DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2020

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on August 5 and 6, 2020. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May 2020 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the May 2020 DoD P&T Committee meeting on July 24, 2020.

2. **Clarification of Previous Minutes**

   a) **February 2020 Meeting—Re-evaluation of nonformulary (NF) generics: Antidepressant-1s (AD-1s) and Non-Opioid Pain Syndrome Drugs: pregabalin controlled release (Lyrica CR):** Generic pregabalin (Lyrica) was returned to UF, status, the step-therapy and manual Prior Authorization (PA) that had previously required a trial of other AD-1 drugs including gabapentin was removed, and the medical necessity (MN) criteria were removed. However, Lyrica CR remains NF, with step-therapy and manual PA required. Slight modifications were made to the Lyrica CR PA and MN forms, to list generic pregabalin as a formulary alternative.

   b) **November 2019 Meeting—OTC Test List: OTC Artificial Tear Products:** Some OTC ophthalmic Artificial Tear products originally added to the list are no longer available in sufficient quantities. Clinically similar replacement products that have consistent availability that currently are not on the list were added in addition to the original products (Refresh PM, Refresh Lacri-lube, Systane Overnight Lubricating Eye). Implementation occurred in early June 2020.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All 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. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. 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. MN criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

IV. UF DRUG CLASS REVIEWS

A. Sleep Disorders: Wakefulness Promoting Agents Subclass

Background—The Wakefulness Promoting Agents were last reviewed for formulary status in February 2012. The drugs in the subclass include modafinil, armodafinil, sodium oxybate (Xyrem), solriamfetol (Sunosi), and pitolisant (Wakix). The two newest entrants were previously reviewed as new drugs, solriamfetol (Sunosi) in August 2019, and pitolisant (Wakix) in November 2019. The FDA indications vary between agents; all five drugs are approved to treat excessive daytime sleepiness (EDS) associated with narcolepsy. Modafinil, armodafinil, and solriamfetol are also approved for obstructive sleep apnea (OSA), while modafinil and armodafinil also carry an indication for shift work sleep disorder. Sodium oxybate (Xyrem) is the only drug in the class approved for cataplexy associated with narcolepsy. The wakefulness promoting agents differ in several other aspects including mechanism of action, drug enforcement agency (DEA) scheduling, and safety profiles.

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

- **Narcolepsy and cataplexy** guidelines from the American Academy of Sleep Medicine (AASM) (2007) discuss modafinil and sodium oxybate as effective treatments for EDS due to narcolepsy. An updated guideline is in progress that will address the newer products solriamfetol and pitolisant.
    - Stimulant medications (e.g., amphetamine, methylphenidate) are widely used for a variety of sleep disorders and are mentioned in the 2007 AASM guidelines.
- **For OSA,** the AASM 2019 guidelines and VA/DoD 2019 clinical practice guideline both recommend sleep hygiene and continuous positive airway pressure as key interventions.
- **Modafinil and armodafinil** have been available for many years to treat EDS due to narcolepsy or OSA, and are available in generic formulations. With regard to efficacy, safety and tolerability, there are no clinically relevant differences between modafinil and armodafinil.

- **Sodium oxybate (Xyrem)** fills a unique niche in therapy for cataplexy associated with narcolepsy for adults and children as young as 7 years. However, limitations include a boxed warning for abuse/misuse (C-III) and a restricted distribution program requiring dispensing from one centralized pharmacy.
    - Off-label unsupportable uses of sodium oxybate include fibromyalgia, jet lag disorder, and OSA, among other sleep disorders.
    - The most common adverse drug reactions (ADRs) leading to discontinuation of sodium oxybate include headache, nausea, vomiting, and anxiety.
- **Solriamfetol (Sunosi)** is a new dopamine and norepinephrine reuptake inhibitor (DNRI) approved in March 2019 for wakefulness in adult patients with EDS associated with narcolepsy or OSA.
    - Solriamfetol was evaluated in 4 placebo-controlled trials conducted to gain FDA approval; modest efficacy was shown in a patient's ability to remain awake during usual daily activities.
    - Advantages of Sunosi include the additional indication for OSA and no requirements for restricted distribution. Solriamfetol is a C-IV scheduled drug. Other disadvantages include the lack of comparative efficacy studies, and adverse reactions of increased blood pressure, heart rate, and psychiatric symptoms, including anxiety, insomnia, and irritability. It should be used with caution in patients with a history of psychosis or bipolar disorder.
- **Pitolisant (Wakix)** was approved in August 2019 for EDS in patients with narcolepsy. It is the only non-scheduled drug in the class for this indication.
    - In clinical trials, pitolisant was superior to placebo but did not meet non-inferiority requirements when compared to modafinil.
    - Common adverse effects include nausea, anxiety, and insomnia.
    - Advantages of Wakix include its novel mechanism of action and non-controlled option for narcolepsy, however efficacy is not superior to existing therapies, and it has several safety issues including renal and hepatic impairment, drug interactions with CYP2D6 inhibitors and CYP3A4 inducers, and QT prolongation. Wakix is subject to restricted distribution requirements.
- Reviewers from the Oregon Health Science University Drug Effectiveness Review Project concluded there is insufficient evidence to evaluate long-term efficacy or safety of solriamfetol and pitolisant.
- Statements regarding comparative efficacy among the drugs in the subclass are difficult to make, given the lack of head-to head studies and heterogeneity in clinical trial designs.
- Military Health System (MHS) Provider feedback from sleep medicine specialists supports use of stimulants (methylphenidate and mixed amphetamine salts) and the older drugs, modafinil and armodafinil, prior to use of the newer agents for their respective indications.

- For narcolepsy, the wakefulness promoting agents are highly therapeutically interchangeable. However, multiple wakefulness promoting drugs with differing mechanisms of action and indications are needed on the formulary to meet the needs of DoD beneficiaries.

Relative Cost-Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that armodafinil (Nuvigil, generics) and modafinil (Provigil, generics) were the most cost-effective wakefulness promoting agents when compared to pitolisant (Wakix), sodium oxybate (Xyrem), and solriamfetol (Sunosi).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating armodafinil, modafinil, and sodium oxybate (Xyrem) as UF, with pitolisant (Wakix) and solriamfetol (Sunosi) as NF demonstrated significant cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: SLEEP DISORDERS: WAKEFULNESS-PROMOTING AGENTS UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following formulary recommendations for the wakefulness promoting agents, as outlined below, based on clinical and cost-effectiveness. Note that there are no changes to the current formulary status.

    - UF
        - armodafinil
        - modafinil
        - sodium oxybate (Xyrem)

    - NF
        - solriamfetol (Sunosi)
        - pitolisant (Wakix)

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) not to add a Wakefulness Promoting Agent to the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Manual PA criteria currently apply to Xyrem (originally placed in February 2012, and most recently

updated in August 2019 for pediatric use); solriamfetol (Sunosi) from the August 2019 meeting; and pitolisant (Wakix) from the November 2019 meeting. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) minor updates to the manual PA criteria for new users of solriamfetol and pitolisant, to more accurately reflect the inclusion criteria from the clinical trials used to gain FDA approval. No changes were recommended for the sodium oxybate PA criteria. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current MN criteria for solriamfetol and pitolisant. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent), maintaining Sunosi on the EMMPI list, and excluding Xyrem and Wakix (limited distribution requirements).

6. ***COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent): an effective date of the first Wednesday one week after signing of the P&T minutes at all points of service (POS); Based on the P&T Committee's recommendation, the effective date is November 4, 2020.

B. White Blood Cell Stimulants — Filgrastims and Pegfilgrastims

Background—The White Blood Cell (WBC) Stimulants are comprised of the filgrastims and pegfilgrastims. The class has not been previously reviewed for formulary status, although several products were reviewed as newly approved drugs. There are four filgrastims and four pegfilgrastims in the class.

This is first time that the P&T Committee is evaluating biosimilars and follow-on biologics for formulary status as part of a drug class review. The FDA definition of a biosimilar is that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Note that sargramostim (Leukine) is a WBC stimulant that was not included in the clinical or cost effectiveness review; it will remain designated as UF.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- The filgrastims and pegfilgrastims are most commonly used for the prophylaxis of chemotherapy-related febrile neutropenia in patients with nonmyeloid malignancies.

- Several professional guidelines from the American Society of Clinical Oncology (ASCO, 2015), European Society for Medical Oncology (2016), and the National Comprehensive Cancer Network (NCCN, 2020), state that all the products are effective for preventing febrile neutropenia; that pegfilgrastim is equally effective as filgrastim; and that biosimilars provide an opportunity to decrease healthcare expenditures while ensuring patients receive high-quality cancer care. The guidelines do not give a preference for one individual product over another.
- A systematic review of 90 studies evaluating switching between a variety of reference products and their biosimilars reported no differences in safety, efficacy, or immunogenicity (Hillel, 2018). One study specifically studying switching between the filgrastim reference product and biosimilars in breast cancer patients also showed no differences in efficacy, overall safety or immunogenicity development (Blackwell, 2015).
- The filgrastims require once daily dosing for febrile neutropenia, in contrast to the pegfilgrastims, which have a longer half-life and are administered once per chemotherapy cycle. However, the filgrastims are used in patients receiving weekly chemotherapy regimens, since the pegfilgrastims cannot be administered between 14 days prior to and 24 hours after the administration of chemotherapy.
- The safety profiles of the filgrastims and pegfilgrastims are similar. Bone pain and pain in the extremities are the most commonly reported adverse reactions, which are seen more frequently with the pegfilgrastims.
- Data from the FDA-approved labeling show there is a low incidence of immunogenicity for the filgrastims and pegfilgrastims.

Filgrastims

- **filgrastim (Neupogen)** is the reference biologic for the filgrastims. Advantages include availability in both a syringe and vial, and approval for both subcutaneous (SC) and intravenous (IV) administration. One disadvantage is that the syringe (but not the vial) contains latex, which is a concern in patients with latex allergy.
- **tbo-filgrastim (Granix)** is a follow-on biologic to Neupogen, which means it was approved via a different pathway than the biosimilars. Granix is available in both syringes and vials, which do not contain latex. Both formulations are only approved for SC administration.
- **filgrastim-sndz (Zarxio)** disadvantages include that it is only available in a syringe, which contains latex, and that volumes smaller than 0.3 mL cannot be accurately measured due to limitations of the measuring units in the syringe.
- **filgrastim-aafi (Nivestym)** advantages include availability in both a syringe and vial, that it does not contain latex and can be administered by both SC and IV routes.

Pegfilgrastims

- The pegfilgrastims are only available in syringes and not vials, and are only approved for SC administration. None of the syringes are designed to administer doses less than

0.6 mL although pediatric dosing with lower mL doses are listed in the package labeling for the products.

- **pegfilgrastim (Neulasta)** is the reference biologic for the pegfilgrastims. In addition to the syringe, it also comes in an on-body injector (Neulasta OnPro) which allows for delayed administration 27 hours after application. This provides a convenience for patients who cannot self-inject at home. Both formulations contain latex.
- **pegfilgrastim-jmdb (Fulphila)** and **pegfilgrastim-cbqv (Udenyca)** do not contain latex. Udenyca has the highest utilization of the pegfilgrastims in the MHS.
- **pegfilgrastim-bmez (Ziextenzo)** has latex in the syringe, and has very low utilization in the MHS.
- According to FDA guidance, providers can interchange biosimilars at the time of prescribing, but the FDA requires further data for substitution by other than the prescriber (e.g., a pharmacist cannot substitute products at the pharmacy window). However, overall, there is a very high degree of interchangeability within the filgrastims subclass, and within the pegfilgrastims subclass.
- The overall choice for prescribing a particular filgrastim or pegfilgrastim should be based on the patient's chemotherapy regimen (e.g., cycle frequency and the risk for causing febrile neutropenia), convenience, and cost.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and BIA were performed to the WBC Stimulants class. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- Filgrastims: CMA results showed that for the filgrastims, Granix and Nivestym were more cost-effective than Neupogen, and Zarxio.
- Pegfilgrastims: For the pegfilgrastims, CMA showed that Udenyca and Fulphila were more cost-effective than Neulasta and Ziextenzo.
- Filgrastims: BIA was performed to evaluate the potential impact of designating selected filgrastims as formulary, NF, or Tier 4 on the UF. BIA results showed that for the filgrastims, designating Granix and Nivestym as UF and step-preferred, with Neupogen and Zarxio as UF and non-step-preferred demonstrated significant cost avoidance for the MHS.
- Pegfilgrastims: For the pegfilgrastims, the BIA showed that designating Udenyca and Fulphila as UF and step-preferred, with Neulasta syringes), Neulasta OnPro infuser, and Ziextenzo as UF and non-step-preferred demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF and STEP THERAPY RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

FILGRASTIMS

- UF and step-preferred
  - tbo-filgrastim vial and syringe (Granix) *(Granix vials moves from NF to UF and step-preferred status)*
  - filgrastim-aafi vial and syringe (Nivestym) *(moves from NF to UF and step-preferred status)*
- UF and non-step-preferred
  - filgrastim vial and syringe (Neupogen) *(moves to non-step-preferred status)*
  - filgrastim-sndz syringe (Zarxio) *(moves to non-step-preferred status)*
  - Note that as part of the formulary recommendation, a trial of both Granix and Nivestym are required in new users before patients can try Neupogen or Zarxio.
- NF - None
- Tier 4/Not Covered - None

PEG FILGRASTIMS

- UF and step-preferred
  - pegfilgrastim-cbqv syringe (Udenyca)
  - pegfilgrastim-jmdb syringe (Fulphila)
- UF and non-step-preferred
  - pegfilgrastim syringe (Neulasta) *(moves to non-step-preferred status)*
  - pegfilgrastim on-body injector (Neulasta OnPro) *(moves to non-step-preferred status)*
  - pegfilgrastim-bmez syringe (Ziextenzo) (*moves to non-step-preferred status)*
  - Note that as part of the formulary recommendation, a trial of both Udenyca and Fulphila are required in new users before patients can try Neulasta, Neulasta OnPro, or Ziextenzo.
- NF - None
- Tier 4/Not Covered - None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding Udenyca syringe and Granix vial and syringe to the BCF. BCF addition will

assist with standardizing at the MTFs for these most cost-effective WBC stimulants.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA—*** The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the non-step-preferred WBC stimulants, requiring the step-preferred products first, unless the patient has had an inadequate response or could not tolerate the preferred WBC stimulants. For new users of Neupogen and Zarxio, a trial of Granix and Nivestym is required. New users of Neulasta, Neulasta OnPro, or Ziextenzo are required to try Udenyca and Fulphila first. Patients requiring a pegfilgrastim who cannot self-inject will be able to receive Neulasta OnPro. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the current QLs for the pegfilgrastims (Neulasta, Neulasta OnPro, Fulphila, Udenyca, and Ziextenzo), as there is a low risk of inappropriate quantities being prescribed. The filgrastims do not currently require QLs. See Appendix D for the full criteria.

5. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—***The filgrastims and pegfilgrastims are used for limited treatment durations. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing Neupogen, Granix syringe, Neulasta, Neulasta OnPro, and Udenyca from the program. Granix vials, Zarxio, Nivestym, Fulphila, and Ziextenzo are not currently on the EMMPI program. In summary, neither the filgrastims nor pegfilgrastims are included on the program.

6. ***COMMITTEE ACTION***: ***TIER 1 COST SHARE—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) lowering the current Tier 2 cost-share for the filgrastim Granix (both syringe and vial) and the pegfilgrastim Udenyca (both syringe and vial) to the generic Tier 1 cost-share.

The authority for this recommendation 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." Lowering the cost-share for both Granix and Udenyca will provide a greater incentive for beneficiaries to use the most cost-effective WBC stimulant for the filgrastims and pegfilgrastims, in the purchased care points of service.

7. ***COMMITTEE ACTION: UF PA, QL, EMMPI and Tier 1 COST SHARE IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service. Based on the P&T Committee's recommendation, the effective date is December 30, 2020. Note that the BCF addition of Granix and Udenyca will occur two weeks after signing of the minutes.

C. Psoriasis Agents

Background—The Psoriasis Agents have not previously been reviewed for formulary status. The twelve members in the class are classified by their mechanisms of action, which include the topical vitamin D analogs (calcipotriene, calcitriol), retinoids (tazarotene), and combinations of topical vitamin D analogs with topical corticosteroids (calcipotriene/betamethasone).

The tazarotene cream and gel formulations are classified as Psoriasis Agents for purposes of formulary considerations, even though they are also labeled for acne. The injectable biologics indicated for plaque psoriasis are included in the Targeted Immunomodulatory Biologics (TIBs) drug class, and were not reviewed here.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- The psoriasis drugs have a long history of use and are well established in professional treatment guidelines and clinical practice. These agents are used to treat localized plaque psoriasis affecting less than 20% of the body surface area. Patients who have a more widespread disease are candidates for systemic therapy or phototherapy, rather than topical treatment.
- The 2009 American Academy of Dermatology (AAD) guidelines support topical corticosteroids as first-line therapy for localized plaque psoriasis. However, well recognized adverse effects limit treatment duration to 2 to 4 weeks. Patients with limited disease who are refractory to higher potency topical corticosteroids typically transition to the topical vitamin D analogs or retinoids.
- The psoriasis agents are available in several vehicles (e.g., cream, ointment, gel, solution/suspension, foam). However, the vehicles all have alternatives, which can attain the same clinical effect while treating various body areas. Scalp-friendly vehicles in the class include lotions, foams, solutions, topical suspensions, and gels.
- Drugs with the same mechanism of action are clinically interchangeable (e.g., among the vitamin D analogs and among the retinoids, respectively), provided that any differences in vehicle formulation will not affect the application site.
- For non-corticosteroid therapies, the AAD recognizes both the vitamin D analogs (calcipotriene and calcitriol), and the retinoids (tazarotene) as having the highest quality of

evidence for treating plaque psoriasis. (Level 1 with grade "A" strength of recommendation)

- Combining a topical corticosteroid with either a vitamin D analog or retinoid can replace or supplement higher potency corticosteroids by providing greater efficacy than the individual components, while reducing total cumulative corticosteroid exposure.
- The fixed-dose combinations of a vitamin D analog with a higher potency topical corticosteroid provide a convenience to the patient. However, combined therapy that uses two products separately (e.g., vitamin D analog applied in the morning and corticosteroid applied at night) achieves similar effects, allows for more dosing flexibility, and is as well tolerated as using a fixed-dose combination product.
- The **vitamin D analogs** are either equivalent or superior to other treatment options. Common adverse reactions of the vitamin D analogs include application site irritation, contact dermatitis and potential increases in serum calcium levels.
    - **Calcipotriene 0.005% cream, ointment, and solution** together comprise approximately 50% of the MHS utilization for the entire psoriasis drug class. Provider feedback frequently mentioned calcipotriene cream as a preferred and required agent for the formulary.
    - **Calcitriol 3 mcg/g ointment (Vectical)** is clinically interchangeable with calcipotriene ointment and has low utilization across the MHS.
    - **Calcipotriene 0.005% foam (Sorilux)** offers no therapeutic advantages over other scalp-friendly products, including calcipotriene solution.
- **The retinoid tazarotene** may be less effective and is used less frequently than the vitamin D analogs. Adverse reactions associated with tazarotene include embryo-fetal toxicity (pregnancy category X rating), local irritation, and photosensitivity. Tazarotene has a higher discontinuation rate due to adverse events than the vitamin D analogs (18% vs. 4.6%, respectively). Tazarotene provides a niche for treating areas with very thick plaques or disease affecting the fingernails.
    - **Tazarotene 0.1% cream** has the highest utilization of the retinoids in the MHS.
    - **Tazarotene 0.05% gel and cream (Tazorac), and tazarotene 0.01% gel (Tazorac)** offer little to no therapeutic advantages over the 0.1% cream.
- Other than providing patient convenience, the **vitamin D analogs/corticosteroid combination** products offer no therapeutic advantages over applying an individual calcipotriene and a high-potency topical corticosteroid concurrently.
    - **Calcipotriene 0.005% / betamethasone 0.064% ointment (Taclonex, generic**) offers no compelling clinical advantages over the other products.
    - **Calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar)** provides a scalp-friendly vehicle, but is flammable.
    - **Calcipotriene 0.005% / betamethasone 0.064% suspension (Taclonex)** can be used on the scalp, however there are numerous alternatives including using the individual agents applied concurrently, as well as Enstilar foam.

- In order to meet the needs of MHS patients, for the vitamin D analogs, at least one ointment, cream, and scalp-friendly agent are each required on the formulary. For the retinoids, a cream is required.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA at the time of the review, showed that formulations ranked from most cost effective to least cost effective in the class are as follows: calcipotriene 0.005% cream (Dovonex, generics), calcipotriene 0.005% solution (generics), calcipotriene 0.005% ointment (Calcitrene, generics), tazarotene 0.1% cream (Tazorac, generics), calcitriol 3 mcg/g ointment (Vectical, generics), tazarotene 0.05% cream (Tazorac), tazarotene 0.1% gel (Tazorac), tazarotene 0.05% gel (Tazorac), calcipotriene 0.005% foam (Sorilux), Enstilar foam, calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex), and calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex).
- A BIA was performed to evaluate the potential financial impact of various formulary placement scenarios by designating selected psoriasis agents as Tier 4, NF, and UF. The BIA results showed that designating calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex) as Tier 4 and with all remaining psoriasis agents designated as UF or NF, demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: PSORIASIS AGENTS UF/TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following formulary recommendations for the Psoriasis Agents as outlined below, based on clinical and cost-effectiveness.

    - UF:
        - calcipotriene 0.005% ointment (Calcitrene, generics)
        - calcipotriene 0.005% cream (Dovonex, generics)
        - calcipotriene 0.005% solution (generics)
        - tazarotene 0.1% cream (generics)
    - NF: *(all move from UF to NF status)*
        - calcipotriene 0.005% foam (Sorilux)
        - calcitriol 3 mcg/g ointment (Vectical, generics)
        - calcipotriene 0.005%/betamethasone 0.064% ointment (Taclonex, generics)
        - calcipotriene 0.005%/betamethasone 0.064% foam (Enstilar)
        - tazarotene 0.1% gel (Tazorac)
        - tazarotene 0.05% cream (Tazorac)

- tazarotene 0.05% gel (Tazorac)

- Tier 4/Not Covered:
  - calcipotriene 0.005%/betamethasone 0.064% suspension (Taclonex) (*moves from UF to Tier 4 status)*

    For Taclonex suspension, which was recommended for Tier 4/Not Covered status, the P&T Committee concluded that it provides very little to no additional clinical effectiveness relative to the other psoriasis agents. Overall, the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other combination products, and by use of the single ingredient vitamin D analogs and corticosteroids used separately. See Appendix H for the formulary alternatives for the Tier 4 drugs.

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding calcipotriene 0.005% cream to the BCF, based on existing high utilization at the MTF, preferred place in therapy based on AAD guidelines, and provider feedback.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Sorilux foam, Enstilar foam and Taclonex ointment in all new and current users, requiring a trial of a high potency corticosteroid and calcipotriene first, due to the large number of clinically and cost-effective formulary alternatives available. Manual PA criteria were also recommended for new and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel, requiring a trial of tazarotene 0.1% cream and a high potency topical steroid, for plaque psoriasis affecting the body. For acne, a trial of tazarotene 0.1% cream will be required before the other Tazorac formulations. See Appendix C for the full criteria

4. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Sorilux foam, calcitriol 3 mcg/g ointment (Vectical), Enstilar foam, calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex), Tazorac 0.1% gel, and 0.05% cream and gel. See Appendix B for full requirements.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1

absent) excluding the NF psoriasis agents from the NF to mail requirement due to acute use. See Appendix F for details.

6. ***COMMITTEE ACTION: UF/TIER 4, PA, MN, AND EMMPI IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 120 days after the signing of the minutes; 2) DHA send letters to beneficiaries who are affected by the by the change from UF to NF status and PA requirements, and 3) DHA send letters to beneficiaries who are affected by the Tier 4/not covered recommendations at 30 and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is February 24, 2021. Note that the BCF addition of calcipotriene 0.005% cream will occur 2 weeks after signing of the minutes.

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent), and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2020 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.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF:
  - apomorphine sublingual film (Kynmobi) – new formulation of apomorphine for Parkinson's disease
  - capmatinib (Tabrecta) – oncological agent for non-small cell lung cancer (NSCLC)
  - elagolix/estradiol/norethindrone (Oriahnn) – luteinizing hormone-releasing hormone agonists-antagonists for heavy bleeding with fibroids
  - fenfluramine oral solution (Fintepla) – anticonvulsant for Dravet syndrome
  - insulin lispro-aabc (Lyumjev) – another insulin lispro formulation for diabetes mellitus
  - lemborexant (Dayvigo) – dual orexin receptor antagonist for insomnia

- nimodipine oral syringe (Nymalize) – new oral syringe formulation of nimodipine
- octreotide acetate injection (Bynfezia Pen) – new formulation of octreotide in a pre-filled pen
- osilodrostat (Isturisa) – miscellaneous endocrine agent for Cushing's disease
- ozanimod (Zeposia) – Multiple Sclerosis agent
- pemigatinib (Pemazyre) – oncological agent for cholangiocarcinoma
- ripretinib (Qinlock) – oncological agent for gastrointestinal stromal tumors (GIST)
- selpercatinib (Retevmo) – oncological agent for NSCLC and thyroid cancer
- selumetinib (Koselugo) – oncological agent for Neurofibromatosis type 1
- tucatinib (Tukysa) – oncological agent for breast cancer

- NF:
  - bempedoic acid/ezetimibe (Nexlizet) – antilipidemic-1 fixed dose combination for atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH)
  - diclofenac epolamine 1.3% patch (Licart) – NSAID patch for acute pain
  - lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi) – miscellaneous contraceptive vaginal gel for on-demand contraception
  - leuprolide acetate injection (Fensolvi) – leuprolide formulation for central precocious puberty
  - levonorgestrel/ethinyl estradiol transdermal system (Twirla) – Miscellaneous contraceptive
  - minocycline 1.5% topical foam (Zilxi) – topical formulation of minocycline for rosacea

- Tier 4/Not Covered:
  - halcinonide 0.1% topical solution (Halog) – high potency topical corticosteroid
    - Halog topical solution was recommended for Tier 4 status as it has no clinical benefit relative to other high potency topical corticosteroids, and the needs of TRICARE beneficiaries are met by alternative agents.

        - Formulary alternatives to Halog topical solution include betamethasone propylene glycol 0.05% cream, clobetasol propionate 0.05% cream and ointment, clobetasol propionate/emollient 0.05% cream, desoximetasone 0.25% cream and ointment, fluocinonide 0.05% cream and ointment, fluocinonide/emollient base 0.05% cream, halobetasol propionate 0.05% ointment. (See Appendix H.)
    - tazarotene 0.045% lotion (Arazlo) – topical acne and rosacea agents
        - Arazlo lotion was recommended for Tier 4 status as it has no clinical benefit relative to other topical acne agents, and the needs of TRICARE beneficiaries are met by alternative agents.
            - Formulary alternatives to Arazlo lotion include adapalene (cream, gel, lotion), tazarotene (cream), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel). (See Appendix H.)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) MN criteria for Fensolvi, Licart, Nexlizet, Phexxi vaginal gel, Twirla patch, and Zilxi foam. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following (see Appendix C for the full criteria):

- Topical Acne and Rosacea Agents: Applying step therapy criteria to new and current users of Zilxi foam that is currently in place for the other non-step-preferred rosacea agents, including Mirvaso and Soolantra, requiring a trial of topical metronidazole first.
- Insomnia Drugs: Applying manual PA criteria to new and current users of Dayvigo that is currently in place for the other dual orexin receptor antagonist for insomnia (suvorexant), requiring a trial of zolpidem ER (Ambien CR generic) and eszopiclone (Lunesta generic) first.
- Miscellaneous contraceptives: Applying manual PA criteria to new users of the Twirla patch and Phexxi vaginal gel.
- Oncologic drugs: Applying manual PA criteria to new users of Koselugo, Pemazyre, Qinlock, Retevmo, Tabrecta, and Tukysa.

- Applying manual PA criteria to new users of Fintepla, Isturisa, Licart patch, Nexlizet, Oriahnn, and Zeposia.

D. ***COMMITTEE ACTION: UF, TIER 4/NOT COVERED, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- **New Drugs Recommended for UF or NF Status, MN and PA criteria:** An effective date of the first Wednesday upon two weeks after signing of the minutes in all POS, on November 11, 2020.

- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date of the first Wednesday after a 120-day implementation period at all POS, 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 on February 24, 2021.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

1) ***Narcotic Analgesics and Combinations—tramadol 100 mg IR tablet—*** Cost-effective formulations of tramadol IR 50 mg tablets have been widely available from several manufacturers. The branded Ultram 100 mg tablets have been discontinued. A single manufacturer is now marketing a 100 mg IR tablet that is not cost-effective. The Committee recommended manual PA to encourage use of tramadol 50 mg IR tablets and to discourage the use of the 100 mg strength.

2) ***Vitamins: Prenatal—prenatal multivitamin (Trinaz)—***Trinaz is a prenatal dietary supplement manufactured by a single company and requires a prescription prior to dispensing. The primary ingredients of Trinaz are similar to that found in Azesco and Zalvit, which require manual PA. Several prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria. Manual PA criteria were recommended for all new and current users of Trinaz, to require a trial of cost-effective formulary prenatal vitamins first.

***COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO CFR* 32 CFR 199.21(g)(5): *TRAMADOL 100 MG IR TABLET AND TRINAZ MANUAL PA CRITERIA*—**The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for tramadol 100 mg IR tablets and Trinaz (regardless of the woman's age) in new and current users, due to significant cost differences compared with numerous available alternative agents. See Appendix C for the full criteria.

b) Pulmonary-2 Agents: Long-Acting Beta Agonists (LABAs)—olodaterol (Striverdi Respimat)

Striverdi Respimat was designated as UF when reviewed at the February 2016 P&T Committee meeting. It was the sixth marketed LABA oral inhaler approved for maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). The LABA oral inhalers have seen declining utilization, primarily due to safety concerns, and have been largely replaced by the combination LABA/inhaled corticosteroid products (e.g., Advair) and long-acting muscarinics (e.g., Spiriva). There has been a significant price increase for Striverdi Respimat. Manual PA was recommended in new users to require a trial of the cost effective and more widely used salmeterol inhaler (Serevent Diskus) first, unless the patient is unable to produce the inspiratory flow necessary to use a dry powder inhaler.

c) Gastrointesinal-2 Agents—teduglutide (Gattex)

Gattex is approved for patients with chronic short bowel syndrome (SBS) who are dependent on total parenteral nutrition (TPN), despite aggressive use of conventional measures. The product labeling states the drug should be discontinued in patients where minimal or no response is noted (shown as a clinically meaningful reduction in parenteral support or reduction in days requiring parenteral support), or who experience intolerable side effects. Gattex was identified as a high-cost specialty drug with a potential for off-label use. Provider feedback was solicited to develop manual PA criteria to ensure appropriate use for the small patient population who will benefit, consistent with the package labeling. Manual PA criteria will apply to new patients, with renewal criteria required for the patient to continue therapy after initial approval.

***COMMITTEE ACTION: NEW PA CRITERIA FOR STRIVERDI RESPIMAT AND GATTEX*—**The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria manual PA criteria for Striverdi Respimat in new users and for Gattex in new users. See Appendix C for the full criteria.

2. Updated PA Criteria

Updates to the manual PA criteria and step therapy for several drugs were recommended due to a variety of reasons, including safety information, age indications,

new FDA-approved indications, and availability of cost-effective alternative treatments. The updated PAs and step therapy outlined below will apply to new users with the exceptions of isotretinoin (Absorica and Absorica LD) and minocycline ER (Solodyn) which will apply to new and current users.

a) Updated PA criteria for reasons other than new FDA Indications, NCCN Guideline updates, or age ranges

1) ***Gynecological Agents Miscellaneous—flibanserin (Addyi)—***Manual PA criteria for Addyi were initially recommended at the November 2015 P&T Committee meeting. In October 2019, the FDA removed the Addyi risk evaluation and mitigation strategy (REMS) program and alcohol contraindication; now the boxed warning outlines the risks of concurrent alcohol consumption with Addyi. The Committee agreed to update the manual PA in new users to reflect these safety changes, and to include criteria similar to other agent in the class, bremelanotide (Vyleesi), regarding cognitive-behavioral therapy and counseling.

2) ***Acne Agents: Isotretinoids—isotretinoin (Absorica, Absorica LD)—*** Several AB-rated generic formulations of the original proprietary product Accutane are marketed (e.g., Amnesteem, Claravis, Myorisan). Absorica and Absorica LD are new isotretinoin products specifically formulated to allow for absorption without regard to meals. Other than patient convenience, they offer no compelling advantages over generic isotretinoin for patients with recalcitrant acne. Generic formulations of Absorica are expected in 2021. Existing PA criteria from November 2015 for Absorica and Absorica LD allow use if the patient is unable to comply with the dietary requirements for the generic products. The existing manual PA criteria for Absorica and Absorica LD, were updated to require a trial of generic isotretinoin first in new and current users, due to cost effectiveness.

3) ***Antibiotics: Tetracyclines—minocycline ER (Solodyn, generics)—***The February 2017 Tetracycline drug class review concluded there was no data to support that minocycline ER (Solodyn, generic) formulations are more effective or safer than generic minocycline IR preparations for treating acne. There is a substantial cost difference between the generic IR and ER formulations. Step therapy currently requires a trial of generic doxycycline IR and generic minocycline IR first. The existing Solodyn PA criteria were updated in new and current users to also require the provider to state the clinical reason as to why the patient cannot take generic minocycline IR. Automated step therapy will no longer apply. The new PA criteria will not expire, so patients meeting the updated criteria will not be required to fill out renewal criteria.

***COMMITTEE ACTION*: *UPDATED MANUAL PA CRITERIA*—**The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Absorica, Absorica LD, Solodyn and generics, and Addyi. See Appendix C for the full criteria.

b) Updated Criteria for new FDA Indications, NCCN Guideline Updates, or Age Ranges. Note that since these updates allow for expanded indications or broader age ranges, the updated PAs are not detailed in Appendix C, as minor changes were made.

1) ***Acne Agents: Topical Acne and Rosacea—dapsone 5% and 7.5% gel (Aczone)***—Aczone 7.5% gel is only available in a proprietary formulation; however, generic dapsone 5% gel was first marketed in October 2017. Aczone 7.5% recently received approval for treating acne in patients as young as 9 years of age. Generic dapsone 5% has not been studied in patients younger than age 12. After reviewing clinical trial data, the Committee agreed to remove the age restrictions for both dapsone formulations. The committee also agreed that dapsone was unlikely to be used in children younger than 9, as acne is not commonly seen in this age group. Providers can therefore use the more cost-effective generic dapsone 5% rather than Aczone 7.5% for children. The PA criteria still requires a diagnosis of acne vulgaris and a trial of at least 3 step preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

2) ***Respiratory Interleukins—dupilumab injection (Dupixent)*—**Manual PA criteria for Dupixent were updated to reflect a lowered age indication for pediatric patients with moderate to severe atopic dermatitis 6 years of age or older; the previous age was 12 years. Note that the current age requirements for the other indications are not changed, including patients older than 18 years for chronic sinusitis and for patients as young as 12 years for asthma.

3) ***Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)*—nintedanib (Ofev)**—The IPF drugs were reviewed for formulary status in May 2017, with step therapy requiring a trial of pirfenidone (Esbriet) prior to Ofev. Ofev recently gained a new indication for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. Esbriet lacks this indication, therefore the step therapy requirements for a trial of Esbriet first will not apply here. The renewal criteria from the May 2017 class review was also clarified to exclude concomitant use of Esbriet and Ofev.

4) ***Oncologic Agents: ovarian cancer [niraparib (Zejula), olaparib (Lynparza), and rucaparib (Rubraca)]; melanoma [encorafenib***

(Braftovi)] and multiple myeloma [selinexor (Xpovio)]—Updates to the manual PA criteria for these oncologic agents reflects more detailed safety information, including standardized embryo-fetal toxicity information and male reproductive concerns. New FDA-approved indications or NCCN guideline-supported indications were also updated. A synopsis of the changes are summarized below.

- **niraparib (Zejula)**—Allow use for the new FDA-approved indication as a first-line treatment for ovarian cancer

- **olaparib (Lynparza) and rucaparib (Rubraca)**—Updated for the new FDA-approved indications for treating prostate cancer, and added a urologist as an allowable prescriber, in addition to a hematologist/oncologist. The Lynparza criteria was also updated to allow use for a new pancreatic cancer indication.

- **encorafenib (Braftovi)**—Allow use for the new FDA-approved indication for treating colorectal cancer

- **selinexor (Xpovio)**—Allow use for the new FDA-approved indication for treating diffuse large B-cell lymphoma

5) ***Targeted Immunomodulatory Biologics (TIBs)—***Several updates for the TIBs including both off-label and new FDA-approved indications and clarifications of step therapy requirements were made. A synopsis of the changes are summarized below.

   - **adalimumab (Humira)**—Allow off-label use for moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids, based on supporting clinical data. Additionally, patients with PG or fistulizing Crohn's Disease (CD) can use Humira without a trial of non-biologic systemic therapy (e.g., methotrexate, azathioprine, sulfasalazine, mesalamine, or corticosteroids) first.

   - **ustekinumab (Stelara)**—Updated the PA to include the new indication for pediatric patients down to the age of 6 years for plaque psoriasis; the previous indication was down to the age of 12 years. A trial of Humira is not required in pediatric patients 6 to 17 years old with a diagnosis of plaque psoriasis, since Humira is not indicated for children for this condition.

   - **ixekizumab (Taltz)**—Updated the criteria to allow use in adults with non-radiographic axial spondyloarthritis (nr-axSpA); a trial of both Humira and Cosentyx are required first for this indication. The criteria were also updated for the new indication of plaque psoriasis in pediatric patients 6 to 17 years old. Note that a trial of Humira and

Cosentyx are not required in patient's age 6 to 17 years. However, the requirement to try Stelara first for children between 6 to 17 years of age for this indication still applies.

- **secukinumab (Cosentyx)**—Updated to allow for the new nr-axSpA indication, requiring a trial of Humira first. Also updated to include coverage for moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and to remove "psoriasis of the scalp", since plaque psoriasis also encompasses all body areas.

COMMITTEE ACTION: ***UPDATED MANUAL PA CRITERIA AND STEP THERAPY—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the updates to the manual PA criteria for Aczone, Ofev, and Dupixent, the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs Humira, Stelara, Taltz, and Cosentyx.

3. New FDA-Approved Indications for Drugs with Existing PA Criteria: New Process

The Pharmacy Operations Division (POD) Formulary Management Branch (FMB) developed a process with the POD Purchased Care Branch and the TPharm contractor which, after FMB review, may authorize the contractor to temporarily approve certain new FDA-approved indications or expanded age ranges which impact drugs that have existing PA criteria. This process will occur prior to the P&T Committee review of the new indications. Only certain indications screened and approved by FMB will apply. These new expanded criteria will be presented at the next quarterly DoD P&T Committee meeting. Any new FDA-approved indication approved by this process cannot contradict current TRICARE pharmacy benefit design rules or exclusions.

COMMITTEE ACTION: NEW FDA-APPROVED INDICATIONS FOR DRUGS WITH EXISTING PA CRITERIA: NEW PROCESS—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the process outlined above, in order to expedite updating PA criteria for new FDA-approved indications or expanded age ranges.

B. Quantity Limits

1. **General QLs**: QLs were reviewed for 12 drugs from drug classes where there are existing QLs, and for some of the new drugs, including contraceptive agents, miscellaneous endocrine agents, narcotic analgesics and combinations, pain agents, oncological agents, and pulmonary-1 agents.

COMMITTEE ACTION: QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) QLs for Phexxi, Isturisa, tramadol 100 mg IR

tablets, Licart, Pemazyre, Qinlock, Koselugo, Tukysa, Tabrecta, Retevmo, Rubraca, and Asmanex HFA. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

1. ***COMMITTEE ACTION: PA AND QLs IMPLEMENTATION PERIOD—***The P&T Committee recommended the following implementation periods:

- (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for tramadol 100 mg IR tablets and Trinaz will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Absorica, Absorica LD, and Solodyn in new and current users will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to the beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

- (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for Striverdi Respimat and Gattex in new users will become effective the first Wednesday 60-days after the signing of the minutes.

- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Aczone, Addyi, Dupixent, Ofev, and the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs , Humira, Stelara, Taltz, and Cosentyx in new users will become effective the first Wednesday 60-days after the signing of the minutes.

- (16 for, 0 opposed, 0 abstained, 2 absent) QLs listed in Appendix D will become effective the first Wednesday 2 weeks after the signing of the minutes in all POS.

VII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for several product line extension ("follow-on products") 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.

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA) criteria, QLs, and EMMI List status, and specialty status for

the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes.

- **ADHD Agents: Stimulants**—designating the **authorized generic methylphenidate ER capsules** as UF, similar to the brand Aptensio XR from the same manufacturer.

- **Antiretrovirals: Combinations**—designating **dolutegravir 5 mg tablets for suspension for children (Tivicay PD)** as UF, similar to Tivicay 10 mg, 25 mg and 50 mg oral tablets.

- **Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors—empagliflozin/linagliptin/metformin extended release (Trijardy XR)** is a new triple fixed-dose combination product containing an SGLT-2 inhibitor, DPP-4 inhibitor and metformin. Empagliflozin-containing products (Jardiance, Glyxambi, Synjardy XR) are currently the step-preferred SGLT-2 inhibitor. The P&T Committee recommended designating Trijardy XR as UF, with the same step-therapy and PA criteria requirements as Jardiance, Glyxambi, and Synjardy XR.

- **Hepatitis Agents: Direct Acting Agents**—designating **ledipasvir/sofosbuvir 33.75 mg/150 mg oral pellet pack (Harvoni) and sofosbuvir150 mg oral pellet pack (Sovaldi)** as UF, with the same manual PA requirements, QLs, and specialty reporting requirements similar to Harvoni 45 mg/200 mg pellet pack and Sovaldi 200 mg pellet pack, respectively.

- **Immunological Agents Miscellaneous**—designating **immune globulin SQ syringe (Hizentra)** as UF, similar to the Hizentra vials.

- **Migraine Agents: CGRP Preventative**—designating **fremanezumab autoinjector (Ajovy)** as UF, with the same manual PA requirements, and QLs as the Ajovy prefilled syringe.

- **Oncological Agents: Breast Cancer**—designating **palbociclib (Ibrance) 75 mg, 100 mg, and 125 mg tablets** as UF, with the same manual PA requirements, and same QLs as Ibrance capsules.

- **Pain Agents: NSAIDS**—designating the **authorized generic ketorolac nasal spray** as NF, with the same MN criteria, and QLs as brand ketorolac nasal spray (Sprix) from the same manufacturer.

- **Pulmonary-1 Agents: Inhaled Corticosteroids**—designating **mometasone furoate oral inhaler (Asmanex HFA 50 mcg/actuation)** as UF and non-step preferred, with the same manual PA requirements, and QLs as Asmanex HFA 100 mcg/actuation and 200 mcg/actuation.

- **Targeted Immunomodulatory Biologics**—designating **tofacitinib 22 mg tablets (Xeljanz XR)** as UF, with the same step therapy and PA criteria, EMMI status, and QLs as Xeljanz XR 11 mg.

- **Urinary Agents Miscellaneous—cysteamine bitartrate (Procysbi) is now available in 75 mg and 300 mg delated release (DR) granule packets.** Previously, it was only available as oral DR sprinkle capsules in strengths of 25 mg and 75 mg. The P&T Committee recommended designating the new DR granule packets as UF. Procysbi DR sprinkle capsules have not been previously reviewed by the Committee but were FDA-approved prior to the Innovator Rule in August 2015 and are UF by default.

VIII. BRAND OVER GENERIC AUTHORIZATION FOR MESALAMINE 1.2 gm (LIALDA)

Brand over generic PA requirements have applied to mesalamine 1.2 gram (Lialda) since September 2017, due to cost effectiveness. In April 2020, cost-effective generic mesalamine 1.2 gram formulations were available at the Mail Order and MTFs, however, generic prices at Retail are not cost effective. On May 20, 2020, the brand over generic requirements were administratively removed at the Mail Order and MTF points of service. The brand Lialda over generic PA requirement will remain at the Retail network (i.e., generic mesalamine at the Retail network requires PA). The branded Lialda will remain Tier 1 at Mail Order and the Retail network until further direction from the FMB. Generic prices at Retail are continually monitored and will determine the opportune time to remove brand over generic requirements at the Retail network and when to increase the branded Lialda copay back to Tier 2 at Mail and Retail.

COMMITTEE ACTION: LIALDA BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA AND COPAYMENT—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent), to remove the PA requirement at the Mail Order Pharmacy and MTF but maintain it at the Retail Network. The Tier 1 co-pay for brand Lialda will be maintained at both of the Mail Order Pharmacy and the Retail Network.

IX. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE MAIL ORDER PROGRAM

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

See Appendix F for the mail order status of medications designated UF or NF during the August 2020 P&T Committee meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement. The implementation date for all of the recommendations from the August 2020 meeting listed in Appendices E and F, including those for newly approved drugs, will be effective upon the first Wednesday two weeks after the signing of the minutes.

1. ***COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—*** The P&T Committee recommended (groups 1: 17 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 1 abstained, 0 absent; group 3: 15 for, 0 opposed, 1 abstained, 2 absent), adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMI List) for the reasons outlined in the table. See Appendix F.

X. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFS: ASPIRIN, ARTIFICIAL TEARS GEL, AND PYRANTEL PAMOATE

Background—The DoD P&T Committee continued reviewing the OTC drugs on the MHS GENESIS OTC list. For a full description of the background and process details, refer to the May 2019 and August 2019 DoD P&T Committee meeting minutes, found at http://health.mil/PandT.

Factors influencing whether a particular OTC product is retained or removed from the MHS GENESIS OTC List include volume and utilization across multiple MTFs; feedback from MTF stakeholders to include primary care providers, pediatricians, and other providers, the Primary Care Clinical Community advisory group, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

- **OTC Aspirin:** The most common aspirin formulations dispensed at MTFs are 81 and 325 mg, with enteric-coated options preferred for chronic use in order to alleviate gastrointestinal adverse events. There is minimal to no outpatient dispensing of other available formulations, including 300 and 600 mg suppositories.

- **Artificial Tears (Overnight Treatment)**: The ophthalmology leaders requested a review of hypromellose 0.3% ophthalmic gel (Genteal Tears Severe, Systane Gel) due to its use in neonates for retinopathy of prematurity; the product is also used for laser procedures and for neonatal examinations. The MHS GENESIS OTC List also includes a number of formulations of mineral oil/petrolatum ointments (due to intermittent shortage issues).

- **Pyrantel pamoate for hookworm/pinworm**: The P&T Committee reviewed pyrantel pamoate oral suspension (e.g., Reese's Pinworm, Pin-X) due to an MTF request as it is a cost effective treatment for pinworm/hookworm, particularly in small children, compared to the two legend alternatives (albendazole and mebendazole).

1. ***COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

    - retaining the 81 and 325 mg aspirin products (both enteric and non-enteric coated) currently on the list. Note that following the meeting, aspirin oral suspension was recommended for removal.

- adding hypromellose 0.3% ophthalmic gel (and retaining existing formulations of mineral oil/petrolatum ointment)
- adding pyrantel pamoate oral suspension
- An effective date of the first Wednesday 2 weeks following signing of the minutes for the two products added to the MHS GENESIS OTC List (hypromellose 0.3% gel, pyrantel pamoate suspension). No patient letters are required. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

XI. ADJOURNMENT

The meeting adjourned at 1630 hours on August 6, 2020. The next meeting will be in November 2020.

Appendix A—Attendance: August 2020 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, Nonformulary, or Tier 4 during the August 2020 DoD P&T Committee Meeting
Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives
Appendix I—MHS GENESIS OTC Test List
Appendix J—Table of Abbreviations

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:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

Mr. Guy Kiyokawa
Deputy Director, DHA
for Ronald J. Place
LTG, MC, USA
Director

2 NOV 2
Date

Appendix A—Attendance: August 2020 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Randy Dorsey, MSC, for Col Markus Gmehlin	Chief, DHA Pharmacy Operations Division (POD)
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder) POD
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Maj Wendra J Galfand, MC	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Col Corey Munro, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Kelly Echevarria, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Fakhrudin Valibhai, PharmD	COR Tricare Pharmacy Program

Appendix A—Attendance (continued)

Guests	
Lt Col Matt Cowan	DLA Troop Support
LCDR Kyleigh Hupfl, MSC	DLA Troop Support
Ms. Kimberlymae Wood	DHA Contracting Officer
Ms. Yvette Dluhos	DHA Contracting
Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Dr. Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Dr. Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Dr. Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
Dr. Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
MAJ Triet Nguyen, MSC	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Ebony Moore	DHA Formulary Management Branch Contractor
Mr. Rohan Khalid	University of Maryland Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• pitolisant (Wakix) **Sleep Disorders: Wakefulness Promoting Agents**	• Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure **Formulary Alternatives:** armodafinil, modafinil, methylphenidate, amphetamine
• solriamfetol (Sunosi) **Sleep Disorders: Wakefulness Promoting Agents**	• Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure **Formulary Alternatives:** armodafinil, modafinil, methylphenidate, amphetamine
• calcipotriene 0.005% foam (Sorilux) • calcitriol 3 mcg/g ointment **Psoriasis Drugs: Vitamin D Analogs**	• Patient has experienced adverse effects from one formulary Vitamin D analog agent **Formulary alternatives:** calcipotriene 0.005% ointment, cream, solution
• tazarotene 0.05% cream (Tazorac) • tazarotene 0.05% gel (Tazorac) • tazarotene 0.1% gel (Tazorac) **Psoriasis Drugs: Retinoids**	• Patient has experienced significant adverse effects from tazarotene 0.1% cream • No alternative formulary agent: patient has scalp psoriasis and requires tazarotene gel. **Formulary alternative:** tazarotene 0.1% cream
• calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) • calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex, generic) **Psoriasis Drugs: Vitamin D Analog Combinations**	• Patient has experienced significant adverse effects from at least one formulary Vitamin D analog **AND** at least one formulary high-potency topical corticosteroid agent **Formulary alternatives:** Vitamin D analogs: calcipotriene 0.005% cream, ointment, and solution High-potency topical corticosteroid: clobetasol propionate 0.05% ointment, cream, solution and gel; fluocinonide 0.05% ointment, cream, and solution
• bempedoic acid/ezetimibe (Nexlizet) • bempedoic acid *(Nexletol)* *(updated from May 2020*) **Antilipidemics-1**	• Patient has experienced significant adverse effects from at least 2 formulary alternatives, including at least one statin and ezetimibe • At least 2 formulary alternatives, including at least one statin and ezetimibe have resulted in therapeutic failure **Formulary alternatives:** atorvastatin, simvastatin 10, 20, 40 mg, pravastatin rosuvastatin, alirocumab, evolocumab, ezetimibe
• diclofenac epolamine 1.3% patch (Licart) **Pain Agents: Pain Topical**	• Patient has experienced significant adverse effects from at least 2 oral NSAIDs that are not expected to occur with Licart • **Formulary alternatives**: all oral NSAIDs,

Drug / Drug Class	Medical Necessity Criteria
• lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi) **Contraceptive Agents: Miscellaneous**	• Patient has experienced significant adverse effects from a nonoxynol-9 spermicide plus one other formulary contraceptive agent (e.g. norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, and medroxyprogesterone injection) **Formulary and non-formulary alternatives**: nonoxynol-9 spermicide, norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, medroxyprogesterone injection, or any other formulary contraceptive agent
• leuprolide acetate injection (Fensolvi) **Luteinizing Hormone-Releasing Hormone Agonists-Antagonists**	• No alternative formulary agent: patient is not able to use short-acting leuprolide formulations OR is not able to use leuprolide via the intramuscular route or implant **Formulary alternatives**: leuprolide acetate injection (Lupron Depot-Ped), histrelin (Supprelin LA), triptorelin (Triptodur)
• levonorgestrel/ethinyl estradiol (Twirla) **Contraceptive Agents: Miscellaneous**	• Patient has experienced significant adverse effects from the Xulane patch that are not likely to occur with Twirla **Formulary alternatives**: norelgestromin/ethinyl estradiol transdermal system (Xulane) and etonogestrel/ethinyl estradiol vaginal ring (NuvaRing), other combined hormonal contraceptives
• minocycline 1.5% topical foam (Zilxi) **Acne Agents: Topical Acne and Rosacea**	• Use of metronidazole and azelaic acid are contraindicated • Patient has experienced significant adverse effects from metronidazole and azelaic acid • Metronidazole and azelaic acid have resulted in therapeutic failure **Formulary alternatives**: metronidazole (1% gel; 0.75% lotion, and 0.75% cream) and azelaic acid 15%

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• pitolisant (Wakix) **Sleep Disorders: Wakefulness Promoting Agents**	**Updates from the August 2020 meeting are in bold.** Manual PA is required for all new users of Wakix. Manual PA Criteria: Wakix is approved if all criteria are met: • **Provider acknowledges that PA is not required for modafinil or armodafinil.** • Patient is 18 years of age of older • Wakix is not approved for use in children, adolescents, or pregnant patients. • Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy **and an Epworth Sleepiness Scale (ESS) score ≥ 14** • Narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing • Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Patient is not concurrently taking any of the following: • Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • Patient must have tried and failed and had an inadequate response to modafinil • Patient must have tried and failed and had an inadequate response to armodafinil • Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient does not have a history of severe hepatic impairment • Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, cataplexy, obstructive sleep apnea, major depression, ADHD, or shift work disorder). PA expires in 1 year. Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.

Drug / Drug Class	Prior Authorization Criteria

• solriamfetol (Sunosi)
 	
Sleep Disorders: Wakefulness Promoting Agents
	Updates from the August 2020 meeting are in bold.
	
	Manual PA is required for all new users of Sunosi.
	
	Manual PA Criteria: Sunosi is approved if all criteria are met:
	• **Provider acknowledges that PA is not required for modafinil or armodafinil.**
	• Patient is 18 years of age of older
	• Sunosi is not approved for use in children, adolescents, or pregnant patients.
	• Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy or a documented diagnosis of obstructive sleep apnea (OSA) **and an Epworth Sleepiness Scale (ESS) score ≥ 10**
	• For narcolepsy: narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
	• For narcolepsy: Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea
	• For OSA: Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least 1 month prior to initiation, and the patient demonstrated adherence to therapy during this time
	• For OSA: Patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of treatment
	• Sunosi is prescribed by a neurologist, psychiatrist, or sleep medicine specialist
	• The patient is not concurrently taking any of the following:
	  • Central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic
	  • Monoamine oxidase inhibitor (MAOI) within the past 14 days
	  • Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate
	• The patient must have tried and failed and had an inadequate response to modafinil
	• The patient must have tried and failed and had an inadequate response to armodafinil
	• The patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)
	• Patient and provider agree to monitor blood pressure and heart rate at baseline and periodically throughout treatment. If the patient has hypertension, the blood pressure is controlled.
	• Patient does not have unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems
	
	Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, major depression, ADHD, or shift work disorder).
	
	Prior authorization expires in 1 year.
	
	Renewal PA criteria: No renewal allowed. A new prescription will require a new PA to be submitted.

Drug / Drug Class	Prior Authorization Criteria

• sodium oxybate (Xyrem)
 	
Sleep Disorders: Wakefulness Promoting Agents
	Note that there were no changes to the PA criteria from Xyrem made at the November 2019 meeting. PA included for completeness.
	
	Manual PA Criteria: Coverage of Xyrem is approved if the following criteria are met:
	• Patient is 18 years of age or older
	• The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic
	• Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND
	• Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.
	  • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR
	• Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND
	  • The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND
	• Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)
	OR
	• Patient is child 7 years of age or older AND
	• The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND
	• Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND
	• Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.
	  • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR
	• Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND
	  • The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND
	• Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders)
	
	Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.
	
	PA expires after 1 year.
	
	Renewal PA criteria: Renewal not allowed. A new prescription will require a new PA to be submitted.

Drug / Drug Class	Prior Authorization Criteria
• filgrastim (Neupogen) • filgrastim-sndz (Zarxio) **WBC Stimulants Class: Filgrastim subclass**	Manual PA criteria apply to all new users of filgrastim (Neupogen) and filgrastim-sndz (Zarxio) Note that Granix is available at the Tier 1 copay at the Mail Order and Retail Network pharmacies. <u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met • Provider acknowledges that tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) are the TRICARE preferred filgrastims and are available without a PA. • Drug is prescribed by or in consultation with a hematologist or oncologist • Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio) • Patient has experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio) PA does not expire
• pegfilgrastim (Neulasta) • pegfilgrastim (Neulasta Onpro) • pegfilgrastim-bmez (Ziextenzo) **WBC Stimulants Class: Pegfilgrastim subclass**	Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo) Note that Udenyca is available at the Tier 1 copay at the Mail Order and Retail Network pharmacies. <u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met: • Provider acknowledges that pegfilgrastim-cbqv (Udenyca) and pegfilgrastim-jmdb (Fulphila) are the TRICARE preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist or oncologist • For Neulasta OnPro: Patient requires use of an on-body injector because the patient and/or caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration **OR** • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-cbqv (Udenyca) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) PA does not expire

Drug / Drug Class	Prior Authorization Criteria
• calcipotriene 0.005% foam (Sorilux) **Psoriasis Agents**	Manual PA is required for all new and current users of Sorilux foam. Manual PA Criteria: Coverage approved if ALL criteria are met: • The provider acknowledges that Sorilux has several cost-effective alternatives, including generic calcipotriene 0.005% cream, ointment and solution, which do not require a PA. Calcipotriene 0.005% solution can be applied to the scalp. • Patient is 12 years of age of older • The patient has 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 at least one formulary high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution) • For scalp psoriasis: the patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% solution OR • For all other body areas: the patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% ointment, cream, AND solution Non-FDA-approved uses are NOT approved. PA does not expire.

• calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex generic)
• calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar)
 	
Psoriasis Agents
	Manual PA is required for all new and current users of Enstilar foam and Taclonex ointment.
	
	Manual PA Criteria: Coverage approved if ALL criteria are met:
	• The provider acknowledges that Enstilar foam and Taclonex ointment have several cost effective alternatives, including the following, none of which require PA.
	  • For the calcipotriene (vitamin D analog) component, alternatives include generic calcipotriene 0.005% cream, ointment, and solution.
	  • For the betamethasone (high-potency topical corticosteroid) component, alternatives include clobetasol propionate 0.05% ointment, cream, solution, and shampoo and fluocinonide 0.05% cream, ointment, and solution.
	• Patient is 12 years of age of older
	• The patient has diagnosis of plaque psoriasis
	• The patient must have tried for at least 2 weeks and failed or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution)
	• The patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% ointment, cream, OR solution
	• The patient must have tried and failed an individual calcipotriene agent (calcipotriene 0.005% ointment, cream or solution) AND an individual high-potency topical corticosteroid agent used concurrently
	• Additionally, the provider must describe why Enstilar foam or Taclonex ointment is required as opposed to available alternatives.
	
	Non-FDA-approved uses are NOT approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• tazarotene 0.05% cream (Tazorac)
• tazarotene 0.05% gel (Tazorac)
• tazarotene 0.1% gel (Tazorac)
 	
Psoriasis Agents
	Manual PA is required for all new and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel.
	
	<u>Manual PA Criteria:</u> Coverage approved if ALL criteria are met:
	• The provider acknowledges that tazarotene 0.1% cream is a cost effective alternative that does not require a PA.
	• The patient has a diagnosis of acne vulgaris or plaque psoriasis
	• For acne vulgaris:
	  • Patient is 12 years of age of older
	  • The patient must have tried and failed, have a contraindication to, or have had an adverse reaction to tazarotene 0.1% cream.
	• For scalp psoriasis
	  • Patient is 18 years of age of older
	  • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% solution, shampoo; fluocinonide 0.05% solution)
	• For plaque psoriasis in other body areas:
	  • Patient is 18 years of age of older
	  • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution)
	  AND
	  • The patient must have tried and failed or have had an adverse reaction to tazarotene 0.1% cream.
	
	Non-FDA-approved uses are NOT approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	

• bempedoic acid/ezetimibe (Nexlizet)
• bempedoic acid (Nexletol) *(updated from May 2020)*
 	
Antilipidemics-1
	Manual PA is required for all new users of Nexletol and Nexlizet.
	
	Manual PA Criteria: Nexletol or Nexlizet is approved if all criteria are met:
	• Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization)
	• Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following:
	  • History of clinical (ASCVD), including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA), peripheral artery disease (PAD) **OR**
	  • Heterozygous Familial Hypercholesterolemia (HeFH)
	• For Nexletol:
	  • Patient is taking concurrent ezetimibe and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR
	  • Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR
	• For Nexlizet:
	  • Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started, and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) OR
	• Patient is statin intolerant based on one of the following:
	  • Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, cramp) with at least 2 statins **OR**
	  • History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use **OR**
	  • History of statin-associated rhabdomyolysis **OR**
	• Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy)
	
	Non-FDA-approved uses other than use without concurrent statin not allowed.
	Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• capmatinib (Tabrecta) **Oncological Agents**	Manual PA is required for all new users of Tabrecta Manual PA Criteria: Tabrecta is approved if all criteria are met: • The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test. • Patient is 18 years of age of older • Must be prescribed by or in consultation with a hematologist/oncologist • Patient will be monitored for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity • Provider is aware and has counseled patient that capmatinib can cause photosensitivity and has counseled patients to avoid direct UV exposure • 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.
• diclofenac epolamine 1.3% patch (Licart) **Pain Agents: Pain Topical**	Manual PA is required for all new users of Licart. Manual PA Criteria: Licart is approved if all criteria are met: • Patient has acute pain due to minor strains, sprains, and/or contusions • Patient is 18 years of age or older • Patient cannot tolerate an oral NSAID due to renal insufficiency, history of gastrointestinal bleed, or other adverse events **OR** • Patient has tried and failed TWO oral NSAIDs Non-FDA-approved uses are not approved. PA expires after 6 months. Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.

Drug / Drug Class	Prior Authorization Criteria
• elagolix/estradiol/ norethindrone (Oriahnn) **Luteinizing Hormone-Releasing Hormone Agonists-Antagonists**	Manual PA is required for all new users of Oriahnn. Manual PA Criteria: Oriahnn is approved if all criteria are met: • Patient is 18 years of age of older • Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • 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 confirmed by (-) HCG • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 years • 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 (abnormal protrusion of the eye), diplopia (double vision), papilledema (optic disc swelling), 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 assess baseline and periodic bone mineral density • 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 Non-FDA-approved uses are not approved including pain associated with endometriosis. Prior authorization expires after 24 months (lifetime expiration).
• fenfluramine oral solution (Fintepla) **Anticonvulsants-Antimania Agents**	Manual PA is required for all new users of Fintepla. Manual PA Criteria: Fintepla is approved if all criteria are met. • Must be prescribed by a neurologist • Patient has a diagnosis of Dravet Syndrome • Must be used as adjunct therapy with other anticonvulsant medications • Prescriber must abide by and the patient has been informed of the REMS program including safety risks and requirements of regular echocardiogram (ECHO) monitoring for valvular heart disease and pulmonary hypertension Non-FDA-approved uses are not approved including for weight loss. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi) **Contraceptive Agents: Miscellaneous**	Manual PA applies to new users of Phexxi. Manual PA Criteria: Phexxi is approved if all criteria are met: • Provider acknowledges that numerous contraceptives are available without a PA and are more effective than Phexxi (e.g. norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, and medroxyprogesterone injection); providers are encouraged to consider changing the prescription to a formulary contraceptive. • Phexxi is being used for contraceptive purposes • Patient has tried a nonoxynol-9 spermicide and has experienced significant adverse effects Non-FDA approved uses are NOT approved PA does not expire
• lemborexant (Daywigo) **Sleep Disorders: Insomnia**	Manual PA criteria apply to all **new and current** users of Daywigo. <u>Manual PA Criteria</u>: Daywigo is approved if all criteria are met: • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release • Patient has tried and failed or had clinically significant adverse effects to eszopiclone • Patient has no current or previous history of narcolepsy • Patient has no current or previous history of drug abuse Non FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• levonorgestrel/ethinyl estradiol transdermal system (Twirla) **Contraceptive Agents: Miscellaneous**	Manual PA is required for all new users of Twirla. Manual PA Criteria: Twirla is approved if all criteria are met: • The provider acknowledges that norelgestromin/ethinyl estradiol transdermal system (Xulane) and numerous other contraceptives are available for TRICARE patients that do not require a PA. Providers are encouraged to consider changing the prescription to Xulane or another formulary contraceptive. • The patient has had an adverse reaction to Xulane that is not expected to occur with Twirla. OR • The patient has tried Xulane and could not tolerate it. • The patient does not have a contraindication to an estrogen-containing contraceptive (e.g., history of estrogen-dependent neoplasia, breast cancer, deep venous thrombosis (DVT)/ pulmonary embolism (PE), etc.) • The patient's body mass index (BMI) is less than 30 kg/m2; note that Twirla is contraindicated in patients with a BMI ≥ 30 kg/m2 • Provider acknowledges that patients with a BMI between 25 to 30 kg/m2 have decreased contraceptive effectiveness per the FDA label. Non-FDA-approved uses are not approved. Prior authorization does not expire.

• minocycline 1.5% topical foam (Zilxi)
 	
Acne Agents: Topical Acne and Rosacea
	All **new and current** users of **Zilxi** are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream), which is the current step therapy requirements for Soolantra and Mirvaso.
	
	Automated PA Criteria:
	• The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days.
	
	Manual PA Criteria: If automated PA criteria is not met, Zilxi is approved if all criteria are met:
	• Patient is 18 years of age of older and has the following diagnosis:
	  • For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea
	  • For Soolantra and **Zilxi**: Patient has inflammatory lesions (papulopustular) of rosacea AND
	• Patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) AND
	• Patient has tried and failed topical azelaic acid
	
	Non-FDA-approved uses are not approved.
	Prior authorization expires in 365 days.
	Renewal criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.

Drug / Drug Class	Prior Authorization Criteria
• osilodrostat (Isturisa) **Endocrine Agents Miscellaneous**	Manual PA is required for all new users of Isturisa. Manual PA Criteria: Isturisa is approved if all criteria are met: • Patient is 18 years of age of older • Documented diagnosis of Cushing's disease • Patient has persistent or recurrent Cushing's disease despite pituitary surgery **OR** • Patient in whom pituitary surgery is not indicated • Drug is prescribed by an Endocrinologist, Oncologist, or Neurosurgeon • Provider agrees to correct hypokalemia or hypomagnesemia prior to starting Isturisa • Provider agrees to obtain baseline electrocardiogram (ECG) prior to starting Isturisa and use with caution in patients with risk factors for QTc prolongation • Patient will be monitored closely for hypocortisolism and potentially life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary • Patient will be monitored for hypokalemia, worsening of hypertension, edema, and hirsutism Non-FDA-approved uses are not approved. Prior authorization does not expire.

• ozanimod (Zeposia)
 	
Multiple Sclerosis Agents
	Manual PA is required for all new users of Zeposia.
	
	Manual PA Criteria: Zeposia is approved if all criteria are met:
	• Prescribed by a neurologist
	• Patient has a documented diagnosis of relapsing forms of multiple sclerosis (MS)
	• 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], teriflunamide [Aubagio])
	• Patient has not previously failed a treatment course of fingolimod (Gilenya) and
	• Patient has not previously failed a treatment course of siponimod (Mayzent)
	• Provider acknowledges that all recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes complete blood count (CBC), liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), and macular edema screening as indicated.
	• Zeposia will not be used in patients with significant cardiac history, including:
	  • Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization
	  • Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• pemigatinib (Pemazyre) **Oncological Agents**	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. • 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.
• ripretinib (Qinlock) **Oncological Agents**	Manual PA is required for all new users of Qinlock. Manual PA Criteria: Qinlock is approved if all criteria are met: • Patient is 18 years of age of older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed advanced gastrointestinal stromal tumor (GIST) • Patient has experienced disease progression on or had documented intolerance to imatinib (Gleevec) • Patient has experienced disease progression on or had documented intolerance to sunitinib (Sutent) • Patient has experienced disease progression on or had documented intolerance to regorafenib (Stivarga) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the 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. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• selpercatinib (Retevmo)
 	
Oncological Agents
	Manual PA is required for all new users of Retevmo.
	
	<u>Manual PA Criteria:</u> Retevmo is approved if all criteria are met:
	• Prescribed by or in consultation with a hematologist/oncologist
	• Patient has one of the following indications:
	  • Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
	  • Patients 12 years and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
	  • Patients 12 years and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
	• Patient will be monitored for hepatotoxicity and QT prolongation
	• Patient does not have uncontrolled hypertension
	• Provider is aware and has counseled patient that selpercatinib can cause life-threatening hemorrhage and allergic reactions
	• Female patients of childbearing age are not pregnant confirmed by (-) HCG
	• Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment
	• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy
	• 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.

Drug / Drug Class	Prior Authorization Criteria
• selumetinib (Koselugo) **Oncological Agents**	Manual PA is required for all new users of Koselugo. Manual PA Criteria: Koselugo is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • Patient is diagnosed with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas • Patient will be monitored for cardiomyopathy including a left ventricular functional assessment prior to initiation and at regular intervals during treatment • Patient will be monitored for ocular toxicity including retinal vein occlusion and retinal detachment via ophthalmic exams prior to initiation and at regular intervals during treatment • Patient will be monitored for gastrointestinal toxicity and will receive co-administration of an anti-diarrheal if patient develops loose stools • Patient will be monitored for severe skin rashes • Patient will be monitored for rhabdomyolysis • Provider is aware that Koselugo contains Vitamin E, which can increase bleeding risk if co-administered with a Vitamin K antagonist (e.g., warfarin) • 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.
• tucatinib (Tukysa) **Oncological Agents**	Manual PA is required for all new users of Tukysa. Manual PA Criteria: Tukysa is approved if all criteria are met: • The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting. • Patient is 18 years of age or older • Medication is prescribed by or consultation with a hematologist or oncologist • Tucatinib will be used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda) • Provider agrees to monitor for hepatotoxicity • Patient has been counseled on risk of diarrhea • 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 the 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.

Drug / Drug Class	Prior Authorization Criteria
New PAs	
• tramadol 100 mg IR tab **Narcotic Analgesic and Combinations**	Manual PA criteria applies to all new **and current users** of tramadol 100mg IR. Manual PA Criteria: tramadol 100 mg IR is approved if all criteria are met: • Provider is aware and acknowledges that tramadol 50 mg IR is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred tramadol 50 mg immediate release tablets. • The provider must explain why the patient requires tramadol 100 mg IR tablets and cannot take the cost-effective tramadol 50 mg IR tablets. Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• prenatal multivitamin (Trinaz) **Vitamins: Prenatal**	Manual PA criteria applies to new **and current users** of **Trinaz**, regardless of the woman's age. Manual PA Criteria: Azesco, Zalvit, or **Trinaz** is approved if all criteria are met: • Provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, and Prenatal Plus DHA are the preferred products and are covered without a prior authorization for women who are under the age of 45 years and planning to become pregnant or who are pregnant. The provider is encouraged to consider changing the prescription to one of these agents. • The provider must explain why the patient requires Azesco, Zalvit or **Trinaz** and cannot take the available alternatives. Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• olodaterol (Striverdi Respimat) **Pulmonary-2 Agents: Long Acting Beta Agonists**	Manual PA criteria applies to all new users of Striverdi Respimat. Manual PA Criteria: Striverdi Respimat is approved if all criteria are met: • The patient has tried and failed salmeterol (Serevent Diskus) OR • The patient is unable to produce inspiratory flow necessary to use a dry powder inhaler Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• teduglutide (Gattex) **Gastrointestinal-2 Agents**	Manual PA criteria applies to all new users of Gattex. Manual PA Criteria: Gattex is approved if all criteria are met: • The patient is at least1 year of age or older • Gattex is prescribed by or in consultation with a gastroenterologist • Patient has a documented diagnosis of Short Bowel Syndrome • The patient is currently receiving parenteral nutrition on 3 or more days per week Non-FDA-approved uses are NOT approved including patients not receiving parenteral nutrition. PA expires after 6 months. Renewal PA criteria: expires in one year. Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND • Documented improvement (a decrease from baseline) in the weekly volume of parenteral nutrition or a reduction in the number of days requiring parenteral support
Updated PAs	
• flibanserin (Addyi) **Gynecological Agents Miscellaneous**	**Changes from the August 2020 meeting are BOLD and strikethrough.** Manual PA criteria applies to all new users of Addyi. Manual PA Criteria: Addyi is approved if all criteria are met: • **Patient is 18 years of age or older** • The drug is prescribed for a premenopausal female with hypoactive sexual desire disorder (HSDD) not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance • **Patient has been counseled to wait 2 hours after consuming 1 or 2 standard alcoholic drinks before taking Addyi at bedtime or to skip their Addyi dose if they have consumed 3 or more standard alcoholic drinks that evening. After taking Addyi, the patient should not use alcohol until the following day** • Patient does not have hepatic impairment (Child-Pugh score > 6) • Patient not on a concomitant moderate or strong CYP3A4 inhibitor (e.g. ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil) • ~~Prescription written from provider who is certified/enrolled in the flibanserin REMS program~~ • **The patient has been informed that other treatment options such as cognitive-behavior therapy, sexual therapy, or couples therapy, may provide benefit without risk of side effects** Non-FDA-approved uses are NOT approved. PA expires after 3 months. Renewal PA criteria: will be approved indefinitely. Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND • Patient has documented improvement in symptoms without serious side effects ~~and continues to abstain from alcohol~~

Drug / Drug Class	Prior Authorization Criteria
• isotretinoin (Absorica, Absorica LD) **Acne Agents: Isotretinoids**	**Changes from the August 2020 meeting are BOLD.** Manual PA criteria applies to all new **and current users** of Absorica and Absorica LD. Manual PA Criteria: Absorica and Absorica LD are approved if all criteria are met: • **The provider acknowledges that generic isotretinoin products (Amnesteem, Claravis, Myorisan) are available without a PA. Providers are encouraged to consider changing the prescription to one of these agents** • **Patient has tried and failed at least one of the following oral isotretinoin products: Amnesteem, Claravis, or Myorisan, AND** • Patient is unable to comply with the dietary requirements of an AB-rated generic oral isotretinoin (e.g, Amnesteem, Claravis or Myorisan) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• minocycline ER (Solodyn, generics) **Antibiotics: Tetracyclines**	**Changes from the August 2020 meeting are BOLD and strikethrough.** **The previous automation requirements for generic minocycline ER and brand Solodyn will no longer apply, and will be replaced with the manual PA criteria described below. The previous renewal criteria will no longer apply.** Manual PA criteria applies to all new **and current users** of generic minocycline ER and brand Solodyn. ~~**Automated PA Criteria:**~~ • ~~**The patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) AND one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180**~~ Manual PA Criteria: Solodyn is approved if all criteria are met: • **Provider acknowledges that minocycline immediate release (IR) is available to DoD beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to minocycline IR.** • Patient has acne with inflammatory lesions AND • ~~Patient is unable to tolerate generic minocycline IR due to gastrointestinal adverse events~~ • **The provider must describe why the patient requires minocycline extended release and cannot be treated with minocycline immediate release.** Non-FDA-approved uses are NOT approved. **Prior authorization does not expire.** ~~PA expires after 12 months. Renewal PA criteria: expires after 12 months.~~ ~~Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND~~ • ~~Patient's therapy has been re-evaluated within the last 12 months~~ • ~~Patient is tolerating treatment and there continues to be a medical need for the medication~~ • ~~Patient has disease stabilization or improvement in disease while on therapy~~

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• pitolisant (Wakix) • solriamfetol (Sunosi) **Sleep Disorders: Wakefulness Promoting Agents**	▪ Retail/MTF/Mail: 30 day supply at all POS Note that the QL for Sunosi was updated; no changes to the existing QL for Wakix.
• pegfilgrastims (Fulphila, Neulasta, Neulasta OnPro, Udenyca, Ziextenzo) **WBC Stimulants**	▪ Existing QLs for the pegfilgrastims will be removed the first Wednesday 60 days after signing of the minutes.
• lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi) **Contraceptive Agents: Miscellaneous**	▪ Retail/MTF/Mail: 12 applicators (1 box)/30 days at all POS Note that Phexxi is packaged as a box of 12 applicators per box
• diclofenac epolamine 1.3% patch (Licart) **Pain Agents: Pain Topical**	▪ Retail/MTF/Mail: 30 patches/30 days at all POS
• osilodrostat (Isturisa) **Endocrine Agents Miscellaneous**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• pemigatinib (Pemazyre) **Oncological Agents**	▪ Retail: 42 day supply ▪ MTF/Mail: 63 day supply Note that Pemazyre is packaged as 14 tabs for a 21 day supply
• tramadol 100 mg IR tablets **Narcotic Analgesics and Combinations**	▪ Retail: 120 tabs/30 days ▪ MTF/Mail: 360 tabs/90 days
• capmatinib (Tabrecta) • ripretinib (Qinlock) • rucaparib (Rubraca) • selumetinib (Koselugo) • tucatinib (Tukysa) **Oncological Agents**	▪ Retail/MTF/Mail: 30 day supply at all POS
• selpercatinib (Retevmo) **Oncological Agents**	▪ Retail: 30 day supply MTF/Mail: 60 day supply
• mometasone furoate (Asmanex HFA) **Pulmonary-1 Agents: Inhaled Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
apomorphine sublingual film (Kynmobi)	Parkinson's Agents	• apomorphine SQ (Apokyn) • levodopa inhaled (Inbrija)	For the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease	• Kynmobi is the 1st sublingual (SL) apomorphine for acutely treating "off" episodes in Parkinson's patients • It is the 3rd as needed treatment of acute "off" episodes • Kynmobi showed superiority over placebo on the Movement Disorder Society-Unified Parkinson's Disease Rating Scale, Part III showing improvement in motor dysfunction typical in patients experiencing "off" episodes • Kynmobi vs Apokyn ▪ Advantages – SL film rather than SQ Injection; easier to administer vs injection; no injection site reactions ▪ Neutral – still requires anti-nausea medication (e.g., trimethobenzamide), and has several adverse events (AEs), in particular hypotension ▪ Disadvantages – significant oropharyngeal adverse events • Kynmobi vs Inbrija ▪ Advantages – SL film is easier to administer than an inhaled powder, which is an advantage in asthma and COPD; and has a faster onset of action. An indirect comparison showed improved efficacy compared to Inbrija ▪ Disadvantages – oral AEs lead to high discontinuation rate; still requires anti-nausea medication (e.g., trimethobenzamide), and has several AEs, in particular hypotension • Kynmobi is another dosage form of apomorphine that will be useful for Parkinson's patients experiencing "off" episodes, with the convenience of an easily administered SL film.	• UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
bempedoic acid/ezetimibe (Nexlizet)	Antilipidemics-1	• simvastatin • atorvastatin • rosuvastatin • ezetimibe • alirocumab (Praluent) • evolocumab (Repatha)	Tx of established atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH), as an adjunct to diet and maximally tolerated statin therapy in patients who require additional LDL lowering	• Antilipidemic with a new mechanism of action: adenosine triphosphate-citrate lyase (ACL) inhibitor • Bempedoic acid alone reduces low density lipoprotein (LDL) an additional 18%-20% when added onto statins • In patients taking statins, bempedoic acid plus ezetimibe reduced LDL levels by about 36% • Minimal impact on triglycerides (TG) or high-density lipoprotein (HDL) • Single ingredient bempedoic acid (Nexletol) evaluated at May 2020 meeting and designated NF • Long-term adverse event profile unknown • Potential place in therapy as an add-on option if patient has had an inadequate response to statin plus ezetimibe and an oral med is preferred over injectable PCSK-9 • Should not replace statins as first-line therapy • Limited place in therapy due to lack of CV outcomes studies; CLEAR OUTCOMES results not expected until 2022	• NF and non-step-preferred • Add to EMMI list
capmatinib (Tabrecta)	Oncological agents: Lung Cancer	• Crizotinib (Xalkori)	Adults with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test	• Tabrecta is the preferred agent for patients with NSCLC with a MET exon 14 skipping mutation per the NCCN guidelines • Tabrecta is the first drug FDA-approved for the treatment of patients with NSCLC and a mutation that leads to MET exon 14 skipping. • FDA-approval and recommendations based on limited available data; no published clinical data. • Available data shows Tabrecta has more favorable response rates in treatment-naïve patients compared with those in previously treated patients. • Serious adverse events occurred in 50% of the patients treated with Tabrecta. • MET exon 14 skipping mutations occur in 3% to 4% of patients with adenocarcinoma and the approval of Tabrecta fulfills an unmet need for treatment of patients with these tumors.	• UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
diclofenac epolamine 1.3% patch (Licart)	Pain agents: Pain topical	• diclofenac 1% gel (Voltaren, generics) • diclofenac 1.3% patch (Flector, generics)	For the topical treatment of acute pain due to minor strains, sprains, and contusions	• Licart is the 2nd FDA approved diclofenac 1.3% patch • Licart is only FDA approved for acute pain of minor strains, sprains, and contusions; it is not approved for arthritis pain • Licart was superior to placebo in clinical trials on the pain visual analog scale at 3 days, the onset of action is unknown, and the comparison to Flector patch did not have valid conclusions due to incorrect administration • Flector is dosed twice daily while Licart is dosed once daily • Licart offers little to no clinical benefit relative to existing formulary agents	• NF • Do not add to EMMI list
elagolix/estradiol/norethindrone (Oriahnn)	Luteinizing hormone-releasing hormone agonists-antagonists	• Lupron Depot IM (leuprolide)	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	• Oriahnn is an oral gonadotropin-releasing hormone (GnRH) antagonist approved for the treatment of heavy menstrual bleeding associated with uterine fibroids • Oriahnn was evaluated in two phase III studies and was effective at decreasing heavy menstrual bleeding in more women than placebo • Oriahnn treatment is limited to 24 months due to bone mineral density loss • Oriahnn is contraindicated in patients with a high risk of arterial, venous thrombotic, or thromboembolic disorders, pregnancy, osteoporosis, current or history of breast cancer or other hormonally-sensitive malignancies, known liver impairment or disease, undiagnosed abnormal uterine bleeding, or known hypersensitivity to ingredients of Oriahnn including FD&C Yellow #5 • Oriahnn is the first agent approved for treatment of heavy menstrual bleeding associated with uterine fibroids for longer than three months; however, other surgical and medical options exist and it is associated with a significant adverse event profile	• UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
fenfluramine oral soln (Fintepla)	Anticonvulsant/ Antimanic	• cannabidiol oral soln (Epidiolex) • clobazam (Onfi) • stiripentol (Diacomit)	Dravet Syndrome	• Fintepla is another formulation of fenfluramine and is now approved as an antiepileptic drug to treat Dravet Syndrome in patients ≥ 2 years • Fenfluramine was previously used as a weight loss agent and was removed from the US market in 1997 due to valvular heart disease and pulmonary hypertension risks. There is now a REMS program requiring regular echocardiogram (ECHO) monitoring • Efficacy is based on limited data but Fintepla is more effective than placebo as adjunct therapy with other anticonvulsants • Limitations include that no head-to-head studies with other agents are available, and treatment guidelines have not yet been updated to reflect its place in therapy • Fintepla is another agent that can be used as adjunct therapy for patients with Dravet Syndrome	• UF • Do not add to EMMI list
halcinonide 0.1% topical solution (Halog)	Corticosteroids-immune modulators: High potency	• betamethasone/ propylene glycol 0.05% cream • clobetasol propionate 0.05% cream/oint • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream/oint • fluocinonide 0.05% cream/oint • fluocinonide/ emollient base 0.05% cream • halobetasol propionate 0.05% oint	Steroid-responsive dermatoses	• Halog topical solution was originally FDA-approved in 1977 • Ownership changed several times however the last label update was in 2004 • Class review of High-Potency Topical Corticosteroids was in August 2019; halcinonide 0.1% ointment and cream (Halog) made Tier 4 • Numerous alternatives identified • No new data • Same manufacturer as Halog cream and ointment (Sun), which are Tier 4 • Provides no additional benefit relative to the other high-potency topical corticosteroids	• Tier 4 (not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
insulin lispro-aabc (Lyumjev)	Insulins: Rapid-acting agents	• Insulin lispro (Admelog, Humalog, authorized generic insulin lispro) • Insulin aspart (Novolog, Fiasp)	Rapid-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus	• Lyumjev is a new formulation of insulin lispro that that may be injected at the start of a meal or up to 20 minutes after the start • Approved by the BLA 351(a) pathway • Evaluated in 2 non-inferiority, active comparator studies with Humalog (PRONTO-T1D and PRONTO-T2D) – Lyumjev was non-inferior to Humalog in both studies at reducing A1c as both a mealtime and post-meal agent – Lyumjev was statistically but not clinically significant compared to Humalog in post-prandial glucose reduction at 1-hour and 2-hours post-meal • Similar adverse effect profile to Humalog • No compelling advantage over existing formulary agents	• UF • Add to EMMI list
lactic acid/ citric acid/ potassium bitartrate vaginal gel (Phexxi)	Contraceptive agents: Miscellaneous	• nonoxynol-9 spermicide	For prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception; limitation: not effective when administered after intercourse	• Phexxi is a non-hormonal, on-demand contraceptive inserted vaginally prior to intercourse • Less effective at preventing pregnancy than any other formulary contraceptive with a Pearl Index of 27.5 pregnancies/100 women-years of use (Pearl Index of less than 5 associated with oral combined hormonal contraceptives) • > 20% of women using Phexxi and ~10% of male partners had local adverse reactions, but < 2% discontinued due to adverse reactions • Can be used concomitantly with other vaginal medications and other methods of contraception including OCPs and condoms • Nonoxynol-9 based spermicides have similar efficacy and side effects and are available OTC in a variety of formulations • At this time, Phexxi has no compelling clinical advantages over existing formulary and OTC contraceptive agents	• NF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lemborexant (Dayvigo)	Sleep disorders: Insomnia	• suvorexant (Belsomra) • zolpidem ER • eszopiclone	Insomnia characterized by difficulties with sleep onset and/or maintenance	• Lemborexant is the 2nd FDA-approved orexin receptor antagonist indicated for insomnia associated with sleep onset and maintenance • Evaluated in 2 placebo-controlled studies with zolpidem ER as an active comparator in one study ▪ Lemborexant was statistically significant in all measures providing an additional 5-14 minute difference in sleep onset from placebo and an additional 13-28 min difference from placebo in sleep maintenance ▪ The 10 mg strength conferred no additional efficacy but had more adverse effects ▪ No clinically significant differences in any efficacy measure in an indirect comparison to suvorexant or zolpidem ER • The most common adverse effect is somnolence; patients taking 10 mg should be cautioned against driving the next day due to daytime somnolence • Similar to other agents in the class and suvorexant, lemborexant is a controlled medication, has several drug interactions, and has the same extensive warnings regarding sleep-related behaviors • Lemborexant is contraindicated in patients with narcolepsy; same as suvorexant • Patients should only take Dayvigo if they can stay in bed for a full night (at least 7 hours) before being active again and food may delay the effect of Dayvigo • Lemborexant provides another treatment option for insomnia but has no compelling advantages over suvorexant or older "z" drugs	• UF and non-step-preferred • Add to EMMI list
leuprolide acetate injection (Fensolvi)	Luteinizing hormone-releasing hormone (LHRH) agonists-antagonists	• leuprolide acetate IM (Lupron Depot-Ped) • histrelin implant (Supprelin LA) – not a pharmacy benefit • triptorelin IM (Triptodur) – not a pharmacy benefit	Treatment of pediatric patients ≥ 2 years of age with central precocious puberty	• Another formulation of leuprolide acetate supplied in a kit for subcutaneous (SQ) injection however it must be administered by a healthcare professional • Only SQ formulation indicated for treatment of pediatric patients ≥ 2 years with central precocious puberty (CPP) • Other than patient convenience in the administration route and the duration of action (long-acting formulation), provides no additional compelling advantages compared to other available agents	• NF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
levonorgestrel/ ethinyl estradiol transdermal system (Twirla)	Contraceptive Agents: Miscellaneous	• norelgestromin/ ethinyl estradiol (EE) transdermal system (Xulane)	Contraception in women of reproductive potential with a BMI < 30 kg/m2 for whom a combined hormonal contraceptive is appropriate; Limitations: decreased effectiveness in women with a BMI ≥ 25 to < 30 kg/m^2	• Twirla is the second available contraceptive patch in the US • Contains less estrogen than Xulane, the other contraceptive patch (30 mcg/day vs. 35 mcg/day) • Decreased effectiveness in women with a BMI ≥ 25 kg/m^2 and contraindicated in women with a BMI ≥ 30 kg/m^2 • Indirectly compared to Xulane, Twirla has a higher Pearl Index and a higher rate of venous thromboembolism (VTEs) • Support for FDA approval was not unanimous • Post-marketing trials are required to assess thrombotic risk and residual drug content in the patch • Twirla is less effective and less safe than other available contraceptive agents	• NF • Do not add to EMMI list
minocycline 1.5% topical foam (Zilxi)	Acne agents: Topical acne and rosacea	• minocycline 50 mg capsule • minocycline 4% foam (Amzeeq) • metronidazole 1% gel (MetroGel) • azelaic acid 15% foam (Finacea) • brimonidine tartrate 0.33% gel (Mirvaso) • ivermectin 1% cream (Soolantra)	For the treatment of inflammatory lesions of rosacea in adults	• Zilxi is the 2nd FDA-approved topical minocycline and 1st with an indication for rosacea • It has not yet been incorporated into rosacea treatment guidelines • Only compared to vehicle in pivotal clinical trials • Zilxi was well-tolerated; warnings and precautions are identical to that of oral minocycline except flammability • Storage requirements represent a disadvantage compared to other available topical rosacea treatments • There are many other available topical and oral rosacea medications that can be used first-line that do not have flammability concerns and storage constraints	• NF and non-step-preferred • Add to EMMI list
nimodipine oral syringe (Nymalize)	Calcium Channel Blocker	• nimodipine oral dosing cups (Nymalize) • nimodipine liquid-filled capsule (Nimotop) – discontinued	subarachnoid hemorrhage (SAH)	• nimodipine (Nimotop) liquid-filled capsules were first approved for subarachnoid hemorrhage (SAH) in 1988 • Nimotop was withdrawn from the market due to frequent administration and dosing errors • nimodipine oral solution (Nymalize) was approved in 2013 in unit-dose oral dosing cups, then a multi-dose bottle of the oral syrup; 6 mg/mL and 3 mg/mL (discontinued) • nimodipine oral syringe (Nymalize) is a new formulation of nimodipine available in 60 mg/20 mL or 30 mg/10 mL prefilled oral syringes that decrease the risk of dosing/administration errors	• UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
octreotide acetate injection (Bynfezia Pen)	Endocrine agents miscellaneous	• octreotide (Sandostatin, generics) • octreotide (Sandostatin LAR Depot) Kit – not a pharmacybenefit	• Acromegaly • Carcinoid tumors • Vasoactive intestinal peptide secreting tumors (VIPomas) in adults	• Bynfezia Pen is a new immediate-release formulation of octreotide acetate in a prefilled syringe • No new data • Other than providing patient convenience in a pre-filled multi-dose syringe, Bynfezia Pen provides no compelling advantage over existing formulary agents	• UF • Add to EMMI list
osilodrostat (Isturisa)	Endocrine agents miscellaneous	• Signifor/Signifor LAR • Korlym • Ketoconazole • Metyrapone • Mitotane	Treatment of adult patients with Cushing's disease for whom pituitary surgeryis not an option or has not been curative	• Isturisa is the 1st drug FDA-approved to prevent cortisol synthesis in patients with Cushing's disease (CD) for whom pituitary surgeryis not an option or has not been curative • A single, multi-center, double-blind, randomized withdrawal study following a 24-week, single arm, open-label dose titration period demonstrated that treatment with osilodrostat in patients with non-surgical or recurrent CD is effective in reducing mean 24-hour urinary free cortisol levels from baseline • Osilodrostat is effective in approximately 52% of all treatment-naïve patients and the response can be maintained in ~ 80% of patients who responded to and tolerated the drug after 6 months of treatment • Patients must be monitored for hypocortisolism and potentially life-threatening adrenal insufficiency, QTc prolongation, and hypokalemia, worsening of hypertension, edema, and hirsutism • Limitations: data are not fully-published and no head-to-head trials with other agents are available • Osilodrostat adds to the armamentarium in treating patients with Cushing's disease	• UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
ozanimod (Zeposia)	Multiple Sclerosis Agents	• fingolimod (Gilenya) • siponimod (Mayzent)	• Relapsing Remitting multiple sclerosis (RMS) • Clinically isolated syndrome (CIS) • Secondary progressive MS (SPMS)	• Zeposia is the 3rd sphingosine 1-phosphate receptor modulator approved for MS • Study data shows improvements over interferon beta-1a in annualized relapse rates, and MRI lesions • Zeposia is not significantly different compared to interferon beta-1a in disease progression • Advantages: Zeposia is similar in efficacy to the other S1P modulators. The safety profile of Zeposia appears largely similar to that of the S1P modulator Gilenya, with the exceptions of milder, but not absent, cardiac effects. Zeposia does not require 1st dose monitoring • Disadvantage: Like Mayzent, Zeposia requires titration to target dosing • Overall, Zeposia adds an additional option for treating MS, but has no compelling advantages over the other sphingosine 1-phosphate receptor modulators, other than a slightly reduced risk of cardiac adverse events	• UF • Add to EMMI list • Note following the meeting, available information shows that Zeposia can't be available at mail
pemigatinib (Pemazyre)	Oncological Agents	• none	Adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test	• Pemazyre is the only non-chemotherapeutic option for cholangiocarcinoma with a FGFR alteration • Data support the therapeutic potential of pemigatinib in previously treated patients with cholangiocarcinoma who have FGFR2 fusions or rearrangements	• UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
ripretinib (Qinlock)	Oncological Agents	• imatinib (generics) • sunitinib (Sutent) • regorafenib (Stivarga) • avapritinib (Ayvakit)	For advanced GI stromal tumors (GIST) with disease progression after tx w/ ≥3 kinase inhibitors	• Ripretinib is a tyrosine kinase inhibitor (TKI) FDA-approved for 4th line therapy of unresectable or metastatic GIST, evaluated in one phase 3 study for FDA approval • The primary endpoint of progression-free survival (PFS) resulted in a statistically-significant median PFS of 6.3 months v. 1 month for placebo • The secondary endpoints included overall response rate (ORR) and overall survival (OS); ORR was not statistically significant and OS was statistically significant • Most common AEs include alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodyesthesia (PPES), and vomiting • Utility in practice: 4th line option for unresectable or metastatic GIST	• UF • Do not add to EMMI list
selpercatinib (Retevmo)	Oncological Agents: Lung Cancer	• cabozantinib (various, generics) • vandetanib (Caprelsa)	Adults with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) 12+ years with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy 12+ years with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory	• Retevmo is indicated for RET-(+) NSCLC and MTC • Retevmo is the preferred agent for RET-(+) NSCLC	• UF • Add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
selumetinib (Koselugo)	Oncological Agents	• none	Pediatric patients ≥ 2 years with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)	• Koselugo is the only FDA-approved medication for the treatment of plexiform neurofibromas in pediatric patients with NF1 • No other drugs are recommended for the treatment of plexiform neurofibromas in the medical literature • Efficacy established with pivotal Phase 2 trial; efficacy durable • Adverse events common but discontinuation rate low • Koselugo has a unique place in the treatment of pediatric patients with NF1 and plexiform neurofibromas	• UF • Do not add to EMMI list
tazarotene 0.045% lotion (Arazlo)	Acne agents: Topical acne & rosacea	• tazarotene 0.1% foam (Fabior) • tazarotene 0.05% and 0.1% cream (Tazorac, generics to cream only) • tazarotene 0.05% and 0.1% gel (Tazorac)	For the topical treatment of acne vulgaris in patients ≥ 9 years of age	• Arazlo is FDA-approved for the treatment of acne in patients ≥ 9 years old • It is the only single-agent tazarotene lotion; however, tazarotene is also available as a cream, gel, and foam • Available at a slightly lower dose than other single-agent tazarotene products (0.045% vs. 0.05%), although difference is unlikely to be clinically significant • Similar to other tazarotene products in that it has the same dosing schedule, drug interactions, and contraindication in pregnancy • Phase 3 clinical trials only compared Arazlo to vehicle so there is no evidence of superiority to any other topical acne product • Several other topical retinoids are available on the uniform formulary in a variety of formulations and strengths including numerous tretinoin and adapalene products • Offers little to no clinical advantage over other topical retinoids	• Tier 4 (not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tucatinib (Tukysa)	Oncological agents: Breast cancer	• trastuzumab (various brands; generic) • pertuzumab (Perjeta) • lapatinib (Tykerb)	In combination with trastuzumab and capecitabine for adults with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting	• Tukysa is the 3rd available tyrosine kinase inhibitor (TKI) available for advanced HER2-(+) breast cancer refractory to 1st line treatment • Tukysa improves survival, including survival in patients with brain metastatic disease • Adverse events are common but serious adverse events are less so. • Tukysa is an additional treatment option for patients with advanced disease	• UF • Do not add to EMMI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 during the August 2020 DoD P&T Committee Meeting

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)
August 2020	**Sleep Disorders: Wakefulness Promoting Agents Designated NF** *No reason to exempt from EMMPI requirement* • maintain solriamfetol (Sunosi) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Similar agents are already on list* ▪ insulin lispro-aabc (Lyumjev) – assuming availability at mail order ▪ octreotide acetate injection (Bynfezia Pen) ▪ ozanimod (Zeposia)- note that following the meeting, available information shows that Zeposia can't be dispensed from mail, therefore it won't be added to the EMMPI list. *No reason for exception:* ▪ lemborexant (Dayvigo) ▪ selpercatinib (Retevmo) **Designated NF:** *No reason to exempt from EMMPI requirement and similar agents are already on list:* ▪ bempedoic acid/ezetimibe (Nexlizet) ▪ minocycline 1.5% topical foam (Zilxi) **Line Extensions** *Similar agents are already on list:* ▪ empagliflozin-linagliptin-metformin XR (Trijardy XR) ▪ tofacitinib XR 22 mg (Xeljanz XR)	**Sleep Disorders: Wakefulness Promoting Agents UF (brand maintenance only)** *Maintain current status as not yet clear if feasible to provide through mail order:* • maintain sodium oxybate (Xyrem) **Sleep Disorders: Wakefulness Promoting Agents Designated NF** *Maintain current status as not yet clear if feasible to provide through mail order:* • maintain pitolisant (Wakix) **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims Designated BCF or UF** *Drugs for limited duration use/not maintenance medications:* • remove filgrastim (Neupogen), tbo-filgrastim syringe (Granix), pegfilgrastim (Neulasta, Neulasta OnPro), and pegfilgrastim-cbqv (Udenyca) • do not add tbo-filgrastim vial (Granix), filgrastim-sndz (Zarxio), filgrastim-aafi (Nivestym), pegfilgrastim-jmdb (Fulphila), and pegfilgrastim-bmez (Ziextenzo) **Psoriasis Agents: Designated NF** *Drugs for acute or limited duration use:* • none of the Psoriasis agents added to the EMMPI program **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Comparable pricing at mail order vs MTFs or retail:* ▪ apomorphine sublingual film (Kynmobi) ▪ capmatinib (Tabrecta) ▪ elagolix/estradiol/norethindrone (Oriahnn) *Drugs for acute or limited duration use:* ▪ nimodipine oral syringe (Nymalize)

		Not yet clear if feasible to provide through mail order: ▪ fenfluramine (Fintepla) ▪ osilodrostat (Isturisa) ▪ pemigatinib (Pemazyre) ▪ ripretinib (Qinlock) ▪ selumetinib (Koselugo) ▪ tucatinib (Tukysa) **Designated NF:** *Drugs for acute or limited duration use:* ▪ diclofenac epolamine 1.3% patch (Licart) *Not yet clear if feasible to provide through mail order:* ▪ leuprolide acetate injection (Fensolvi) *(limited distribution)* *Contraceptive exception/existing exclusion applies*: ▪ levonorgestrel/ethinyl estradiol (Twirla) ▪ lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi)

Appendix G—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2020	**Sleep Disorders: Wakefulness Promoting Agents Subclass**	UF Class Review Class last reviewed February 2012	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ None			Pending signing of the minutes / one week The effective date is November 4, 2020	▪ Updated manual PA criteria were added for new users of Sunosi and Wakix. ▪ Maintained existing Manual PA criteria for Xyrem.	See Appendices B and C for MN and PA criteria.
			▪ None	▪ modafinil ▪ armodafinil ▪ sodium oxybate (Xyrem)	▪ solriamfetol (Sunosi) ▪ pitolisant (Wakix)			

TRICARE Formulary Search tool: https://www.express-scripts.com/frontend/open-enrollment/tricare/fst#/home

<table>
<tr><th>Date</th><th>DoD PEC Drug Class</th><th>Type of Action</th><th>BCF/ECF Medications

MTFs must have BCF meds on formulary</th><th>UF Medications

MTFs may have on formulary</th><th>Nonformulary Medications

MTFs may not have on formulary</th><th>Decision Date / Implement Date</th><th>PA and QL Issues</th><th>Comments</th></tr>
<tr><td rowspan="2">Aug 2020</td><td rowspan="2">WBC Stimulants: Filgrastim Subclass and Pegfilgrastim Subclass</td><td rowspan="2">UF Class Review

Class not previously reviewed</td><td colspan="3">Tier 4/Not Covered Medications

MTFs <u>must not</u> have on formulary

Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies

▪ None</td><td rowspan="2">Pending signing of the minutes / 60 days

The effective date is December 30, 2020</td><td rowspan="2">PA applies to non-step-preferred agents

The UF step-preferred agents do not have a PA

No QLs for these agents</td><td rowspan="2">This is the first biosimilar review

See Appendix C for PA criteria.</td></tr>
<tr><td><u>BCF step-preferred</u>

filgrastims
▪ tbo-filgrastim (Granix)

pegfilgrastims
▪ pegfilgrastim-cbqv (Udenyca)</td><td><u>UF step-preferred</u>

filgrastims
▪ filgrastim-aafi (Nivestym)

pegfilgrastims
▪ pegfilgrastim-jmdb (Fulphila)

<u>UF non-step-preferred</u>

filgrastims
• filgrastim (Neupogen)
• filgrastim-sndz (Zarxio)

pegfilgrastims
• pegfilgrastim (Neulasta)
• pegfilgrastim (Neulasta OnPro)
• pegfilgrastim-bmez (Ziextenzo)</td><td>▪ None</td></tr>
</table>

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2020	**Psoriasis Agents**	UF Class Review	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex)			Pending signing of the minutes / 120 days The effective date is February 24, 2021	▪	▪ Manual PA criteria applies to all users of the NF drugs, except for Vectical ▪ See Appendices B and C for MN and PA Criteria. ▪ One Tier 4 product
			▪ calcipotriene 0.005% cream (Dovenex, generics)	▪ calcipotriene 0.005% ointment (Calcitrene, generics) ▪ calcipotriene 0.005% solution (generics) ▪ tazarotene 0.1% cream (Tazorac, generics)	▪ calcipotriene 0.005% foam (Sorilux) ▪ calcitriol 3 mcg/g ointment (Vectical, generics) ▪ calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex) ▪ calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) ▪ tazarotene 0.1% gel (Tazorac) ▪ tazarotene 0.05% cream (Tazorac) ▪ tazarotene 0.05% gel (Tazorac)			

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	• calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic)	*Scalp Psoriasis:* • calcipotriene 0.005% solution • clobetasol 0.05% solution, shampoo • fluocinonide 0.05% solution • calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] *Psoriasis involving areas other than the scalp:* • calcipotriene 0.005% ointment, cream, solution • clobetasol 0.05% ointment, cream • fluocinonide 0.05% cream, ointment	• 120 days after signing • February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	• halcinonide 0.1% topical solution (Halog)	• betamethasone propylene glycol 0.05% cream • clobetasol propionate 0.05% cream and ointment • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream and ointment • fluocinonide 0.05% cream and ointment • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% ointment	• 120 days after signing • February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	• tazarotene 0.045% lotion (Arazlo)	• adapalene 0.1% lotion, gel, cream • adapalene 0.3% gel • clindamycin phosphate 1% gel, cream, lotion, and solution • clindamycin/ benzoyl peroxide 1.2% - 5% gel • tazarotene 0.1% cream • tretinoin 0.025%, 0.05%, and 0.1% cream • tretinoin 0.01% and 0.025% gel	• 120 days after signing • February 24, 2021
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			
Feb 2020	Pain Agents Class; NSAIDs Subclass	• amlodipine/celecoxib (Consensi)	• Dihydropyridine calcium channel blockers: amlodipine, felodipine, nifedipine, isradipine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs)	• August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2020	Pain Agents Class; NSAIDs Subclass	• diclofenac potassium liquid-filled capsules (Zipsor) • diclofenac submicronized (Zorvolex) • fenoprofen capsules • indomethacin submicronized (Tivorbex) • meloxicam submicronized (Vivlodex)	• celecoxib • diclofenac • ibuprofen • meloxicam • naproxen • Also includes other NSAIDs	• August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	• ibuprofen and famotidine tablets (Duexis)	• H2 blockers: famotidine, ranitidine, cimetidine, nizatidine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs)	• August 26, 2020
Feb 2020	Pain Agents – Combinations	• naproxen / esomeprazole (Vimovo)	• PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs)	• Aug 28, 2019 • Note that Vimovo reaffirmed as Tier 4 at the February 2020 NSAID subclass review
Feb 2020	Pain Agents Class; Pain Topical Subclass	• diclofenac 1.3% patch (Flector) • diclofenac 2% solution (Pennsaid)	• oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) • diclofenac 1.5% solution • diclofenac 1% gel	• August 26, 2020
Feb 2020	Pain Agents Class; Pain Topical Subclass	• lidocaine 1.8% patch (ZTlido)	• lidocaine 5% patch	• August 26, 2020
Feb 2020	Acne Agents: Topical Acne and Rosacea	• benzoyl peroxide 9.8% foam (Enzoclear)	• clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) • clindamycin/benzoyl peroxide 1% - 5% gel (Benzaclin, generics) • clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit)	• August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2020	Anti-Infectives: Miscellaneous	• omeprazole magnesium, amoxicillin and rifabutin (Talicia)	• omeprazole PLUS amoxicillin PLUS rifabutin (given separately) • omeprazole PLUS clarithromycin PLUS amoxicillin • bismuth subsalicylate OTC PLUS metronidazole PLUS tetracycline PLUS PPI	• August 26, 2020
Feb 2020	Pulmonary-1: Short Acting Beta2 Agonists (SABA)	• albuterol dry powder inhaler (ProAir Digihaler)	• albuterol MDI (ProAir HFA) • albuterol DPI (ProAir Respiclick) • albuterol MDI (Proventil HFA) [Nonformulary] • albuterol MDI (Ventolin HFA) [Nonformulary] • levalbuterol MDI (Xopenex HFA) [Nonformulary]	• August 26, 2020
Nov 2019	PDE-5 inhibitor	• avanafil tablet (Stendra) • brand Viagra tablet • brand Cialis tablet • vardenafil tablet (Levitra and generics) • vardenafil oral disintegrating tablet (ODT) (Staxyn and generics)	• sildenafil tablet (generic Viagra only) • tadalafil tablet (generic Cialis only)	• June 3, 2020
Nov 2019	Rapid Acting Insulins	• insulin plus niacinamide (Fiasp)	• insulin aspart (Novolog) • insulin lispro (Humalog or authorized generic lispro) • insulin lispro (Admelog) [nonformulary] • insulin glulisine (Apidra) [nonformulary]	• July 1, 2020
Nov 2019	Pulmonary-2 Agents: COPD	• formoterol/aclidinium (Duaklir Pressair)	• umeclidinium/vilanterol (Anoro Ellipta) • tiotropium/olodaterol (Stiolto Respimat) • ~~glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary]~~ *(discontinued from market March 2020)* • glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary]	• June 3, 2020
Nov 2019	Migraine Agents: Triptans	• sumatriptan nasal spray (Tosymra)	• sumatriptan nasal spray (Imitrex, generics) • sumatriptan nasal powder (Onzetra Xsail) [nonformulary] • zolmitriptan nasal spray (Zomig)	• June 3, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2019	GI2 Agents: CIC and IBS-C	• tegaserod (Zelnorm)	• linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Amitiza) • prucalopride (Motegrity) [nonformulary]	June 3, 2020
Aug 2019	ADHD	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.025% cream (Impoyz) • diflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog)	• betamethasone/propylene glycol 0.05% cream • clobetasol propionate 0.05% cream • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream • fluocinonide 0.05% cream • fluocinonide/emollient base 0.05% cream	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• halcinonide 0.1% ointment (Halog)	• betamethasone dipropionate 0.05% ointment • betamethasone/propylene glycol 0.05% ointment • clobetasol propionate 0.05% ointment • desoximetasone 0.25% ointment • fluocinonide 0.05% ointment • halobetasol propionate 0.05% ointment	• March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit) • halobetasol propionate 0.05% lotion (Ultravate) • halobetasol propionate 0.05% foam (authorized generic for Lexette) *(see Feb 2019 for brand Lexette)* • halobetasol propionate 0.01% lotion (Bryhali)	• betamethasone propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % emulsion foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• March 4, 2020
May 2019	PPIs	• dexlansoprazole (Dexilant) • esomeprazole strontium	• esomeprazole • omeprazole • pantoprazole • rabeprazole	• Nov 28, 2019 MTF Tier 4 implementation for Dexilant delayed to Jan 31, 2020
Feb 2019	High-Potency Topical Corticosteroids	• halobetasol propionate 0.05% foam (Lexette brand)	• betamethasone/propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % emulsion foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• Aug 28, 2019 Note that Lexette reaffirmed as Tier 4 at the August 20219 High Potency Topical Steroid review
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	• metformin ER gastric retention 24 hours (Glumetza)	• metformin IR (Glucophage generic) • metformin ER (Glucophage XR generic)	• Aug 28, 2019
Feb 2019	Pain Agents – Combinations	• naproxen / esomeprazole (Vimovo)	• PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs)	• Aug 28, 2019 • Note that Vimovo reaffirmed as Tier 4 at the February 2020 NSAID subclass review

*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, based on an interim final rule published on December 11, 2018. https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. 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. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. 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.

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
Aspirin		
August 2020	**Retain these GCNs** ▪ 16713 – aspirin 81 mg chewable tab ▪ 00161 – aspirin 81 mg delayed release tab (enteric-coated) ▪ 16701 – aspirin 325 mg tab ▪ 16720 – aspirin 325 mg delayed release tab (enteric-coated)	**Remove these GCNs:** ▪ 26911 – aspirin suspension
Artificial Tears (Overnight Treatment)		
August 2020	**Retain these GCNs** ▪ 98935 – mineral oil/petrolatum 15%-83% ointment (Artificial tears) ▪ 99250 – mineral oil/petrolatum 20%-80% ointment (Retaine PM, Soothe) ▪ 99952 – mineral oil/petrolatum 3%-94% ointment (Overnight Lubricating Eye, Systane) ▪ 99222 – mineral oil/petrolatum 42.5%-56.8% ointment (Refresh Lacri-Lube) ▪ 28068 – mineral oil/petrolatum 42.5%-57.3% ointment (Refresh PM) **Add these GCNs** ▪ 27956 – hypromellose 0.3% gel (Genteal Tears Severe, Systane Gel)	
Antihelminthics		
August 2020	**Add these GCNs** ▪ 43170 – pyrantel pamoate 50 mg/mL suspension	

***GCN Additions will be implemented the first Wednesday two weeks after signing of the minutes, with the deletions implemented at 120 days.**

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
AAD	American Academy of Dermatology	JNC	Joint National Contract
AASM	Academy of Sleep Medicine	MHS	Military Health System
ADR	Adverse reaction	MN	Medical Necessity
AE	Adverse event	MTF	Military Treatment Facility
BCF	Basic Core Formulary	NCCN	National Comprehensive Cancer Network
BIA	Budget impact analysis	NDAA	National Defense Authorization Act
CFR	Code of Federal Regulations	NDC	National Drug Codes
CMA	Cost minimization analysis	nr-axSpA	Non-radiographic axial spondyloarthritis
CV	Cardiovascular	ODT	Orally Dissolving Tablet
DHA	Defense Health Agency	OSA	Obstructive Sleep Apnea
DNRI	dopamine and norepinephrine reuptake inhibitor	OTC	Over the counter
DoD	Department of Defense	P&T	Pharmacy and Therapeutics
DR	Delayed release	PA	Prior authorization
ECF	Extended Core Formulary	PBM	Pharmacy Benefit Manager
EDS	Excessive daytime sleepiness	POD	Pharmacy Operations Division
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	POS	Point of service
ER	Extended release	QL	Quantity limits
FDA	U.S. Food and Drug Administration	Rx	Medical Prescription
FMB	Formulary Management Branch	SC	Subcutaneous
FY	Fiscal year	TIB	Targeted immunomodulatory biologic
GCN	Generic code number	UC	Ulcerative colitis
GI	Gastrointestinal	UF	Uniform Formulary
HCL	Hydrochloride	WBC	White Blood Cell
HTN	Hypertension	XR	Extended Release
ILD	Interstitial lung disease		
IPF	Idiopathic Pulmonary Fibrosis		
IR	Immediate release		
IV	Intravenous		