DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2020

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 5 and 6, 2020, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2019 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2019 DoD P&T Committee meeting on February 3, 2020 for the recommendations other than the rapid acting insulin aspart with niacinamide (Fiasp), which was signed on February 11, 2020.

2. **Clarification of Previous Minutes**

   a) **November 2019 Meeting—Pulmonary -1 Agents: Combinations: budesonide/formoterol (Symbicort) and mometasone/formoterol (Dulera) updated PA criteria:** At the November 2019 meeting, the PA criteria were updated for Symbicort and Dulera to allow use as rescue therapy, without a trial of fluticasone/salmeterol (Advair) first. The existing step therapy for the drug class allows children 12 years and older to bypass the Advair step, which also applies for rescue use.

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. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018. Medical necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a non-formulary (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. Pain Agents: Nonsteroidal Anti-Inflammatory Drug (NSAID) Subclass

Background—The NSAIDs were last reviewed for formulary status in August 2011. There are approximately 50 different marketed products in the class, comprised of 21 individual chemical entities. Since the last review, five branded products were reviewed as new drugs. Data published since the August 2011 meeting was evaluated for the efficacy and safety review.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- There was no new data to change the previous clinical conclusion that the NSAIDs do not have clinically relevant differences in efficacy in treating a wide range of indications. The NSAIDs are highly therapeutically interchangeable.
- Evidence from several sources, including clinical practice guidelines from five organizations (for acute gout, primary dysmenorrhea, ankylosing spondylitis, juvenile arthritis, and headache), four Cochrane Reviews (for rheumatoid arthritis, osteoarthritis, low back pain, and axial spondyloarthritis), and an Agency for Healthcare Research and Quality (AHRQ) report for osteoarthritis do not distinguish between the NSAIDs for efficacy. Although a few trials and systematic reviews showed improved efficacy for individual products, overall for most disease states there is insufficient evidence to recommend any one NSAID based on efficacy alone.
- The August 2011 P&T safety conclusions remain largely unchanged. The NSAIDs as a class have an increased risk of serious gastrointestinal (GI) and cardiovascular (CV) adverse events, and all the products include black box warnings to this effect in their Food and Drug Administration (FDA) labeling. Using the lowest effective dose for the shortest amount of time possible is recommended to decrease the risk of adverse events, particularly in elderly patients.
- Individual NSAIDs are associated with varying risk of GI and CV adverse events.
    - In terms of GI adverse events, ibuprofen and celecoxib have the lowest risk, diclofenac and naproxen have moderate risk, and ketorolac and piroxicam are high-risk NSAIDs. For GI protection, the following strategies are listed in order from most effective to least effective: administering a COX-2 inhibitor with a proton pump inhibitor (PPI), a COX-2 inhibitor alone, an NSAID with a PPI, an NSAID with misoprostol, and an NSAID with an H2-blocker.
    - In terms of CV adverse events, diclofenac is associated with higher CV risk while naproxen has lower CV risk. Although there is some mixed data for celecoxib and ibuprofen, their CV risk falls between that of diclofenac and naproxen.
- The P&T Committee considered twelve formulations for Tier 4 status. Clinical factors considered for not covered status were based on comparative pharmacokinetic profiles, efficacy and safety, data from FDA summary reviews

and published primary literature, formulary status from commercial health plans, and Military Health System (MHS) provider feedback.

- **Diclofenac potassium liquid-filled capsule (Zipsor)** is the only NSAID available in a liquid-filled formulation. Head-to-head clinical trials with other NSAIDs are lacking. The potentially faster onset of action of Zipsor compared to generic diclofenac potassium is negated if Zipsor is taken with food. Two generic formulations of diclofenac are currently on the formulary, the sodium salt (generic Voltaren) and the potassium salt (generic Cataflam). Over 95% of the MHS market share for diclofenac is for the sodium salt.
- **Diclofenac potassium powder packet (Cambia)** is the only prescription NSAID with a specific FDA indication for treating migraine headache. However, other prescription and over-the-counter (OTC) NSAIDs are widely accepted and used for treating migraines, including diclofenac 50 mg and 100 mg tablets, naproxen, ibuprofen, and aspirin/acetaminophen/caffeine (Excedrin).
- **Submicronized formulations of diclofenac (Zorvolex), indomethacin (Tivorbex), and meloxicam (Vivlodex)** were designed to have a greater extent of absorption than standard versions of these drugs, but the FDA summary review noted that the manufacturer failed to demonstrate this. These three products offer no compelling clinical advantages over existing generic formulary medications.
- **Ketorolac nasal spray (Sprix)** is indicated for the short-term management of moderate to moderately severe pain that requires analgesia at the opioid level. It poses a significant risk if used beyond the labeling for five days, including nephrotoxicity and GI toxicity.
- **Meloxicam orally disintegrating tablet (ODT) (Qmiiz)** was previously reviewed as a new drug and designated as nonformulary in May 2019. No new clinical trials were used to gain FDA approval, and Qmiiz is limited for use only in adults and pediatric patients who weigh at least 60 kg. The FDA review noted that Qmiiz has comparable efficacy and safety as the referenced drug, generic meloxicam.
- **Naproxen sodium extended release (Naprelan, generics)** provides a convenience to the patient, as this formulation is dosed once daily, rather than twice daily. Other NSAIDs, including nabumetone, are dosed once daily. One head-to-head trial showed similar safety and efficacy between Naprelan and nabumetone. Trials comparing Naprelan with generic naproxen show no difference in efficacy, however, varying safety results were shown, as two trials found weak evidence of an improved GI adverse event profile with Naprelan.
- **Ibuprofen/famotidine (Duexis)** contains a fixed-dose combination of an NSAID and an H2-blocker; these active ingredients are available OTC. A 2016 GI Safety Network Analysis found that the combination of an NSAID with an H2-blocker was the least effective strategy for providing GI protection, compared to other GI protective strategies.
- **Naproxen/esomeprazole (Vimovo)** contains components that are readily available as generic drugs already included on the uniform formulary. Vimovo

was designated Tier 4 at the February 2019 DoD P&T meeting, which was implemented on August 29, 2019. There is no new data to support changing Vimovo's Tier 4 status.

- **Celecoxib/amlodipine (Consensi)** was approved in December 2019 for adults in whom treatment with the calcium channel blocker amlodipine (generic Norvasc) for hypertension and celecoxib for osteoarthritis are appropriate. There is minimal data available with this formulation. Other than patient convenience, this particular fixed-dose combination has limited clinical utility, due to a narrow potential patient population, difficulty with titrating patients, and risk of long-term safety concerns.
- **Fenoprofen (Nalfon and generics)** has very limited MHS market share (less than 0.08%), and a literature review did not identify any unique indications. Currently, both tablets and capsules are marketed.
- **Ketoprofen (generic Orudis), indomethacin rectal suppositories, meclofenamate sodium (generic Meclomen) and tolmetin (generic Tolectin)** do not provide any compelling clinical advantages over the other NSAIDs, are infrequently prescribed in the MHS, and were identified by prescribers as potential options for NF status and Prior Authorization.
- Although the efficacy of the NSAIDs is similar from a population perspective, individual patient response to a particular drug may vary. Providers must also consider relative safety when selecting an NSAID for an individual patient.
- In order to meet the needs of MHS beneficiaries, a wide range of NSAIDs is required on the formulary, to account for differences in COX-2 selectivity, frequency of dosing, GI and CV safety profiles, and to allow for individual variability in patient response. At a minimum, one generic formulation of celecoxib, diclofenac sodium, ibuprofen, meloxicam, and naproxen are required, as these are the NSAIDs with the highest MHS utilization, comprising 94% of the NSAID market share. Additionally, a few alternative dosage forms are necessary for patients with swallowing difficulties, with the options including naproxen suspension, indomethacin suspension, or indomethacin suppositories.

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

- CMA showed that generic formulations in the class were the most cost-effective agents, with Qmiiz, fenoprofen, tolmetin, Naprelan, ketoprofen, Vivlodex, Tivorbex, Zorvolex, meclofenamate, Zipsor, Vimovo, Duexis, Consensi, Cambia and Sprix as substantially less cost-effective than the other NSAIDs.
- A BIA was performed to evaluate the potential financial impact of various formulary placement scenarios for the NSAIDs, designating selected NSAID agents as Tier 4, NF, and UF. The BIA results showed that designating fenoprofen capsules, naproxen/esomeprazole (Vimovo), ibuprofen/famotidine

(Duexis), Zipsor, Zorvolex, Tivorbex, Vivlodex, and Consensi as Tier 4; and Cambia, Sprix, Naprelan brand and generic, Qmiiz, fenoprofen tablets, tolmetin, ketoprofen, and meclofenamate as NF; with the remaining NSAID agents in the class as UF, demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: NSAIDs UF/TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (12 for, 5 opposed, 0 abstained, 1 absent) the following formulary recommendations for the NSAIDs as outlined below, based on clinical and cost-effectiveness.

- UF
  - celecoxib
  - diclofenac/misoprostol
  - diclofenac potassium
  - diclofenac sodium
  - diflunisal
  - etodolac
  - flurbiprofen
  - ibuprofen 400 mg, 600 mg and 800 mg
  - indomethacin IR 25 mg and 50 mg
  - indomethacin ER 75mg
  - indomethacin rectal suppository
  - ketorolac tablets
  - meloxicam 7.5 mg and 15 mg
  - nabumetone
  - naproxen 250 mg and 500 mg
  - naproxen 125 mg/5 ml oral suspension
  - naproxen IR 375 mg
  - naproxen delayed release (DR) 375mg and 500 mg
  - naproxen sodium 275 mg and 550 mg
  - oxaprozin
  - piroxicam
  - sulindac
  - mefenamic acid 250 mg (generic Ponstel) (*moves from NF to UF*)
  - Note that the older non-FDA-approved products, salsalate and choline magnesium trisalicylate will remain UF

- NF
  - diclofenac potassium powder packets 50 mg (Cambia)
  - fenoprofen tablets (*moves from UF to NF*)

- indomethacin oral suspension (*moves from UF to NF*)
- ketoprofen (*moves from UF to NF*)
- ketorolac nasal spray (Sprix)
- meclofenamate (*moves from UF to NF*)
- meloxicam ODT (Qmiiz)
- naproxen sodium controlled release (Naprelan, generic) 375 mg, 500 mg, and 750 mg ER tabs, dosing card
- tolmetin (*moves from UF to NF*)

- Tier 4/Not Covered
  - amlodipine/celecoxib (Consensi)
  - diclofenac potassium liquid-filled capsules (Zipsor)
  - diclofenac submicronized (Zorvolex)
  - fenoprofen capsules (*moves from UF to Tier 4*)
  - ibuprofen/famotidine tablets (Duexis)
  - indomethacin submicronized (Tivorbex)
  - meloxicam submicronized (Vivlodex)
  - naproxen/esomeprazole (Vimovo) (*remains Tier 4*)

Committee members with opposing votes were not opposed to the agents being considered for their respective formulary status as recommended, noting they wanted the recommendation to include more agents for Tier 4 status. The Committee commented and considered Cambia powder packets, Qmiiz, Naprelan, and Sprix nasal spray as potential additional Tier 4 candidates. The opinion to move all these additional agents to Tier 4 was not unanimous.

When considering the NSAID candidates for Tier 4/Not Covered status, the P&T Committee considered the information outlined in the interim rule, Section 702(b)(10) of the NDAA 2018 published on December 11, 2018, and found at: https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. The interim rule allows for complete exclusion of drugs from TRICARE pharmacy benefit coverage when certain criteria are met. Tier 4/Not Covered status will apply to all users of the recommended candidates.

For the eight NSAIDs recommended for Tier 4/Not Covered status, The P&T Committee concluded that they provide very little to no additional clinical effectiveness relative to the other NSAIDs. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries can be met by the formulary NSAIDs. Formulary alternatives for the Tier 4 candidates include generic NSAIDs. See Appendix H.

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

    - Maintaining the following drugs
        - ibuprofen 400 mg, 600 mg, and 800 mg tablets (generic)
        - indomethacin IR 25 mg and 50 mg capsules (generic)
        - meloxicam 7.5 mg and 15 mg tablets (generic)
        - naproxen 250 mg and 500 mg tablets (generic)
    - Adding the following drugs
        - celecoxib capsules (generic)
        - diclofenac sodium tablets (generic)
    - Removing the following drugs
        - naproxen 125mg/5ml suspension
        - salsalate tablets

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Existing PA criteria currently apply to Naprelan brand and generic) from the November 2018 meeting,-and for Qmiiz, when it was reviewed as an innovator in May 2019. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated manual PA criteria for new users of Naprelan brand and generic, and Qmiiz. Additionally, new manual PA criteria for all new and current users of diclofenac potassium powder packets (Cambia), was recommended, limiting use to patients with a contraindication, therapeutic failure or intolerance to a triptan who have failed two previous NSAIDs. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for diclofenac potassium powder packets (Cambia), fenoprofen tablets, ketoprofen, ketorolac nasal spray (Sprix), meclofenamate, meloxicam ODT (Qmiiz), naproxen sodium ER (Naprelan, brand and generic), and tolmetin; and recommended (16 for, 0 opposed, 0 abstained, 2 absent) MN criteria for indomethacin oral suspension. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QL)—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for diclofenac potassium powder packets (Cambia), similar to that currently in place for the Triptans for migraine headache. The QLs for ketorolac nasal spray (Sprix) were updated. See Appendix D for the full criteria.

6. ***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), not adding

the NF NSAIDs Cambia, Sprix, fenoprofen tablets, ketoprofen, meclofenamate, naproxen sodium ER (Naprelan, generic), and indomethacin suspension to the EMMPI program due to the acute use exception. The Committee also recommended adding diclofenac/misoprostol, Qmiiz, and tolmetin to the list; and maintaining the existing NSAIDs that are currently on the program, with the exception that Voltaren and Voltaren XR will be removed, as these are discontinued brand names.

7. ***COMMITTEE ACTION: UF/TIER 4, PA, MN, EMMPI PROGRAM AND 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 signing of the P&T minutes at all points of service (POS); 2) DHA send letters to beneficiaries affected by the NF recommendations and the Cambia PA; and 3) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is August 26, 2020. Note that the QLs for Cambia and Sprix will be implemented along with the other QLs, as outlined in Section VI. C. 1 on page 19.

B. Pain Agents: Topical Pain Subclass

Background—The Topical Pain drugs were previously reviewed at the February 2013 DoD P&T Committee meeting. The subclass is comprised of topical NSAIDs (diclofenac preparations) and lidocaine patches. Since the last class review, several products are now available in generic formulations, and currently only diclofenac 2% solution (Pennsaid 2%) and lidocaine 1.8% patch (ZTlido) remain branded products. Manual PA criteria apply to both Pennsaid 2% and ZTlido, requiring a trial of the generics first.

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

Topical diclofenac

- There was no new data to change the clinical conclusions from the February 2013 formulary review that the topical diclofenac products are highly interchangeable, effective for treating superficial musculoskeletal pain, and are similar in efficacy to oral diclofenac.
- Professional treatment guidelines from several organizations, including the UK National Institutes for Health and Care Excellence (NICE), the Osteoarthritis Research Society International (OARSI) and the American Academy of Orthopaedic Surgeons (AAOS) state that topical NSAIDs are appropriate for treating osteoarthritis affecting the knee and hand joints. Topical NSAIDs may be interchanged with oral NSAIDs when oral NSAIDs are not appropriate (e.g., geriatric population).
- The 2014 VA/DoD Clinical Practice Guidelines comment that topical NSAIDs have a decreased absolute risk of GI adverse events compared to oral diclofenac but note that

there is insufficient evidence to compare topical versus oral diclofenac in terms of serious GI events (perforation, ulcers, or bleeding), CV events, renal impairment, and hepatotoxicity.

- The FDA package labeling for the topical diclofenac products still carries warnings about GI and CV risks and includes recommendations for liver function monitoring, similar to the oral NSAIDs.
- **Diclofenac 1% gel (Voltaren generic)** is the highest utilized topical NSAID in the MHS. Other advantages including easy application to multiple joints, including the fingers, and FDA approval for osteoarthritis of both the hand and knees.
- The **diclofenac 1.5% topical solution (Pennsaid 1.5% generic)** FDA-approved indication is limited to treating osteoarthritis of the knee. Clinical usefulness may also be limited by the multiple daily dosing (four times daily) and the need to count out 40 drops for application.
- **The 2% diclofenac solution (Pennsaid 2%)** is bioequivalent to the 1.5% solution. The only difference between the products is that the 2% solution is available in a pump and has a slightly more viscous consistency. Provider comments noted that only one diclofenac solution is required on the formulary. Other than patient convenience, Pennsaid 2% offers no compelling advantages over diclofenac 1% gel or the 1.5% solution.
- **Diclofenac 1.3% patch (Flector, generic)** is the only topical NSAID approved for treating acute pain due to musculoskeletal injuries; it does not have approval for treating osteoarthritis. A 2017 Cochrane review showed that diclofenac is effective for acute pain lasting for less than7 days. Disadvantages to Flector include the large size, making it difficult to apply to small joints. Additionally only one patch can be applied at a time. Providers commented that there are many alternatives to Flector including oral NSAIDs and other topical NSAIDs.

Lidocaine Patches

- The clinical conclusions from February 2013 remain unchanged, finding that lidocaine patches are probably effective for treating postherpetic neuralgia (PHN), likely effective for neuropathic pain, and lacking in evidence for musculoskeletal pain. The most common adverse event for the lidocaine patch is application site reactions, specifically pruritus.
- **Lidocaine 5% patch (Lidoderm, generic)** has the highest utilization of all the topical pain drugs in the MHS. Advantages include that up to three patches can be used at a time and patches can be cut to size. There are three generic manufacturers on the market, so patients can try different products if there are adhesion issues.
- **Lidocaine 1.8% patch (ZTlido)** is a new formulation of lidocaine that is bioequivalent to the Lidoderm 5% patch, delivering the same amount of lidocaine to the patient. Although the manufacturer claims that ZTlido has improved adhesion over Lidoderm, FDA reviewers questioned the supporting evidence for this claim. There was no new data to change the conclusions from the ZTlido new drug review in November 2018 that it is a candidate for Tier 4 status.

- In order to meet the needs of MHS beneficiaries, one topical diclofenac product and one lidocaine patch are required on the formulary.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and BIA were performed to evaluate the topical pain agents. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that the following agents were substantially less cost-effective than the remainder of the class: diclofenac 1.3% patch (Flector, generics), diclofenac 2% solution (Pennsaid 2%), and lidocaine 1.8% patch (ZTlido).
- 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 diclofenac 1% gel (Voltaren, generics), diclofenac 1.5% drops (generics), and lidocaine 5% patch (Lidoderm, generics) as UF, and diclofenac 1.3% patch (Flector, generics), diclofenac 2% solution (Pennsaid 2%), and lidocaine 1.8% patch (ZTlido) as Tier 4 demonstrated significant cost avoidance for the MHS.

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

    - UF
        - diclofenac 1% gel (Voltaren, generics)
        - diclofenac 1.5% solution (Pennsaid 1.5%, generics)
        - lidocaine 5% patch (Lidoderm, generics)
    - NF
        - None
    - Tier 4/Not Covered
        - diclofenac 2% solution (Pennsaid 2%)
        - diclofenac 1.3% patch (Flector, generics)
        - lidocaine 1.8% patch (ZTlido)

    When considering the candidates for Tier 4/not covered status, the P&T Committee considered the information previously stated in section IV. A. 1. on page 6.

    For the three products recommended for Tier 4/Not Covered status, Pennsaid 2%, Flector and ZTlido, the P&T Committee concluded that they provide very little to no additional benefit relative to the other topical pain agents. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries can be met by the formulary topical pain drugs. Formulary

alternatives for the Tier 4 candidates also include the generic oral NSAIDs. See Appendix H.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***Currently there are no Topical Pain drugs on the BCF, as the subclass is part of the larger Pain class, and several oral NSAIDs are on the BCF. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) adding generic diclofenac 1% gel and generic lidocaine 5% patch to the BCF.

3. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current lidocaine 5% patch QLs of 90 patches per 30 days at retail network pharmacies and 270 patches per 90 days at the MTFs and Mail Order pharmacy, consistent with the FDA-approved labeling. See Appendix D for the full criteria.

4. ***COMMITTEE ACTION: UF /TIER 4/NOT COVERED IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 120-day implementation period in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF/Tier 4 recommendations at 30 and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is August 26, 2020.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). 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 (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
  - benralizumab injection (Fasenra Pen) — Miscellaneous Pulmonary 1 Agent in a new self-administered pen for eosinophilic and severe asthma
  - elexacaftor/tezacaftor/ivacaftor (Trikafta) — Cystic Fibrosis triple fixed-dose combination
  - pegfilgrastim-bmez injection (Ziextenzo) — Hematological Agents: White Blood Cell Stimulants; another biosimilar for Neulasta

        - pretomanid — Antitubercular drug for extensively drug-resistant (XDR) or treatment intolerant/nonresponsive multidrug-resistant (MDR) tuberculosis
        - voxelotor (Oxbryta) — Sickle cell anemia agent for sickle cell disease
        - zanubrutinib (Brukinsa) — Oral oncologic agent for mantle cell lymphoma
    - NF:
        - asenapine transdermal system (Secuado) — New patch formulation of asenapine for schizophrenia in adults
        - baclofen oral solution (Ozobax) — New oral solution formulation of baclofen for spasticity associated with multiple sclerosis
        - colchicine oral solution (Gloperba) — Anti-Gout Agents; a new oral solution formulation of colchicine
        - diroximel fumarate (Vumerity) — Multiple Sclerosis Agents; another methyl fumarate formulation
        - minocycline 4% foam (Amzeeq) — Topical Acne and Rosacea Agents in a new formulation of minocycline
        - testosterone undecanoate capsules (Jatenzo) — Testosterone Replacement Therapy (TRT) in an oral capsule
        - trifarotene 0.005% cream (Aklief) — Topical Acne and Rosacea agents in a new retinoid formulation

    - Tier 4/Not Covered:
        - albuterol dry powder inhaler (ProAir Digihaler) — Pulmonary-1: Short Acting Beta Agonist (SABA) for asthma
            - ProAir Digihaler was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for treating asthma symptoms and the needs of TRICARE beneficiaries are met by alternative agents.
                - Formulary alternatives to ProAir Digihaler include albuterol MDI (ProAir HFA), albuterol DPI (ProAir Respiclick); nonformulary alternatives include albuterol MDI (Proventil HFA), albuterol MDI (Ventolin HFA), and levalbuterol MDI (Xopenex HFA). (See Appendix H.)
        - benzoyl peroxide 9.8% foam (Enzoclear) — Keratolytic for acne vulgaris
            - Enzoclear was recommended for Tier 4 status as it is not an FDA-approved drug, has no clinical benefit relative to other agents

approved for acne vulgaris, and the needs of TRICARE beneficiaries are met by alternative agents.

- Formulary alternatives to Enzoclear include clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics), clindamycin/ benzoyl peroxide 1% - 5% gel (Benzaclin, generics), and clindamycin/benzoyl peroxide 1% - 5% gel with pump (Duac CS Kit) (See Appendix H.)

- omeprazole magnesium/amoxicillin/rifabutin (Talicia) - Miscellaneous Anti-infective for *Helicobacter pylori* salvage therapy
  - Talicia was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for *H. pylori* and the needs of TRICARE beneficiaries are met by alternative agents.
    - Formulary alternatives to Talicia include amoxicillin, omeprazole, rifabutin, clarithromycin, metronidazole, and tetracycline (See Appendix H.)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Aklief, Amzeeq, Gloperba, Jatenzo, Ozobax, Secuado, and Vumerity. See Appendix B for the full criteria.

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

- TRTs: Applying the same manual PA criteria in new and current users of Jatenzo, as is currently in place for the other non-step-preferred TRT products. Patients must first try generic Fortesta or generic Androgel 1%. Also for Jatenzo, additional safety requirements are included in the PA to exclude patients with uncontrolled hypertension or those at high risk for CV adverse events.
- Applying manual PA criteria to new and current users of Aklief, Amzeeq, Fasenra Pen, Oxbryta, Vumerity, and Trikafta.
- Applying manual PA criteria to new users of Brukinsa, Gloperba, and Ozobax.

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

- **New Drugs Recommended for UF or NF Status, MN and PA criteria:** An effective date upon two weeks after signing of the minutes in all points of service, on May 13, 2020.

- **New Drugs Recommended for Tier 4 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. Based on the P&T Committee's recommendation, the effective date is August 26, 2020.

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) Acne: Topical Acne and Rosacea subclass—Sulfacetamide and sulfacetamide/sulfur products

Sulfacetamide sodium is an antibacterial agent used for acne and rosacea that exhibits a bacteriostatic effect. The addition of sulfur is theorized to increase effectiveness. Rosacea treatment guidelines list sulfacetamide/sulfur as a second-line agent for mild to moderate rosacea, and as a third-line agent for moderate to severe rosacea. Acne treatment guidelines differ in their recommendations with regard to the efficacy of sulfacetamide sodium; however, there is a lack of evidence for sulfur.

There are various strengths and formulations of sulfacetamide alone (i.e. cream, foam, lotion, shampoo), as well as other combination products with sulfur and other ingredients, but none of these products are FDA-approved. The only FDA-approved product is a 10% lotion/suspension of sulfacetamide available under the trade name of Klaron; this is the most cost-effective single ingredient product, and the one most commonly used in the MHS. The most cost-effective combination product is sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar generics). The Committee recommended adding a manual PA to encourage use of the most common strengths of sulfacetamide 10% lotion/suspension (Klaron, generics) and sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar, generics), and to discourage use of all nonstandard dose sulfacetamide products. PA is not required for branded or generic formulations of Klaron, Rosanil, or Avar.

2) Antidepressants and Non-opioid Pain Syndrome Agents—Venlafaxine hydrochloride (HCL) ER 37.5 mg, 75 mg, 150 mg, and 225 mg tablets

Venlafaxine HCL ER 24 hr. tablets were first approved in 2008. There are various generic manufacturers and the ER 24 hr. tablets are all significantly more costly than the ER 24 hr. capsules or immediate-release (IR) tablets. The venlafaxine ER 24 hr. tablets have fewer indications than the venlafaxine ER 24 hr. capsule (Effexor XR, generic) formulation. Equal doses of venlafaxine HCL ER 24 hr. tablets are bioequivalent to venlafaxine HCL ER 24 hr. capsules when

administered under fed conditions but they do not carry an "AB-rating" for interchangeability to each other. The cost-effective venlafaxine formulations, HCL ER capsules (Effexor XR, generics) and venlafaxine HCL IR tablets, are available to patients without a PA. Manual PA was recommended for the venlafaxine HCL ER tablets, based on cost effectiveness.

3) Vitamin: Prenatal—Prenatal vitamin (Zalvit)

Zalvit is a prenatal dietary supplement manufactured by a single company and requires a prescription prior to dispensing. The primary ingredients of Zalvit are 13 mg of iron and 1 mg of folic acid (similar to Azesco presented at August 2019 P&T Committee meeting). Certain prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than age 45 and do not require prior authorization criteria. This agent was identified as having numerous cost-effective alternatives (including Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin Plus Low Iron, and Prenatal Plus DHA) that are available on the UF, where a PA is not required.

COMMITTEE ACTION: SULFACETAMIDE AND COMBINATION PRODUCTS, VENLAFAXINE HCL ER 24 HR TABLETS, AND ZALVIT MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria in all new and current users of sulfacetamide and combination products other than Klaron, Rosanil, Avar or generics, venlafaxine HCL ER 24 hr. tablets, and Zalvit (regardless of the woman's age), due to significant cost differences compared with the numerous available alternative agents. See Appendix C for the full criteria.

b) Insulins: Rapid Acting Agents—generic insulin aspart (authorized generic for Novolog)

The Rapid Acting Insulins were reviewed for formulary status in November 2019, and branded Novolog is now step-preferred and remains on the BCF.
An authorized generic for Novolog entered the market in January 2020. An "authorized generic" is the brand company's own product repackaged and marketed without the trade name. An authorized generic is considered therapeutically equivalent to the name brand drug because it is the same drug. The FDA does not consider authorized generics as AB-rated generic formulations for tablets of AP-rated generic formulations for injections. The insulin aspart authorized generic is less cost effective than the branded Novolog.

COMMITTEE ACTION: GENERIC INSULIN ASPART AUTHORIZED GENERIC MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for the authorized generic insulin aspart in new and current users, requiring a trial of branded Novolog or branded Humalog, due to cost-effectiveness. The PA

requirement will be removed when it is no longer cost advantageous. See Appendix C for the full criteria.

c) Respiratory Agents Miscellaneous—epinephrine auto injector (Auvi-Q)

The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. Manual PA were recommended at the February 2017 P&T Committee meeting for all epinephrine devices, including Auvi-Q. Although Auvi-Q is significantly more expensive than both branded and generic Epi-Pen, the manual PA requirements were temporarily lifted at the August 2018 P&T Committee meeting due to national shortages of Epi-Pen, and intermittent availability of generic epinephrine auto-injectors. It now appears that the shortages of brand and generic Epi-Pen have mostly resolved, and another product, a pre-filled syringe (Symjepi) was launched in May 2019.

COMMITTEE ACTION: ***AUVI-Q MANUAL PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) re-instating the manual PA criteria for epinephrine (Auvi-Q) auto-injector that were previously in place. The PA criteria will apply to new users only. See Appendix C for the full criteria.

2. Updated PA and MN Criteria—Updates to the manual PA criteria and step therapy for several drugs were recommended due to a variety of reasons, including clinical trial data, new dosing for FDA indications, age indications, new FDA-approved indications, and cost-effective alternative treatments being available. The updated PAs and step therapy outlined below will apply to new users with the exception of doxycycline (Oracea) which will apply to new and current users. See Appendix C for the PA criteria.

a) Migraine Agents: Calcitonin Gene-related Peptide (CGRP) Preventatives—erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm (Emgality)—Manual PA criteria for Aimovig, Ajovy, and Emgality were originally recommended at the August 2018 and November 2018 P&T meetings. The PAs for all the CGRP inhibitors were updated at the February 2019 P&T meeting and do not allow concurrent use with botulinum toxin; additionally the patient must not have received a botulinum toxin injection within 2 months of receiving a CGRP inhibitor.

The Committee considered whether to remove the prohibition of concurrent use with botulinum toxin. The Committee reviewed the data, which included comments from the American Migraine Foundation, the 2018 American Headache Society Consensus Statement on Initiation of CGRP antagonists, and a Neurology Times article. The available adverse event (AE) data suggests that there are minimal interactions between CGRPs and botulinum toxin. There is limited information on the effectiveness of concurrent use of CGRPs with botulinum toxin, as a portion of

the patients experienced some benefit and others demonstrated no benefit or even an increased frequency of migraines. More data is needed to make a definitive conclusion on the benefit or harm of concurrent use. The service specialists were also contacted, and their recommendation was to remove this particular criterion. The Manual PA criteria for Aimovig, Ajovy, and Emgality were updated to remove the requirement to not allow concurrent use with botulinum toxin.

b) Antilipidemic 2's-omega-3 fatty acids—icosapent ethyl (Vascepa)—Manual PA criteria for Vascepa were updated to reflect a new indication for CV outcome reduction (i.e., to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization). Patients will be required to meet the study inclusion criteria from the REDUCE-IT trial published in the New England Journal of Medicine. For patients with hypertriglyceridemia and triglyceride (TG) levels ≥ 500 mg/dL, patients are required to have tried and failed generic Lovaza prior to use of Vascepa. Concurrent use of Vascepa with Lovaza will not be allowed. PA criteria will apply to new users.

c) Targeted Immunomodulatory Biologics (TIBs): tofacitinib (Xeljanz XR)— Manual PA criteria for Xeljanz and Xeljanz XR were updated to reflect the new dosage strengths of 11 mg XR and 22 mg XR tablets administered once daily for treatment of ulcerative colitis (UC). Previously the only approved dosing regimens were 5 mg and 10 mg twice daily.

d) Pulmonary 1's-Pulmonary Miscellaneous: mepolizumab (Nucala)—Manual PA criteria for Nucala were updated to remove the age requirement for the eosinophilic asthma indication. The FDA recently lowered the age indication to ≥ 6 years for patients with eosinophilic asthma. The Manual PA criteria and age indication for eosinophilic granulomatosis with polyangiitis (EPGA) will not change and will remain limited to patients ≥ 18 years, consistent with the package insert.

e) Basal Insulins: insulin glargine U-300 (Toujeo)—Manual PA criteria for Toujeo were updated to reflect a new pediatric indication to improve glycemic control in patients with diabetes mellitus ≥ 6 years.

f) Corticosteroids: Immune Modulators—deflazacort (Emflaza)—Manual PA criteria for Emflaza were updated to reflect a lowered age indication to ≥ 2 years for patients with Duchenne muscular dystrophy (DMD).

g) Acne Agents: Tetracyclines—doxycycline monohydrate IR/ER 40 mg capsules (Oracea)—Manual PA criteria for Oracea were last updated during the Tetracyclines class review at the February 2017 P&T Committee meeting. Treatment guidelines for papulopustular rosacea list oral doxycycline as a second-line therapy option following topical medications. Oracea branded and generic formulations are much less cost effective than the immediate release (IR) formulation of doxycycline. The FDA-approved label for Oracea also states that efficacy beyond 16 weeks and safety beyond 9 months have not been established. The Oracea PA was updated to require the provider to document why the patient

cannot be treated with the cost-effective formulary alternatives. Oracea will be removed from the current automated step therapy that is in place for the tetracyclines drug class and will be on its own individual manual PA form.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND STEP THERAPY—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the updates to the manual PA criteria for Aimovig, Ajovy, Emgality, Xeljanz, Xeljanz XR, Nucala, Toujeo, Emflaza, Vascepa, and Oracea. See Appendix C for the full criteria.

3. Reviewed PA Criteria

a) TIBS: apremilast (Otezla)—Manual PA criteria and step therapy for apremilast (Otezla) was reviewed to consider creating an exception to the requirement to use the step-preferred product, Humira, in patients with plaque psoriasis. Professional treatment Guidelines, a meta-analysis from the Institute for Clinical and Economic Review (ICER), provider feedback, consultant feedback, and service policy and guidance for deployment were all presented and reviewed by the P&T Committee.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND STEP THERAPY—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) to make no changes to the current manual PA criteria and step therapy for Otezla; a trial of Humira will still be required first.

B. Quantity Limits

1. **General QLs**: QLs were reviewed for five drugs from drug classes where there are existing QLs, including the cystic fibrosis agents, oncological agents, pulmonary-1 agents, and white blood cell stimulants.

COMMITTEE ACTION: QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) QLs for Brukinsa, Fasenra pen, Kalydeco, Trikafta, and Ziextenzo. See Appendix D for the QLs.

2. **Default QLs for Cystic Fibrosis Drugs:** QLs already apply to the cystic fibrosis drugs, limiting dispensing to a 28- or 30-day supply, based on the need for titration, risk of adverse effects, and cost. In order to apply QLs to new cystic fibrosis drugs in a timely manner, default QLs are recommended. The default QLs will be a quantity per dispensing event and either a 28- or 30-day supply limit, based on packaging. Any new oral cystic fibrosis agent approved by the FDA will be subject to the new default QLs.

COMMITTEE ACTION: CYSTIC FIBROSIS DRUGS DEFAULT QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the default QLs for the cystic fibrosis drugs, as outlined in Appendix D.

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 sulfacetamide and combination products, venlafaxine HCL ER 24 hr. tablets, and the prenatal vitamin Zalvit 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) Implementing the new PA for the authorized generic for insulin aspart will become effective upon signing of the minutes.

    - (16 for, 0 opposed, 0 abstained, 2 absent) Re-instating the previous PA criteria for Auvi-Q in new users will become effective the first Wednesday 30-days after the signing of the minutes.

    - (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Aimovig, Ajovy, Emgality, Xeljanz, Xeljanz XR, Nucala, Toujeo, Emflaza, and Vascepa in new users will become effective the first Wednesday 60-days after the signing of the minutes.

    - (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Oracea brand and generics in new and current users will become effective the first Wednesday 90-days after the signing of the minutes.

    - (16 for, 0 opposed, 0 abstained, 2 absent) QLs for five drugs listed in section VI. B.1 above on page 18 and in Appendix D become effective the first Wednesday 2 weeks after signing of the minutes in all POS. Note that the QLs for Cambia and Sprix from section IV. A. 6 on page 8 will also be implemented 2 weeks after the signing of the minutes.

    - (16 for, 0 opposed, 0 abstained, 2 absent) The new default QLs for the cystic fibrosis drugs become effective the first Wednesday 2 weeks after signing of the minutes.

VII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for one-product line extension ("follow-on products") by the original manufacturer. Line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***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 product to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday after signing of the minutes.

- **Acne Agents: Isotretinoids**—isotretinoin, micronized (Absorica LD) is now available in 8 mg, 16 mg, 24 mg, and 32 mg capsules. Previously, Absorica was only available as oral capsules in strengths of 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg. The P&T Committee recommended designating the Absorica LD as NF, with the same MN criteria, and same manual PA requirements as Absorica oral capsules.

VIII. RE-EVALUATION OF NF GENERICS

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, TRICARE Management Agency (TMA), on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes.

A. Antidepressant-1s (AD-1s) and Non-Opioid Pain Syndrome Drugs: pregabalin (Lyrica)

Lyrica has been designated as NF and non-step-preferred since the AD-1 drug class review in November 2011. Step therapy requires a trial of gabapentin and duloxetine prior to use of Lyrica. The P&T Committee re-evaluated the formulary status of Lyrica due to price reductions in generic pregabalin formulations available across all three points of service (POS). New clinical information comparing pregabalin with gabapentin was reviewed. Current utilization trends, numbers of generic products on the market, and relative cost-effectiveness, including the weighted average cost per unit for generic pregabalin (Lyrica) were also reviewed. The unit cost of generic pregabalin formulations has dropped significantly from the previous generic and brand cost, and the generic supply appears stable, as 13 manufacturers are producing product.

1. ***COMMITTEE ACTION: PREGABALIN (GENERIC LYRICA) FORMULARY STATUS, PA, AND EMMPI RECOMMENDATION AND IMPLEMENTATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following, effective the first Wednesday 30 days after signing of the minutes at all POS:

   - Returning pregabalin (Lyrica, generics) to formulary status.

- Removing the current step-therapy and manual PA requirements for pregabalin.
- Removing generic pregabalin from the Select Maintenance Drug List. Brand Lyrica will remain on the list.

B. AD-1s: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs): desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER

Desvenlafaxine succinate ER (Pristiq) and desvenlafaxine ER are NF, with step therapy requiring an initial trial of venlafaxine ER. The Desvenlafaxine ER product was approved under a New Drug Application (NDA) and is considered a brand agent, with no generics available; a previously available desvenlafaxine ER product (Khedezla) has been discontinued. As of November 2019, generic desvenlafaxine succinate ER is available from multiple manufacturers and the weighted average cost across DoD POS is lower than that for venlafaxine ER. The P&T Committee also noted that, although the weighted average cost for the branded Desvenlafaxine ER products was much higher than venlafaxine ER or desvenlafaxine succinate ER (generic Pristiq), utilization was very low (fewer than 300 30-day equivalent prescriptions over a 90-day period).

1. ***COMMITTEE ACTION: DESVENLAFAXINE SUCCINATE ER (GENERIC PRISTIQ) FORMULARY STATUS, PA EMMPI RECOMMENDATION AND IMPLEMENTATION***—The P&T Committee recommended the following (16 for, 0 opposed, 0 abstained, 2 absent), effective the first Wednesday 30 days after signing of the minutes at all POS.

    - Returning desvenlafaxine succinate ER (Pristiq, generics) to UF status; and retaining the brand product (Pristiq), but not the generics, on the EMMPI list.

    - Making no changes to the formulary status for the branded Desvenlafaxine ER product, which will remain NF and subject to the mail order requirement.

    - Removing the step therapy requirement for both desvenlafaxine succinate ER (Pristiq, generics) and Desvenlafaxine ER, which reduces administrative burden in this class.

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

A. Pulmonary-1 Agents: Combinations—budesonide/formoterol (Symbicort) and mometasone/formoterol (Dulera)—Manual PA criteria and MN criteria for Symbicort and Dulera were recently updated at the November 2019 P&T Committee meeting to allow for acute use, due to the Global Initiative for Asthma (GINA) 2019 consensus statement

recommendation. Accordingly, the acute use exception to the NF to mail requirement now applies. There is also a minimal difference in price when comparing costs at the three POS. Symbicort and Dulera will remain NF but will be exempt from the NF to mail requirement due to the acute use exception.

1. ***COMMITTEE ACTION: SYMBICORT AND DULERA NF TO MAIL REQUIREMENT—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent), exempting Symbicort and Dulera from the NF to mail requirement and removing them from the EMMI List for acute use exception. See Appendix F.

B. 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 February 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 February 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: (18 for, 0 opposed, 0 abstained, 0 absent), adding or exempting the drugs listed in Appendix F to/from the 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: LAXATIVES, CALCIUM, AND VITAMIN D

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.

Available clinical data was reviewed for the OTC laxatives and cathartics, (including stool softeners, osmotic laxatives, stimulant laxatives, bulk-forming agents, saline laxatives, and rectally administered agents), OTC calcium products, and OTC vitamin D products. Factors influencing whether a particular OTC product was retained, added or removed from the MHS GENESIS OTC List included volume and utilization across multiple MTFs; feedback from MTF providers to include primary care providers, other provider specialties, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

1. ***COMMITTEE ACTION: STATUS OF OTC LAXATIVES AND CATHARTICS, OTC CALCIUM AND OTC VITAMIN D ON THE MHS GENESIS OTC LIST—***The P&T Committee recommended (17

for, 0 opposed, 0 abstained, 1 absent) for the OTC laxatives and cathartics, and vitamin D products, and (18 for, 0 opposed, 0 abstained, 0 absent) for the calcium products, changes to the MHS GENESIS OTC test list, as outlined in Appendix I of the minutes on page 56. With one exception, the recommended changes are expected to have relatively low impact at current MHS GENESIS sites, including the most recent Wave Travis Sites (Travis, Lemoore, Monterey, and Mountain Home), which implemented MHS GENESIS as of September 2019. (See Appendix I for a detailed list of these agents and specific GCNs.)

2. ***COMMITTEE ACTION: IMPLEMENTATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent for the OTC laxatives and cathartics and OTC vitamin D) and (18 for, 0 opposed, 0 abstained, 0 absent for OTC calcium) an effective date of the first Wednesday 120 days following signing of the minutes for all of the recommendations noted above, with the exception that the three GCNs added to the OTC test list will implement upon signing of the minutes.

   For the OTC laxatives, letters will be sent to all patients at MHS GENESIS sites affected by the removal of agents used chronically (e.g., docusate calcium, PEG 3350), but not mineral oil enema, which is for acute use. Letters are further not required for patients receiving the psyllium products with sugar or aspartame that are being removed from the list, since patients can be changed to similar agents on the MHS GENESIS list. Letters will be sent to all patients at MHS GENESIS sites affected by the removal of calcium products and the removal of vitamin D products.

XI. ITEMS FOR INFORMATION

A. Prenatal Legend Vitamins Moving to OTC Status

In November 2019, First Databank moved several legend prenatal vitamin preparations to the status of legend Multivitamin preparations. Prenatal vitamins are required to have ingredients containing folic acid 400 mcg; vitamin D 10 mcg/400 units; and iron 27mg (or Low/No iron products with 0 to 26 mg of iron). Several vitamin combinations that do not contain the adequate ingredients for classification as prenatal vitamins or are not labeled as prenatal vitamins are affected. Due to the CFR 199.4 regulations for coverage of vitamins, the products moving to multivitamin status will no longer be covered under the TRICARE pharmacy benefit.

Patients impacted by this change at the Mail, Retail, and MHS GENESIS sites will receive letters in February 2020, and the products will be removed from the Pharmacy Benefit on April 1, 2020.

B. Annual Review of Newly Approved Drugs

The Committee was briefed on the utilization and cost trends for the newly approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. Since the start of the program, 276 drugs have been reviewed, including 81 in calendar year 2019 alone, with the first selections for Tier 4/Not Covered formulary status also occurring in 2019. For 2019, 49 (61% of the drugs) were designated with UF status, 27 (33%) remained NF, and 5 (6%) were selected for Tier 4/Not Covered status. Updates on the metrics for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

C. Implementation Results from Tetracyclines

The tetracyclines were reviewed for formulary status in February 2017, and several products were designated as NF and non-step-preferred. Overall trends in utilization and expenditures were reviewed. Following implementation in August 2017, the analysis showed that the annual cost avoidance exceeded the conservative BIA estimate, without negatively impacting overall patient counts or total prescriptions for the class.

D. DoD Long-Term Opioid Therapy Trends and Opioid Prescribing Update

The Committee was briefed on long-term opioid therapy trends in the DoD, including the MHS population, factors associated with high risk of overdose, and impact of Guideline recommendations on prescribing practices. Another presentation reviewed the overall utilization of opioids and naloxone in the MHS, and DoD and non-DoD actions to mitigate opioid prescribing risks.

XII. ADJOURNMENT

The meeting adjourned at 1600 hours on February 6, 2020. The next meeting will be in May 2020.

Appendix A—Attendance: February 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 February 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 27 APR 2020

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

27 APR 20
Date

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

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Paul Hoerner, BSC 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
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Peter Cole, 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
Capt Matthew Bezzant, MC for 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 Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Kelly Echevarria, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Salvatore Maida	Acting General Counsel, DHA
Eugene Moore, PharmD, BCPS, for CDR Eric Parsons, MSC	COR Tricare Pharmacy Program

Appendix A—Attendance (continued)

Guests	
MAJ William Kirby	DLA Troop Support
Capt Joseph Brinkman	Air Force Consultant Guest
LCDR Karsten Smith	Indian Health Service
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
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
MAJ Matthew Krull, MSC	DHA Formulary Management Branch
Dr. Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA MTF Management 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
CPT Leslie Armstrong, MSC	BAMC Pharmacy Resident

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• diclofenac potassium powder packets 50 mg (Cambia) **Pain Agents: NSAIDs**	• Patient has experienced significant adverse effects from at least three formulary NSAIDs • Use of at least 3 formulary NSAIDs has resulted in therapeutic failure **Formulary alternatives**: celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)
• fenoprofen tablets • ketoprofen • ketorolac nasal (Sprix) • meclofenamate • naproxen sodium ER (Naprelan, generic) • tolmetin **Pain Agents: NSAIDs**	• Patient has experienced significant adverse effects from at least three formulary NSAIDs **Formulary alternatives**: celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)
• indomethacin oral suspension **Pain Agents: NSAIDs**	• No alternative formulary agent – patient requires an oral suspension formulation due to swallowing difficulties (e.g. stroke, developmental delay, etc.) **Formulary alternatives**: celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)
• meloxicam ODT (Qmiiz) **Pain Agents: NSAIDs**	• Patient has experienced or is expected to experience significant adverse effects from at least three formulary NSAIDs • No alternative formulary agent - patient has failed therapy with an NSAID in an alternative dosage form and cannot swallow due to some documented medical condition – dysphagia, oral candidiasis, NG tube placement, systemic sclerosis, etc. and not due to convenience **Formulary alternatives**: naproxen oral suspension, celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)
• trifarotene 0.005% cream (Aklief) **Acne Agents: Topical Acne and Rosacea**	• Patient has experienced significant adverse effects from both tretinoin and adapalene that are not expected to occur with the non-formulary, non-step-preferred agent • Patient has tried at least 3 step-preferred topical acne products, including at least two different retinoids (e.g., generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, tazarotene cream, or adapalene) which resulted in therapeutic failure **Formulary Alternatives:** adapalene (cream, gel, lotion), tazarotene (cream), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel)

Drug / Drug Class	Medical Necessity Criteria
• asenapine patch (Secuado) **Antipsychotic Agents: Atypical**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure • Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** risperidone, quetiapine, aripiprazole, olanzapine, olanzapine/fluoxetine, ziprasidone, paliperidone, lurasidone
• baclofen oral solution (Ozobax) **Skeletal Muscle Relaxants and Combinations**	• No alternative formulary agent. Patient cannot swallow and crushed tablets are not an option **Formulary Alternatives:** baclofen tablets
• colchicine oral solution (Gloperba) **Anti Gout Agents: Acute**	• No alternative formulary agent – Patient requires colchicine but cannot swallow colchicine tablets/capsules **Formulary Alternatives:** colchicine capsules/tablets
• diroximel fumarate (Vumerity) **Multiple Sclerosis Agents: Methyl Fumarate**	• Patient has experienced significant adverse effects from formulary agents **Formulary Alternatives:** dimethyl fumarate (Tecfidera)
• minocycline 4% foam (Amzeeq) **Acne Agents: Topical Acne and Rosacea**	• Patient has experienced significant adverse effects from at least 3 formulary agents • At least 3 formulary agents (including combination therapy with clindamycin and benzoyl peroxide products) have resulted in therapeutic failure **Formulary Alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel)
• testosterone undecanoate capsules (Jatenzo) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	• Use of all listed formulary agents are contraindicated • Patient has experienced or is likely to experience significant adverse effects from all listed formulary agents • All listed formulary agents resulted in or are likely to result in therapeutic failure **Formulary Agents:** Androderm patch, testosterone 2% gel (Fortesta), testosterone 1% gel (generic to Androgel), and Testim 1% gel

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• diclofenac potassium powder packets 50 mg (Cambia) **Pain Agents; NSAIDs**	PA criteria apply to all new and current users of **diclofenac potassium powder (Cambia)** Note that multiple formulary NSAIDs and triptans are available without a PA including ibuprofen, indomethacin, naproxen, diclofenac potassium tablets, sumatriptan, rizatriptan, and zolmitriptan. Manual PA Criteria: Cambia is approved if all criteria are met: • Patient is ≥ 18 years of age • Patient has a diagnosis of migraine • Prescription is written by or in consultation with a Neurologist • Patient has tried and failed at least two formulary NSAIDs including diclofenac potassium tablets (Cataflam generic) • Patient has tried and failed or has a contraindication to at least one formulary triptan (e.g., sumatriptan, rizatriptan, and zolmitriptan) Non-FDA-approved uses are NOT approved. Prior authorization expires in one year. No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.
• meloxicam ODT (Qmiiz) **Pain Agents; NSAIDs**	PA criteria apply to all new users of **meloxicam ODT (Qmiiz)** Note that multiple formulary NSAIDs, including meloxicam oral tablets, are available for DoD beneficiaries without a PA Manual PA Criteria: Qmiiz is approved if all criteria are met: • Provider must explain why the patient requires meloxicam ODT and cannot take any of the formulary NSAIDs. Non-FDA-approved uses are NOT approved. PA does not expire.
• naproxen sodium ER (Naprelan brand and generic) **Pain Agents; NSAIDs**	PA criteria apply to all new users of **naproxen CR (Naprelan)** Note that multiple formulary NSAIDs are available without a PA including ibuprofen, indomethacin, meloxicam, naproxen, and celecoxib. Manual PA Criteria: naproxen CR is approved if all criteria are met: • Provider must provide clinical rationale of why patient cannot take any of the formulary NSAIDs. Non-FDA-approved uses are NOT approved. PA does not expire

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
• baclofen oral solution (Ozobax) **Skeletal Muscle Relaxants and Combinations**	Manual PA is required for all new users of Ozobax. Manual PA Criteria: Ozobax is approved if all criteria are met: • Ozobax will be used for the treatment of spasticity • Patient requires baclofen and cannot use the tablet formulation or crushed tablet due to a documented medical condition such as dysphagia, oral candidiasis, or systemic sclerosis, and not due to convenience • Presence of an NG/J-tube alone is not a reason for approval Non-FDA-approved uses are not approved including nystagmus, trigeminal neuralgia, hiccups, GERD, alcohol abstinence in alcoholic liver disease, and low back pain. Prior authorization does not expire.
• benralizumab injection (Fasenra Pen) **Pulmonary 1-Agents: Pulmonary Miscellaneous**	Manual PA is required for all new and current users of Fasenra Pen. Manual PA Criteria: Fasenra Pen is approved if all criteria are met: • The patient has a diagnosis of severe persistent eosinophilic asthma • Patient must be ≥ 12 years • The drug is prescribed by an allergist, immunologist, or pulmonologist • Patient must have an eosinophilic phenotype asthma as defined as either – Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR – Eosinophils ≥ 300 cells/mcL • Patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: – Hospitalization for asthma in past year – Two courses oral corticosteroids in past year – Daily high-dose inhaled corticosteroids with inability to taper off • The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: – LABA (e.g., salmeterol), LAMA (tiotropium), or leukotriene receptor antagonist Non-FDA-approved uses are not approved. Prior authorization does not expire.
• colchicine oral solution (Gloperba) **Anti-Gout Agents: Acute**	Manual PA is required for all new users of Gloperba. Note: other formulations of colchicine (e.g. Colcrys) do not require prior authorization. Manual PA Criteria: Gloperba is approved if all criteria are met: • Provider must explain why the patient requires liquid colchicine and cannot take colchicine capsules or tablets Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• diroximel fumarate (Vumerity) **Multiple Sclerosis Agents: Methyl Fumarate**	Manual PA criteria apply to all new and current users of Vumerity. Manual PA Criteria: Vumerity is approved if all criteria are met: • Documented diagnosis of a relapsing form of Multiple Sclerosis (MS) • Patient must have had at least a two-week trial of Tecfidera and either – Have failed therapy OR – Patient continues to have GI side effects not expected to occur with Vumerity • Complete blood count drawn within six months prior to initiation of therapy, due to risk of lymphopenia • Coverage is NOT provided for concomitant use with other disease-modifying drugs of MS Non-FDA-approved uses are not approved. PA does not expire.
• elexacaftor/tezacaftor/ ivacaftor (Trikafta) **Cystic Fibrosis Agents**	Manual PA is required for all new and current users of Trikafta. Manual PA Criteria: Trikafta is approved if all criteria are met: • Prescribed by or in consultation with a pulmonologist • Prescribed for the treatment of cystic fibrosis (CF) for an FDA-approved age • Patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test • Not approved in combination therapy with Symdeko, Orkambi or Kalydeco Non-FDA-approved uses are not approved. PA does not expire.
• minocycline 4% foam (Amzeeq) **Acne Agents: Topical Acne and Rosacea**	Manual PA applies to new and current users of Amzeeq. Note: Amzeeq is not included in the automated step therapy for the topical acne and rosacea agents Note: Adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, and gel) are available without a PA; providers are encouraged to consider changing the prescription to one of these agents. Manual PA Criteria: Amzeeq is approved if all criteria are met: • Patient has a diagnosis of acne vulgaris • This agent has been identified as having cost-effective alternatives. The provider must explain why the patient requires Amzeeq and cannot take the formulary alternatives. (blank write-in) Non-FDA-approved uses (including rosacea) are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• testosterone undecanoate capsules (Jatenzo)
 	
Androgens-Anabolic Steroids: Testosterone Replacement Therapies
	Manual PA is required for all new and current users of Jatenzo
	
	Manual PA Criteria: Jatenzo is approved if all criteria are met:
	• Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions
	  • Patient is a male age ≥ 18 years
	  • Patient has a diagnosis of deficiency or absence of endogenous testosterone associated with structural or genetic etiologies
	  • Patient is experiencing signs and symptoms usually associated with hypogonadism
	  • Patient has tried testosterone 2% gel (Fortesta) OR testosterone 1% gel (Androgel generic) for a minimum of 90 days AND failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after use of the agent) AND without improvement in symptoms
	OR
	• Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta OR generic testosterone 1% gel, that is not expected to occur with Jatenzo
	• The patient requires a testosterone replacement therapy (TRT) that has a low risk of skin-to-skin transfer between family members
	OR
	• The requested medication is being used for female-to-male gender reassignment (endocrinologic masculinization)
	  • Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND
	  • Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the DSM; AND
	  • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND
	  • Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria; AND
	  • For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding.
	• Patient does not have any of the following:
	  • Hypogonadism conditions not associated with structural or genetic etiologies (e.g. “age-related” hypogonadism), carcinoma of the breast or suspected carcinoma of the prostate
	  • Uncontrolled hypertension or is at risk for cardiovascular events (e.g., myocardial infarction or stroke) prior to start of Jatenzo therapy or during treatment (based on the product’s boxed warning of increased risk of major adverse cardiovascular events and hypertension)
	• Not approved for concomitant use with other testosterone products.
	
	Non-FDA-approved uses are not approved.
	
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• trifarotene 0.005% cream (Aklief) **Acne Agents: Topical Acne and Rosacea**	Manual PA applies to new and current users of Aklief. Note: Aklief is not included in the automated step therapy for the topical acne and rosacea agents. Note: adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, and gel) are available without a PA; providers are encouraged to consider changing the prescription to one of these agents. Manual PA criteria: Aklief is approved if all criteria are met: • Patient has a diagnosis of acne vulgaris • This agent has been identified as having cost-effective alternatives. The provider must explain why Aklief is required and the patient cannot take the formulary alternatives. (blank write-in) Non-FDA-approved uses are not approved. PA does not expire
• voxelotor (Oxbryta) **Hematological Agents: Sickle Cell Anemia Agents**	Manual PA criteria apply to all new and current users of Oxbryta. Manual PA criteria: Oxbryta is approved if all criteria are met: • Patient meets FDA-indicated age requirements for Oxbryta • Patient has a diagnosis of sickle cell disease • Patient has had at least one vaso-occlusive crisis in the last 12 months AND has a hemoglobin between 5.5 g/dL and 10.5 g/dL • Patient has had an inadequate treatment response to a 3 month trial of hydroxyurea • Drug is prescribed by or in consultation with a hematologist • For patients on a strong or moderate CYP3A4 inducer (e.g. carbamazepine, phenytoin, rifampin, etc.): – Provider acknowledges that prior to starting Oxbryta patient should be switched to a drug that does not interact with Oxbryta. If, and only if, this is not possible, provider should continue the CYP3A4 inducer and increase the dose of Oxbryta per the package insert. Non-FDA-approved uses are not approved. PA expires after 1 year. Renewal criteria: PA will be approved indefinitely if • There is documented improvement in Hb by ≥ 1 g/dL from baseline OR • The patient has demonstrated a decreased number of vaso-occlusive crises by ≥ 1 crisis/year from baseline in past 12 months

Drug / Drug Class	Prior Authorization Criteria
• zanubrutinib (Brukinsa) **Oncologic Agents**	Manual PA criteria apply to all new users of Brukinsa. Manual PA Criteria: Brukinsa is approved if all criteria are met: • Patient is ≥ 18 years • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL). • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment • The diagnosis Is NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Non-FDA-approved uses are not approved. PA does not expire.
New PAs	
• epinephrine (Auvi-Q) auto-injector **Respiratory Agents Miscellaneous**	Manual PA criteria apply to all new users of epinephrine (Auvi-Q) auto-injector. Note: Auvi-Q has been identified as having cost-effective alternatives including EpiPen, EpiPen generic, and Symjepi. These agents do not require prior authorization. Manual PA Criteria: Coverage for Auvi-Q is approved if all criteria are met: • The provider documents a patient-specific reason as to why the patient cannot use the formulary alternatives (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• generic insulin aspart (authorized generic for Novolog) **Insulin: Rapid-Acting Agents**	Manual PA criteria apply to new and current users of authorized generic insulin aspart. Note: Brand Novolog or brand Humalog are the preferred rapid acting insulins and do not require prior authorization. Manual PA Criteria: Coverage for authorized generic insulin aspart is approved if all criteria are met: • The provider explains a patient-specific justification as to why the brand Novolog or brand Humalog product cannot be used (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• prenatal multivitamin (Zalvit) **Vitamins: Prenatal**	Manual PA criteria apply to new and current users of Zalvit, regardless of the woman's age. Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco and Zalvit and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant. Manual PA Criteria: Coverage for Azesco or Zalvit is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• sulfacetamide and sulfacetamide/sulfur and combination products **Topical Acne and Rosacea Agents**	Manual PA criteria apply to new and current users of sulfacetamide and sulfacetamide combination products. Note: sulfacetamide 10% lotion/suspension (Klaron, generics) and sulfacetamide/sulfur 10%-5% cleanser (Rosanil, Avar, generics) are available without requiring prior authorization. Providers are encouraged to consider changing the prescription to these preferred sulfacetamide formulations. Manual PA Criteria: Coverage for sulfacetamide and sulfacetamide combination products is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• venlafaxine HCL ER 24 hr. tablets **Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin-Norepinephrine Reuptake Inhibitors**	Manual PA criteria apply to new and current users of venlafaxine HCL ER 24 hr. tablets. Note: venlafaxine ER capsules and venlafaxine IR tablets are available without requiring prior authorization; providers are encouraged to consider changing the prescription to the preferred venlafaxine formulations, venlafaxine ER capsules, or venlafaxine IR tablets. Manual PA Criteria: Coverage for venlafaxine HCL ER 24 hr. tablets is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to the available alternatives (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
Updated PAs (on next page)	

Drug / Drug Class	Prior Authorization Criteria
• deflazacort (Emflaza) **Corticosteroids-Immune Modulators**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** Manual PA criteria applies to all new users of Emflaza. Manual PA Criteria: Emflaza is approved if all criteria are met: • The patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) • The drug is prescribed by a neurologist • Patient is age ~~5~~ **2 years** or older • Patient has tried prednisone for at least 6 months and has experienced at least 1 of the following adverse events (AEs): – Unmanageable weight gain OR – Experienced severe behavioral adverse events that requires a reduction in prednisone dose Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• doxycycline (Oracea) **Acne Agents: Tetracyclines**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** [Note that Oracea will be removed from the current automated step therapy that is in place for the tetracyclines drug class and will be on its own individual manual PA form.] **Manual PA criteria applies to all new and current users of Oracea.** **Note: The following agents are available without prior authorization: doxycycline IR 20 mg tablet, doxycycline 50 mg and 100 mg capsule or tablet, and metronidazole 1% gel; providers are encouraged to consider changing the prescription to one of these preferred agents.** Manual PA Criteria: Oracea is approved if all criteria are met: • The patient is ≥ 18 years of age • The patient has a diagnosis of rosacea with inflammatory lesions (papules and pustules) • **The provider describes why Oracea is required as opposed to available alternatives. _____ (blank write-in)** Non-FDA-approved uses are NOT approved. **Prior authorization expires after 1 year.** **Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if all of the following are met (Note that initial TRICARE PA approval is required for renewal):** • **The provider acknowledges that Oracea efficacy beyond 16 weeks and safety beyond 9 months have not been established** • **The patient's therapy has been reevaluated within the last 12 months (unless re-evaluation not clinically appropriate)** • **The patient is tolerating treatment and there continues to be a medical need for Oracea** • **The patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient's condition)**

Drug / Drug Class	Prior Authorization Criteria
• erenumab-aooe (Aimovig) • fremanezumab-vfrm (Ajovy) • galcanezumab-gnlm (Emgality) **Migraine Agents: CGRP Preventative**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** Manual PA criteria applies to all new users of Aimovig, Ajovy, and Emgality. Manual PA Criteria: Aimovig, Ajovy, or Emgality is approved if all criteria are met: • Patient is ≥ 18 years old and not pregnant • Must be prescribed by or in consultation with a neurologist • The patient also meets one of the following: – Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR – Patient has episodic migraine at a rate a migraine diagnosis with of at least 8 migraine days per month for 3 months OR – Patient has a diagnosis of chronic migraine • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: – Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate – Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol – Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine • ~~**Patient is not currently on botulinum toxin or patient must not have received a botulinum toxin injection within the last 2 months**~~ • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed • For Emgality, a loading dose will be allowed Non-FDA-approved uses are NOT approved. Prior authorization expires after 6 months. Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if one of the following apply (Note that initial TRICARE PA approval is required for renewal): • The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR • The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: – Migraine Disability Assessment (MIDAS) • Reduction of ≥ 5 points when baseline score is 11–20 • Reduction of ≥ 30% when baseline score is > 20 – Headache Impact Test (HIT-6) • Reduction of ≥ 5 points – Migraine Physical Functional Impact Diary (MPFID) • Reduction of ≥ 5 points

Drug / Drug Class	Prior Authorization Criteria
• icosapent ethyl (Vascepa) **Antilipidemic-2: Omega-3 Fatty Acids**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** **Note that the existing criteria for Lovaza will remain, with the exception that concurrent use with Vascepa will not be allowed. Both Vascepa and Lovaza will remain on the same PA form.** Manual PA criteria applies to all new users of Vascepa and Lovaza. Manual PA Criteria: Vascepa is approved if all criteria are met: • The patient has a diagnosis of hypertriglyceridemia • The patient has a triglyceride (TG) level ≥ 500 mg/dL • ~~The patient has TG level < 500 mg/dL~~ • ~~The patient is currently taking a statin AND had an inadequate TG-lowering response to a therapeutic trial of niacin (1-2 g/day) OR fibrates, OR is unable to tolerate niacin or fibrates, or is not a candidate for niacin or fibrate therapy~~ ~~OR~~ • ~~The patient is not currently taking a statin AND had an inadequate TG-lowering response to a therapeutic trial of niacin (1-2 g/day) AND fibrates, AND is unable to tolerate BOTH niacin AND fibrates, OR is not a candidate for BOTH niacin AND fibrate therapy~~ • **The patient has tried and failed generic Lovaza** • **The patient is not receiving Vascepa and Lovaza concurrently** **OR (below only applies to Vascepa)** • **The patient requires Vascepa for cardiovascular (CV) outcome reduction (i.e. reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization)** • **The patient does not have a history of acute or chronic pancreatitis** • **TG level between 200 mg/dL and 499 mg/dL** • **The patient is currently receiving a statin with low-density lipoprotein (LDL) < 100 mg/dL** • **The patient has established CV disease and Vascepa is being used for secondary prevention OR** • **Vascepa is being used for primary prevention and the patient has:** – **diabetes mellitus (DM) AND** – **at least one additional risk factor for CV disease (hypertension, hyperlipidemia, age > 50 years)** • **The patient is not receiving Vascepa and Lovaza concurrently** Non-FDA-approved uses are NOT approved including the following: Attention Deficit Hyperactivity Disorder, Alzheimer's disease, bipolar disease, Crohn's disease, cystic fibrosis, dementia, depression, inflammatory bowel disease, intermittent claudication, metabolic syndrome, osteoporosis, post-traumatic stress disorder, renal disease (immunoglobulin A nephropathy), rheumatoid arthritis, schizophrenia, Type 2 diabetes mellitus, and ulcerative colitis. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• insulin glargine U-300 (Toujeo) **Insulin: Basal**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** Manual PA criteria apply to new users of Toujeo. Manual PA Criteria: Coverage for Toujeo is approved if all criteria are met: • Patient is ≥ ~~18~~ **6** years of age • Patient has diagnosis of diabetes and is using a minimum of 100 units of insulin glargine (Lantus) per day • Patient requires a dosage increase with Lantus and has experienced a clinically significant, severe hypoglycemia episode, despite splitting the Lantus dose • Patient, **parent, or caregiver** has been counseled regarding the risk of dosing errors • The following are not acceptable reasons for receiving Toujeo – Non-adherence to previous insulin treatment OR – Patient or prescriber preference for the use of Toujeo OR – Patient or prescriber preference for a smaller injection volume Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• mepolizumab (Nucala) **Pulmonary-1 Agents: Pulmonary Miscellaneous**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** Manual PA criteria applies to new users of Nucala. Manual PA Criteria: Coverage for Nucala is approved if all criteria are met: For eosinophilic asthma: • The patient has a diagnosis of severe persistent eosinophilic asthma • ~~**Patient must be ≥ 12 years**~~ • The drug is prescribed by an allergist, immunologist, or pulmonologist • Patient has an eosinophilic phenotype asthma as defined as either – blood eosinophil count of > 150 cells/mcL within the past month while on oral corticosteroids OR – ≥ 300 cells/mcL within the past year • The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen, with uncontrolled asthma defined as – Hospitalization for asthma in the past year OR – Required course of oral corticosteroids twice in the past year OR – Daily high-dose inhaled corticosteroid (ICS) with inability to taper off the ICS • The patient has tried and failed an adequate course (3 months) of at least two of the following while using a high-dose inhaled corticosteroid: – Inhaled long-acting beta agonist (LABA) (e.g., Serevent, Striverdi), long-acting muscarinic antagonist (LAMA) (e.g., Spiriva, Incruse), leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) OR For eosinophilic granulomatosis with polyangiitis (EGPA): • Patient must have diagnosis of EGPA • The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist, or hematologist • Patient must be ≥ 18 years • The patient has had an adequate trial of at least 3 months of one of the following with either an inadequate response to therapy or significant side effects/toxicity or the patient has a contraindication to therapy with – Corticosteroids, cyclophosphamide, azathioprine, or methotrexate • An quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication only Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• tofacitinib (Xeljanz, Xeljanz XR) **Targeted Immunomodulatory Biologics (TIBs): Miscellaneous**	**Changes from the February 2020 meeting are in BOLD and strikethrough.** Step therapy and manual PA criteria apply to new users of Xeljanz, Xeljanz XR. Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, coverage for Xeljanz, Xeljanz XR is approved if all criteria are met: • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira • Age ≥ 18 years • Patient has a diagnosis of: o Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate ▪ The prescription is for 5 mg BID or 11 mg once a day o Active psoriatic arthritis (PsA) ▪ The prescription is for 5 mg BID or 11 mg once a day o Moderately to severely active ulcerative colitis (UC) ▪ Will allow doses up to 10 mg BID **OR up to 22 mg once a day** • Patient has no history of thromboembolic disease • Patient hemoglobin (Hgb) must be > 9 g/dL • Patient absolute neutrophil count (ANC) < 1,000/mm^3 • Patient absolute lymphocyte count (ALC) < 500/ mm^3 • The patient is not receiving potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.) • May not be used concomitantly with other TIBs agents except for Otezla Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• Diclofenac potassium powder packets (Cambia) **Pain Agents: NSAIDs**	▪ Retail: 18 packets/30 days ▪ MTF/Mail: 54 packets/90 days Note that Cambia is packaged in boxes of 9 packets Note that implementation will occur 2 weeks after signing of the minutes, along with the rest of the QLs in this table
• ketorolac nasal (Sprix) **Pain Agents: NSAIDs**	▪ Retail/MTF/Mail: 5 bottles/30-day supply at all POS Note that implementation will occur 2 weeks after signing of the minutes, along with the rest of the QLs in this table
• lidocaine 5% patch (Lidoderm generic) **Pain Agents: Pain Topical**	▪ Retail: 90 patches per fill ▪ MTF/Mail: 270 patches per fill
• benralizumab injection (Fasenra Pen) **Pulmonary-1 Agents: Pulmonary Miscellaneous**	▪ Retail/MTF/Mail: 1 pen per fill at all POS
• elexacaftor/tezacaftor/ ivacaftor (Trikafta) **Cystic Fibrosis Agents**	▪ Retail/MTF/Mail: 84 tabs/28 days at all POS
• ivacaftor (Kalydeco) **Cystic Fibrosis Agents**	▪ Retail/MTF/Mail: 60 tabs/30 days at all POS
• Newly approved drugs **Cystic Fibrosis Agents**	▪ Retail/MTF/Mail: “x number” tabs/28 days or “y number” tabs/30 days (based on packaging) at all POS
• pegfilgrastim-bmez (Ziextenzo) **White Blood Cell Stimulants: Pegfilgrastims**	▪ Retail: 1 syringe per 21 days and a 21-day supply ▪ MTF/Mail: 2 syringes per 45 days and a 45-day supply
• zanubrutinib (Brukinsa) **Oncological Agents**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply

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
amlodipine and celecoxib (Consensi)	Pain Agents Class; NSAIDs Subclass	• amlodipine and celecoxib taken separately	Adult patients for whom treatment with amlodipine for hypertension (HTN) and celecoxib for osteoarthritis (OA) are appropriate.	• Limited clinical utility due to a narrow potential treatment population • Package labeling contains the NSAID usual black box warning regarding CV risk, but does not have the usual antihypertensive labeling for beneficial CV outcomes • May cause harm as NSAIDs should be used for the shortest time possible and at the lowest possible dose to decrease adverse CV outcomes • Patients who are partially compliant to their pain management are at risk for having suboptimal management of their HTN • Provides little to no additional clinical effectiveness relative to giving the individual components separately; the needs of TRICARE beneficiaries are met by available alterative agents	• Tier 4/Not Covered (part of NSAID class review)
albuterol dry powder inhaler (ProAir Digihaler)	Pulmonary-1 Agents: Short Acting Beta Agonists	• albuterol MDI (ProAir HFA) • albuterol DPI (ProAir Respiclick) • albuterol MDI (Proventil HFA) • albuterol MDI (Ventolin HFA) • levalbuterol MDI (Xopenex HFA)	Treatment or prevention of bronchospasm in patients ≥ 4 years of age with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm (EIB) in patients ≥ 4 years of age	• ProAir Digihaler is another albuterol inhaler similar to the dry powder inhaler ProAir Respiclick but with App technology • There are no new clinical efficacy studies undertaken for the approval of ProAir Digihaler • There is no evidence that the use of the App leads to improved clinical outcomes • ProAir Digihaler provides little to no clinical benefit relative to existing formulary agents	• Tier 4/Not Covered
asenapine transdermal system (Secuado)	Antipsychotic Agents: Atypical	• aripiprazole oral liquid (Abilify, generics) • asenapine sublingual tab (Saphris, generics) • brexpiprazole (Rexulti) • cariprazine (Vraylar) • lurasidone (Latuda, generics)	Schizophrenia in adults	• Secuado is a new formulation of asenapine available in a patch • Secuado is the first transdermal atypical antipsychotic (AAPs) • Evaluated in one unpublished study with the Positive and Negative Syndrome Scale (PANSS) score as the primary end point • Statistically and clinically superior to placebo in change in PANSS from baseline • No head-to-head studies with other AAPs indicated for schizophrenia • Most common ADRs included extrapyramidal disorder, application site reaction and weight gain • Secuado provides another alternative AAP dosage form however it has no compelling clinical advantages compared to existing formulary agents	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
baclofen oral solution (Ozobax)	Skeletal Muscle Relaxants and Combinations	• baclofen tablets • dantrolene tablets • tizanidine tablets	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity	• Ozobax is another formulation of baclofen in an oral solution • Approved based on bioequivalence to baclofen 20 mg tablets • Liquid formulation may be helpful to the patients who require an alternate dosage form • Although Ozobax provides a formulation for patients with swallowing difficulties, it provides no compelling clinical advantage over existing agents	• NF • Do not add to EMMI list
benralizumab injection (Fasenra Pen)	Pulmonary 1-Agents: Pulmonary Miscellaneous	• dupilumab injection (Dupixent) • mepolizumab injection (Nucala) • omalizumab injection (Xolair) (medical benefit) • reslizumab (Cinqair) (medical benefit)	Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype	• Fasenra Pen is the 3rd pharmacy benefit biologic therapy for treating type 2 inflammatory asthma; it is 1 of 5 FDA-approved biologic therapies for type 2 inflammatory asthma • Fasenra Pen was statistically superior compared to placebo in terms of reducing the daily oral corticosteroid dose and annual asthma exacerbation rates when compared to placebo • A 2017 Cochrane review, 2017, 2018 ICER report , and a 2019 network meta analysis (J Allergy Clin Immunol) show that Fasenra pen produced a statistically significant difference over placebo in reducing asthma exacerbations • Fasenra Pen provides another option in the treatment of type 2 inflammatory asthma utilizing the IL-5 rα pathway	• UF • Do not add to EMMI list
benzoyl peroxide 9.8% foam (Enzoclear)	Keratolytics	• benzoyl peroxide 5% topical gel (OTC) • benzoyl peroxide 10% foaming wash (OTC)	Indicated for use in the topical treatment of mild to moderate acnes vulgaris	• Enzoclear is a benzoyl peroxide 9.8% foam for the treatment of mild to moderate acne • It is an unapproved drug which means that it has not been reviewed by the FDA for safety, effectiveness or quality • There are several other products available to treat acne including prescription combination products containing benzoyl peroxide and OTC benzoyl peroxide products • Enzoclear has very little to no additional clinical effectiveness relative to formulary topical agents for acne and is not FDA-approved	• Tier 4/Not Covered
colchicine oral solution (Gloperba)	Anti Gout Agents: Acute	• colchicine 0.5mg/probenecid 500 mg (Col-Probenecid) • colchicine 0.6 mg tablet (Colcrys) • colchicine 0.6 mg capsules (Mitigare)	Prophylaxis of gout flares in adults	• Gloperba is a new oral solution formulation of colchicine • No new clinical data • Gloperba offers another formulation for patients with swallowing difficulties but provides no compelling clinical advantages compared to existing formulary agents	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
diroximel fumarate (Vumerity)	Multiple Sclerosis Agents: Methyl Fumarate	▪ dimethyl fumarate (Tecfidera)	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	• Vumerity is the 2nd methyl fumarate product approved • Approval was based on bioequivalence to dimethyl fumarate (Tecfidera) which has the same manufacturer • No new clinical trial data; Tecfidera data was used for approval • Dimethyl fumarate and diroximel fumarate rapidly convert to the active substrate monomethyl fumarate • Based on an unpublished study and a theorized difference in the metabolic pathways between the two drugs, Vumerity may cause less GI adverse events compared to Tecfidera however, clinical relevance is unknown • Expect to see future competition with recently approved FDA generics for Tecfidera as well as the expected monomethyl fumarate (Bafiertam) launch in June 2020 • Vumerity provides little to no clinical benefit relative to existing formulary agents	• NF and non-step-preferred • Do not add to EMMI list
elexacaftor/ tezacaftor/ ivacaftor (Trikafta)	Cystic Fibrosis (CF) Agents	• lumacaftor/ivacaftor (Orkambi) • tezacaftor/ivacaftor (Symdeko)	Treatment of CF in patients ≥ 12 yo who have at least one F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation	• Trikafta is the 4th drug available for CF treatment and 3rd combination product • Trikafta is a combination of two existing cystic fibrosis transmembrane regulators (CFTRs) available as a single tablet called Symdeko and one new CFTR, elexacaftor • Two pivotal phase III studies showed statistically significant improvement in the absolute change from baseline in percent predicted forced expiratory volume in 1 second (ppFEV1) compared to placebo (Study 1) and Symdeko (Study 2) • Trikafta offers a more effective treatment than Symdeko in patients homozygous for F508del mutation and is the only effective therapy for patients with one F508del mutation and one minimal function mutation	• UF • Do not add to EMMPI list
minocycline 4% topical foam (Amzeeq)	Acne Agents: Topical Acne and Rosacea	• clindamycin 1% foam • minocycline 50 mg capsule • clindamycin-benzoyl peroxide 1%-5% gel	To treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients ≥ 9 years of age	• Amzeeq is the 1st FDA-approved topical minocycline and the 5th topical antibiotic available for acne • Amzeeq was only compared to placebo; statistical significance was reached for the majority, but not all of the primary efficacy endpoints in the 3 pivotal clinical studies • Headache is the most common ADR • Storage requirements may limit utility • Warnings and precautions with Amzeeq are identical to that of oral minocycline except flammability • There are many other available topical acne products with better efficacy that do not have flammability and storage constraints	• NF and non-step-preferred • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
omeprazole Mg/amoxicillin/ rifabutin (Talicia)	Anti-infective: Miscellaneous	• omeprazole + amoxicillin + clarithromycin • omeprazole + amoxicillin + rifabutin (given separately)	For the treatment of *Helicobacter pylori* infection in adults	• Talicia is fixed-dose combination of 3 drugs (omeprazole, amoxicillin, and rifabutin) to treat *H. pylori* • American College of Gastroenterology (ACG) 2017 guidelines list rifabutin + PPI + amoxicillin as a salvage regimen, not a first-line treatment option • Talicia is dosed more frequently (TID) and contains more pills per day (12) than many *H. pylori* regimens • Efficacy was established in 2 unpublished phase III trials, but active-comparator trial did not compare against a first-line treatment regimen • Talicia has several drug interactions and the most common ADRs include diarrhea, headache, and nausea • Other than providing a fixed-dose combination, Talicia provides no compelling advantages over the individual generic components and patients would pay a higher copay for Talicia vs copays for 3 individual ingredients	• Tier 4/Not Covered
pegfilgrastim-bmez injection (Ziextenzo)	Hematological Agents: White Blood Cell Stimulants	• pegfilgrastim (Neulasta) • pegfilgrastim-jmdb (Fulphila) • pegfilgrastim-cbqv (Udenyca)	To decrease the incidence of infection in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs	• Ziextenzo is the 4th biosimilar of pegfilgrastim (Neulasta) • No new clinical data exists • Ziextenzo provides no compelling advantage or disadvantage over existing formulary agents	• UF • Do not add to EMMPI list
pretomanid	Anti-tubercular agents	• levofloxacin + bedaquiline + linezolid + cycloserine + ethambutol (among others)	Only for the treatment of adults with pulmonary extensively drug-resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis as part of a combination therapy with bedaquiline and linezolid (as part of BPaL regimen)	• Indicated for the treatment of adults with pulmonary XDR-TB, treatment-intolerant or nonresponsive MDR-TB in combination with bedaquiline and linezolid (BPaL regimen) • MDR-TB and XDR-TB are difficult to treat diseases associated with significant morbidity and mortality • Approval based on limited safety and efficacy data • Several serious warnings and precautions, but all regimens used to treat these diseases have serious warnings and precautions • Guidelines do not yet mention pretomanid's role in therapy • Low expected utilization in the US • Pretomanid provides clear clinical benefit relative to existing formulary agents due to a higher cure rate and lower pill burden	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
testosterone undecanoate capsules (Jatenzo)	Androgens-Anabolic Steroids: Testosterone Replacement Therapies	• testosterone 2% gel (Fortesta, generics) • testosterone 1% gel (Testim, generics) • Striant buccal • Xyosted injection	Primary hypogonadism, hypogonadotropic hypogonadism	• Jatenzo is the 1st oral testosterone and 13th available testosterone replacement therapy (TRT) in the class approved for primary hypogonadism, hypogonadotropic hypogonadism • Jatenzo differs from other TRTs in safety including mild GI adverse effects and a clinically significant increase in blood pressure • Efficacy of Jatenzo was evaluated in three phase 3 trials and one long term extension study showing similar results to Axiron in average testosterone concentration • Jatenzo requires periodic monitoring for HTN due to boxed warnings of increased risk of HTN and major adverse CV events (MACE) • Although Jatenzo provides the first oral capsule formulation for testosterone, it provides no compelling clinical advantages over other TRT products	• NF and non-step-preferred • Add to EMMI list
trifarotene 0.005% cream (Aklief)	Acne Agents: Topical Acne and Rosacea	• tretinoin 0.1% cream • adapalene 0.1% cream • tazarotene 0.1% cream • tazarotene 0.1% foam	For topical treatment of acne vulgaris in patients ≥ 9 years old	• 4th topical retinoid for acne available in US • Topical retinoids are recommended as first-line treatment for most acne patients • Aklief has a unique mechanism of action as a selective RAR-γ agonist • Limited clinical data available; no head to head studies with other retinoids • Two 2 vehicle-controlled trials showed efficacy for facial and truncal acne • Similar to the other retinoids, application site irritation, application site pruritus, and sunburn were the most common ADRs • Although Aklief targets a different receptor than the other retinoids and theoretically may cause less irritation, head to head studies with other retinoids are necessary to confirm this theory • Aklief offers another retinoid option, however there are no compelling advantages over existing formulary topical retinoids	• NF and non-step-preferred • Add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
voxelotor (Oxbryta)	Hematological agents: Sickle cell anemia agents	• hydroxyurea capsule (Droxia) • hydroxyurea tablet (Siklos) • l-glutamine powder (Endari)	For the treatment of sickle cell disease (SCD) in adults and pediatric patients ≥ 12 years old	• 1st SCD agent that treats the cause of the disease versus only managing symptoms • Oxbryta can be used in combination with hydroxyurea • Approximately 50%of patients treated with high-dose Oxbryta had a Hb response of ≥ 1 g/dL • Annualized incidence rate of vaso-occlusive crisis was slightly lower, but similar overall between Oxbryta and placebo-treated patients • Headache and diarrhea were the most common ADRs • Oxbryta offers another treatment option for a serious disease with limited treatment options	• UF • Do not add to EMMI list
zanubrutinib (Brukinsa)	Oncological agents	• ibrutinib (Imbruvica) • acalabrutinib (Calquence)	adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy	• Brukinsa is the 6th option for relapsed/refractory MCL and the 3rd 'brutinib' aka BTK inhibitor • Brukinsa has comparable efficacy and safety to other brutinibs • Brukinsa offers an additional treatment option as an alternative to ibrutinib or acalabrutinib	• UF • Do not add to EMMI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 during the February 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)
February 2020	**Pain Agents: NSAIDs UF (brand maintenance only)** • add diclofenac /misoprostol • maintain Anaprox DS, Celebrex, Daypro, Feldene, Mobic, Nalfon, and Naprosyn **Pain Agents: NSAIDs Designated NF** *No reason to exempt from EMMPI requirement* • add meloxicam ODT (Qmiiz ODT) and tolmetin N**ewly Approved Drugs per 32 CFR 199.21 (g)(5)** **Designated UF:** *Similar agents are already on list* ▪ benralizumab (Fasenra Pen) ▪ pegfilgrastim-bmez (Ziextenzo) **Designated NF:** *No reason to exempt from EMMPI requirement:* ▪ baclofen oral solution (Ozobax) ▪ minocycline 4% foam (Amzeeq) ▪ testosterone undecanoate capsule (Jatenzo) ▪ trifarotene 0.005% cream (Aklief) *Similar agents are already on list:* ▪ diroximel fumarate (Vumerity)	**Pain Agents: NSAIDs Designated NF** *Drugs for acute or limited duration use - Do not add* • diclofenac potassium powder packets (Cambia), fenoprofen tabs, indomethacin oral susp, ketoprofen, ketorolac nasal (Sprix), meclofenamate, naproxen sodium ER (Naprelan) *Remove* • Voltaren, Voltaren XR (discontinued brand names) • Duexis and Vivlodex (due to Tier 4 status) **Pain Agents: Pain Topical UF (brand maintenance only)** *Maintain current status and do not add any agents* • Lidoderm 5% patch, Pennsaid 1.5% solution, and Voltaren 1% gel N**ewly Approved Drugs per 32 CFR 199.21 (g)(5)** **Designated UF:** *Not yet clear if feasible to provide through mail order:* • elexacaftor/tezacaftor/ivacaftor (Trikafta) • voxelotor (Oxbryta) • zanubrutinib (Brukinsa) *Drugs in classes not currently on the list* • pretomanid **Designated NF:** *Antipsychotic exemption* • asenapine transdermal system (Secuado) *Acute use exception* • colchicine oral solution (Gloperba) **Pulmonary-1 Agents: Combinations Designated NF** *Drugs for acute use* • remove Symbicort and Dulera (approved for acute use at Nov 2019 P&T Committee meeting)

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
Feb 2020	**Pain Agents: NSAID Subclass**	UF Class Review Class last reviewed August 2011	**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** ▪ amlodipine/celecoxib (Consensi) ▪ diclofenac potassium liquid-filled capsules(Zipsor) ▪ diclofenac submicronized (Zorvolex) ▪ fenoprofen capsules ▪ ibuprofen/famotidine tablets (Duexis) ▪ indomethacin submicronized (Tivorbex) ▪ meloxicam submicronized (Vivlodex) ▪ naproxen and esomeprazole (Vimovo)			Pending signing of the minutes / 120 days The effective date is August 26, 2020.	▪ Updated manual PA criteria were added for new users for naproxen CR and Qmiiz ▪ Manual PA criteria for new and current Cambia users was added. ▪ QLs were added for Cambia and updated for Sprix	▪ Celecoxib and diclofenac sodium were added to the BCF ▪ Note that salsalate and naproxen oral suspension were removed from the BCF ▪ See Appendices B and C for MN and PA criteria.
			▪ celecoxib (added) ▪ diclofenac sodium (added) ▪ ibuprofen 400 mg, 600 mg & 800 mg (generic) ▪ indomethacin IR 25 mg & 50 mg (generic) ▪ meloxicam 7.5 mg & 15 mg (generic) ▪ naproxen 250 mg & 500 mg (generic)	▪ celecoxib (Celebrex) ▪ choline mag trisalicylate ▪ diclofenac/misoprostol (Arthrotec) ▪ diclofenac potassium tablets (Cataflam generic) ▪ diclofenac sodium tablets (Voltaren generic) ▪ diflunisal ▪ etodolac ▪ flurbiprofen ▪ ibuprofen 400 mg, 600 mg & 800 mg (generic) ▪ indomethacin IR 25 mg & 50 mg (generic) ▪ indomethacin ER 75mg (generic) ▪ indomethacin rectal suppository ▪ ketorolac ▪ meloxicam 7.5 mg & 15 mg (generic) ▪ nabumetone ▪ naproxen 250 mg & 500 mg (generic) ▪ naproxen 125mg/5ml oral susp (generic) ▪ naproxen IR 375 mg (generic) ▪ naproxen DR 375mg & 500 mg (generic) ▪ naproxen sodium 275 mg & 550 mg (Anaprox, generic) ▪ oxaprozin ▪ piroxicam ▪ salsalate ▪ sulindac ▪ mefenamic acid (Ponstel, generic) 250 mg	▪ diclofenac potassium powder packets 50 mg (Cambia) ▪ fenoprofen tablets ▪ indomethacin oral suspension ▪ ketoprofen ▪ ketorolac nasal (Sprix) ▪ meclofenamate ▪ meloxicam ODT (Qmiiz) ▪ naproxen sodium ER (Naprelan, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card ▪ tolmetin			

TRICARE Formulary Search tool: http://www.express-scripts.com/tricareformulary

<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">Feb 2020</td><td rowspan="2">Pain Agents: Topical Pain Subclass</td><td rowspan="2">UF Class Review

Class previously reviewed February 2013</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

▪ diclofenac 2% solution (Pennsaid)
▪ diclofenac 1.3% patch (Flector)
▪ lidocaine 1.8% patch (ZTlido)</td><td rowspan="2">Pending signing of the minutes / 120 days

The effective date is August 26, 2020</td><td rowspan="2">▪ QL for lidocaine 5% patch (Lidoderm) will remain at 90 patches for 30 days at retail and 270 patches for 90 days at MTF and mail.</td><td rowspan="2">Note that diclofenac 1% gel and lidocaine 5% patch were added to the BCF</td></tr>
<tr><td>▪ diclofenac 1% gel (added)
▪ lidocaine 5% patch (added)</td><td>▪ diclofenac 1% gel
▪ diclofenac 1.5% solution (Pennsaid)
▪ lidocaine 5% patch</td><td>▪ None</td></tr>
</table>

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
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)	• 120 days after signing • August 26, 2020
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	• 120 days after signing • 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)	• 120 days after signing • 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 (Pennsaid) • diclofenac 2% solution (Pennsaid)	• oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) • diclofenac 1.5% solution • diclofenac 1% gel	• 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; Pain Topical Subclass	• lidocaine 1.8% patch (ZTlido)	• lidocaine 5% patch	• 120 days after signing • August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
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)	• 120 days after signing • August 26, 2020
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	• 120 days after signing • 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]	• 120 days after signing • 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] • glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary]	• June 3, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
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
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 recommendation)* • 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
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 (see above)

*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 .

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
OTC Laxatives and Cathartics		
February 2020	**Retained GCNs** ▪ 09131 docusate sodium 50 mg/5 mL liquid ▪ 09101 docusate sodium 100 mg cap ▪ 86212 polyethylene glycol 3350 17 g/dose powder ▪ 08762 bisacodyl 5 mg tab DR ▪ 08731 bisacodyl 10 mg supp ▪ 00701 sennosides 8.6 mg tab ▪ 13483 sennosides/docusate sodium 8.6-50 mg tab ▪ 08660 sennosides 8.8 mg/5 mL syrup ▪ 09240 magnesium citrate solution ▪ 08860 glycerin adult rectal supp ▪ 08861 glycerin pediatric rectal supp ▪ 66559 sodium phosphate, mono-dibasic 19G-7G/188 enema ▪ 98276 sodium phosphate, mono-dibasic 9.5-3.5/59 enema **Added GCNs*** ▪ 46303/45889 psyllium husk (with sugar) ▪ 43199 psyllium husk/aspartame 3 G/5.8 G powder	**Removed GCNs** ▪ 09152 docusate sodium 60 mg/15 mL syrup ▪ 09171 docusate sodium 100 mg tab ▪ 09102 docusate sodium 250 mg cap ▪ 30916 docusate sodium 283 mg/5 mL enema ▪ 09061 docusate calcium 240 mg cap ▪ 86211 polyethylene glycol 3350 17 g powder pack ▪ 14356 psyllium husk (with sugar) 3.4 G/7 G powder ▪ 14567 psyllium husk (with sugar) 3.4 G/12 G powder ▪ 35998 psyllium husk/aspartame 3.5 G/5.8 G powder ▪ 66610 psyllium seed (with sugar) powder ▪ 66600 psyllium seed (with dextrose) powder ▪ 36049 psyllium husk (with dextrose) 3.4 G/6.5 G powder ▪ 27533 psyllium husk/aspartame 3.4 G powder pack ▪ 09020 mineral oil (oral) ▪ 09049 mineral oil enema
OTC Calcium and Vitamin D Preparations		
February 2020	**Retained GCNs** ▪ 07872 calcium carbonate 500 mg/5 mL oral susp ▪ 03721 calcium carbonate 500 mg tab ▪ 23323 calcium carbonate/vit D3 600 mg-400 mg tab ▪ 09821 calcium citrate 200 mg tab ▪ 26416 Vit D3 400 unit/mL drops ▪ 53740 Vit D3 400 unit tab ▪ 00223 Vit D3 1000 unit tab ▪ 93242 Vit D3 5,000 unit cap ▪ 94411 Vit D2 (ergocalciferol) 8,000/mL drops	**Removed GCNs** ▪ 03723 calcium carbonate 600 mg tab ▪ 41585 calcium carbonate/vit D3 250 mg-125 mg tab ▪ 89397 calcium carbonate/vit D3 500 mg-100 mg tab chew ▪ 24718 calcium carbonate/vit D3 500 mg-200 mg tab ▪ 18276 calcium carbonate/vit D3 500 mg-400 mg tab ▪ 50815 calcium carbonate/vit D3 600 mg-200 mg tab ▪ 99137 calcium carbonate/vit D3 600 mg- 400 mg tab chew ▪ 33249 calcium carbonate/vit D3 600 mg-800 mg tab ▪ 21472 calcium citrate/vit D3 200 mg-250 mg tab ▪ 15989 calcium citrate/vit D3 315 mg-250 mg tab ▪ 27228 Vit D3 400 units/drop ▪ 93241 Vit D3 1000 unit cap ▪ 27818 Vit D3 1000 unit tab chew ▪ 12309 Vit D3 2,000 unit tab ▪ 24518 Vit D3 10,000 unit cap ▪ 32668 Vit D3 50,000 unit tab* ▪ 98425 Vit D3 50,000 unit cap* ▪ 28662 Vit D3 50,000 unit wafer* *Vit D2 (ergocalciferol) 50,000 unit cap remains available

***GCN Additions will be implemented upon signing of the minutes, with the deletions implemented at 120 days.**

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
AAOS	American Academy of Orthopaedic Surgeons	MIDAS	Migraine Disability Assessment
ADR	Adverse reaction	MDR	Multi-drug resistant TB
AE	Adverse event	MHS	Military Health System
AHRQ	Agency for Healthcare Research and Quality	MN	Medical Necessity
BCF	Basic Core Formulary	MTF	Military Treatment Facility
BIA	Budget impact analysis	MPFID	Migraine Physical Functional Impact Diary
CFR	Code of Federal Regulations	NCCN	National Comprehensive Cancer Network
CFTR	Cystic fibrosis transmembrane regulator	NDAA	National Defense Authorization Act
CGRP	Calcitonin Gene-Related Peptide	NDC	National Drug Codes
CHCS	Composite Health Care System	NF	Non-Formulary
CMA	Cost minimization analysis	NICE	UK National Institutes for Health and Care Excellence
CV	Cardiovascular	ORSI	Osteoarthritis Research Society International
DHA	Defense Health Agency	ODT	Orally dissolving tablet
DMD	Duchenne muscular dystrophy	OTC	Over the counter
DoD	Department of Defense	P&T	Pharmacy and Therapeutics
DR	Delayed release	PA	Prior authorization
ECF	Extended Core Formulary	PANSS	Positive and Negative Syndrome Scale
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	PHN	Postherpetic neuralgia
EPGA	Eosinophilic Granulomatosis with Polyangiitis	POD	Pharmacy Operations Division
ER	Extended release	POS	Point of service
FDA	U.S. Food and Drug Administration	QL	Quantity limits
FMB	Formulary Management Branch	Rx	Medical Prescription
FY	Fiscal year	SNRI	Serotonin and Norepinephrine Reuptake Inhibitors
GCN	Generic code number	TIB	Targeted immunomodulatory biologic
GI	Gastrointestinal	UC	Ulcerative colitis
GINA	Global Initiative for Asthma	UF	Uniform Formulary
HCL	Hydrochloride	XR	Extended release
HIT-6	Headache Impact Test-6	XDR	Extensively drug resistant TB
HTN	Hypertension		
IR	Immediate release		