant achievement of reduction in Investigator Assessment and Eczema Area Severity Index (EASI) scores (which measures the extent and severity of disease) for atopic dermatitis compared to placebo.
- A 2022 JAMA Dermatology network meta-analysis (NMA) assessed new systemic treatment options for atopic dermatitis, and included several RCTs for Rinvoq and Cibinqo, along with other products approved for this indication.
    - The NMA concluded the higher strengths of Rinvoq 30 mg and Cibinqo 200 mg daily were associated with slightly improved scores than Dupixent 300 mg given every other week (standard adult dosage). Rinvoq 15 mg daily was associated with similar scores to standard dose Dupixent, while Cibinqo 100 mg daily was associated with slightly worse scores.
- A 2021 Institute for Clinical and Economic Review (ICER) NMA also evaluated newer systemic treatment options for atopic dermatitis. The results reported that Rinvoq 30 mg was more likely to achieve a 75% reduction in the Eczema Area Severity Index (EASI-75) score thresholds than Cibinqo 200 mg or other systemic interventions, including Dupixent. However Rinvoq 30 mg was not statistically superior to Cibinqo 200 mg in achieving EASI-75 thresholds.

Safety

- Pooled trial data show that Rinvoq and Cibinqo have similar discontinuation rates due to adverse events, both reported at 5%. Rinvoq is associated with a higher proportion of adverse events related to upper respiratory infection and acne, while Cibinqo carries a higher risk for nausea.
- Rinvoq and Cibinqo both require similar pre-treatment and post-treatment screenings. The black box warnings are identical for both products, and include serious infection, increased all-cause mortality, malignancy, major adverse

cardiac events, and thrombosis. Of note, this black box warning was issued as a result of increased safety signals from another JAK inhibitor, Xeljanz, during studies conducted in patients with rheumatoid arthritis.

- For Rinvoq, the RCTs enrolled sufficient numbers of patients from special populations (e.g., geriatric, pediatric, compromised renal or hepatic function), resulting in a recommendation for dose modification for geriatric patients and an indication for pediatric patients; additionally, dose reduction is required in severe renal failure patients. Cibinqo currently has insufficient geriatric and pediatric data and must be avoided in severe renal and hepatic failure.

Individual Agents

- *upadacitinib (Rinvoq):* Advantages of Rinvoq include FDA-approval for diseases other than atopic dermatitis. For atopic dermatitis, Rinvoq is approved for adults and for children as young as 12 years of age and weighing more than 40 kilograms. Additional indications are under investigation.
- *abrocitinib (Cibinqo):* Cibinqo's product labeling is limited to treating atopic dermatitis in adults, and there is insufficient data for treating special populations.

Overall Conclusions

- When treating atopic dermatitis, indirect comparisons from NMAs suggest higher doses of Rinvoq and Cibinqo are somewhat more effective than Dupixent. Direct efficacy comparisons of Rinvoq and Cibinqo have yet to be conducted.
- In terms of efficacy, there is a high degree of therapeutic interchangeability between Rinvoq and Cibinqo. In terms of safety, there is a moderate degree of therapeutic interchangeability as each medication carries a few unique adverse events, and long-term safety will need to be further defined for both agents.
- In order to meet the needs of MHS beneficiaries, one oral JAK inhibitor is required for treatment of atopic dermatitis.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and also conducted a cost minimization analysis (CMA) and budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 2 absent) the following

- CMA results showed upadacitinib (Rinvoq) was more cost effective than abrocitinib (Cibinqo), based on designating Rinvoq as UF and Cibinqo as NF.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA

results showed that designating upadacitinib (Rinvoq) as UF, with abrocitinib (Cibinqo) as NF demonstrated the most cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following:
    - UF
        - upadacitinib (Rinvoq) *moves from NF to UF*
    - NF
        - abrocitinib (Cibinqo) remains *NF*
    - Tier 4 (Not covered) – None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***PA criteria were originally recommended when the individual oral JAK inhibitors were first evaluated by the Committee as new drugs. The current PA criteria for both Rinvoq and Cibinqo require trial of topical medications (corticosteroid and a topical calcineurin inhibitor), first, consistent with professional guidelines for treating atopic dermatitis.

    The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining the current manual PA criteria for Rinvoq, and updates to the manual PA criteria for Cibinqo in new users. Note that for Rinvoq, the current PA requirements for indications other than atopic dermatitis still apply (e.g., a trial of Humira is still required before Rinvoq in patients with arthritis).

    The updated PA criteria for Cibinqo in new users will now include the requirement for a trial of the injectable interleukin antagonist Dupixent, and a trial of Rinvoq; this is in addition to a trial of a topical corticosteroid and a topical calcineurin inhibitor. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining the medical necessity criteria currently in place for Cibinqo. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QL)—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining the specialty quantity limits for Rinvoq and Cibinqo which was recommended at the August 2022 DoD P&T Committee meeting, and will include a 60 day supply at all points of service. See Appendix D for the full QLs.

5. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS —*** The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining Rinvoq on the EMMPI program and adding Cibinqo to the EMMPI program.

6. ***COMMITTEE ACTION: UF, MN, PA, EMMPI and IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. See Appendix G for the actual implementation dates.

B. Hematological Agents—Red Blood Cell (RBC) Stimulants Erythropoietins Subclass

Background—This is the first formulary review for the erythropoietin RBC stimulants. The three marketed erythropoietin alfa products are epoetin alfa (Epogen and Procrit), and epoetin alfa-epbx (Retacrit). Epogen and Procrit are the reference biologics, while Retacrit is the biosimilar. *(See Biosimilar section on pages 23-24 for additional information).* Retacrit was reviewed as an innovator drug in August 2018 and designated as UF. Note that darbepoetin alfa (Aranesp) was not included in the class review.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Background

- Epogen, Procrit and Retacrit all have the same FDA-approved indications, including for treating anemia caused by chronic kidney disease, zidovudine therapy, or chemotherapy, and to reduce the need for RBC transfusions in patients undergoing elective, non-cardiac surgery. There are several well-accepted off-label uses.
- These products are available in vials ranging from 2,000 units/mL to 40,000 units/mL. Epogen is not available in a 40,000 units/mL vial.

Professional Treatment Guidelines

- Clinical practice guidelines in the field of nephrology and oncology address the place in therapy for RBC stimulants and the selection of biosimilars. There is no preference for any one erythropoietin agent, either a reference product or a biosimilar, over the others. There is a lack of evidence that any one erythropoietin product is superior to another.
    - The 2012 Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guideline for anemia in chronic kidney disease recommend erythropoietin agents in patients with anemia who have exhausted all other

means of correcting anemia (iron administration, inflammatory states) and who wish to avoid excessive blood transfusions or symptoms of anemia. No one specific product is recommended, and an individual agent should be chosen based on the balance of pharmacokinetic/pharmacodynamics profiles, safety, clinical outcome data, costs and availability.

- The 2019 American Society of Clinical Oncology/American Society of Hematology guidelines state that erythropoietin stimulating agents may be used in individuals with chemotherapy-induced anemia who have incurable cancer and whose hemoglobin is less than 10 g/dL. The expert panel considers epoetin beta, epoetin alfa, darbepoetin alfa, and biosimilar epoetin alfa-epbx equivalent with respect to effectiveness and safety.

Efficacy

- A large retrospective study in patients with chronic kidney disease evaluated switching between originator and biosimilar epoetin alfa products. The results showed that there were no reported differences in safety or efficacy outcomes when patients were switched between the biosimilar and originator products (Belleudi 2019).

Safety

- The adverse event profiles for the epoetin alfa products differ based on indication. Commonly reported side effects include upper respiratory tract infection, headache, diarrhea, bone and joint pain, and injection site irritation.

Overall Conclusions

- Overall, there is a high degree of therapeutic interchangeability between Epogen, Procrit and Retacrit, as there are no clinically meaningful differences between the reference drug products and the biosimilar.
- In order to meet the needs of MHS beneficiaries, at least one erythropoietin RBC stimulant is required on the formulary.

Relative Cost-Effectiveness Analysis and Conclusion—P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that epoetin alfa-epbx (Retacrit) was more cost effective than epoetin alfa (Epogen, Procrit).
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating epoetin alfa-epbx (Retacrit) as UF and step-preferred, with epoetin alfa (Epogen, Procrit) as UF and non-step-preferred, generated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

   - UF step-preferred
     - epoetin alfa -epbx (Retacrit)
   - UF non-step-preferred
     - epoetin alfa (Epogen)
     - epoetin alfa (Procrit)
   - NF – None
   - Tier 4 (Not covered) – None
   - Note that for Procrit and Epogen a trial of Retacrit is required

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) PA criteria for Epogen and Procrit. A trial of Retacrit will be required first in new users, unless the patient has failed therapy with or cannot tolerate it. See Appendix C for full criteria.

3. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining Epogen, Procrit and Retacrit on the EMMPI program.

4. ***COMMITTEE ACTION: UF, PA, EMMPI IMPLEMENTATION PERIOD*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. (See Appendix G for the actual implementation date.)

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) AND NEW MEDICAL DEVICES

The products were divided into three groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Aspruzyo, Hyftor, Ryaltris, Vivjoa, and Zoryve; Group 2 was comprised of the 2 medical devices, FreeStyle Libre 3 and Omnipod 5, and Group 3 included Tascenso, Sotyktu, Xaciato, Zonisade and Entadfi.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 16 for, 0 opposed, 0 abstained, 2 absent; Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0

absent; and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved pharmaceutical agents.

Addition of new medical devices to the TRICARE pharmacy benefit is also reviewed in this section. Medical devices are primarily covered by the TRICARE medical benefit, and any additions to the TRICARE pharmacy benefit are not meant to replace this pathway for procuring medical devices. See the August 2022 DoD P&T Committee meeting minutes (found at https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Pharmacy-Operations/DOD-PT-Committee/Meeting-Minutes) for details regarding the clinical and cost effectiveness review of new medical devices. The Committee identified two medical devices for review at this meeting, Omnipod 5 and FreeStyle Libre 3.

See Appendix E for the complete list of newly approved pharmaceutical agents reviewed at the November 2022 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 Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended: Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and for Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent; the following:

    - UF
        - FreeStyle Libre 3 - Therapeutic Continuous Glucose Monitoring System (CGMS); new version of a CGMS for monitoring diabetes. Note that as part of this recommendation FreeStyle Libre 3 was added to the TRICARE pharmacy benefit.
        - Omnipod 5 – Miscellaneous insulin device; new version of an External Insulin Infusion Pump for administering insulin. Note that as part of this recommendation Omnipod 5 was added to the TRICARE pharmacy benefit. Additionally, due to noncompliance with the Trade Agreements Act, Omnipod 5 is excluded from the TRICARE Mail Order pharmacy and MTF points of service; it is available at retail pharmacies.
        - sirolimus 0.2% topical gel (Hyftor) – Immunosuppressives; a topical treatment for facial angiofibromas associated with tuberous sclerosis complex (TSC)
        - zonisamide oral suspension (Zonisade) – Anticonvulsant-Antimania Agents; new liquid formulation of zonisamide
    - NF:
        - clindamycin 2% vaginal gel (Xaciato) – Antibiotic; vaginal formulation for treating bacterial vaginosis

- deucravacitinib (Sotyktu) – Targeted Immunomodulatory Biologics (TIBs); an oral tyrosine kinase 2 (TYK2) inhibitor used for systemic treatment of moderate-to-severe plaque psoriasis. Note that as part of this recommendation Sotyktu will be added to the Rapid Response program.
- fingolimod orally dissolving tablet (Tascenso ODT) – Oral Miscellaneous Multiple Sclerosis Agents; new oral disintegrating formulation of fingolimod for patients 10 years of age or older who weigh less than 40 kg
- oteseconazole (Vivjoa) – Antifungal; for treatment of recurrent vulvovaginal candidiasis (RVVC) in females who are not of reproductive potential
- ranolazine ER granule (Aspruzyo Sprinkles) – Miscellaneous Cardiovascular Agent; a new sprinkle formulation for treating chronic angina
- roflumilast 0.3% cream (Zoryve) – Psoriasis Agents; topical phosphodiesterase 4 (PDE-4) for treatment of plaque psoriasis

- Tier 4 (Not covered): The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents. See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
  - finasteride/tadalafil (Entadfi) – Benign Prostatic Hyperplasia (BPH) Agents; combination product of two drugs already available as in generic formulations, a PDE-5 inhibitor and a 5-alpha reductase inhibitor
    - Entadfi was recommended for Tier 4 placement as it has little to no additional clinical effectiveness relative to similar agents in the class, and the needs of TRICARE beneficiaries are met by available alternative agents. Alternatives include finasteride, dutasteride, and tadalafil tablets.
  - olopatadine/mometasone nasal spray (Ryaltris) – Nasal Allergy Agents – Corticosteroids; combination product of two drugs available in generic formulations, a nasal steroid and a nasal antihistamine
    - Ryaltris was recommended for Tier 4 placement as it has little to no additional clinical effectiveness relative to similar agents in the class, the needs of TRICARE beneficiaries are met by available alternative agents, and it

contains at least one ingredient that is not covered under the TRICARE benefit (e.g., OTC drug combo product). Alternatives include other legend and OTC treatments formulations for allergic rhinitis: azelastine (Astelin, Astepro), olopatadine (Patanase) flunisolide (Nasarel), fluticasone propionate (Flonase), ipratropium (Atrovent), fluticasone/azelastine (Dymista), budesonide (Rhinocort), triamcinolone (Nasacort), mometasone (Nasonex), beclomethasone (Beconase AQ, QNASL), ciclesonide (Omnaris, Zetonna).

2. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for clindamycin 2% vaginal gel (Xaciato), deucravacitinib (Sotyktu), fingolimod ODT (Tascenso ODT), oteseconazole (Vivjoa), ranolazine ER granule (Aspruzyo Sprinkles), and roflumilast 0.3% cream (Zoryve). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: PA CRITERIA—*** The P&T Committee recommended Group 1: 17 for, 0 opposed, 0 abstained, 1 absent; Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent; and Group 3: 15 for, 2 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Applying automated and manual PA criteria to new users of Sotyktu. A trial of both Humira and Cosentyx will be required for the treatment of moderate to severe plaque psoriasis.
- Applying manual PA criteria to new users of Tascenso ODT. The PA will require an alternate dosage form of a sphingosine-1 phosphate (S1p) receptor modulator to treat MS to be used first.
- Applying manual PA criteria to new users of Vivjoa for recurrent vulvovaginal candidiasis. Failure of a previous six-month course of oral fluconazole is required.
- Applying manual PA criteria to new users of Aspruzyo Sprinkle, Zonisade, Zoryve, and Hyftor, consistent with the existing PA requirements for using alternate dosage forms for readily available generic tablets.
- Applying PA criteria to new users of FreeStyle Libre 3 and Omnipod 5, consistent with what is already in place for the earlier versions of these two medical devices.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs) —***The P&T Committee recommended (Group 1: 17 for, 0 opposed, 0 abstained, 1 absent; Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3:

18 for, 0 opposed, 0 abstained, 0 absent; Group 3: 15 for, 2 opposed, 0 abstained, 1 absent) QLs for Xaciato, Sotyktu, Tascenso ODT, Vivjoa, Hyftor, FreeStyle Libre 3, and Omnipod 5. The reasons for the QLs were due to existing QLs for the class, or due to recommended treatment course durations. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI—***The P&T Committee recommended (Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI 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 EMMPI program and the NF to mail requirement.

6. ***COMMITTEE ACTION: UF, TIER 4, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

   - **New Drugs Recommended for UF or NF Status:** an effective date of the first Wednesday two weeks after signing of the minutes in all points of service.
   - **New Drugs Recommended for Tier 4 Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

Addendum to the UF recommendation for tadalafil oral suspension (Tadliq) – Pulmonary Arterial Hypertension (PAH) drugs –alternative dosage form of a PDE-5 inhibitor: Tadliq was initially recommended for Tier 4 placement. However, after the DoD P&T Committee meeting was held, specialist feedback supported off-label use to treat children with congenital heart disease who have failed sildenafil therapy. An electronic vote was taken to determine whether Tadliq should be designated as nonformulary, with PA and MN criteria, and an implementation of 2 weeks.

COMMITTEE ACTION: ADDENDUM TO UF, PA, MN and IMPLEMENTATION RECOMMENDATION FOR TADALAFIL ORAL SUSPENSION (TADLIQ)—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) nonformulary status for Tadliq.

- NF:
    - tadalafil oral suspension (Tadliq), Pulmonary Arterial Hypertension (PAH) drugs; alternative dosage form

The Committee also recommended PA criteria in new and current users and MN criteria, with implementation occurring the first Wednesday 2 weeks after signing of the minutes at all points of service. See appendices B and C for the MN and PA criteria.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) Glaucoma Agents: Cholinergics/Cholinesterase Inhibitors—echothiophate ophthalmic solution (Phospholine Iodide)—Phospholine Iodide was reviewed as part of the Ophthalmic Glaucoma Agents class review in February 2007 and was designated as UF. At that time, it was considered a third-line treatment for glaucoma with a unique niche in therapy. In May 2021, national supplies of Phospholine Iodide were depleted after the sole manufacturer discontinued production. A new manufacturer has started producing Phospholine Iodide and it is now significantly less cost effective than prior to market withdrawal. MHS provider feedback relayed that this product is rarely used and recommended prior authorization criteria to ensure appropriate use.

COMMITTEE ACTION: ECHOTHIOPHATE OPHTHALMIC SOLUTION (PHOSPHOLINE IODIDE) NEW PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria in new users of Phospholine Iodide, in order to restrict use to optometrists with a glaucoma specialty, or ophthalmologists. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

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

Manual PA criteria were recommended for two recently marketed drugs that 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. These drugs all have numerous cost-effective formulary alternatives available that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users of oxycodone/acetaminophen, and new users of venlafaxine besylate, requiring a trial of cost effective generic formulary medications first.

a) **Narcotic Analgesics and Combinations—oxycodone 2.5-, 5-, 7.5-, and 10 mg/acetaminophen 300 mg tablets and oxycodone 10 mg/acetaminophen 300 mg/5 mL oral solution—**The fixed dose combination of oxycodone/acetaminophen (Percocet, generic) is a narcotic pain reliever, commonly combined with 325 mg of acetaminophen. Numerous cost-effective generic formulations, are available along with several other short-acting opioids (e.g., hydrocodone/acetaminophen, codeine/acetaminophen, oxycodone IR, etc.). Alternatives in an oral solution include oxycodone 5 mg/acetaminophen 325 mg/5mL and oxycodone 5 mg/5 mL. The various combinations of oxycodone/acetaminophen 300 mg are not cost effective compared to other available short-acting opioids.

b) **Antidepressants: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs):—venlafaxine besylate 112.5 mg tablets—** Venlafaxine hydrochloride (HCl) is available in a variety of doses in both capsules and tablets including 37.5 mg and 75 mg dosages which can be taken together to obtain a dose of 112.5 mg. Venlafaxine HCl is more cost-effective than the venlafaxine besylate 112.5 mg formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for oxycodone/acetaminophen 300 mg tablets and solution in new and current users, and venlafaxine besylate 112.5 mg tablets in new users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to patients affected by the new oxycodone/acetaminophen PA. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA criteria for several drugs, due to new FDA-approved indications or expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for the full criteria.

a) **Cystic Fibrosis Agents—lumacaftor/ivacaftor oral granules (Orkambi)—** Manual PA criteria were updated to expand the age indication for patients with Cystic Fibrosis as young as 1 year of age. Orkambi was previously indicated for children over the age of 2.

b) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass—ibrutinib (Imbruvica)**

i. **Pediatric chronic graft versus host disease (cGVHD):** Manual PA criteria were updated to include the expanded age indication in pediatric patients age 1 year and older with cGVHD after failure of one or more lines of systemic therapy.

ii. **Capsules and tablet formulations:** Manual PA criteria were also revised for the Imbruvica tablet formulation, which previously required a trial of

Imbruvica capsules first, due to cost-effectiveness (See the May 2018 the DoD P&T Committee meeting minutes). Due to recent pricing changes, the requirement for a trial of Imbruvica capsules prior to using the 420 mg and 560 mg tablets will be removed. Note that a trial of capsules will continue to be required before use of the lower strength Imbruvica tablets (140 mg and 280 mg tablets). The PA updates will apply to new patients.

c) **Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—relugolix/estradiol/norethindrone (Myfembree) and elagolix (Orilissa)**—The manual PA criteria were updated for Myfembree to expand use for treating moderate to severe pain associated with endometriosis. Myfembree when used for this indication will require a trial of nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives first; this is also required for a similar agent already approved for endometriosis, elagolix (Orilissa). Additionally, the PA expiration section of the Orilissa PA was updated to more closely align with the Myfembree PA. Both PAs are now approved for a lifetime expiration of 24 months without a need for renewal, according to the package insert limits for 2 years of therapy.

d) **Oncological Agents: Lung Cancer—crizotinib (Xalkori)—**Manual PA criteria were updated to expand use to adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is anaplastic lymphoma kinase-positive.

e) **Oncological Agents: 2nd-Generation Antiandrogens—darolutamide (Nubeqa)—**The manual PA criteria were updated to allow use for the treatment of adult patients with metastatic hormone-sensitive prostate cancer in combination with docetaxel. The current step-therapy requirements for the class will still apply; a trial of enzalutamide (Xtandi) is required first unless the patient has a contraindication, inadequate response, or adverse reaction to Xtandi.

f) **Oncological Agents: Acute Myelogenous Leukemia (AML)—ivosidenib (Tibsovo)—**Manual PA criteria were updated to expand use in combination with azacitidine for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

g) **Oncological Agents—pemigatinib (Pemazyre)—**The manual PA criteria were updated to include a new indication for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor (FGFR1) rearrangement

h) **Oncological Agents—trametinib (Mekinist)**—The manual PA criteria were updated to expand use for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Note that this indication is approved under accelerated approval based on overall response rate and duration of

response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

i) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors —risankizumab On-Body Injector (Skyrizi OBI)**—PA criteria have applied to Skyrizi since August 2019 for the original indication of moderate-to-severe plaque psoriasis in adults who are candidates for phototherapy or systemic therapy. An expanded indication for psoriatic arthritis was reviewed at the February 2022 DoD P&T Committee meeting.

   Skyrizi's package labeling was recently expanded to include adults with moderately to severely active Crohn's disease. The new OBI is solely approved for Crohn's disease, and Skyrizi syringes and pens are only indicated for plaque psoriasis and psoriatic arthritis. In pivotal trials, Skyrizi was only compared to placebo, and practice guidelines do not yet mention Skyrizi's role in therapy for Crohn's disease. Step-therapy applies to the TIB class, requiring a trial of Humira first. In addition, the other Skyrizi indications (plaque psoriasis and psoriatic arthritis) require a trial of Cosentyx and Stelara first. Since Cosentyx is not approved for Crohn's disease, the step therapy will only require a trial of Humira and Stelara when Skyrizi is used for Crohn's disease. The current PA for the pen and syringe formulations of Skyrizi will also be updated to exclude use for Crohn's disease, consistent with package labeling.

j) **TIBs: Non-TNF Inhibitors—ustekinumab (Stelara)—**Manual PA criteria were updated for Stelara for treating active psoriatic arthritis to now include patients 6 to 17 years of age. Although there is currently a step-therapy for Stelara requiring a trial of Humira first, this will not apply to pediatric patients, as Humira is not indicated for active psoriatic arthritis in this patient population. This is similar to the current PA criteria for Stelara for the pediatric plaque psoriasis indication (e.g., a trial of Humira first is not required).

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Orkambi, Imbruvica, Myfembree, Orilissa, Xalkori, Nubeqa, Tibsovo Pemazyre, Mekinist, Skyrizi, and Stelara.in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

4. Updated PA Criteria for Reasons other than new Indications: Androgens-Anabolic Steroids: Testosterone Replacement Therapies- testosterone cypionate and testosterone enanthate injection

At the February 2022 DoD P&T Committee meeting, a new PA was placed on injectable versions of testosterone cypionate and testosterone enanthate, allowing use in adult males with hypogonadism and transgender males 16 years of age and older. Implementation of this PA occurred in July 2022. Updated criteria were recommended during the November 2022 P&T Committee as noted below.

Additional updates will be considered for all dosage forms, including the injectable form, of testosterone during the February 2023 class review. The following PA revisions were recommended:

1. Allow children less than one year of age to bypass the PA via an age edit. This will account for use in micropenis, which is typically treated with three doses of injectable testosterone within the first year of life.
2. Allow for use in males (assigned male at birth) if they are less than 18 years old and the prescription is written by or in consultation with a pediatric endocrinologist.
3. Allow for use in breast cancer in females if the medication is prescribed by an oncologist. Injectable testosterone is FDA-approved for use in breast cancer in females.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PLAN FOR THE TESTOSTERONE REPLACEMENT THERAPIES—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for the testosterone replacement therapies in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

5. Updated PA Criteria for Removal of Indication

Over the past several months, the FDA has removed certain indications from several oncology drugs due to safety issues. The P&T Committee recommended updates to the PAs below, based on recent FDA action.

a) Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)—The indication for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy has been removed, due to an increased risk of death. Other Lynparza indications remain for ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer.

b) Oncologic Agents - Multiple Myeloma—ixazomib (Ninlaro) —A new limitation of use states that Ninlaro is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials due to an increased risk of death. The indication for use in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy remains

COMMITTEE ACTION: LYNPARZA and NINLARO-UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) to

remove the Lynparza indication for the treatment of adult patients with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. The new limitation of use for Ninlaro about not using this drug in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials will be incorporated into the Ninlaro PA. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

B. Quantity Limits

1. **Newly approved drugs:** See pages 11-12 for the QLs for the Newly Approved drugs, which are outlined in Appendix. D.
2. **Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon (Baqsimi nasal, and Gvoke, Zegalogue and Glucagon injections)–**The QLs for these products were increased to allow for situations such as school use, summer camp, and multiple caregiver's homes. The new QLs are 6 kits/fill at all points of service (Retail, TRICARE Mail Order, and MTF).
3. **Migraine Agents: Oral Calcitonin-Gene Related Peptide (CGRP) Antagonists: ubrogepant (Ubrelvy)–**QLs for Ubrelvy were updated to account for a larger bottle size recently introduced from the manufacturer.
4. **SARS-CoV-2 treatments: nirmatrelvir and ritonavir kit (Paxlovid)**–The committee recommended to update the QLs to allow for one treatment course per 90 days at all points of service, which will align with other commercial health plans. The Committee will continue to monitor the emerging research and practice guidance, and revise accordingly, if needed.

COMMITTEE ACTION: QLs AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the QLs as discussed above, with implementation occurring 2 weeks after signing of the minutes. See Appendix D for the QLs.

C. Line Extensions

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

a) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors—** designating **acalabrutinib (Calquence)** tablets with the same formulary status (UF), QL and PA as the parent Calquence capsules.

b) **Diabetes Non-insulin: Glucagon-like Peptide-1 Receptor Agonists (GLP1RAs)—**designating **semaglutide (Ozempic) 2mg** injection as NF, with the same formulary status (NF) and PA as the parent Ozempic 0.5 and 1 mg injections

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the formulary status and PA status for the line extension products as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BCF CLARIFICATION: CONTRACEPTIVES

There is currently at least one BCF agent for all categories of oral contraceptives and emergency contraceptives; there are three categories (injection, contraceptive patch, and vaginal contraceptive ring) that do not currently have a BCF agent. Clinical evidence, utilization trends, and cost data informed the selection of generic Xulane patch, NuvaRing vaginal ring, and Depo-Provera injection as the recommended BCF agents for these three categories adding to the MTF availability of contraceptive care.

COMMITTEE ACTION: CONTRACEPTIVES ADDED TO THE BCF AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) adding the most cost-effective generic version of the following contraceptive agents to the BCF: norelgestromin 150 mcg/ethinyl estradiol 35 mcg transdermal system (Xulane; equivalent to the discontinued Orto-Evra patch), etonogestrel 0.12 mg/EE/ethinyl estradiol 15 mcg vaginal ring (NuvaRing), and medroxyprogesterone acetate 150 mg/vial (Depo-Provera), with implementation occurring 2 weeks after signing of the minutes. Note that the Depo-SubQ Provera 104 injection will remain designated as UF, but was not added to the BCF.

VIII. CHANGE IN COPAY: TIER 1 COPAY

A copay change from the current tier 2 copay to the tier 1 copy was recommended for two products, a narcotic antagonist and an emergency contraceptive.

a) **Emergency Contraceptives: ulipristal acetate (Ella)**: Ella was added to the BCF at the August 2018 DoD P&T Committee meeting and is currently available at the Tier 2 copay. Ella was recommended for Tier 1 status to provide a high-value medication at a lower cost to beneficiaries

b) **Narcotic Antagonists: naloxone injection 5 mg/0.5 mL (Zimhi)**: Zimhi was recommended for Tier 1 status as it is a high value and cost-effective reversal agent for opioids. Commercial health plans commonly lower naloxone copays, and another new naloxone formulation, Kloxxado, was designated with the tier 1 copay at the November 2021 DoD P&T Committee meeting.

COMMITTEE ACTION: TIER 1 COPAY FOR ZIMHI AND ELLA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0

opposed, 1 abstained, 1 absent) applying the Tier 1 copay to Zimhi and Ella, with implementation occurring 2 weeks after signing of the minutes.

The authority for the above recommendations is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes."

IX. RE-EVALUATION OF NF GENERICS/EMMPI REQUIREMENTS: Alzheimer's Agents, 2nd Generation Antihistamines, and Proton Pump Inhibitors

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The historical standard for reevaluating generically available Tier 3/NF agents for return to formulary status was established at the May 2007 DoD P&T Committee meeting and reiterated in the DoD P&T Committee meeting minutes from November 2012. To summarize, generic products must be "A-rated" as listed in the Orange Book as therapeutically equivalent to the reference product, available in stable and sufficient supply, and the NF agent must be cost effective relative to similar agents on the Uniform Formulary, defined as a weighted average cost per day (or alternative measure) less than or equal to similar agents in the UF class.

The P&T Committee discussed the above standard and agreed that considerations in addition to relative cost should be taken into consideration when discussing formulary status changes. Additionally, reassessing relative clinical and cost effectiveness of generically available Tier 3/NF agents could result in changes to other formulary management tools, including manual and step prior authorizations, quantity limits, and status on the Maintenance Drug List (EMMPI program). Other considerations may include but are not limited to place in therapy and clinical evidence relative to formulary options; desire for a broader choice of formulary options; administrative burden; volume of use; likelihood of inappropriate use if formulary management tools are removed; and the requirement that Tier 3/NF agents generally be filled only at Mail.

The DoD P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30-day equivalent prescriptions for three drugs from the Alzheimer's Agents, 2nd Generation Antihistamines, and Proton Pump Inhibitors (PPIs), when compared to their respective formulary alternatives.

a) ***Alzheimer's Agents (Cholinesterase Inhibitors): donepezil 23 mg (Aricept 23 mg, generics)***—Donepezil 23 mg tabs were compared to formulary alternatives, including galantamine tabs, galantamine 24h ER caps, rivastigmine caps, and rivastigmine

transdermal patch. The P&T Committee concluded that, although the weighted average cost per 30-day equivalent prescription for donepezil 23 mg tabs is currently somewhat higher than donepezil 5 or 10 mg tablets or orally dissolving tablets, it is within the range of other formulary options. In addition, there is currently low utilization of the 23 mg tab, which is unlikely to substantially increase in volume.

b) 2nd Generation Antihistamines: levocetirizine (Xyzal, generics); desloratadine (Clarinex, generics) —Levocetirizine and desloratadine were compared to formulary alternatives, including cetirizine, loratadine, and fexofenadine (which are included on the Uniform Formulary as covered OTCs). The P&T Committee concluded that the two generically available desloratadine products (the 5 mg tab and 2.5- and 5-mg rapidly dissolving tabs), as well as levocetirizine 2.5 mg/5 mL oral solution, are still substantially more costly than the formulary alternatives. Generic levocetirizine 5 mg tabs, on the other hand, are now comparable in price to generic fexofenadine 180 mg, which is on the Uniform Formulary. Of particular note in this class is that many products are available in both OTC and legend versions; desloratadine is the only remaining product that is legend-only. The P&T Committee also noted that the cost of generic desloratadine 5 mg tabs is lower at retail network pharmacies than at MTFs or Mail Order. Utilization of desloratadine rapidly dissolving tabs is very low.

c) PPIs (Tabs/Caps subclass): lansoprazole (Prevacid, generics)—The Tier 3/NF agents lansoprazole 15 and 30 mg caps were compared to formulary alternatives, including tab or cap formulations of omeprazole, pantoprazole, rabeprazole, and esomeprazole, all of which are on the UF. Additional formulary tools apply to the Tabs/Caps subclass: a step PA requires a trial of either omeprazole or pantoprazole prior to receiving rabeprazole or esomeprazole, while a manual PA requiring a trial of all UF agents applies to the two Tier 3/NF agents, lansoprazole, and omeprazole/sodium bicarb caps. Dexlansoprazole (Dexilant, generics) is Tier 4/not covered.

The P&T Committee noted that while generic lansoprazole capsules are still more costly than omeprazole or pantoprazole, they are less costly than esomeprazole, which is on the UF. In addition, the cost of generic lansoprazole caps is lower at retail network pharmacies than at MTFs or Mail Order.

COMMITTEE ACTION: FORMULARY STATUS, EMMPI STATUS AND IMPLEMENTATION—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes. (See Appendix F for implementation dates).

- *Alzheimer's Agents (Cholinesterase Inhibitors):* Return donepezil 23 mg tabs to UF status; remove from the EMMPI program

- *2nd Generation Antihistamines: levocetirizine (Xyzal, generics); desloratadine (Clarinex, generics)*
  - Return levocetirizine 5 mg tabs to UF status
  - Maintain levocetirizine 2.5 mg/5 mL solution as Tier 3/NF

- Maintain all desloratadine products (5 mg tabs, 2.5 and 5 mg rapidly dissolving tabs, and desloratadine/PSE [Clarinex D 12H]) as Tier 3/NF, but exempt desloratadine 5 mg tabs and the 2.5 and 5 mg rapidly dissolving tabs from the mail order requirement on the basis of cost effectiveness and remove them from the Maintenance Drug List

- *Proton Pump Inhibitors (Tabs/Caps subclass): lansoprazole (Prevacid, generics)*
  - Return lansoprazole 15 and 30 mg caps to UF status, remove them from the EMMPI program and remove the manual PA, but place them behind the step in the same status as rabeprazole and esomeprazole
  - Maintain omeprazole/sodium bicarb caps as Tier 3/NF

X. TIER 4/NOT COVERED RE-REVIEW: REVIEW OF CURRENT TIER 4 PRODUCTS AND RAPID ACTING INSULINS—INSULIN ASPART/NIACINAMIDE (FIASP)

If the P&T Committee determines that a pharmaceutical agent provides very little or no clinical effectiveness relative to similar agents, it may recommend complete or partial exclusion of that agent from the TRICARE pharmacy benefits program. Drugs designated as Tier 4/Not Covered status are not available at the MTFs or Mail Order points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies**.**

With respect to the pharmaceutical agents currently designated as Tier 4/Not Covered, the P&T Committee concluded that there is a lack of new clinical data that supports a specific clinical need for these products which is not met by formulary agents. Additionally, there is a lack of new clinical data to challenge the conclusion that the current Tier 4/Not Covered drug offer little or no clinical effectiveness relative to formulary agents.

Rapid Acting Insulins: insulin aspart/niacinamide (Fiasp)—The P&T Committee reviewed specific data regarding the July 1, 2020 implementation of Tier 4/Not Covered status for insulin aspart/niacinamide (Fiasp) as well as new clinical evidence published after the November 2019 DoD P&T Committee evaluation of the rapidly-acting insulins.

For insulin aspart/niacinamide (Fiasp), the P&T Committee concluded that:

- Fiasp is a formulation of insulin aspart that contains niacinamide, a form of vitamin B3.
- Although Fiasp has a faster onset of action of approximately 2.5 minutes, the change in pharmacokinetic profile does not show a clinically significant difference in A1C or post-prandial blood glucose compared to insulin aspart (Novolog).

- There is no data to show that Fiasp is superior to other rapid-acting insulins. Pivotal studies demonstrated that Fiasp is non-inferior when compared to Novolog, but did not show superiority.
- New data since 2019 evaluating use of Fiasp in insulin pumps found Fiasp was comparable to insulin aspart (Novolog) in term of efficacy and safety, but failed to demonstrate any significant differences in glycemic control (i.e., time-in-range as measured by continuous glucose monitoring). Limitations of the data include small patient enrollment and short study duration.
- There is no new data to change the previous clinical conclusion that Fiasp provides very little to no clinical effectiveness for treating diabetes relative to formulary rapid acting insulins.

COMMITTEE ACTION: FIASP TIER 4 STATUS—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent), to maintain Tier 4/Not Covered status for insulin aspart/niacinamide (Fiasp).

XI. PROCESS FOR REVIEWS OF BIOLOGICS AND BIOSIMILARS

The DoD P&T Committee reviews newly approved drugs per 32 CFR 199.21(g)(5) to include new drugs approved through the 505(b) New Drug Applications (NDA) as well as 351(a) Biologics License Applications (BLA) pathways. These two pathways have follow-on approvals. For NDA pathway drugs, generic drugs are approved and listed in the Orange Book. BLA products also have follow-on products approved as 351(k) biosimilars or 351(k) interchangeable products and are listed in the Purple Book. Although these processes are similar, there are distinct differences in the approvals of biosimilars. The Committee reviewed these processes and recommended a procedure of reviewing these products as they are approved.

The Committee concluded the following regarding biologics and their biosimilars.

- By FDA approval and definition, biosimilars are equally safe and efficacious. This provides strong competition within products for biosimilar drug classes.
- Not all biosimilars are cost-effective when compared to the reference biologic.
- Biosimilars can be in direct competition to other biologics, and Utilization Management (UM) Tools can be effectively applied.
- Currently there are a limited number of interchangeable biosimilars marketed. States will allow for individual pharmacies to interchange biosimilars under certain circumstances, to include notifying the provider. There are slight differences between individual states in documentation requirements.
- Unbranded biologics are marketed under the same 351(a) BLA as the reference product. These unbranded biologics can have differing formulary status

compared to their reference product. Unbranded biologics will be reviewed by the DoD P&T Committee as either a newly approved drug, a line extension, or using other UM tools.

- Current UM tools are routing prescription utilization to the most cost-effective agents. This is seen in the basal insulin class.
- Interchangeable biosimilars will not default to a generic Tier 1 copay, but the DoD P&T Committee can make this decision to make certain biosimilar products Tier 1.

The P&T Committee discussed and approved a process of reviewing biologics and biosimilars for inclusion on the DoD Uniform Formulary. Newly approved biosimilars will be reviewed using the new drug process outlined in 32 CFR 199.21(g)(5). Biosimilars will not default to the Tier 1 generic copay. Unbranded Biologics will either be treated like a New Drug, as a line extension, or managed using other UM tools. Interchangeable products approved under the 351(k) pathway can still have a PA requiring trial of a step preferred product. The Committee will continue to evaluate this process for future improvements.

COMMITTEE ACTION: ***PROCESS FOR REVIEWING BIOLOGICS AND BIOSIMILARS—***The P&T Committee recommended (17 for, 0 against, 0 abstained, 1 absent) that newly approved biosimilars will be reviewed using the new drug process outlined in 32 CFR 199.21(g)(5). Biosimilars will default to Tier 2 or Tier 3 copays depending on formulary placement. Unbranded Biologics will either be treated like a New Drug, as a line extension, or managed using other UM tools.

XII. ITEMS FOR INFORMATION

A. Post-Implementation Review: White Blood Cell (WBC) Stimulants: The Committee reviewed utilization and cost trends for the WBC Stimulants, which were reviewed for formulary placement in August 2020. The WBC Stimulants class review resulted in significant and sustained cost avoidance for the MHS. Savings from UF class reviews can vary based on competition, comparator interchangeability, and other market factors (and many were observed with this class). Class reviews can create or maintain conditions (e.g., step therapy) where future agents are placed behind a step and subject to prior authorization. Formulary management tools can increase market share of cost-effective agents and drive reductions in total cost, observed outcomes may vary. Optimum scenarios were selected and implemented during this review.

B. Addition of Solu-Cortef 100 mg Act-O-Vials (GCN 028302) to the TRICARE Pharmacy Benefit: Hydrocortisone sodium succinate (Solu-Cortef) was not previously part of the TRICARE pharmacy benefit, due to the requirement for IV/IM administration. Due to several requests from the field using the DHA 111 form, and supporting information from the 2016 Endocrine Society guidelines for primary adrenal insufficiency which

recommends every patient have a glucocorticoid injection kit for emergency use, the Solu-Cortef Act-O-Vials were added to the TRICARE Pharmacy benefit at all three points of service. Quantity limits of two vials per prescription fill will also apply. Solu-Cortef is also available under the TRICARE Medical benefit.

C. Annual MHS Prescribing and Cost Trends: The Committee was briefed on various aspects of MHS prescribing and cost trends, including overall trends and spends, the top 25 drug classes, and increasing specialty spend. During Fiscal Year 2022, the DoD P&T Committee performed 8 drug class reviews (comprised of 15 subclasses), 55 new drug reviews, and approximately 81 UM actions. A significant amount of time was spent implementing the 2021 formulary recommendations which were affected by the BAP delay. One major accomplishment was completion of the MHS GENESIS OTC list.

XIII. ADJOURNMENT

The meeting adjourned at 1615 hours on November 3, 2022. The next meeting will be in February, 2023.

Appendix A—Attendance: November 2-3, 2022 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
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 2022 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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:

Brian C. Lein, MD
Assistant Director,
Healthcare Administration
for Telita Crosland LTG, MC, USA
Director

31 Jan 2023
Date

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, Col (Ret), MC, USA	Army Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
COL Aatif Sheik, MSC	Army, Pharmacy Consultant
LCDR Caitlin Cruz for CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CAPT Tiffany Cline for CAPT Bridgette Faber, MSC Day #1 AM	Navy, Pharmacy Consultant
CAPT Bridgette Faber, MSC Day #1 PM and Day #2	Navy, Pharmacy Consultant
Lt Col Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Maj Burke Wilson for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD	Physician at Large, DHA
LTC Jason Burris, MC	Army, Oncology Physician
Ms. Beth Days	Oncology Pharmacist
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
COL Yang Xia	TRICARE Latin America and Canada
Nonvoting Members Present	

Megan Gemunder, DHA	Attorney Advisor, Contract Law
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Dean Valibhai, PharmD	TPharm5 Clinical COR
Eugene Moore, PharmD	TPharm4 Clinical COR
Lt Col Francisco Boral	Defense Logistics Agency
Maj Charles (Josh) Stallings	Defense Logistics Agency
Guests	
Ms. Marsha Peterson	Contracting Officer
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Sydney Roman	DHA Contracting
Ms. Victorkia Reed	DHA Contracting, TPharm5
Mr. Dwight Bonham	DHA Contracting, COR TPharm5
Others Present	
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
David Folmar, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, RPh	DHA Formulary Management Branch Contractor
Michael Lee, RPh	DHA Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA Formulary Management Branch Contractor
CDR Marie Manteuffel	TDY PHS Pharmacist to the FMB

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• **abrocitinib (Cibinqo)** **Atopy Agents: Oral JAK-I Inhibitors**	**Updates are in bold** • Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives: upadacitinib (Rinvoq),** dupilumab (Dupixent), topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus), high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
New Drugs MN Criteria	
• **clindamycin 2% vaginal gel (Xaciato)** **Antibiotics**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** metronidazole (oral tabs, vaginal gel), clindamycin (vaginal cream)
• **deucravacitinib tablets (Sotyktu)** **Targeted Immunomodulatory Biologics (TIBs)**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** apremilast (Otezla), secukinumab (Cosentyx), adalimumab (Humira)
• **fingolimod ODT (Tascenso)** **Multiple Sclerosis: Miscellaneous Oral Agents**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** fingolimod capsules (Gilenya, generics), siponimod (Mayzent), ponesimod (Ponvory), ozanimod (Zeposia)
• **oteseconazole (Vivjoa)** **Antifungals**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** fluconazole (Diflucan, generics)
• **ranolazine ER granule (Aspruzyo Sprinkles)** **Cardiovascular Agents Miscellaneous**	• No alternative formulary agent - patient cannot swallow tablets **Formulary alternatives:** ranolazine ER tablets (Ranexa, generics)

• **roflumilast 0.3% cream (Zoryve)** **Psoriasis Agents**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** moderate to high potency topical corticosteroids (e.g., betamethasone, clobetasol, fluocinonide), topical calcineurin inhibitors (i.e., pimecrolimus, tacrolimus)
• **tadalafil oral suspension (Tadliq)** **PAH**	• No alternative formulary agent: patient cannot take sildenafil and requires an additional therapeutic agent for PAH **Formulary Alternatives**: sildenafil suspension, tadalafil tablets

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	

• abrocitinib (Cibinqo)
 	
Atopy Agents: Oral JAK-I Inhibitors
	Updates from Nov 2022 are in bold and strikethrough
	
	Manual PA criteria apply to all new users of abrocitinib (Cibinqo).
	
	Manual PA criteria: abrocitinib (Cibinqo) is approved if all criteria are met:
	• Patient is 18 years of age or older
	• Medication is prescribed by an allergist, dermatologist, or immunologist
	• Drug is used to treat moderate to severe atopic dermatitis
	• **The patient's disease is not adequately controlled with other systemic drug products including biologics (ex Dupixent) OR it is inadvisable to use other systemic drug products including biologics**
	• Patient failed, has a contraindication, or intolerability to one medication in EACH of the following **four ~~two~~** categories:
	  • Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
	  • Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
	  • **Injectable interleukin antagonist: dupilumab (Dupixent)**
	  • **Oral JAK: upadacitinib (Rinvoq)**
	• Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy
	• Patient has had a negative TB test in the last 12 months (or is adequately managed)
	• Patient has no history of venous thromboembolism (VTE)
	• Provider is aware of the boxed FDA warnings
	• Patient does not have neutropenia (ANC < 1000)
	• Patient does not have lymphocytopenia (ALC < 500)
	• Patient does not have anemia (Hgb < 8 mg/dL)
	• Patient is not taking a concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulatory agents
	
	Non-FDA-approved uses are not approved.
	PA expires in 1 year. Renewal PA criteria will be approved indefinitely.
	
	Renewal criteria: (initial TRICARE PA approval is required for renewal) The patient's disease severity has improved and stabilized to warrant continued therapy

• **upadacitinib (Rinvoq)** **Atopy Agents: Oral JAK-I Inhibitors**	**Note that there were no changes to the current Rinvoq criteria for the other indications (RA, PsA, Ulcerative Colitis or Ankylosing Spondylitis – see the August 2022 P&T Committee meeting minutes for the full criteria)** Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq ER). Manual PA Criteria: Rinvoq is approved if all criteria are met: ***For Atopic Dermatitis*** • The patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent) **OR it is inadvisable to use other systemic drug products including biologics** • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: o 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) o For patients 12 to 17 year of age: any topical corticosteroid ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy *For all indications* • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved. PA expires in 1 year for atopic dermatitis. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, or ankylosing spondylitis. Renewal criteria: (initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if the following apply: Atopic Dermatitis - The patient's disease severity has improved and stabilized to warrant continued therapy
• **epoetin alfa (Epogen)** • **epoetin alfa (Procrit)** **RBC Stimulants: Erythropoietins**	Manual PA criteria apply to all new users of epoetin alfa (Procrit and Epogen) Manual PA Criteria: Coverage will be approved if all criteria are met: • Provider acknowledges that epoetin alfa-epbx (Retacrit) is the preferred epoetin alfa for TRICARE and is available without a PA • The patient has experienced an inadequate response or • The patient has had an adverse reaction to Retacrit that is not expected to occur with Procrit or Epogen Prior Authorization does not expire

Newly Approved Drug PAs	
• **deucravacitinib tablets (Sotyktu)** **Targeted Immunomodulatory Biologics (TIBs)**	Step therapy and manual PA criteria apply to all new users of Sotyktu Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) and secukinumab (Cosentyx) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, Sotyktu is approved if all criteria are met: • The provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira and Cosentyx AND: • The patient had an inadequate response to Humira and Cosentyx OR • The patient experienced an adverse reaction to Humira and Cosentyx that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira and Cosentyx • Patient is 18 years of age or older • Patient has diagnosis of moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, or corticosteroids) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIB agents • Provider acknowledges the FDA safety alerts and boxed warnings and precautions associated with Sotyktu Non-FDA-approved uses are not approved PA does not expire
• **fingolimod ODT (Tascenso)** **Multiple Sclerosis: Miscellaneous Oral Agents**	Manual PA criteria apply to all new users of Tascenso ODT. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is ≥ 10 years and weighs ≤ 40 kg • Patient has a documented diagnosis of a relapsing form of multiple sclerosis (MS) • Medication is prescribed by a neurologist • Patient has tried and failed or has a contraindication (i.e., swallowing difficulties) to fingolimod capsule • Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunomide [Aubagio]) • Patients of childbearing potential agree to use effective contraception during treatment and for 2 months after stopping therapy • Patient has not failed a course of another S1p receptor modulator (e.g., Gilenya, Mayzent, Zeposia, Ponvory) • Provider acknowledges that all recommended Tascenso ODT monitoring has been completed and the patient will be monitored throughout treatment as recommended in the package insert. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), pulmonary function tests (PFTs), blood pressure, skin assessments and macular edema screening as indicated. Non-FDA approved uses are not approved, including for patients weighing > 40 kg PA does not expire.

• **oteseconazole (Vivjoa)** **Antifungals**	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 • 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
• **ranolazine ER granule (Aspruzyo Sprinkles)** **Cardiovascular Agents Miscellaneous**	Manual PA criteria apply to all new users of Aspruzyo Sprinkle Manual PA criteria: Coverage is approved if all criteria are met: • The patient is 18 years of age or older • The patient has a diagnosis of chronic angina • Provider must document why the patient requires Aspruzyo Sprinkle and cannot take ranolazine ER tablets *(write in)* Non-FDA approved uses are not approved. PA does not expire

• **roflumilast 0.3% cream (Zoryve)**
 	
Psoriasis Agents
	Manual PA criteria apply to all new users of Zoryve.
	
	Manual PA criteria: Coverage is approved if all criteria are met:
	• Patient is 12 years of age or older
	• The medication is being prescribed by, or in consultation with, a dermatologist
	• The patient has a diagnosis of plaque psoriasis
	• 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:
	  • A topical corticosteroid
	  ▪ 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 year of age: any topical corticosteroid
	  • A topical calcineurin inhibitor (i.e., tacrolimus, pimecrolimus)
	
	Non-FDA approved uses are not approved.
	PA does not expire.

• **sirolimus 0.2% gel (Hyftor)** **Immunosuppressives**	Manual PA criteria apply to all new users of Hyftor Manual PA criteria: Coverage is approved if all criteria are met: • Hyftor is prescribed by or in consultation with a dermatologist or other provider experienced in tuberous sclerosis treatment • Patient has a documented diagnosis of facial angiofibroma associated with Tuberous Sclerosis Complex (TSC) • Provider acknowledges the recommendation to monitor for hyperlipidemia during treatment Non-FDA approved uses are not approved. PA does not expire

• **zonisamide oral suspension (Zonisade)** **Anticonvulsants-Antimania Agents**	Manual PA criteria apply to all new users of Zonisade Manual PA Criteria: Coverage is approved if all criteria are met: • Provider acknowledges generic zonisamide capsule are available to TRICARE patients and do not require a PA • Medication is prescribed by a neurologist • Patient has diagnosis of partial-onset epilepsy • Patient requires a liquid formulation due to swallowing difficulty • Patient has tried and failed or has a contraindication to at least one formulary anti-epileptic drug Non-FDA approved uses are not approved. PA does not expire
• **tadalafil oral suspension (Tadliq)** **PAH**	Manual PA criteria apply to new and current users of Tadliq. Automated PA Criteria: PA does not apply to patients younger than 18 years of age (age edit) AND if the patient has filled a prescription for sildenafil oral suspension at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. If automated criteria are not met: Manual PA Criteria: Tadliq is approved if all criteria are met: • Tadliq is prescribed by a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 pulmonary arterial hypertension (PAH) ▪ Patient has had a right heart catheterization (documentation required) ▪ Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH • Patient is not receiving other PDE-5 inhibitors, nitrates, or riociguat (Adempas) concomitantly • Patient requires a liquid formulation due to swallowing difficulty AND • Patient has had an adequate trial and failure OR has had an adverse reaction to sildenafil Non-FDA-approved uses are not approved, including for erectile dysfunction or for benign prostatic hyperplasia (BPH) Prior authorization does not expire.
• **Freestyle Libre 3** **CGM: Therapeutic Continuous Glucose Monitoring Systems**	**Updates from the current CGMS PA criteria are in bold** Manual PA criteria apply to all new users of Dexcom G6, FreeStyle Libre2, or **FreeStyle Libre 3**. Patients who have previously received a CGM under the TRICARE medical benefit (e.g., DME) must still fill out the prior authorization criteria below in order to receive these CGMs under the TRICARE pharmacy benefit. Note: other CGM systems are not part of the TRICARE pharmacy benefit but may be covered through the TRICARE DME process. Manual PA criteria: Coverage is approved if all criteria are met: • The patient has a diagnosis of Type 1 diabetes mellitus OR Type 2 diabetes mellitus • One of the following situations applies: • Patient is using basal and prandial insulin injections; OR • Patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR

	• Patient has Type 2 diabetes mellitus and is receiving insulin therapy and has a history of severe hypoglycemia episodes requiring medical intervention • **CGM** is prescribed by an endocrinologist or diabetes specialist • **Diabetes management expert is defined as: licensed independent practitioner experienced in the management of insulin dependent diabetics requiring basal and bolus dosing or a pump and familiar with the operation and reports necessary for proper management of continuous glucose monitoring systems. This is a self-certification.** • Documentation from the patient record must be submitted with all of the following: • Diagnosis • Medication history, including use of insulin • Completion of a comprehensive diabetes education program for the patient • Patient agrees to wear CGM as directed • Patient agrees to share device readings with managing healthcare professional for overall diabetes management • Patient meets the following age requirements • Dexcom G6: Patient is 2 years of age or older • FreeStyle Libre 2 **or FreeStyle Libre 3**: Patient is 4 years of age or older • Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips, with the goal of minimizing/discontinuing use Initial prior authorization expires in 1 year PA renewal will be required annually <u>Renewal criteria</u>: Coverage will be approved on a yearly basis if all of the following apply (Note that initial TRICARE PA approval is required for renewal) • Confirmation that the patient has seen an endocrinologist or diabetes specialist at least once within the past year • Confirmation that the patient has utilized CGM daily • Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips at every visit, with the goal of minimizing/discontinuing use • Patients with T2DM continue to require daily basal and prandial insulin injections • Patient continues to agree to share data with managing healthcare professional for the purposes of clinical decision making
• **Omnipod 5** **Insulins: Miscellaneous Insulin Devices**	Note that Omnipod 5 is currently only available at retail pharmacies. Manual PA criteria apply to all new users of Omnipod 5 pods and kits <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Note: Current utilization of Omnipod 3 and 4 is not automatic approval for Omnipod 5. A new PA is required for Omnipod 5 • Omnipod 5 is prescribed by or in consultation with an endocrinologist • The patient has a documented diagnosis of Type 1 diabetes mellitus • Patient meets one of the following: • The patient is on an insulin regimen of 3 or more injections per day using both basal and prandial insulin and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy *OR* • Patient is utilizing another insulin-pump device and is switching to Omnipod 5 • The patient has completed a comprehensive diabetes education program • The patient has demonstrated willingness and ability to play an active role in diabetes self-management Initial prior authorization expires after 1 year <u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Omnipod 5 is approved for 1 year for continuation of therapy if all criteria are met

	• Patient has been successful with therapy as shown by increased time in range (TIR), improved A1c, *OR* • Patient has experienced decreases in hypoglycemic episodes
Utilization Management New PAs	
• **echothiophate (Phospholine Iodide)** **Glaucoma Agents: Cholinergics/ Cholinesterase Inhibitors**	Manual PA criteria apply to all new users of Phospholine Iodide. Manual PA criteria: Phospholine Iodide is approved if all the following criteria are met: • The provider acknowledges that most other eye drops for glaucoma are available to TRICARE patients without a prior authorization. Providers are encouraged to consider changing the prescription to a different glaucoma agent if appropriate. • The prescription is written by an optometrist with a glaucoma specialty or an ophthalmologist Prior authorization does not expire.
• **oxycodone 2.5-, 5-, 7.5-, and 10 mg/ acetaminophen 300 mg tablet** • **oxycodone 10 mg/acetaminophen 300 mg/5 mL oral solution** **Narcotic Analgesics and Combinations**	Manual PA criteria apply to all new and current users of oxycodone/acetaminophen 300 mg tablets and solution. Manual PA criteria: Oxycodone/acetaminophen 300 mg tablets and solution are approved if all criteria are met: • Provider acknowledges other oxycodone/acetaminophen formulations, including oxycodone/acetaminophen 325 mg tablets and solution are available without requiring prior authorization. • The provider must explain why the patient can't take a different oxycodone/acetaminophen formulation. (*write-in*) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• **venlafaxine besylate 112.5 mg tablet** **Antidepressants: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)**	Manual PA criteria apply to all new users of venlafaxine besylate 112.5 mg tablet. Manual PA criteria: Venlafaxine besylate 112.5 mg tablet is approved if all criteria are met: • Provider acknowledges other formulations of venlafaxine, including venlafaxine hydrochloride are available without requiring prior authorization. • The provider must explain why the patient can't take a different formulation of venlafaxine. (*write-in)* Non-FDA-approved uses are not approved. Prior authorization does not expire.

Utilization Management Updated PAs	

• **lumacaftor/ivacaftor oral granules (Orkambi)**
 	
Cystic Fibrosis Agents
	Updates from the November 2022 meeting are in bold and strikethrough.
	
	Manual PA criteria apply to all new users of Orkambi granules.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Orkambi is prescribed for the treatment of cystic fibrosis in an age appropriate patient population according to the product label.
	  • For Orkambi granules – the patient is between the ages of ~~**two**~~ **1** to 5 years; or the patient is older than 5 years with documented swallowing difficulties
	  • For Orkambi tablets – the patient is 6 years of age or older
	• The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected/confirmed by an FDA-approved test
	• Concomitant use of Orkambi granules with Orkambi tablets is not allowed.
	• Concomitant use of Orkambi granules or tablets is not allowed with ivacaftor (Kalydeco) or tezacaftor/ivacaftor (Symdeko).
	
	Non-FDA-approved uses are not approved, including:
	• Patients who are heterozygous for the F508del mutation in the CFTR gene
	
	PA does not expire.

• **ibrutinib capsules and tablets (Imbruvica)**
 	
Leukemia and Lymphoma Agents: BTKis
	Updates from the November 2022 meeting are in bold.
	
	Manual PA is required for new users of Imbruvica capsules and tablets.
	
	Manual PA Criteria: Imbruvica is approved if all criteria are met:
	• The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for TRICARE patients (**at the 140 mg and 280 mg strengths**).
	• If the Rx is for Imbruvica tablets at the 140 mg or 280 mg strengths, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below.
	• If the Rx is for the Imbruvica capsules or **for the higher strengths of Imbruvica tablets (420 mg and 560 mg),** please continue with the PA criteria below.
	• Drug is prescribed by or in consultation with a hematologist/oncologist
	• **Patient is 1 to 17 years of age with a diagnosis of chronic graft-versus-host disease OR**
	• Patient is 18 years of age or older
	• Will be used in one of the following contexts:
	  ▪ Pretreatment to limit the number of cycles of RhyperCVAD/rituximab maintenance therapy for Mantle Cell Lymphoma
	  ▪ Second line (or subsequent therapy) for Mantle Cell Lymphoma
	  ▪ Second line (or subsequent therapy) for Marginal Zone Lymphoma
	  ▪ Second line (or subsequent therapy) for non-germinal center B cell-like Diffuse Large B Cell Lymphoma if unable to receive chemotherapy
	  ▪ Frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation
	  • Patient fits one of the following categories:
	  – Frail patient with significant comorbidity (not able to tolerate purine analogues)
	  – Patient ≥ 65 years old with significant comorbidity
	  – Patients < 65 years old

	▪ Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation ▪ Waldenström macroglobulinemia ▪ Chronic graft-versus-host disease • Monitor for bleeding, infection, hypertension, cardiac arrhythmias, cytopenias, and Tumor Lysis Syndrome • If the patient is female, she is not pregnant or planning to become pregnant • Breastfeeding female patients will be advised that the potential harm to the infant is unknown • All patients (males and females) of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation • 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: _____. Other non-FDA-approved uses are not approved, except as noted above PA does not expire.
• **relugolix/estradiol/ norethindrone (Myfembree)** **Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists**	**Updates from the November 2022 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Myfembree. <u>Manual PA criteria</u>: Myfembree is approved if all criteria are met: • Patient is 18 years of age or older • Patient is a premenopausal woman • Patient has a diagnosis of: ▪ Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **OR** ▪ **Moderate to severe pain association with endometriosis AND** • **Patient has had inadequate relief after at least three months of therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) or NSAIDs are contraindicated** **AND** • Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD) • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or a history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 • Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs or if the patient has a sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions • Patient does not have uncontrolled hypertension • Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly • Patient does not have osteoporosis • Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes • Patient does not have a history of breast cancer or other hormonally-sensitive malignancies • Patient does not have known liver impairment or disease • Provider agrees to counsel patients on the signs and symptoms of liver injury • Patient does not have undiagnosed abnormal uterine bleeding • Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors • ~~**Patient is not using Myfembree with oral P-gp inhibitors (e.g., erythromycin) or combined P-gp and strong CYP3A inducers (e.g., rifampin)**~~

	• **Provider is aware of drug interactions with Myfembree and oral P-gp inhibitors (e.g., erythromycin) and combined P-gp and strong CYP3A inducers (e.g., rifampin) and will counsel patient on these interactions as appropriate** Non-FDA-approved uses are not approved including **contraception ~~or pain associated with endometriosis.~~** Prior authorization expires after 24 months (lifetime expiration). **Cumulative treatment with Oriahnn and Myfembree will not exceed 24 months during the patient's lifetime.**
• **elagolix (Orilissa)** **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	**Updates from the November 2022 meeting are in bold and strikethrough.** Manual PA applies to all new users of elagolix (Orilissa). <u>Manual PA Criteria</u>: Elagolix is approved if all criteria are met: • The patient is 18 years of age or older • Patient is a premenopausal woman with endometriosis • Patient has had inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, unless contraindicated • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have severe hepatic impairment (Child-Pugh Class C) • Patient does not have osteoporosis • Patient is on concurrent calcium supplementation. • Patient is not using Orilissa concomitantly with cyclosporine or gemfibrozil Non-FDA approved uses are not approved. **~~PA Expiration 9 months; Renewal expiration 24 months.~~ Prior authorization expires after 24 months (lifetime expiration). Cumulative treatment with Orilissa and Myfembree will not exceed 24 months during the patient's lifetime.** **~~<u>Renewal Criteria</u>: PA will be approved for an additional 15 months (lifetime usage not to exceed 24 months) if all criteria are met~~** **~~• The patient meets the original PA criteria~~** **~~• Patient does not have moderate hepatic impairment (Child-Pugh Class B);~~** **~~Patient is taking the Orilissa 150 mg dose (note that the 200 mg dose is only approved for up to 6 months)~~**
• **crizotinib (Xalkori)** **Oncological Agents: Lung Cancer**	**Updates from the November 2022 meeting are in bold.** Manual PA criteria apply to all new users of crizotinib (Xalkori). <u>Manual PA Criteria</u>: Xalkori is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following diagnoses: ▪ Metastatic non-small cell lung cancer (NSCLC) AND • Tumors are anaplastic lymphoma kinase (ALK) positive OR ROS1-positive (as detected by an approved test) ▪ Relapsed or refractory systemic anaplastic large cell lymphoma (ALK) positive AND • Patient is 1 year of age and older or a young adult (Note – limitation of use: safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory systemic ALK-positive anaplastic large cell lymphoma) ▪ **Unresectable, recurrent, or refractory inflammatory myofibroblastic tumor in patients 1 year of age or older AND** • **Tumors are ALK-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: _____. Other non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.
• **darolutamide (Nubeqa)** **Oncological Agents: 2nd-Generation Antiandrogens**	**Updates from the November 2022 meeting are in bold.** Manual PA is required for all new users of Nubeqa. Manual PA Criteria: Nubeqa is approved if all criteria are met: • Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. The patient is required to try Xtandi first. **OR** • Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Nubeqa AND • Patient is 18 years of age or older AND • Drug is prescribed by or in consultation with an oncologist or urologist AND • Patient has diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) AND • The patient has had a negative CT scan of abdomen/pelvis and/or negative bone scan AND • Prostate-specific antigen doubling time (PSADT) is ≤ 10 months OR • **Patient has a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel** • 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: _____ • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non-FDA-approved uses are not approved. PA expires in 1 year. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Nubeqa is approved for 1 year for continuation therapy if all criteria are met: • The patient continues to be metastases-free • The patient has not progressed onto subsequent therapy (such as abiraterone)
• **ivosidenib (Tibsovo)** **Oncological Agents: Acute Myelogenous Leukemia**	**Updates from the November 2022 meeting are in bold.** Manual PA criteria apply to all new users of ivosidenib (Tibsovo). Manual PA Criteria: Tibsovo is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has a diagnosis of: ▪ Relapsed/refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by a FDA-approved test OR ▪ Patient has newly diagnosed AML **AND is using Tibsovo as monotherapy OR in combination with azacitidine (Vidaza)** and is aged 75 years of age or older OR has comorbidities that preclude use of intensive induction chemotherapy with a susceptible IDH1 mutation as detected by a FDA-approved test OR ▪ Patient has previously treated, locally advanced, or metastatic cholangiocarcinoma with an IDH1 mutation as detected by a FDA approved test 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: _____. • The patient will be monitored for differentiation syndrome

	• The patient will be monitored for Guillain-Barre syndrome Other Non-FDA-approved uses are not approved Prior Authorization does not expire.
• **pemigatinib tablets (Pemazyre)** **Oncological Agents**	**Updates from the November 2022 meeting are in bold.** Manual PA is required for all new users of Pemazyre. Manual PA Criteria: Pemazyre is approved if all criteria are met: • The patient has a diagnosis of pathologically confirmed unresectable or advanced/metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test OR • **The patient has a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement** • Patient is 18 years of age of older • Prescribed by or in consultation with a hematologist/oncologist • Patient will be monitored for ophthalmologic disorders including pre-treatment screening for retinal disorders. • Patient will be monitored for hyperphosphatemia. • 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. • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. Non-FDA approved uses are not approved except as noted above. Prior authorization does not expire.
• **trametinib (Mekinist)** **Oncological Agents**	**Updates from the November 2022 meeting are in bold.** Manual PA criteria apply to all new users of Mekinist. Manual PA criteria: • Coverage will be approved if all criteria are met: ▪ Treatment (alone or in combination with dabrafenib [Tafinlar]) of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation; OR ▪ In combination with dabrafenib (Tafinlar), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation ▪ **For the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options** • Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy • Combination with dabrafenib (Tafinlar) for locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) Non-FDA-approved uses are not approved. Prior Authorization does not expire.

• **risankizumab On-Body Injector (Skyrizi OBI)** **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the November 2022 meeting are in bold and strikethrough (from the current PA for Skyrizi for plaque psoriasis or psoriatic arthritis).** PA criteria apply to all new users of **Skyrizi OBI. The patient must have tried Humira and Stelara~~, and Cosentyx~~.** Manual PA Criteria: Skyrizi **OBI** is approved if all criteria are met: • The patient has a contraindication or 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 the requested non-step-preferred TIB AND • Patient is 18 years of age or older • ~~**The patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy**~~ • **The patient is diagnosed with moderately to severely active Crohn's disease** • Patient has tried and had an inadequate response 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: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, or Xeljanz/Xeljanz XR • The patient has had a negative TB test result in past 12 months (or TB is adequately managed) ~~**Non-FDA-approved uses are not approved.**~~ **Use of the on-body injector for non-FDA-approved indications, 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.** PA does not expire.
• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the November 2022 meeting are in bold.** 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 network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Stelara if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis **(patients between the ages of 6 and 17 may receive Stelara for active psoriatic arthritis without the requirement to try Humira first)** • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy (patients between the ages of 6 and 17 may receive Stelara for plaque psoriasis without the requirement to try Humira first) • Moderate to severe active Crohn′s disease who have failed or intolerant to immunomodulators, corticosteroids, or Humira. Alternatively, for moderate to severe ulcerative colitis (UC); infliximab may be used first in lieu of Humira • 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, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept

	(Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), apremilast (Otezla), or rituximab (Rituxan Non-FDA approved uses are not approved. PA does not expire.
• **testosterone cypionate** • **testosterone enanthate** **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the November 2022 meeting are in bold and strikethrough.** **PA does not apply to patients less than 1 year of age (age edit)** Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections. <u>Manual PA Criteria</u>: testosterone cypionate and testosterone enanthate IM injections are approved if all criteria are met: • Coverage approved for male patients **(patients male at birth)** if: ▪ **Patient is younger than 18 years of age if:** • **Prescription is written by or in consultation with a pediatric endocrinologist OR** ▪ Patient is 18 years of age or older AND • Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND • Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND • The patient does not have prostate cancer AND • The patient is experiencing symptoms usually associated with hypogonadism OR • Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if: ▪ Patient has diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to the most current edition of the DSM ▪ Patient is an adult, or is 16 years or older ▪ Patient has experienced puberty to at least Tanner stage 2 ▪ Patient has no signs of breast cancer AND ▪ For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND ▪ Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) OR • **Coverage approved for females if:** ▪ **Patient has diagnosis of breast cancer** ▪ **Prescription is written by or in consultation with an oncologist** Non-FDA-approved uses are NOT approved. Not approved for concomitant use with other testosterone products. Prior Authorization ~~**does not expire**~~ **expires in 1 year** **<u>Renewal Criteria</u>: 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 positive response to therapy** • **The risks of continued therapy do not outweigh the benefits**

Drug / Drug Class	Quantity Limits
• **abrocitinib (Cibinqo)** • **upadacitinib (Rinvoq)** **Atopy Agents: Oral JAK-1 Inhibitors**	▪ Retail/MTF/Mail: 60-days supply
• **clindamycin 2% vaginal gel (Xaciato)** **Antibiotics**	▪ Retail/MTF/Mail: 1 carton per fill
• **deucravacitinib tablets (Sotyktu)** **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail/MTF/Mail: 60 day supply
• **oteseconazole (Vivjoa)** **Antifungals**	▪ Retail/MTF/Mail: 1 package per fill
• **sirolimus 0.2% gel (Hyftor)** • **Immunosuppressives**	▪ Retail: 3 tubes/30 days ▪ MTF/Mail: 9 tubes/90 days
• **Freestyle Libre 3** **CGM: Therapeutic Continuous Glucose Monitoring System**	▪ Sensors: o Retail: 2 sensors in 28 days o MTF/Mail: 6 sensors in 84 days
• **Omnipod 5** **Insulins: Miscellaneous Insulin Devices**	▪ Retail: o Omnipod 5: 15 pods/30 days o Omnipod 5 Kit: 1 kit/2 years
• **glucagons (Baqsimi, Gvoke, Zegalogue, and Glucagon)** **Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents**	▪ Zegalogue and Gvoke: Retail/MTF/Mail: 6 syringes/pens per fill (three two-pack or six individual packs) ▪ Baqsimi: Retail/MTF/Mail: 6 nasal spray units per fill (three two-pack or six individual)
• **ubrogepant (Ubrelvy)** **Migraine Agents: Oral CGRP Antagonists**	▪ Retail: 16 tablets/30 days ▪ MTF/Mail: 48 tablets/90 days

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• clindamycin 2% vaginal gel (Xaciato) **Antibiotics**	• metronidazole tabs • tinidazole tabs • metronidazole vaginal gel • clindamycin vaginal cream • secnidazole granule (Solosec)	• Each applicator of 5 gram of gel contains 100 mg clindamycin • One user-filled disposable applicatorful administered intravaginally as a single dose	Bacterial vaginosis (BV) for female patients age ≥12 years of age	• vulvovaginal candidiasis (17% treatment vs. 4% placebo) • vulvovaginal discomfort (6% treatment vs. 5% placebo)	• Single dose clindamycin phosphate vaginal gel • Xaciato was evaluated in one study; the primary endpoint of clinical cure at day 21 – 30 Test of Cure visit was statistically greater in comparison to placebo • Lower peak serum levels and systemic exposure to clindamycin with vaginal application, relative to oral or IV clindamycin formulations • Xaciato offers an additional option for the treatment of BV, and one-time dosing may enhance patient compliance: however, alternative formulary agents are also available • As of time of review, no head to head studies with other BV treatments to inform if formulation and/or shortened treatment duration imparts benefit relative to existing formulary agents	• NF • Do not add to EMMPI list
• deucravacitinib tablets (Sotyktu) **Targeted Immuno-modulatory Biologics (TIBs)**	• adalimumab (Humira) • apremilast (Otezla) • secukinumab (Cosentyx)	• 6 mg tabs • Dosing: 6 mg PO QD	for adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	• URI • increased CPK • herpes simplex • mouth ulcers • folliculitis • acne	• New MOA: tyrosine kinase 2 (TYK2) inhibitor • RCTs demonstrated statistically significant improvement of Sotyktu for achieving PASI-75 scores vs. placebo and Otezla at week 16; with additional maintenance of response in patients who continued treatment with Sotyktu through week 52 • Well tolerated with nasopharyngitis and upper respiratory infections reported as most frequently reported adverse effects • Sotyktu mediates its effects via Tyrosine Kinase 2 Inhibitor (TYK2) as member of the JAK family of proteins; JAK inhibitors carry a black box safety warning and it is currently unknown whether Sotyktu may be associated with these same potential adverse events • Sotyktu provides another oral systemic treatment options for moderate to severe plaque psoriasis	• NF and Non-Step Preferred • Add to EMMPI list

• fingolimod ODT (Tascenso) **Multiple Sclerosis: Miscellaneous Oral Agents**	• fingolimod capsule (Gilenya) • siponimod (Mayzent) • ozanimod (Zeposia) • ponesimod (Ponvory)	• Form/Strength: ODT, 0.25 mg • Dosing: 0.25 mg PO QD	Relapsing forms of MS, to include clinically isolated syndrome, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg	• headache • elevated LFT • diarrhea • cough • influenza • sinusitis • back pain • abdominal pain • extremity pain	• Tascenso offers a pediatric, ODT formulation of fingolimod for patients 10 years of age and older and weighing < 40 kg • There is no new clinical data for Tascenso ODT; approval based on 505(b)(2) and demonstrated bioequivalence to fingolimod capsules; active ingredient approved by the FDA since 2010 • Fingolimod 0.25 mg dose was evaluated in one pediatric study using oral capsules; the primary end point of reducing the annualized relapse rate was statistically significant in comparison to interferon beta-1a IM injections • Tascenso ODT offers a pediatric indication compared to other S1P modulators for MS treatment • It carries the same daily dosing schedule, and has a mid-range half-life compared to other S1P modulators • In addition to standard CBC, LFT, and skin cancer screenings; fingolimod is the only S1PM that recommends a baseline and 3 month fundoscopic exam after starting treatment • Among S1PM, rare reports of PRES and PML have been reported with fingolimod use • Provides little compelling advantages over other S1p receptor modulators other than being a pediatric dose for those 10 years of age and older and weighing < 40 kg	• NF • Do not add to EMMPI list

• olopatadine/mometasone nasal spray (Ryaltris) **Nasal Allergy Agents: Corticosteroids**	• olopatadine (Patanase) • mometasone furoate (Nasonex) • azelastine/ fluticasone propionate (Dymista) • fluticasone (Flonase)	• Available as a nasal spray: 665 mcg of olopatadine HCl and 25 mcg of mometasone furoate in each spray (240 sprays per bottle) • Dosing: 2 sprays/nostril BID	Treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older	ADRs ≥1%: • dysgeusia • epistaxis • nasal discomfort	• Combination of intranasal antihistamine and intranasal corticosteroid that demonstrates modest nasal relief vs. placebo & monotherapy • rTNSS and iTNSS change from baseline were statistically significant as compared to placebo and monotherapy • Intranasal antihistamine provides quick onset of action for symptom relief (15 minutes), but can use single ingredient products for this effect • Ryaltris has not been compared to azelastine and fluticasone nasal spray (Dymista) • Provides little to no compelling clinical advantage over existing agents	• Tier 4/Not Covered
• oteseconazole (Vivjoa) **Antifungals**	• fluconazole (Diflucan)	• 150 mg capsules; 18 count blister pack per wallet, 1 wallet per carton • **Day 1**: Vivjoa 600 mg, **Day 2**: Vivjoa 450 mg, **Day 14**: Vivjoa 150 mg QW for 11 weeks • fluconazole/ oteseconazole dosing - **Day 1/Day 4/Day 7**: fluconazole 150mg, **Day 14 - Day 20**: oteseconazole 150 mg QD, **Day 28**: oteseconazole 150 mg QW for 11 weeks; take with food, swallow whole	Recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential	ADRs >2%: • headache (7.4%) • nausea (3.6%)	• Reduces incidence of recurrent vulvovaginal candidiasis (RVVC) in non-childbearing females • Significantly longer half-life (138 days) relative to other azoles • In 3 pivotal trials, Vivjoa had a statistically significantly lower rate of infection recurrence than placebo; was not directly compared to fluconazole for maintenance therapy • Shorter treatment duration and fewer drug interactions than fluconazole • Has not been associated with QT prolongation • Vivjoa is contraindicated in females of reproductive potential; may cause fetal harm • Embryofetal toxicity concerns limit Vivjoa's utility; likely to be used as a second-line medication for RVVC	• NF • Do not add to EMMPI list

• ranolazine ER granule (Aspruzyo Sprinkles) **Cardiovascular Agents Miscellaneous**	• amlodipine • metoprolol succinate XL • ranolazine ER tabs • metoprolol succinate sprinkle (Kapspargo)	• ER granules in sachets of 500 or 1000 mg • 500 mg BID; max: 1,000 mg BID	Chronic angina	• dizziness (6.2%) • headache (5.5%) • constipation (4.5%) • nausea (4.4%) • Do not consume EtOH – rapid release of drug from granules; AE risk	• Aspruzyo is a new "sprinkle" formulation of ranolazine ER tab which has similar BID dosing as ranolazine ER tabs • It is allowed for NG or G tube administration per manufacturer's label • No new clinical data is available; approval was based on data from Ranexa • Provides no compelling clinical advantages over ranolazine ER tablets, other than convenience to patients who cannot swallow tablets	• NF • Do not add to EMMPI list
• roflumilast 0.3% cream (Zoryve) **Psoriasis Agents**	• 0.005% calcipotriene (Dovonex) • 0.005%/ 0.064% calcipo-betameth (Taclonex) • 1% pime-crolimus (Elidel) • 1% tapinarof (Vtama) • apremilast (Otezla)	• Form/Strength: cream, 0.3% • Dosing: Apply topically QD	Topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older	• diarrhea, headache, insomnia, nausea, site pain, URI, UTI	• MOA: topical phosphodiesterase 4 inhibitor • Evaluated in 2 unpublished studies; significant reduction in IGA scores in comparison to vehicle cream. No head-to-head studies with other agents (as of time of review) • Unclear duration of use; extension study (ARQ-151-306) in subjects ≥2 years of age final report submission due June 2025 • FDA deferred pediatric studies for ages 2 – 5 years and 6 to 11 years, given recruitment challenges • Zoryve offers an additional option for the treatment of plaque psoriasis, however numerous alternative formulary agents are available • Use is currently limited to a single indication and place in therapy is currently unknown	• NF • Add to EMMPI list

• sirolimus 0.2% gel (Hyftor) **Immunosuppressives**	• no pharmacy benefit alternatives	• Form/Strength: Topical gel (0.2%) in a 10 g tube; 2 mg sirolimus/1 g • Dosing: Apply to affected areas on face BID	Treatment of facial angiofibroma associated with tuberous sclerosis (TSC) in adults and pediatric patients 6 years of age and older	• Dry skin, irritation, pruritus, acne, acneiform dermatitis, ocular hyperemia, skin hemorrhage, skin irritation	• Topical treatment for facial angiofibromas associated with tuberous sclerosis complex (TSC) • Demonstrates efficacy for reducing the size and erythema of facial angiofibromas associated with TSC from one pivotal trial vs placebo; no head to head studies available • Therapeutic effects dissipate once medication is discontinued – long term therapy required • Long term extension studies demonstrated low discontinuation rates due to adverse effects with continued therapeutic benefit during daily administration. Found no advantage of combining oral and topical mTOR inhibitors • Hyftor provides an alternative to non-pharmacologic options (e.g., lasers) for removal of angiofibromas associated with TSC	• UF • Do not Add to EMMPI
• finasteride/ tadalafil (Entadfi) **Benign Prostatic Hyperplasia (BPH) Agents**	• finasteride tab • tadalafil tab	• Fixed dose capsule of finasteride 5 mg and tadalafil 5 mg • One capsule orally once daily for up to 26 weeks	Initial treatment of the signs and symptoms of (BPH) in men with enlarged prostates for up to 16 weeks	• >2%: back pain, headache, dyspepsia, influenza • Contraindications: Use with any form of organic nitrate; hypersensitivity; pregnancy; use with guanylate cyclase stimulators	• Approved via the 505b2 pathway • Individual components are available as generics in the dosages found in the fixed-dose combination product • One placebo controlled, 26-week trial in 696 patients reported improvement in the signs and symptoms of BPH, as measured by the International Prostate Symptom Score (IPSS) at 12 weeks. • The IPSS results were not clinically significant, as they did not meet the minimally clinically important difference of at least 3 point change in the IPSS • Provides little to no clinical benefit compared to using finasteride and/or tadalafil	• Tier 4/Not Covered
• tadalafil oral suspension **Pulmonary Arterial Hypertension (PAH): PDE-5 Inhibitor**	• sildenafil tab (Revatio) • sildenafil susp (Revatio) • tadalafil tab (Adcirca, Alyq)	• Form/Strength: oral suspension, 20mg/5ml • Dosing: 40 mg (10mL) PO QD	Pulmonary Arterial Hypertension (PAH)	• headache	• Approved to treat PAH WHO Group 1) to improve exercise ability. • Tadliq is the second PDE5 inhibitor available as an oral suspension • No new clinical studies are available for Tadliq, approved via 505(b)(2) • Package insert in the special populations sections state safety and effectiveness in pediatrics not established • Provides little to no clinical advantage relative to existing formulary alternatives	• NF

• zonisamide oral suspension (Zonisade) **Anticonvulsants -Antimania Agents**	• zonisamide capsules (Zonegran)	• Form/Strength: suspension, 100 mg/5 mL	Adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years and older	• somnolence, anorexia, dizziness, ataxia, irritability, memory and concentration difficulty	• Zonisade is another formulation of zonisamide used for treatment of partial onset epilepsy • Zonisade was approved via 505(b)(2) and demonstrated bioequivalence to zonisamide capsules; no new clinical data • Zonisade provides an alternative treatment formulation for partial onset epilepsy and provides no significant clinical advantage compared to existing agents	• UF • Do not add to EMMPI

• Freestyle Libre 3
 	
CGMS: Therapeutic Continuous Glucose Monitoring System
	• FreeStyle Libre 2
	• Dexcom G6
		• 1 sensor applied every 14 days	Continuous Glucose Monitoring	• Refer to product labeling for information	• FreeStyle Libre 3 is the 3rd CGMS available through the pharmacy benefit.
					• Advantages over FreeStyle Libre 2 include:
					  • Real-time glucose results automatically displayed every minute on smartphone
					  • Real-time glucose alarms with current glucose and trend arrow, viewable in the alarm notification
					  • Sensor stores up to 14 days of glucose data, so decreased risk of lost data
					  • Smaller, thinner, and more discreet Sensor
					  • Bluetooth connection range increased by 50% between Sensor and App (33 feet)
					• Data is lacking with FreeStyle Libre 3 to show effectiveness in increasing Time-In-Range (TIR)
					• Other than eliminating the need for patient to scan the sensor at least every 8 hours, FreeStyle Libre 3 provides little compelling clinical advantage over existing CGMs
						• UF
						• EMMPI – not applicable

• Omnipod 5 **Insulins: Miscellaneous insulin devices**	• Omnipod Generation 3 pods • Omnipod Generation 4 DASH • Vgo • Medtronics hybrid closed loop insulin deliver system • Tandem hybrid closed loop insulin deliver system	• Used as part of system with software algorithm and an integrated CGM • Apply pod with u100 insulin every 3 days	Delivers insulin through pod system in children and adults 2 years of age and older who have Type 1 diabetes mellitus	• Refer to product labeling for information	• Omnipod 5 is the 4th available tubeless insulin delivery device through the pharmacy benefit (Others are the Omnipod classic, Omnipod Dash, V-go) • It is the 3rd hybrid closed loop system available (insulin delivery, CGM data and an algorithm to monitor both). Others available through the medical benefit are Tandem product and the Medtronics product. • Type 1 Diabetics: Omnipod 5 data shows a decrease in A1c and an increase in Time in Range (TIR). Indirect comparison shows similar results to other hybrid closed loop systems and when compared to Omnipod 4 there are similar lowering of A1c. • Type 2 Diabetes: Data is lacking for Omnipod 5 to show effectiveness in lowering A1c and increasing TIR. • Studies lack rigor typically seen in medication reviews in that there are small numbers of patients studied, short duration of the study (longest was 90 days), and a lack of an active comparison group. Studies with Omnipod 5 did not compare to another closed system and did not compare to other tubeless systems • MHS providers relayed they would like a device on the formulary that allows for overnight coverage (hybrid closed loop), is tubeless, and available for children • Omnipod 5 provides little compelling clinical advantage over existing devices/supplies other than combining a hybrid closed loop system and a tubeless insulin delivery system	• UF • EMMPI – not applicable • Due to noncompliance with the Trade Agreements Act, Omnipod 5 is excluded from mail order and military treatment facilities (MTFs)

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
November 2022	**Drug Class Reviews** **Atopy** **Designated UF:** • upadacitinib (Rinvoq) *(already on the program)* **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • abrocitinib (Cibinqo) **RBC Stimulants: Erythropoietins** **Designated UF:** *Already on the program* • Epogen (*already on the program)* • Procrit (*already on the program)* • Retacrit (*already on the program)* **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF** *Similar agents are already on list* • deucravacitinib (Sotyktu) **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • roflumilast 0.3% cream (Zoryve) **Line Extensions** • Ozempic 2 mg	**Alzheimer's Agents** *Comparable pricing at mail order vs MTFs or retail:* • donepezil 23 mg (Aricept 23 mg generics) **2nd Generation Antihistamines** *Comparable pricing at mail order vs MTFs or retail:* • desloratadine 5 mg tabs • desloratadine 2.5 mg and 5 mg rapidly dissolving tabs (Clarinex generics **Proton Pump Inhibitors** *Comparable pricing at mail order vs MTFs or retail:* • lansoprazole (Prevacid generics) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF:** *Comparable pricing at mail order vs MTFs or retail:* • ranolazine ER sprinkle (Aspruzyo) *Consistent with others in the class* • Zonisamide oral suspension (Zonisade) *New Medical Devices* • FreeStyle Libre 3 • Omnipod 5 † **Designated NF:** *Acute use exception* • clindamycin phosphate vaginal gel (Xaciato) • oteseconazole (Vivjoa)

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (9) and NDAA 2015, which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

† For pharmaceutical agents that are non-Trade Agreement Act compliant, dispensing is limited to retail pharmacies.

Implementation Dates*

Upon signing: January 31, 2023

Two weeks after signing: February 15, 2023

30 Days after Signing: March 8, 2023

60 days after signing: April 5, 2023

90 days after signing: May 10, 2023 (moved from May 3rd due to the quarterly P&T Committee meeting)

120 Days after signing: May 31, 2023

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
November 2022	Benign Prostatic Hyperplasia Agents; 5-alpha Reductase Inhibitors	• finasteride/ tadalafil (Entadfi)	• finasteride tab • dutasteride tab • tadalafil tab	• 120 days
November 2022	Nasal Allergy Agents: Corticosteroids	• olopatadine 665 mcg /mometasone 25 mcg nasal spray (Ryaltris Nasal Spray)	• azelastine (Astelin, Astepro) • olopatadine (Patanase) • fluticasone/azelastine (Dymista) • fluticasone propionate (Flonase) • mometasone (Nasonex) • ipratropium (Atrovent) • budesonide (Rhinocort) • triamcinolone (Nasacort) • beclomethasone (Beconase AQ, QNASL) • ciclesonide (Omnaris, Zetonna) • flunisolide (Nasarel)	• 120 days
August 2022	Skeletal Muscle Relaxants	• baclofen oral solution (Lyvispah)	• baclofen oral solution (Ozobax) • baclofen oral suspension (Fleqsuvy) • baclofen tablets	• March 1, 2023 (120 days)
August 2022	Acne Agents: Topical Acne & Rosacea	• benzoyl peroxide 5% cream (Epsolay)	• benzoyl peroxide gel OTC and Rx versions • azaleic acid 15% gel (Finacea gel) • metronidazole 1% gel • brimonidine 0.33% gel (Mirvaso) • ivermectin 1% cream (Soolantra) • minocycline 1.5% topical foam (Zilxi) • minocycline 4% foam (Amzeeq) • minocycline 50 mg tablets	• March 1, 2023 (120 days)
May 2022	Nephrology Agents Miscellaneous	• budesonide (Tarpeyo)	• prednisone • methylprednisolone • budesonide delayed release capsules (Entocort EC, generics)	• November 30, 2022 (120 days) • Implementation delayed
May 2022	Narcotic Analgesics and Combinations	• celecoxib/ tramadol (Seglentis)	• tramadol • celecoxib	• November 30, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2022	Anticholinergics-Antispasmodics	• glycopyrrolate (Dartisla ODT)	• glycopyrrolate tablets • glycopyrrolate oral solution (Cuvposa) • omeprazole • famotidine	• November 30, 2022 (120 days)
May 2022	Endocrine Agents Miscellaneous	• levoketoconazole (Recorlev)	• ketoconazole • metyrapone (Metopirone) • osilodrostat (Isturisa) • pasireotide (Signifor LAR -medical benefit)	• November 30, 2022 (120 days)
May 2022	Diuretics	• torsemide 20 mg and 60 mg tablets (Soaanz)	• torsemide • furosemide • bumetanide • ethacrynic acid	• November 30, 2022 (120 days)
May 2022	Acne Agents: Topical Acne & Rosacea	• tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twyneo)	• tretinoin cream • benzoyl peroxide cream	• November 30, 2022 (120 days)
February 2022	Pain Agents: NSAIDs	• celecoxib oral solution (Elyxyb)	• celecoxib tablets • ibuprofen • naproxen • diclofenac • numerous other NSAIDs or combos	• August 24, 2022 (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	• lorazepam ER capsule (Loreev XR)	• lorazepam IR tablets • alprazolam IR and XR tablets	• June 15, 2022 (120 days)
Nov 2021	Migraine Agents	• dihydroergotamine mesylate nasal spray (Trudhesa)	• DHE nasal spray • sumatriptan nasal and oral • rizatriptan • zolmitriptan • eletriptan	• June 15, 2022 (120 days)
Aug 2021	Antilipidemic-1s	• rosuvastatin/ ezetimibe (Roszet)	• rosuvastatin with ezetimibe • atorvastatin with ezetimibe • simvastatin/ezetimibe (Vytorin)	• June 15, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			• evolocumab (Repatha) • alirocumab (Praluent)	
May 2021	Anticonvulsants-Antimania Agents	• levetiracetam (Elepsia XR)	• levetiracetam ER • lamotrigine XR • topiramate ER	• June 15, 2022 (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 Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms.

Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service.

The first Tier 4 products were designated at the February 2019 P&T Committee meeting, with implementation occurring on August 28, 2019. For a cumulative listing of all Tier 4 drugs to date, refer to previous versions of the DoD P&T Committee quarterly meeting minutes, found on the heatlh.mil website.