

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

November 2020

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on November 4 and 5, 2020. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

- 1. Approval of August 2020 Minutes**—Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the August 2020 DoD P&T Committee meeting on November 2, 2020.
- 2. Clarification of Previous Minutes**
 - a) August 2020 Meeting—Targeted Immunomodulatory Biologics: PA criteria for Stelara and Taltz:** After the August 2020 P&T meeting, ustekinumab (Stelara) received FDA-approval for treating patients as young as 6 years of age with plaque psoriasis. The PA for Stelara was updated to reflect this indication. Ixekizumab (Taltz) is also approved for treating pediatric patients with plaque psoriasis. The August minutes reflected that a trial of Stelara for this population will be required before Taltz, consistent with the existing step therapy for the class.
 - b) November 2019 Meeting—Pulmonary 2 Agents: COPD Tier 4 formulary alternatives:** Glycopyrrolate/indacaterol (Utibron Neohaler) was removed from the market on March 30, 2020. It is no longer included on the list of alternatives for the Tier 4 product formoterol/aclidinium (Duaklir Pressair), listed in Appendix H.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at <https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms>. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/Not Covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors

including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018. Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the 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. Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass

Background—The ADHD Stimulants were most recently reviewed for formulary status in November 2015. There are currently 32 products in the subclass. The ten newest entrants include several methylphenidate formulations (Adhansia XR, Jornay PM, Quillichew ER, Cotempla XR-ODT); several amphetamine products (Adzenys XR-ODT, Adzenys ER OS, Dyanavel XR, Evekeo ODT); one mixed amphetamine salt (Mydayis); and a new lisdexamfetamine (Vyvanse) chewable tablet formulation. The new entrants do not contain new chemical entities; FDA approval was based on data from previously approved ADHD drugs, and there are no head-to-head studies available. The active ingredients for the new entrants are already available in generic formulations that are designated as UF, with the exception of lisdexamfetamine which is still a branded agent and is currently NF.

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

Guidelines and Systematic Reviews

- The published literature is limited by several methodological problems, low quality evidence, and general inadequacy of clinical ADHD research. Longer-term studies are needed. Many guidelines recommend medications only after behavioral or environmental modification have failed, particularly for children (e.g., American Academy of Pediatrics).
- The United Kingdom National Institute for Health and Care Excellence (NICE) 2018 guidelines recommend the following, in descending order of preference:
 - Adults – Methylphenidate or lisdexamfetamine (or dexamphetamine if there is an unacceptable side effect profile with lisdexamfetamine) should be used only after environmental modification and if ADHD symptoms persist in at least one area of functioning.
 - Children older than 5 years of age and young people – The same medication preferences apply as with adults, except that medications should be used along with ADHD-focused support (e.g., education and information on the causes and effects of ADHD, advice on parenting strategies, and liaison with school). Medications should be used only after environmental modification and if ADHD symptoms persist in at least one area of functioning.

- Children younger than 5 years of age – ADHD-focused group training for parents is recommended as first-line. Medication is recommended second-line only after a second specialist opinion; no specific medications are cited in the guideline.
- A 2018 systematic review and network meta-analysis published in *Lancet Psychiatry* concurred with the NICE guidelines for methylphenidate as first choice of drug in children, and methylphenidate or lisdexamfetamine as first choice in adults when considering efficacy alone. However when both efficacy and safety or tolerability were considered for adults, the authors could not recommend lisdexamfetamine over other amphetamines, due to the limited number of studies available, and inability to draw firm conclusions.

Safety

- The ADHD stimulants are controlled substances (C-II) and contain a boxed warning for potential abuse and dependency. All the ADHD stimulants also now carry a label warning and precaution regarding the risk of cardiovascular events and sudden death.

Special Populations

- There are many alternative dosage forms for patients with swallowing difficulties. The contents of Vyvanse capsules are dissolvable in water and the chewable tablet is now available. Adderall XR, Focalin XR, Metadate CD, and Ritalin LA are formulated in capsules that can be opened and sprinkled on food. Aptensio XR sprinkle capsule, Evekeo ODT, Methylin oral solution, ProCentra oral solution, and Quillivant XR oral suspension are currently available on the UF for patients with swallowing difficulties.
- Multiple ADHD stimulants are currently on the formulary that are approved for children ranging in age from the 6 to 17 years.

Clinical Considerations

- The P&T Committee specifically evaluated the 13 branded products that do not have generic equivalents available; one additional product with recent generic entrants (Aptensio XR) was also reviewed in detail. Factors discussed included duration of action, efficacy and safety, data from FDA summary reviews, published primary literature, formulary status from commercial health plans, and Military Health System (MHS) provider feedback.
 - *lisdexamfetamine* (Vyvanse) has been designated NF since November 2007. It is a prodrug that is converted to the stimulant amphetamine and the amino acid lysine. The duration of action ranges between 8 to 14 hours, and it is approved for children as young as 6 years. Generic formulations are expected in 2023.

- Vyvanse is the only ADHD stimulant with an additional indication. Approval for Binge Eating Disorder was granted in 2015, based on two 12-week, placebo controlled trials enrolling approximately 350 patients. However, pharmacotherapy is generally regarded as less efficacious than psychotherapy (e.g., cognitive-behavioral therapy) for binge eating disorder. Other treatments, including the SSRIs, topiramate, and zonisamide are used to treat binge eating disorder.
 - There was no new data to change the original conclusion that there is insufficient evidence to suggest there are clinically relevant differences between Vyvanse and other ADHD stimulant products in terms of efficacy or safety.
 - A survey of MHS providers found that Vyvanse was commonly requested for formulary addition. Providers mentioned the longer duration of action than Adderall XR, and that Vyvanse may be useful after patients have failed mixed amphetamine salts (Adderall XR) and methylphenidate ER formulations (e.g., Concerta).
- *methylphenidate ER sprinkle capsule (Adhansia XR)* was designated Tier 4 in August 2019. Currently it is the only Tier 4/Not Covered ADHD Stimulant agent. Its stimulating effects can last up to 16 hours.
 - Several long-acting methylphenidate products are on the UF, including three products that are formulary alternatives for those who have difficulty swallowing (Focalin XR, Quillivant XR, and Aptensio XR). Other methylphenidate ER formulations have 12-hour durations of action (e.g., Concerta, Focalin XR, Quillivant XR, and Jornay PM) and one has a similar duration of 16 hours (Aptensio XR).
 - The new data reviewed by the P&T Committee did not change the previous conclusion, and provider feedback strongly reaffirmed that Adhansia XR has little to no additional clinical effectiveness relative to similar drugs in the class, and the needs of TRICARE beneficiaries are met by alternative agents.
- *methylphenidate ER sprinkle capsule nighttime dosing (Jornay PM)* was the 12th methylphenidate product marketed, and is approved for patients as young as 6. Jornay is administered at night before bedtime, and has a delayed onset of action so that therapeutic effects occur 8 hours after administration, in the morning. Stimulating effects may last 10 to 14 hours.
 - Overall, Jornay PM shows no clinical advantage when compared to current formulary alternatives and had a higher rate of insomnia (up to 33%) when indirectly compared to other methylphenidate formulations, where insomnia occurred at a rate up to 13%.

- MHS providers commented Jornay PM should remain UF, since it is helpful for children with developmental delays because of the bedtime dosing.
- *methylphenidate ER orally disintegrating tablets (Cotempla XR-ODT)* is only approved for children between the ages of 6 to 17 years of age and is not approved for adults. The effects can last 12 hours, similar to other methylphenidate ER formulations. Providers commented that a young child would not need an ODT with such a long duration of action. Cotempla XR ODT offers no compelling advantages over the existing UF ADHD drugs.
- *methylphenidate ER sprinkle capsules (Aptensio XR)* are approved for children as young as 6 years. The contents can be opened up and sprinkled on food and the long duration of action can last up to 16 hours. Generic formulations are now available.
- *methylphenidate ER oral suspension (Quillivant XR)* is the only long-acting methylphenidate oral suspension marketed. Immediate release methylphenidate (Methylin) and dextroamphetamine (ProCentra) oral solutions are therapeutic alternatives to Quillivant XR, but must be dosed twice daily.
- *methylphenidate ER chewable tablet (Quillichew ER chew tab)* is the first 8-hour duration chewable tablet; however, an additional short-acting agent will be required for children after school to complete homework. While Quillichew ER tablets provide an alternative ADHD dosage form, there are several UF products available for patients with swallowing difficulties.
- *methylphenidate transdermal system patch (Daytrana)* remains the only patch available for ADHD, but is associated with dermatologic adverse reactions. It has been designated as NF since 2006.
- *amphetamine ER oral suspensions (Dyanavel XR OS and Adzenys ER OS)* provide ER alternative amphetamine dosage formulations; however, they do not offer any additional clinical effectiveness, safety, or tolerability benefit over other amphetamine ER products.
- *amphetamine ER orally disintegrating tablet (Adzenys XR-ODT)* is the first and currently only amphetamine ER product available in an ODT formulation, however, amphetamine is not a first-line drug for ADHD treatment in children, and other amphetamine alternative dosage products are available.
- *amphetamine IR orally disintegrating tablet (Evekeo ODT)* is the only short acting ODT in the amphetamine category, with effects lasting 4 to 6 hours, similar to other short-acting stimulants in the class. It has been designated as UF since 2019. Evekeo IR tablets, the original product, are available in generic formulations.

- *amphetamine mixed salts ER capsule triphasic release (Mydayis)* was designated NF in August 2017. It is approved for children down to 13 years of age, but not for younger children as the effects can last up to 16 hours, including insomnia and appetite suppression. Multiple alternative products are available in generic formulations, including Adderall XR caps. Mydayis offers no compelling advantage over existing formulary agents.
- *dextroamphetamine IR tablet (Zenzedi)* is currently designated UF. It is available in additional strengths (2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg, along with 5 mg and 10 mg) compared to the original dextroamphetamine IR product Dextrostat, which is only available in generic formulations of 5 mg and 10 mg.

Therapeutic Interchangeability

- There is insufficient evidence to suggest that one stimulant is more effective or associated with fewer adverse events than another. The stimulants may vary in terms of duration of action but are highly therapeutically interchangeable.

Overall Clinical Conclusion

- The Committee agreed that in order to treat the needs of MHS beneficiaries, a variety of ADHD drugs are required on the formulary, including amphetamine type products and methylphenidates, and both long-acting and short-acting formulations in each of these categories. Additionally, alternative dosage formulations in each category are needed in order to treat special populations, including young children or patients with developmental delays.

Relative Cost-Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- CMA results showed that the products with generic formulations are generally significantly more cost-effective than brand-only products.
- CMA results for certain branded products that have generic formulations available showed that dextroamphetamine ER capsule was the most cost-effective ADHD stimulant, followed by Adderall XR, Methylphenidate CD, and Evekeo IR tablet.
- CMA results for the brand-only agents showed that the cost-effectiveness for several of the agents varied depending on formulary status, and that Evekeo ODT was the least costly agent, followed by Quillivant XR, Jornay PM, Zenzedi, Vyvanse, Quillichew ER, Dyanavel XR, Mydayis, Adzenys XR-ODT, Adhansia XR, Adzenys, Daytrana and Cotempla XR-ODT, which was the most costly agent.
- BIA results for all branded products with generic formulations showed that maintaining the existing formulary status was the most cost-effective.

- BIA was performed to evaluate the potential impact of designating selected brand –only agents as UF, NF or Tier 4. BIA results showed that maintaining the existing formulary status of all current UF, NF and Tier 4 products, with the exception of moving Vyvanse capsule and chewable tablet from NF to UF status, resulted in significant cost avoidance.

1. **COMMITTEE ACTION: ADHD AGENTS: STIMULANTS UF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the following formulary recommendations for the ADHD Stimulants, as outlined below, based on clinical and cost-effectiveness. Note that the only change to the current formulary status is for lisdexamfetamine (Vyvanse), which moves to UF status.

- UF
 - amphetamine sulfate IR tabs (Evekeo, generics)
 - amphetamine sulfate orally disintegrating tablet (ODT) (Evekeo ODT)
 - dextroamphetamine ER (Dexedrine Spansule, generics; Dextrostat tabs)
 - dextroamphetamine IR tablets (Zenedi)
 - dextroamphetamine oral solution (ProCentra, generics)
 - lisdexamfetamine capsules and chewable tablets (Vyvanse) (*moves from NF to UF*)
 - methamphetamine HCl (Desoxyn, generics)
 - mixed amphetamine salts IR tablets (Adderall, generics)
 - mixed amphetamine salts XR capsules (Adderall XR, generics)
 - dexmethylphenidate IR (Focalin, generics)
 - dexmethylphenidate ER (Focalin XR, generics)
 - methylphenidate CD (Metadate CD, generics)
 - methylphenidate chewable tablets and oral solution (Methylin, generics)
 - methylphenidate ER (Methylin ER, generics)
 - methylphenidate ER sprinkle caps (Aptensio XR, generics)
 - methylphenidate ER sprinkle capsules nighttime dosing (Jornay PM)
 - methylphenidate ER oral suspension (Quillivant XR)
 - methylphenidate IR (Ritalin, generics)
 - methylphenidate long-acting (LA) (Ritalin LA, generics)
 - methylphenidate osmotic controlled release oral delivery system (OROS) tablets and other (Concerta, generics)

- Note: methylphenidate SR (Ritalin-SR, generic), Metadate ER tablet, and Dextrostat tablet will remain UF but are no longer marketed
 - NF
 - amphetamine ER orally disintegrating tablets (ODT) (Adzenys XR-ODT)
 - amphetamine ER oral suspension (Adzenys ER OS)
 - amphetamine ER oral suspension (Dyanavel XR)
 - mixed amphetamine salts ER capsules triphasic release (Mydayis)
 - methylphenidate transdermal system (Daytrana)
 - methylphenidate ER chew tab (Quillichew ER)
 - methylphenidate XR-ODT (Cotempla XR-ODT)
 - Tier 4/Not Covered
 - methylphenidate ER sprinkle caps (Adhansia XR) See Appendix H for the formulary alternatives for the Tier 4 drugs
2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) maintaining mixed amphetamine salts XR (generic Adderall XR) and methylphenidate OROS tablets and other (generic Concerta) on the BCF.
 3. **COMMITTEE ACTION: MANUAL PA CRITERIA**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current manual PA criteria for Evekeo ODT, Mydayis, Cotempla XR-ODT, and Jornay PM. The P&T Committee also recommended PA criteria for Vyvanse in new users to encourage use of cost-effective generic agents first, standardize the clinical criteria across all points of service, and allow for binge eating disorder (BED) when certain criteria are met. See Appendix C for the full criteria.
 4. **COMMITTEE ACTION: MN RECOMMENDATION**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current MN criteria for the NF agents, Adzenys XR-ODT, Adzenys ER, Dyanavel XR, Mydayis, Daytrana, Quillichew ER, and Cotempla XR-ODT. See Appendix B for the full criteria.
 5. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS**— Schedule II drugs are exempted from the EMMPI program requirements, as originally outlined in the August 2015 DoD P&T Committee meeting minutes. However, due to

beneficial pricing at the MTF and Mail order POS, the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent), adding Vyvanse to the EMMPI program, pending any operational issues (e.g., sourcing at the prime vendor, state laws). See Appendix F for the mail order status of medications.

6. **COMMITTEE ACTION: UF/TIER 4, PA, MN, EMMPI AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the P&T minutes at all points of service (POS). Based on the P&T Committee’s recommendation, the effective date is March 3, 2021.

B. Respiratory Interleukins

Background—The Respiratory Interleukins is a newly created drug class, although the three products have been reviewed individually as innovators. The TRICARE pharmacy benefit medications are benralizumab (Fasenra), dupilumab (Dupixent), and mepolizumab (Nucala). Both benralizumab (Fasenra) and mepolizumab (Nucala) were formerly available under the TRICARE medical benefit before receiving FDA approval for self-administration. A new pen formulation of Dupixent was recently launched and is included in the class. The respiratory biologics differ in their FDA-approved indications, although all three products are approved for treating asthma with eosinophilic phenotype. Loading dose requirements and administration frequency vary depending on the indication.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

Pathophysiology

- The respiratory interleukins act on Type 2 inflammatory pathways, which are associated with eosinophilic or allergic inflammation. These medications target interleukin 4 (Dupixent) and interleukin 5 (Nucala and Fasenra [5 alpha-receptor]). It is unclear if these differences in biologic target result in clinically relevant differences in efficacy or safety.
- Type 2 inflammatory pathway-related diseases include asthma with an eosinophilic phenotype, atopic dermatitis, and chronic rhinosinusitis with nasal polyposis, among others. There is significant overlap with Type 2 diseases, and patients often have multiple Type 2 conditions.

Asthma with an Eosinophilic Phenotype and Oral Corticosteroid Dependent Asthma

- Guidelines from the Global Initiative for Asthma (GINA 2019) recommend adding-on mepolizumab (Nucala) or benralizumab (Fasenra) for patients with uncontrolled severe eosinophilic asthma, and adding-on dupilumab (Dupixent) for patients with severe Type 2 asthma or those requiring treatment with maintenance

oral corticosteroids. It was also noted there is urgent need for head-to head comparisons of the biologics.

- The European Academy of Allergy and Clinical Immunology (EAACI 2020) guidelines concluded there is high certainty that benralizumab, dupilumab, and mepolizumab reduce both the rate of severe asthma exacerbations and the need for oral corticosteroids. The biologics probably improve asthma control, quality of life measures and forced expiratory flow in one second (FEV1), without reaching the minimal important difference.
- A 2017 Cochrane review concluded that benralizumab and mepolizumab roughly halved the rate of asthma exacerbations requiring systemic steroids or hospitalization.
- A 2018 Institute for Clinical and Economic Research (ICER) review concluded the biologics are all safe and effective. Overall, the net health benefit of the respiratory interleukins is at best incremental, but ICER did not recommend one agent over the others.

Severe Atopic Dermatitis

- Dupilumab (Dupixent) is currently the only respiratory biologic with an indication for atopic dermatitis.
- Treatment guidelines differ in their recommendations for dupilumab's place in therapy. The 2017 Consensus-Based US recommendations list dupilumab as first-line therapy in adults after failure of topical therapies (e.g., emollients, topical corticosteroids). In contrast, the 2018 Consensus-Based European Guidelines recommend dupilumab as second-line therapy after topical treatments, or if other systemic treatments (e.g., azathioprine, cyclosporine, methotrexate) are inadvisable. The 2017 International Eczema Council states phototherapy should be considered first, before dupilumab.
- The 2017 ICER review concluded there was high certainty that dupilumab provides at least a small net health benefit relative to treatment with topical therapies.
- Mepolizumab (Nucala) is an option in selected cases unresponsive to standard therapy (2018 Consensus-Based European Guidelines), but this use is currently off-label in the US.
- Both benralizumab (Fasenra) and mepolizumab (Nucala) are currently undergoing studies for treating atopic dermatitis.

Chronic Rhinosinusitis with Nasal Polyposis

- Dupilumab is the only biologic indicated for treating adults with chronic rhinosinusitis with nasal polyposis (CRSwNP), although both benralizumab and mepolizumab have been evaluated in clinical trials for this condition.
- FDA-approval for dupilumab was based on a pooled analysis of two trials where 63% of the enrolled patients had previous sinus surgery, with an average of two prior surgeries. While a prespecified analysis showed a reduction in patients requiring systemic corticosteroids or nasal polyp surgery, the proportion of surgically naïve patients who benefited from dupilumab was not reported. (*Bachert C, Lancet 2019 and JAMA 2016*)
- A joint 2014 US practice parameter from several professional organizations state that although biologic treatments other than dupilumab lack FDA-approval for treating nasal polyps, they have demonstrated benefit.
- There is one large sufficiently powered study with Nucala given intravenously at a higher dose that showed a statistically significant reduction in the proportion of patients requiring surgery and improvement in symptoms of nasal obstruction and nasal polyp size. (*Bachert C, J Allergy Clin Immunol 2017*)
- The 2020 European Position Paper on Rhinosinusitis and Nasal Polyposis (EPOS) lists both dupilumab and mepolizumab for patients meeting certain criteria, including presence of bilateral nasal polyps in a patient with prior endoscopic sinus surgery, and three of the following factors: high eosinophil count, continued use of corticosteroids, impaired quality of life, loss of the sense of smell (anosmia), and comorbid asthma.
- Provider feedback from MHS Otolaryngologists concurred that dupilumab should be reserved as a last resort when nasal polyp disease is recalcitrant despite traditional surgical therapy and maintenance therapy with intranasal steroids.

Other Type-2 Inflammatory Pathway Conditions

- *Eosinophilic granulomatosis with polyangiitis (EGPA)* (also known as Churg-Strauss syndrome) is a rare vascular disease that can cause asthma symptoms, along with chest pain, muscle aches, and rashes. Mepolizumab (Nucala) is the only biologic approved for EGPA. Studies are currently evaluating benralizumab for this condition.
- *Hypereosinophilic Syndrome (HES)* is another rare disorder that causes patients to have extremely high eosinophil counts resulting in inflammation affecting the skin, lungs, heart, and nervous system. Mepolizumab (Nucala) recently received

FDA approval for HES, based on one clinical trial where a reduction in disease flare was noted.

Safety

- The three respiratory interleukins are associated with relatively mild adverse effects; injection site reactions and hypersensitivity can occur.
- Dupilumab is distinct in that conjunctivitis was noted in the atopic dermatitis clinical trials. However, the incidence of conjunctivitis associated with dupilumab in the clinical trials for asthma was not significantly different from placebo.
- Increased systemic eosinophilia is a possible adverse event associated with dupilumab and providers should use caution when initiating therapy in patients with elevated eosinophil counts.
- The EAACI 2020 asthma guidelines state there is low to very low certainty of evidence that drug-related serious adverse events may increase with the use of dupilumab. For benralizumab and mepolizumab, the results are inconclusive.

Clinical Considerations

- *Benralizumab (Fasenra)* is only approved for one indication, severe eosinophilic asthma in patients at least 12 years of age, and requires a loading dose. However, advantages include the long frequency of dosing (every 8 weeks). It is only available in one formulation as part of the TRICARE pharmacy benefit, a pen device.
- *Dupilumab (Dupixent)* advantages include multiple FDA approvals (moderate to severe eosinophilic asthma in children down to the age of 12; atopic dermatitis in children as young as 6 years; and CRSwNP in adults) and availability in multiple devices (prefilled syringe and the newly marketed pen device). MHS prescription data shows relatively good persistence, as about 50% of patients remain on therapy after one year. Disadvantages include the requirement for a loading dose for treating asthma and atopic dermatitis, the need for every 2-week dosing for all indications, and potential dosing errors due to availability in several dosage strengths.
- *Mepolizumab (Nucala)* advantages include multiple indications (severe asthma in patients as young as 6 years; EGPA in adults; and HES in patients down to the age of 12). A loading dose is not required, but the dosing frequency is every 4 weeks for all indications. It is available in an autoinjector (reserved for patients 12 years and older) and prefilled syringe. The dosing for EGPA and HES will

require three separate injections given simultaneously to achieve the recommended 300 mg dose.

Therapeutic Interchangeability

- For eosinophilic asthma, there is a moderate degree of therapeutic interchangeability for the products. However, for the other indications, there is a low degree of therapeutic interchangeability.

Overall Clinical Conclusion

- Based on MHS provider feedback, all three products are required on the formulary due to differences in biologic target, individual patient variation in response (e.g., for asthma due to genetic differences, environment and asthma type), and differences in current FDA approved indications and age ranges.

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

- CMA results showed that benralizumab (Fasenra), dupilumab (Dupixent), and mepolizumab (Nucala) were all cost-effective respiratory interleukin products.
- 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 benralizumab (Fasenra), dupilumab (Dupixent), and mepolizumab (Nucala) as UF demonstrated the greatest cost avoidance for the Military Health System (MHS).

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

- UF
 - benralizumab (Fasenra)
 - dupilumab (Dupixent)
 - mepolizumab (Nucala)
- NF:
 - None
- Tier 4/Not Covered:
 - None

2. **COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) not to add any Respiratory Interleukin to the BCF.
3. **COMMITTEE ACTION: PRIOR AUTHORIZATION CRITERIA**—Manual PA criteria currently apply to the class. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent for Fasentra and Nucala, and 15 for, 0 opposed 0 abstained, 2 absent for Dupixent) updated PA criteria for the Respiratory Interleukins, including prohibiting concomitant treatment with multiple biologics and standardizing renewal criteria based on indication. The new indication of HES was added to the Nucala criteria. For the Dupixent indication for atopic dermatitis, provider feedback resulted in removal of the current requirement for previous use of immunosuppressant therapy. The PAs take into account package insert labeling and lab data for eosinophils for the asthma indication. Updated PA criteria will apply to new users. See Appendix C for the full criteria.
4. **COMMITTEE ACTION: QUANTITY LIMITS (QL)**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) standardizing the current Quantity Limits for Fasentra, Dupixent, and Nucala to allow for a 30 day supply at Retail and a 60 day supply at MTF and Mail. See Appendix D for the full criteria.
5. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining benralizumab (Fasentra), dupilumab (Dupixent), and mepolizumab (Nucala) on the EMMPI program.
6. **COMMITTEE ACTION: UF, PA, QL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. Based on the P&T Committee’s recommendation, the effective date is March 3, 2021.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent), and group 3: (16 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 November 2020 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. Note that dupilumab (Dupixent) pens was included in the Respiratory Interleukin section. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. COMMITTEE ACTION: UF/TIER 4 RECOMMENDATION—The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
 - azacitidine (Onureg) – Oral oncologic agent for acute myeloid leukemia (AML)
 - budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri) – Triple combination Pulmonary-3 Agent for COPD
 - cysteamine 0.37% ophthalmic solution (Cystadrops) – Miscellaneous Ophthalmic for corneal cystine crystal deposits
 - decitabine/cedazuridine (Inqovi) – Oral combination oncologic agent for Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)
 - factor VIIa [recombinant]-jncw (Sevenfact) – Antihemophilic Factor for hemophilia A or B
 - fostemsavir (Rukobia) – Oral antiretroviral for multi-drug resistant HIV-1 infection in heavily treatment-experienced adults
 - nifurtimox (Lampit) – Miscellaneous Anti-infective agent for Chagas Disease in pediatrics
 - ofatumumab injection (Kesimpta) – Multiple Sclerosis Agent
 - opicapone (Ongentys) – Oral agent for “off episodes” associated with Parkinson’s Disease
 - pralsetinib (Gavreto) – Oral oncologic agent for non-small cell lung cancer (NSCLC)
 - risdiplam (Evrysdi) – Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)
 - satralizumab-mwge injection (Enspryng) – Miscellaneous Neurological Agent for neuromyelitis optica spectrum disorder (NMOSD)
 - triheptanoin (Dojolvi) oral liquid – Miscellaneous Metabolic Agents; oral liquid for long-chain fatty acid oxidation disorders in pediatrics and adults
 - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) – Wakefulness Promoting Agent for narcolepsy (*line extension pp 22-23*)

- NF:
 - insulin glargine (Semglee, Semglee Pen) – Basal Insulin
 - monomethyl fumarate (Bafiertam) – Multiple Sclerosis Agent
 - octreotide (Mycapssa) – Miscellaneous Endocrine Agent for acromegaly
 - oxymetazoline ophthalmic solution (Upneeq) – Miscellaneous Ophthalmic agent for acquired blepharoptosis

- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
 - budesonide extended-release (Ortikos) – Gastrointestinal -1 GI Steroid for mild to moderate Crohn’s Disease
 - Ortikos was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other formulations of budesonide, and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Ortikos include budesonide (Entocort EC) generics and other corticosteroids.

 - dexamethasone (Hemady) 20 mg tablets – Corticosteroids-Immune Modulator for multiple myeloma
 - Hemady was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other formulations of dexamethasone, significant safety concerns exist due to potential dosing errors, and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Hemady include various strengths of generic dexamethasone.

 - fluticasone oral inhaler (Armonair Digihaler) – Pulmonary-1 Agents: Inhaled Corticosteroids (ICS) for asthma
 - Armonair Digihaler was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other ICS approved for treating asthma symptoms and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Armonair Digihaler include both step-preferred [fluticasone (Flovent Diskus and Flovent HFA)] and non-step preferred agents [beclomethasone (QVAR), budesonide (Pulmicort Flexhaler), ciclesonide

(Alvesco), flunisolide (Aerospan), mometasone (Asmanex Twisthaler), and fluticasone (ArmonAir Respiclick)].

- fluticasone/salmeterol oral inhaler (AirDuo Digihaler) – Pulmonary-1 ICS-Long-Acting Beta Agonist (LABA) Combinations for asthma and COPD
 - AirDuo Digihaler was recommended for Tier 4 status/Not Covered as it has little to no clinical benefit relative to other ICS/LABA Combination inhalers and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to AirDuo Digihaler include the step-preferred agent fluticasone/salmeterol (Advair Diskus and Advair HFA), as well as non-step-preferred agents fluticasone/vilanterol (Breo Ellipta), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort), and fluticasone/salmeterol (AirDuo Respiclick).

- levamlodipine (Conjupri) – Dihydropyridine Calcium Channel Blocker for hypertension
 - Conjupri was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to the other calcium channel blockers, there is a significant safety risk compared to the others in the class due to the potential for dosing errors, and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Conjupri include amlodipine, felodipine, and nifedipine, along with verapamil and diltiazem. (See Appendix H.)

- metoclopramide nasal spray (Gimoti) – Gastrointestinal-2 Agent for diabetic gastroparesis
 - Gimoti nasal spray was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other metoclopramide formulations, there is a significant safety risk compared to the other metoclopramide products due to the inability to adjust doses in patients with renal dysfunction, and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Gimoti nasal spray include metoclopramide oral tablets and oral solution (Reglan) and metoclopramide orally disintegrating tablet (Reglan ODT). (See Appendix H).

B. COMMITTEE ACTION: MN CRITERIA—The P&T Committee recommended group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0

abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Bafiertam, Mycapssa, Semglee, and Upneeq. See Appendix B for the full criteria.

C. COMMITTEE ACTION: PA CRITERIA—The P&T Committee recommended group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Basal Insulins: Applying the same manual PA criteria to new users of Semglee that applies to the other non-step-preferred basal insulins, requiring a trial of Lantus first.
- Multiple sclerosis agents: Applying manual PA criteria to new users of Bafiertam and Kesimpta.
- Oncologic drugs: Applying manual PA criteria to new users of Gavreto, Inqovi, and Onureg.
- Applying manual PA criteria to new users of Dojolvi, Enspryng, Evrysdi, Mycapssa, and Upneeq.

D. COMMITTEE ACTION: UF, TIER 4/NOT COVERED, MN, AND PA IMPLEMENTATION PERIOD—The P&T Committee recommended group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:

- **New Drugs Recommended for UF or NF Status:** An effective date of the first Wednesday upon two weeks after signing of the minutes in all POS, on February 10, 2021.
- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date upon 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation, and on implementation on June 2, 2021.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

- a) **Narcotic Analgesics – Tapentadol ER (Nucynta ER)**—Nucynta ER has been designated as UF since February 2012. Tapentadol has a similar mechanism of action to tramadol, which includes mu-opioid activation and norepinephrine reuptake inhibition. It is indicated for treatment of both non-neuropathic pain and neuropathic pain (e.g., diabetic peripheral neuropathy) severe enough to require

daily, around-the-clock, long-term opioid treatment. Tapentadol ER has additional warnings and risk of adverse reactions due to its dual mechanism of action that are not seen with the other narcotic analgesics.

The previous P&T Committee conclusion was that there is no evidence that pain control with tapentadol ER is superior to oxycodone ER. A survey of MHS providers noted that since tapentadol ER is a long-acting opioid it should be reserved for use after a trial of other non-opioid and short-acting opioid agents. Provider feedback supported implementing a PA for this medication based on relative clinical and cost effectiveness concerns.

COMMITTEE ACTION: NEW PA CRITERIA FOR NUCYNTA ER—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Nucynta ER in new users, to ensure that other therapies for neuropathic pain or non-neuropathic pain are tried first. See Appendix C for the full criteria.

2. Updated PA Criteria

Updates to the manual PA criteria and step therapy for several drugs were recommended due to expanded age indications, and new FDA-approved indications. The updated PAs and step therapy outlined below will apply to new users.

a) Targeted Immunomodulatory Biologics (TIBs)

- **etanercept (Enbrel)**—Etanercept (Enbrel) has been labeled for use in children as young as 4 years of age for plaque psoriasis since 2016. Use of Enbrel in this population has been exempt from the requirement to try ustekinumab (Stelara) first, as Stelara was only approved for children down to the age of 12 years with plaque psoriasis. After the August 2020 P&T meeting, Stelara received FDA-approval for treating patients as young as 6 years of age with plaque psoriasis. Therefore a trial of Stelara for pediatric patients ages 6 and older with plaque psoriasis will be required before Enbrel. The current PA form for Enbrel will note that a trial of Stelara is not required first in patients 4 to 5 years of age.
- **guselkumab (Tremfya)**—Updated the manual PA criteria to include the new indication of active psoriatic arthritis for patients 18 years of age and older.
- **tofacitinib (Xeljanz, Xeljanz oral solution)**—Updated the manual PA criteria to include the new indication for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.

b) Hepatitis C Agents: Direct Acting Agents — sofosbuvir/velpatasvir tablets (Epclusa)

—Updated the manual PA criteria to include the expanded age indication

for patients 6 years of age or older or those weighing at least 17 kg with chronic HCV genotype 1, 2, 3, 4, 5, or 6.

- c) **Anticonvulsants-Antimania Agents — cannabidiol oral solution (Epidiolex)**— Updated the manual PA criteria to include the new indication for treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year of age or older. Note that the PA will not specify an age limit.
- d) **Hereditary Angioedema Agents — C1 Esterase Inhibitor [Human] (Haegarda)**—Updated the manual PA criteria to include the expanded age indication for use in patients 6 years of age or older for routine prophylaxis to prevent hereditary angioedema. Previous manual PA criteria specified use in 12 years of age or older. Note that the PA will not specify an age limit.

1. **COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Enbrel, Tremfya, Xeljanz and Xeljanz oral solution, Epclusa, Epidiolex, and Haegarda. See Appendix C for the full criteria.

B. Quantity Limits

General QLS: QLS were reviewed for five newly approved drugs including Breztri, Inqovi, Gavreto, Evrysdi, and Onureg.

1. **COMMITTEE ACTION: QLS**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLS for Breztri, Inqovi, Gavreto, Evrysdi, and Onureg. See Appendix D for the QLS.

C. PA and QLS Implementation Periods

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

- (15 for, 0 opposed, 0 abstained, 2 absent) The new PA for tapentadol ER (Nucynta ER) will become effective in new users the first Wednesday 30 days after the signing of the minutes (March 3, 2021).
- (15 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Enbrel, Tremfya, Xeljanz and Xeljanz oral solution, Epclusa, Epidiolex, and Haegarda in new users will become effective the first Wednesday 60 days after the signing of the minutes (March 31, 2021).

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

VII. SECTION 702, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2018: TRICARE TIER 4/NOT COVERED DRUGS PER 32 CFR 199.21(E)(3) RE-REVIEW

Background—The interim rule allowing for complete exclusion of drugs from TRICARE pharmacy benefit coverage was initially published on December 11, 2018, with the Final Rule published June 3, 2020. The Committee considers several factors in addition to cost when identifying Tier 4/Not Covered candidates, including the quality of clinical efficacy evidence available, determination of significant safety issues in which risks may outweigh potential benefit, identification of drugs that contain ingredients not covered by the TRICARE pharmacy benefit, or other negative concerns. (See the February 2019 P&T minutes for additional details.)

The first Tier 4/Not Covered products were designated at the February 2019 Committee meeting, with implementation occurring on August 28, 2019. For the purposes of the re-review, the Committee considered whether there was any new compelling published clinical data, and evaluated any change in relative cost effectiveness.

Relative Clinical and Cost Effectiveness Summary

- **Diabetes Non-Insulin Drugs – Biguanides Subclass: metformin ER gastric retention 24 hours (Glumetza brand and generics)** is an extended release metformin formulation which uses a polymer-based oral drug delivery system that makes the tablet swell, causing retention in the stomach. Clinical trials show Glumetza is at least as efficacious as metformin immediate-release (IR) (Glucophage) in all measures of glycemic control. There is no evidence to suggest that differences in the extended-release properties of Glumetza confer any benefits in efficacy or safety compared to the other metformin ER formulations (Glucophage XR). A CMA failed to detect any significant changes in cost effectiveness from the February 2019 review.
- **Pain Agents – Combinations Subclass: naproxen/esomeprazole (Vimovo brand and generic)** is a fixed-dose combination of two over-the-counter (OTC) drugs, which offers patients a convenient formulation for improving adherence. However, this particular combination of a nonsteroidal anti-inflammatory drug (NSAID), which is typically targeted for short-term use, and a proton pump inhibitor (PPI), which has limited data to support use beyond eight weeks, is potentially harmful. There is no data to suggest that using other prescription or OTC NSAIDs concurrently with PPIs would not provide the claimed benefit of the individual ingredients found. A CMA failed to detect any significant changes in cost effectiveness from the February 2019 review.

- **Corticosteroids-Immune Modulators – High Potency Corticosteroid for Plaque Psoriasis: halobetasol propionate 0.05% foam (Lexette brand and generic)** is a high potency topical steroid, which can be applied on the scalp and other body areas. There are currently 28 other high-potency topical corticosteroids on the formulary, including 12 products formulated in a hair-friendly vehicle, including foam, gel, lotion, shampoo, and solution. Overall, there is a high degree of therapeutic interchangeability in the class. A CMA failed to detect any significant changes in cost effectiveness from the February 2019 review.

Overall, the information reviewed by the P&T Committee did not change the previous conclusions that Glumetza, Vimovo and Lexette foam have little to no additional clinical effectiveness relative to similar drugs in their respective classes, and the needs of TRICARE beneficiaries are met by alternative agents.

A. COMMITTEE ACTION: TRICARE TIER 4/NOT COVERED RECOMMENDATION—The P&T Committee recommended maintaining the following products as Tier 4/Not Covered under the TRICARE pharmacy benefits program.

- (15 for, 0 opposed, 0 abstained, 2 absent) metformin ER gastric retention 24 hours (Glumetza brand and generics)
- (14 for, 0 opposed, 0 abstained, 3 absent) naproxen/esomeprazole (Vimovo brand and generics))
- (14 for, 0 opposed, 0 abstained, 3 absent) halobetasol propionate 0.05% foam (Lexette brand and generics)

VIII. LINE EXTENSIONS

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

A. COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, and IMPLEMENTATION—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (February 10, 2021).

- **Antibiotics: Tetracyclines—doxycycline hyclate delayed release tablet (Doryx)** has a new strength of 80 mg. The P&T Committee recommend-designating Doryx delayed release 80 mg as NF, with the same PA and MN criteria requirements as Doryx 50 and 200 mg.
- **Diabetes Non-Insulin: Glucagon-Like Peptide 1 Receptor Agonist (GLP1RA)—dulaglutide (Trulicity)** has two new strengths (3 mg and 4.5 mg). Trulicity is a uniform formulary, step-preferred GLP1RA. The P&T Committee recommended designating Trulicity 3 mg and 4.5 mg as UF and step-preferred, with the same step-therapy and PA criteria requirements as Trulicity 0.75 mg and 1.5 mg.
- **Sleep Disorders: Wakefulness Promoting Agents— sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)** is a new salt formulation containing less sodium than the original Xyrem formulation. Xywav and Xyrem share the same indication and dosing, strength. The P&T Committee recommended designating Xywav as UF, with the same PA criteria requirements as Xyrem. See Appendix C for the full criteria.

IX. BRAND ALBUTEROL HFA (PROAIR HFA) COPAYMENT CHANGE

ProAir HFA oral inhaler has been designated BCF since November 2013. Pricing for the branded ProAir HFA inhaler is more cost-effective than the AB-rated generic formulations for albuterol HFA, which were launched earlier this year (February 2020). Currently at the Mail Order POS, patients pay a Tier 1 copay for the branded product, since DoD has instructed ESI to dispense the branded product rather than a generic albuterol inhaler. However, at Retail Network pharmacies the Tier 2 copay applies.

Applying the Tier 1 copay at both Retail and Mail will ensure the same copay for patients across the purchased care points of service, and will also encourage use of the most cost-effective branded ProAir HFA product. Additionally, lowering the copay is also consistent with 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020, in that the P&T Committee “will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries.”

- A. COMMITTEE ACTION: PROAIR HFA BRAND COPAYMENT CHANGE AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) changing the copay for ProAir HFA from Tier 2 (brand) to the Tier 1 (generic) copay at the purchased care points of service. Implementation will occur the first Wednesday two weeks after signing of the minutes (February 10, 2021).

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

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 November 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 November 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: 15 for, 0 opposed, 0 abstained, 2 absent; group 2: 14 for, 0 opposed, 0 abstained, 3 absent; group 3: 16 for, 0 opposed, 0 abstained, 1 absent), adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMI List) for the reasons outlined in the table. See Appendix F.

XI. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFs: VAGINAL ANTIFUNGALS (AZOLES)

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

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

A. OTC Vaginal Antifungals (Azoles)— OTC azole antifungals used for the treatment of vulvovaginal candidiasis include vaginal formulations of clotrimazole, miconazole, and tioconazole, which are available as creams or vaginal suppositories and administered over a period of 1, 3, or 7 days. Prescription alternatives include fluconazole 150 mg oral tablets and two far less commonly used vaginal products (butoconazole and terconazole). The OTC products that are both most commonly used by MTFs and available at lowest cost include clotrimazole 1% cream (7-day regimen), miconazole 2% cream (7-day regimen), and a combination kit containing three 200-mg miconazole vaginal suppositories plus 2% miconazole cream for external use (3-day regimen).

1. COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Retaining clotrimazole 1% cream, miconazole 2% cream, and miconazole 200-mg vaginal suppository/2% cream combination kit
- Removing clotrimazole 2% cream and miconazole 100-mg vaginal suppository, which are rarely used in the MHS
- An implementation date of the first Wednesday 120 days following signing of the minutes for the two products removed from the list. No patient letters are required. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

B. Topical Minoxidil 5% Solution: The Committee considered an MTF request to review topical minoxidil 5% solution for androgenetic alopecia for addition to the OTC GENESIS Test list. A comprehensive review found a high level of evidence supporting topical minoxidil preparations for androgenetic alopecia in both males and females. Guidelines strongly recommend the use of topical minoxidil to improve or prevent progression of androgenetic alopecia in males and females.

While the P&T Committee found clinical support for the use of topical minoxidil for androgenetic alopecia, a review of utilization data showed extremely low use across the MHS enterprise. Additionally, 32CFR199.4(g)(41)(ii)(D) states that any diagnostic or therapeutic method or supply intended to encourage hair growth is excluded. Similarly, the Tricare Operations Manual states in Chapter 8, Section 12.1, Part 3.0 that the treatment of alopecia resulting from conditions other than treatment of malignant disease is excluded from the benefit, and in Part 3.4 that any diagnostic or therapeutic method or supply intended to encourage hair regrowth is excluded from the benefit.

1. COMMITTEE ACTION: TOPICAL MINOXIDIL 5% SOLUTION FOR THE MHS GENESIS OTC LIST—The P&T Committee recommended (13 for, 0 opposed, 4 abstained, 0 absent) the following:

- Do NOT add topical minoxidil 5% solution to the MHS GENESIS OTC list.

XII. SPECIALTY CARE LIST

Background—The Specialty Care Drug List (also known as the Clinical Services Drug List) identifies drugs for which Express Scripts provides additional clinical services at the Mail Order Pharmacy under the TRICARE pharmacy contract, which started in May 2015. Services provided at Mail Order include dedicated call lines for patient support, refill reminders, outgoing clinical calls to encourage adherence and provide patient education, and expedited/scheduled delivery.

Medications on this list must be filled either through Mail Order, at an MTF, or at a retail network pharmacy in the Specialty Drug Network, which currently includes Kroger, Rite-Aid, Walgreens, and Walmart pharmacies. Adding new medications to the Specialty Care Drug List

would require patients currently filling prescriptions for these medications at a retail pharmacy not in the Specialty Drug Network to move their prescriptions to one of these preferred points of service.

The Specialty Care program is distinct from the Enhanced MTF/Mail Pharmacy Initiative (EMMPI) program, which requires select branded maintenance medications to be filled at MTFs or Mail Order after two initial fills at retail. It is possible for medications to be added to both the Specialty Care Program and the EMMPI program: in this case, patients would be required to fill prescriptions for these medications at MTFs or Mail Order after two initial fills at retail and would receive additional clinical services and expedited/schedule delivery at Mail Order. There is less potential patient impact if medications are added to both programs simultaneously, since patients currently receiving their medications at a retail network pharmacy not in the Specialty Drug Network would only have to move their prescriptions once.

Refer to the August 2019 DoD P&T Committee meeting minutes for additional information on the program.

Drugs Added to the Specialty Care Program

Luteinizing Hormone-Releasing Hormone Agonists-Antagonists: leuprolide acetate injection (Fensolvi) – Fensolvi was reviewed as an innovator drug at the August 2020 P&T Committee meeting, and designated as NF; it is approved for treating central precocious puberty. It was not added to the EMMPI program, since at the time of the review, feasibility of availability for dispensing from Mail Order was uncertain. Information shows that Fensolvi is now available at mail. Other leuprolide products (i.e. Lupron, Lupron Depot-Ped, Eligard) are on the Specialty Drug List.

Endocrine Agents Miscellaneous: octreotide acetate injection (Bynfezia Pen) – Bynfezia was also evaluated as an innovator drug at the August 2020 meeting, and was designated as UF and added to the EMMPI program. It is a new octreotide formulation available in a pre-filled pen. Other octreotide acetate products (i.e. ampule, syringe, and vial) are on the Specialty Drug List.

A. COMMITTEE ACTION: SPECIALTY CARE DRUG LIST—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- Adding leuprolide acetate injection (Fensolvi) to the Specialty Care Drug List and the EMMPI program
- Adding octreotide acetate injection (Bynfezia pen) to the Specialty Care Drug List
- Implementation will occur as soon as feasible following signing of the minutes.
- No specific patient letters are necessary since, under the EMMPI program, beneficiaries filling prescriptions for Fensolvi and Bynfezia at retail network pharmacies will receive letters following each of their next two retail

prescription fills. Beneficiaries will also receive an introductory mailing from the Specialty Care program.

XIII. ITEMS FOR INFORMATION

A. DoD P&T Committee Charter

The revised DoD P&T Committee Charter was signed by the Director, DHA on August 26, 2020 and is available at <https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee> (See the “Related Links” box). Committee member duties were updated to include Tier 4/Not Covered drugs and Innovator drugs (newly approved drugs) determination for formulary status. Language was also updated to reflect that physician committee members may fall under the DHA, and the membership will specifically include physician and pharmacy providers with oncology subject matter expertise. The next revision is due in five years.

B. MHS Prescribing and Cost Trends

The Committee was briefed on various aspects of MHS prescribing and cost trends, including overall trends and spends, top 25 drug classes, increasing specialty spend, and a focused review on PPIs.

XIV. ADJOURNMENT

The meeting adjourned at 1730 hours on November 5, 2020. The next meeting will be in February 2021.

Appendix A—Attendance: November 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 November 2020 DoD P&T Committee Meeting

Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

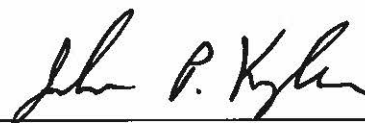
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

Appendix I—MHS GENESIS OTC Test List

Appendix J—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

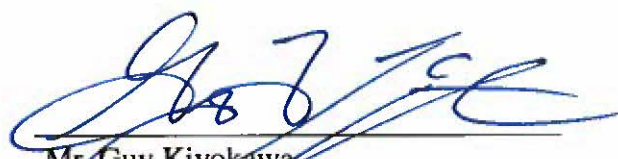
The Director, DHA:

concurs with all recommendations.

concurs with the recommendations, with the following modifications:

1. *I recommend the P&T committee REVIEW THE AGE & OTHER RESTRICTIONS FOR ENRYSOI.*
- 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 JAN 21

Date

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

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Paul Hoerner MSC, for Col Markus Gmehlin MSC	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 Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Maj Wendra J Galfand, MC	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Olaitan Ojo, MSC for CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
CDR Stacey Rustico, MC for Lcdr Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Col Corey Munro, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
LCDR William Agbo	DLA Troop Support
Janet Daily, PharmD for Kelly Echevarria, PharmD	Department of Veterans Affairs
Matthew Fuller, PharmD for Kelly Echevarria, PharmD	Department of Veterans Affairs

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

Guests	
Ms. Kimberlymae Wood	DHA Contracting Officer
Ms. Yvette Dluhos	DHA Contracting
Jeremiah Brinkman, PharmD	Landstuhl Clinical Pharmacist
Others Present	
CDR Heather Rovey, 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
Dr. Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Dr. Julia Trang, PharmD	DHA Formulary Management Branch
MAJ Triet Nguyen, MSC	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Ebony Moore	DHA Formulary Management Branch Contractor
Mr. Aaron Carabajal	University of Texas Pharmacy Student
Ms. Ahyun Sul	University of the Incarnate Word Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> amphetamine ER orally disintegrating tablet (Adzenys XR-ODT) amphetamine ER oral suspension (Adzenys ER) amphetamine ER oral suspension (Dyanavel XR) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to MN criteria recommended at November 2020 meeting</p> <ul style="list-style-type: none"> Use of at least TWO formulary ADHD stimulants is contraindicated Patient has experienced significant adverse events from at least TWO formulary ADHD stimulants Use of at least TWO of the formulary ADHD stimulants has resulted in therapeutic failure <p>Formulary Alternatives: mixed amphetamine salts XR (Adderall XR, generic), methylphenidate ER (Ritalin LA), methylphenidate ER oral suspension (Quillivant XR)</p>
<ul style="list-style-type: none"> mixed amphetamine salts ER capsules triphasic release (Mydayis) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to MN criteria recommended at November 2020 meeting.</p> <ul style="list-style-type: none"> Use of generic mixed amphetamine salts XR (Adderall XR) and generic methylphenidate OROS and other (Concerta) have resulted in therapeutic failure <p>Formulary Alternatives: mixed amphetamine salts XR (Adderall XR, generic), methylphenidate OROS and other (Concerta, generic)</p>
<ul style="list-style-type: none"> methylphenidate transdermal system (Daytrana) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to MN criteria recommended at November 2020 meeting.</p> <ul style="list-style-type: none"> Use of the formulary ADHD stimulants is contraindicated (e.g. due to hypersensitivity) Patient has experienced significant adverse effects from the formulary ADHD stimulants Use of the formulary ADHD stimulants have resulted in therapeutic failure No alternative formulary agent: Patient is unable to take oral medications <p>Formulary Alternatives: mixed amphetamine salts XR (Adderall XR, generic), methylphenidate OROS and other (Concerta, generic), methylphenidate ER (Metadate CD, Ritalin LA, generics)</p>
<ul style="list-style-type: none"> methylphenidate ER chewable tablet (Quillichew ER) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to MN criteria recommended at November 2020 meeting.</p> <ul style="list-style-type: none"> No alternative formulary agent: Patient cannot take methylphenidate ER oral suspension (Quillivant XR) <p>Formulary Alternatives: mixed amphetamine salts (Adderall IR, Adderall XR, generic), methylphenidate OROS (Concerta, generic), methylphenidate ER oral suspension (Quillivant XR),</p>
<ul style="list-style-type: none"> methylphenidate ER orally disintegrating tablet (Cotempla XR-ODT) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to MN criteria recommended at November 2020 meeting.</p> <ul style="list-style-type: none"> Use of generic mixed amphetamine salts XR (Adderall XR) AND generic methylphenidate OROS and other (Concerta) AND Quillivant XR or generic methylphenidate ER (Aptensio XR) have resulted in therapeutic failure <p>Formulary Alternatives: mixed amphetamine salts XR (Adderall XR, generic), methylphenidate OROS and other (Concerta, generic), methylphenidate ER OS (Quillivant XR), methylphenidate ER capsules (Aptensio XR, generic)</p>

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> • monomethyl fumarate (Bafiertam) <p>Multiple Sclerosis Agents</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from formulary agents <p>Formulary alternatives: dimethyl fumarate (Tecfidera)</p>
<ul style="list-style-type: none"> • insulin glargine (Semglee, Semglee Pen) <p>Insulins: Basal</p>	<ul style="list-style-type: none"> • Use of Lantus has resulted in therapeutic failure: Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control <p>Formulary alternatives: insulin glargine (Lantus), insulin glargine U-300 (Toujeo)</p>
<ul style="list-style-type: none"> • oxymetazoline ophthalmic solution (Upneeq) <p>Ophthalmic Miscellaneous</p>	<ul style="list-style-type: none"> • No alternative formulary agent <p>Formulary alternatives: none</p>
<ul style="list-style-type: none"> • octreotide (Mycapssa) <p>Endocrine Agents Miscellaneous</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from formulary agents • Use of one injectable octreotide formulation has resulted in therapeutic failure <p>Formulary alternatives: Octreotide immediate release injection, Bynfezia Pen, Sandostatin LAR Depot</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
<ul style="list-style-type: none"> • lisdexamfetamine capsule and chewable tablet (Vyvanse) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>Manual PA is required for all new users of Vyvanse</p> <p><u>Manual PA Criteria:</u> Vyvanse is approved if <u>all</u> criteria are met:</p> <p>ADHD</p> <ul style="list-style-type: none"> • Patient is 6 years of age or older • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed mixed amphetamine salts ER(Adderall XR, generics) or other long acting amphetamine or amphetamine derivative type drug • Patient has tried and failed methylphenidate OROS and other (Concerta, generics) or other long acting methylphenidate or methylphenidate derivative type drug <p>OR</p> <p>Binge Eating Disorder</p> <ul style="list-style-type: none"> • Note: If patient is an Active Duty Service Member (ADSM), the provider acknowledges the need to consult service specific policy for Binge Eating Disorder (BED) (<i>For ADSM, if the above is acknowledged, continue following remaining criteria; non-ADSM may by-pass this note and go directly to the criteria below</i>) • Patient is 18 years of age or older • Patient has a diagnosis of moderate to severe Binge Eating Disorder • Prescribed by or in consultation with a psychiatrist or other behavioral specialist • Patient has failed, does not have access to, or has had an inadequate response to cognitive behavioral therapy or other psychotherapy • Patient has tried and failed OR has a contraindication to an SSRI (e.g., citalopram, fluoxetine, sertraline) • Patient has tried and failed OR has a contraindication to topiramate or zonisamide • Provider acknowledges that Vyvanse will be discontinued if the patient does not respond by having a positive clinical response of meaningful decrease of binge eating episodes or binge days per week from baseline or improvement in signs and symptoms of binge eating disorder after taking Vyvanse <p>Non-FDA-approved uses are NOT approved to include weight loss/obesity Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> amphetamine sulfate orally disintegrating IR tablet (Evekeo ODT) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to PA criteria recommended at November 2020 meeting</p> <p><u>Manual PA Criteria:</u> Evekeo ODT is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Patient is 6 to 17 years of age Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record Patient has tried, for at least two months, and failed OR has difficulty swallowing Adderall tablets (generic) Patient has tried, for at least two months, and failed OR the patient has a contraindication to methylphenidate IR tablets or solution <p>Non-FDA-approved uses are NOT approved Prior authorization does not expire</p>
<ul style="list-style-type: none"> methylphenidate orally disintegrating XR tablet (Cotempla XR-ODT) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to PA criteria recommended at November 2020 meeting</p> <p><u>Manual PA Criteria:</u> Cotempla XR-ODT is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Patient is 6 to 17 years of age Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) Patient has tried and failed OR has a contraindication to generic Adderall XR Patient has tried and failed OR has a contraindication to generic Concerta Patient has tried and failed OR has a contraindication to Quillivant XR (methylphenidate ER oral suspension), or Aptensio XR (methylphenidate ER cap) <p>Non-FDA-approved uses are NOT approved Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> methylphenidate XR sprinkle capsules nighttime dosing (Jornay PM) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to PA criteria recommended at November 2020 meeting</p> <p><u>Manual PA Criteria:</u> Jornay PM is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Patient is 6 years of age or older Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record Patient has had at least a 2 month trial and failure of generic Concerta, OR have difficulty swallowing pills Patient has had at least a 2 month trial and failure of another long-acting methylphenidate (Methylphenidate ER/CD/LA, Quillivant XR, Aptensio XR) Patient has had at least a 2 month trial and failure of Adderall XR (generic) OR has a contraindication to Adderall XR Patient has tried, for at least two months, an immediate release formulation methylphenidate product in conjunction with generic Concerta or another long-acting methylphenidate Please explain why the patient needs Jornay PM: <i>(fill-in blank question)</i> <p>Non-FDA-approved uses are NOT approved Prior authorization does not expire</p>
<ul style="list-style-type: none"> mixed amphetamine salts ER capsules triphasic release (Mydayis) <p>Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants</p>	<p>No changes to PA criteria recommended at November 2020 meeting</p> <p><u>Manual PA Criteria:</u> Mydayis is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Patient is 13 years of age or older Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) Patient has tried and failed generic mixed amphetamine salts ER capsules (Adderall XR) Patient has tried and failed generic methylphenidate ER tablets (Concerta) <p>Non-FDA-approved uses are NOT approved Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • benralizumab (Fasenra) <p>Respiratory Interleukin Class</p>	<p>Changes from the November 2020 meeting are in bold and strikethrough</p> <p>Manual PA is required for all new users of Fasentra Pen</p> <p><u>Manual PA Criteria:</u> Fasentra Pen coverage will be approved for initial therapy for 12 months is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient has a diagnosis of severe persistent eosinophilic asthma • The patient is 12 years of age or older • The drug is prescribed by an allergist, immunologist, or pulmonologist • The patient must have an eosinophilic phenotype asthma as defined as either <ul style="list-style-type: none"> ▪ Eosinophils \geq 150 cells/mcL within past month while on oral corticosteroids OR ▪ Eosinophils \geq 300 cells/mcL • The patient’s asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: <ul style="list-style-type: none"> ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR ▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: <ul style="list-style-type: none"> ▪ Long-acting beta agonist LABA e.g., Serevent, Striverdi), ▪ Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zflo) • The patient is not currently receiving another immunobiologic (e.g., mepolizumab [Nucala], dupilumab [Dupixent] or omalizumab [Xolair]) <p>Non-FDA-approved uses are not approved Prior authorization does not expire expires after 12 months. Renewal PA criteria will be approved indefinitely</p> <p>Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • dupilumab (Dupixent) <p>Respiratory Interleukin Class</p>	<p>Changes from the November 2020 meeting are in bold and strikethrough</p> <p>Manual PA is required for all new users of Dupixent</p> <p><u>Manual PA Criteria:</u> Dupixent coverage will be approved for initial therapy for 12 months if all criteria are met:</p> <p><i>For Asthma:</i></p> <ul style="list-style-type: none"> • The patient is 12 years of age or older • The drug is prescribed by an allergist, immunologist, pulmonologist, or asthma specialist, • The patient has one of the following <ul style="list-style-type: none"> ▪ Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils \geq 150 cells/mcL OR ▪ Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months • The patient's symptoms are not adequately controlled on stable high-dose inhaled corticosteroid AND either a Long-Acting Beta Agonist or a Leukotriene Receptor Antagonist for at least 3 months. • For eosinophilic asthma, the patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following; <ul style="list-style-type: none"> ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR ▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • Will not be used for relief of acute bronchospasm or status asthmaticus • Dupixent will be used only as add-on therapy to other asthma controller medications • For eosinophilic asthma, the patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: <ul style="list-style-type: none"> ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi), ▪ Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zflo) <p><i>For Atopic Dermatitis:</i></p> <ul style="list-style-type: none"> • The patient is 6 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe or uncontrolled atopic dermatitis • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: <ul style="list-style-type: none"> ▪ Topical Corticosteroids: <ul style="list-style-type: none"> ○ For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) ○ For patients 6 to 17 year of age: any topical corticosteroid <p>AND</p> <ul style="list-style-type: none"> ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
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Appendix C—Table of Prior Authorization (PA) Criteria

	<p style="text-align: center;">— At least one systemic immunosuppressant (i.e., cyclosporine, methotrexate, azathioprine, mycophenolate)</p> <ul style="list-style-type: none"> • The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy <p><i>For Chronic rhinosinusitis with nasal polyposis:</i></p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: <ul style="list-style-type: none"> ▪ Presence of nasal polyposis is confirmed by imaging or direct visualization AND ▪ At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Nasal polyposis is confirmed by imaging or direct visualization • Patient has chronic rhinosinusitis with nasal polyps and is refractory to treatment with other therapies • Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments <ul style="list-style-type: none"> ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND ▪ The patient has failed a trial of two courses of oral corticosteroids in the past year or has a contraindication to oral corticosteroids AND ▪ The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength <p>AND</p> <ul style="list-style-type: none"> • For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) <p>Non-FDA-approved uses are not approved Prior authorization does not expire expires after 12 months. Renewal PA criteria will be approved indefinitely</p> <p>Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • Asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use • Atopic Dermatitis: The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear The patient's disease severity has improved and stabilized to warrant continued therapy • Chronic rhinosinusitis with nasal polyposis : There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score
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Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> mepolizumab (Nucala) <p>Respiratory Interleukin Class</p>	<p>Changes from the November 2020 meeting are in bold and strikethrough</p> <p>Manual PA is required for all new users of Nucala</p> <p><u>Manual PA Criteria:</u> Nucala coverage will be approved for initial therapy for 12 months if all criteria are met:</p> <p><i>For eosinophilic asthma:</i></p> <ul style="list-style-type: none"> The patient has a diagnosis of severe persistent eosinophilic asthma The drug is prescribed by an allergist, immunologist, or pulmonologist The patient must have an eosinophilic phenotype asthma as defined as either <ul style="list-style-type: none"> Eosinophils \geq 150 cells/mcL within past month while on oral corticosteroids OR Eosinophils \geq 300 cells/mcL The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: <ul style="list-style-type: none"> Hospitalization for asthma in past year OR Two courses of oral corticosteroids in past year OR Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: <ul style="list-style-type: none"> Long-acting beta agonist (LABA e.g., Serevent, Striverdi), Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zflo) <p><i>For eosinophilic granulomatosis with polyangiitis (EGPA):</i></p> <ul style="list-style-type: none"> The patient has a diagnosis of EGPA The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist The patient is 18 years of age or older 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 as a contraindication to therapy with <ul style="list-style-type: none"> Corticosteroids, cyclophosphamide, azathioprine, or methotrexate A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication <p><u>For Hypereosinophilic Syndrome (HES):</u></p> <ul style="list-style-type: none"> The patient has a diagnosis of HES The patient has had eosinophil levels $>$ 1,000 cells/mcL in the past year The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist The patient is 12 years of age or older A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the HES indication
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Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
	<p>AND</p> <ul style="list-style-type: none"> For all indications, the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], dupilumab [Dupixent] or omalizumab [Xolair]) <p>Non-FDA-approved uses are not approved Prior authorization does not expire expires after 12 months. Renewal PA criteria will be approved indefinitely</p> <p>Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> Eosinophilic asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use EGPA and HES: The patient’s disease severity has improved and stabilized to warrant continued therapy
Newly Approved Drug PAs	
<ul style="list-style-type: none"> azacitidine (Onureg) <p>Oncological Agents: Acute Myelogenous Leukemia</p>	<p>Manual PA is required for all new users of Onureg</p> <p><u>Manual PA Criteria:</u> Onureg is approved if all criteria are met:</p> <ul style="list-style-type: none"> The drug is prescribed by or in consultation with a hematologist/oncologist The patient is 18 years of age or older Patient does not have a myelodysplastic syndrome (MDS) Patient will use Onureg for maintenance therapy of acute myeloid leukemia (AML) following complete remission (CR) or complete remission with incomplete blood count recovery (CRi) achieved after intensive induction chemotherapy with or without consolidation therapy Patient is not able to complete intensive curative therapy Onureg will not be used for parenteral routes of administration The provider agrees to monitor for myelosuppression/cytopenias Female patients of childbearing age are not pregnant confirmed by (-) HCG Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 months after cessation of therapy if female; 3 months if male 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: _____ <p>Non-FDA-approved uses are not approved Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • decitabine/ cedazuridine (Inqovi) <p style="text-align: center;">Oncological Agents</p>	<p>Manual PA is required for all new users of Inqovi</p> <p><u>Manual PA Criteria:</u> Inqovi is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The drug is prescribed by or in consultation with a hematologist/oncologist • The patient is 18 years of age or older • Patient has myelodysplastic syndromes (MDS) with the following French-American-British subtypes (refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups • The provider agrees to monitor for myelosuppression/cytopenias • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment. • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 months after cessation of therapy if female; 3 months if male. • 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: _____ <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>
<ul style="list-style-type: none"> • insulin glargine (Semglee, Semglee Pen) <p style="text-align: center;">Insulins: Basal</p>	<p>Manual PA is required for all new users of Semglee, Semglee Pen</p> <p><u>Manual PA Criteria:</u> Semglee is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient must have tried and failed insulin glargine (Lantus) <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>
<ul style="list-style-type: none"> • monomethyl fumarate (Bafiertam) <p style="text-align: center;">Multiple Sclerosis Agents</p>	<p>Manual PA is required for all new users of Bafiertam</p> <p><u>Manual PA Criteria:</u> Bafiertam is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has a documented diagnosis of a relapsing form of Multiple Sclerosis (MS) • Patient must have had at least a two-week trial of Tecfidera and has failed therapy • Complete blood count drawn within six months prior to initiation of therapy, due to risk of lymphopenia • Coverage NOT provided for concomitant use with other disease-modifying drugs of MS <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • octreotide (Mycapssa) <p>Endocrine Agents Miscellaneous</p>	<p>Manual PA is required for all new users of Mycapssa</p> <p><u>Manual PA Criteria:</u> Mycapssa is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of acromegaly • The drug is prescribed by or in consultation with an endocrinologist • Patient has tried an injectable formulation of octreotide (e.g., Sandostatin generics, Sandostatin LAR Depot, Bynfezia) and failed therapy due to lack of response <p>Non-FDA-approved uses are NOT approved including vasoactive intestinal peptide tumors (VIPomas) and carcinoid tumors Prior authorization does not expire</p>
<ul style="list-style-type: none"> • ofatumumab injection (Kesimpta) <p>Multiple Sclerosis Agents</p>	<p>Manual PA is required for all new users of Kesimpta</p> <p><u>Manual PA Criteria:</u> Kesimpta is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The drug is prescribed by a neurologist • The patient has a documented diagnosis of relapsing forms of MS • The patient is not currently using another disease-modifying therapy (e.g., interferon, glatiramer, Tecfidera, Vumerity, Aubagio, Gilenya, Mayzent, Zeposia, Mavenclad, etc.) • Patient does not have an active hepatitis B virus infection • Patient has not failed a course of Ocrevus <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>
<ul style="list-style-type: none"> • oxymetazoline ophthalmic solution (Upneeq) <p>Ophthalmic Miscellaneous</p>	<p>Manual PA is required for all new users of Upneeq</p> <p><u>Manual PA Criteria:</u> Upneeq is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient is 13 years of age or older • Patient has a diagnosis of acquired blepharoptosis affirmed by all of the following <ul style="list-style-type: none"> ▪ Positive phenylephrine test indicating ptosis correction is achievable with Müller's muscle contraction ▪ Marginal reflex distance 1 (MRD1) of less than 2 mm • Patient and provider have decided that the patient is not a good candidate for surgical intervention <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • pralsetinib (Gavreto) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Gavreto</p> <p><u>Manual PA Criteria:</u> Gavreto is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The drug prescribed by or in consultation with a hematologist/oncologist • The patient is 18 years of age or older • Patient has unresectable locally advanced or metastatic RET fusion-positive non-small cell lung cancer (NSCLC) • Provider will monitor for hepatotoxicity • Patient does not have uncontrolled hypertension • Provider is aware and has counseled patient that pralsetinib can cause life-threatening lung disease and hemorrhage • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy if male; 2 weeks, if female • 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: _____ <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • risdiplam (Evrysdi) <p>Neurological Agents Miscellaneous</p>	<p>Manual PA is required for all new users of Evrysdi</p> <p><u>Manual PA Criteria:</u> Evrysdi is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient is between the ages of 2 months to 25 years of age (Fill-in-the-blank) • The drug is prescribed by a pediatric or adult neurologist • Patient has genetic confirmation of homozygous deletion or compound heterozygosity predictive of loss of function of the SMN1 gene (documentation required) • Patient has confirmation of at least two SMN2 gene copies (documentation required) • Patient has a confirmed diagnosis of Spinal Muscular Atrophy Types 1, 2, or 3 (Fill-in-the-blank) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients of childbearing potential have been counseled to use effective contraception during treatment and for at least 1 month after the cessation of therapy • Male patients of reproductive potential are counseled about the potential effects on fertility • Patient does not have evidence of hepatic impairment • Patient does not have permanent ventilator dependence • Patient does not have complete paralysis of all limbs • Evrysdi will not be used concurrently with Spinraza (nusinersen injection for intrathecal use) • Patient weight must be documented (Fill-in-the-blank) – (Any answer acceptable) • Patient dose in total mg/day and mg/kg per day must be documented (Fill-in-the-blank) <ul style="list-style-type: none"> ▪ The dose must be 0.2 mg/kg if the patient is 2 months to < 2 years of age; OR 0.25 mg/kg for patients ≥ 2 years of age who weigh < 20 kg; OR 5 mg for patients ≥ 2 years of age who weigh ≥ 20 kg <p>Non-FDA-approved uses are not approved Prior authorization expires in 6 months</p> <p><u>Renewal criteria:</u> (Initial TRICARE PA approval is required for renewal)</p> <ul style="list-style-type: none"> • According to the prescriber, the patient’s level of disease has improved or stabilized to warrant continuation on Evrysdi as determined by an objective measurement and/or assessment tool and/or clinical assessment of benefit. (documentation required) <p>Renewal criteria expires in 1 year</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • satralizumab-mwge injection (Enspryng) <p>Neurological Agents Miscellaneous</p>	<p>Manual PA is required for all new users of Enspryng</p> <p><u>Manual PA Criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The drug is prescribed by or in consultation with a neurologist • The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and is aquaporin-4 (AQP4) antibody positive • Patient has clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening • Patient has laboratory evidence of HBV negative and TB negative <p>Non-FDA-approved uses are not approved Prior authorization does not expire</p>
<ul style="list-style-type: none"> • triheptanoin oral liquid (Dojolvi) <p>Metabolic Agents Miscellaneous</p>	<p>Manual PA is required for all new users of Dojolvi</p> <p><u>Manual PA Criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has a documented diagnosis (molecularly confirmed) of a long-chain fatty acid oxidation disorder (LC-FAOD) • Dojolvi is prescribed by or in consultation with a geneticist, neurologist, or LC-FAOD expert • Patient must be experiencing symptoms of deficiency exhibited by the presence of at least 1 of the following: <ul style="list-style-type: none"> ▪ Severe neonatal hypoglycemia, hepatomegaly, cardiomyopathy, exercise intolerance, frequent episodes of myalgia, recurrent rhabdomyolysis induced by exercise, fasting or illness, cardiomyopathy, and an associated decreased quality of life <p>Non-FDA-approved uses are not approved including use for weight loss in a ketogenic diet Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) <p>ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents</p>	<p>Manual PA criteria apply to all new users of Xywav</p> <p><u>Manual PA Criteria:</u> Coverage of Xywav is approved if the following criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy <ul style="list-style-type: none"> ▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND <ul style="list-style-type: none"> ▪ The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND ▪ Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) <p>OR</p> <ul style="list-style-type: none"> • Patient is a child 7 years of age or older AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. <ul style="list-style-type: none"> ▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND <ul style="list-style-type: none"> ▪ The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders) <p>Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy</p> <p>PA expires after 1 year</p> <p>Renewal PA criteria; Renewal not allowed. A new prescription will require a new PA to be submitted</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
New PAs	
<ul style="list-style-type: none"> • tapentadol ER (Nucynta ER) <p>Narcotic Analgesics</p>	<p>Manual PA criteria applies to new users of Nucynta ER</p> <p><u>Manual PA Criteria:</u> Coverage for Nucynta ER is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Note that tapentadol IR, gabapentin, tramadol and several other immediate release opioids do not require PA. Please consider changing the prescription to one of these other drugs. • The patient is 18 years of age or older • The patient has a diagnosis of one of the following <ul style="list-style-type: none"> ▪ pain severe enough to require daily, around-the-clock, long-term opioid treatment OR ▪ neuropathic pain associated with diabetic peripheral neuropathy in adults severe enough to require daily, around-the-clock, long-term opioid treatment • For non-neuropathic pain, the patient has tried and failed at least one of the following short-acting opioids <ul style="list-style-type: none"> ▪ morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, tapentadol IR • For neuropathic pain, the patient has tried and failed all of the following drugs/drug classes <ul style="list-style-type: none"> ▪ At least two of the following classes of non-opioid medications (unless the patient has a contraindication) <ul style="list-style-type: none"> ○ gabapentin or pregabalin titrated to therapeutic dose ○ a tricyclic antidepressant titrated to therapeutic dose ○ duloxetine titrated to therapeutic dose ▪ Tramadol ▪ At least one of the following short acting opioids morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, tapentadol IR <p>Non-FDA-approved uses are NOT approved Prior authorization does not expire</p>

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • benralizumab (Fasenra) <p>Respiratory Interleukin Class</p>	<ul style="list-style-type: none"> ▪ Retail/Mail/MTF: 1 pen per fill <ul style="list-style-type: none"> ○ allow for loading dose of up to 3 monthly doses <p>Note that implementation will occur 30 days after signing of the minutes.</p>
<ul style="list-style-type: none"> • dupilumab (Dupixent) <p>Respiratory Interleukin Class</p>	<ul style="list-style-type: none"> ▪ Retail: 2 syringes/pens per fill ▪ MTF/Mail: 4 syringes/pens per fill <ul style="list-style-type: none"> ○ allow for loading dose of 2 syringes/pens for first fill <p>Note that implementation will occur 30 days after signing of the minutes</p>
<ul style="list-style-type: none"> • mepolizumab (Nucala) <p>Respiratory Interleukin Class</p>	<ul style="list-style-type: none"> ▪ Retail: 1 syringe/pen per fill ▪ MTF/Mail: 2 syringe/pen per fill ▪ EGPA and HES (300 mg dosing) per PA criteria <ul style="list-style-type: none"> ○ Retail: 3 syringes/pens per fill ○ MTF/Mail: 6 syringes/pens per fill <p>Note that implementation will occur 30 days after signing of the minutes.</p>
<ul style="list-style-type: none"> • budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere) <p>Pulmonary-3 Agents: Combination</p>	<ul style="list-style-type: none"> ▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
<ul style="list-style-type: none"> • decitabine/cedazuridine (Inqovi) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 28 day supply
<ul style="list-style-type: none"> • pralsetinib (Gavreto) <p>Oncological Agents: Lung Cancer</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • risdiplam (Evrysdi) <p>Neurological Agents Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 36 day supply
<ul style="list-style-type: none"> • azacitidine (Onureg) <p>Oncological Agents: Acute Myelogenous Leukemia</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 28 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
azacitidine (Onureg)	Oncological Agents: Acute Myelogenous Leukemia	<ul style="list-style-type: none"> • IV or SQ azacitidine (Vidaza) – medical benefit • IV or SQ decitabine (Dacogen) – medical benefit 	Acute myeloid leukemia (AML)	<ul style="list-style-type: none"> • Novel oral preparation of well-established DNA hypomethylating agent • Progression-free survival advantage over placebo as maintenance after consolidation therapy • High levels of Grade 3+ ADEs with half of patients developing neutropenia; comparable to parenteral preparations 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
budesonide extended-release (Ortikos)	GI-1 Agents: GI Steroids	<ul style="list-style-type: none"> • Entocort EC, generics 	Mild to moderate active Crohn's Disease Maintenance of clinical remission of mild to moderate Crohn's Disease	<ul style="list-style-type: none"> • Another extended-release oral formulation of budesonide approved for Crohn's Disease in patients 8 years or older • No new clinical trials for approval • In one study, Ortikos 9 mg showed bioequivalence to three tablets of 3 mg Entocort EC • There are no head-to-head studies with other budesonide formulations • Ortikos provides competition to Entocort EC but offers no advantage over existing formulary agents 	<ul style="list-style-type: none"> • Tier 4/Not covered
budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere)	Pulmonary-3 Agents: Combination	<ul style="list-style-type: none"> • Trelegy Ellipta • Advair plus Spiriva 	Maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD)	<ul style="list-style-type: none"> • Breztri is the second fixed-dose triple combination of ICS/LAMA/LABA for COPD • GOLD guidelines recommend triple therapy (ICS/LAMA/LABA) for COPD Group D category after failure of dual therapy with LAMA/LABA or LABA/ICS • Lacks an indication to reduce exacerbation in the label, unlike Spiriva • Did not achieve minimally important clinical difference in change in trough FEV1 compared to dual combo Symbicort (ICS/LABA) or Bevespi (LAMA/LABA) • Alternative triple combination (ICS/LAMA/LABA) can be achieved with two inhalers (e.g., Advair + Spiriva, Arnuity + Anoro, etc.) • Other than providing another type of inhaler (pMDI) in a fixed-dose triple combination, Breztri provides little to no compelling advantages over the existing fixed-dose triple combination UF agent 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

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
cysteamine 0.37% ophthalmic solution (Cystadrops)	Ophthalmic Miscellaneous	<ul style="list-style-type: none"> cysteamine 0.44% ophthalmic solution (Cystaran) 	corneal cysteine crystal deposits due to cystinosis	<ul style="list-style-type: none"> Cystadrops is the 2nd available ophthalmic anti-cysteine agent for treatment of corneal cysteine crystal deposits in pediatrics and adults Another cysteine formulation that allows for more convenient dosing and storage Patients with cystinosis will likely develop corneal cysteine crystals in their lifetime, which makes them candidates for Cystadrops therapy Cystadrops was evaluated in two small studies with a total of 40 patients. In 1 active comparator study and 1 open label study, both studies showed decrease in corneal crystal deposits when compared to baseline Other than storage and less frequent dosing, Cystadrops provides little to no compelling advantages over existing formulary agents 	<ul style="list-style-type: none"> UF Do not add to EMMPI list
decitabine/ cedazuridine (Inqovi)	Oncological Agents	<ul style="list-style-type: none"> IV or SQ Azacitidine (Vidaza) – medical benefit IV or SQ Decitabine (Dacogen) – medical benefit 	Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)	<ul style="list-style-type: none"> Inqovi has similar pharmacokinetics to IV decitabine after oral therapy achieves steady state. Inqovi has similar clinical efficacy to IV decitabine in terms of Overall Response Rate, Complete Response, and Duration of Response. Inqovi has a similar clinical safety profile to IV decitabine in terms of Adverse Events (including Treatment-Emergent, Serious, and those of Special Interest) after 1st cycle. 	<ul style="list-style-type: none"> UF Add to EMMPI list
dexamethasone 20 mg oral tablet (Hemady)	Corticosteroids-Immune Modulators	<ul style="list-style-type: none"> dexamethasone betamethasone 	Multiple myeloma	<ul style="list-style-type: none"> Hemady is another strength of oral dexamethasone; available as a 20 mg oral tablet Approved via a 505(b)(2) application and given an orphan drug designation for multiple myeloma Besides decreased pill burden, Hemady provides no clinical advantage over existing agents 	<ul style="list-style-type: none"> Tier 4/Not covered
Factor VIIa [recombinant]-jncw (Sevenfact)	Antihemophilic Factors	<ul style="list-style-type: none"> NovoSeven RT 	Hemophilia A or B with inhibitors	<ul style="list-style-type: none"> Sevenfact is a new product to control bleeding episodes in patients with hemophilia A or B ≥ 12 years old It was evaluated in 1 crossover clinical trial Sevenfact is available in a kit for home administration by the patient or caregiver Due to age restrictions and narrow indication, there is no compelling clinical advantage to using this product compared to NovoSeven 	<ul style="list-style-type: none"> UF Do not add to EMMPI list

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
fluticasone inhaler (Armonair Digihaler)	Pulmonary-1 Agents: Inhaled Corticosteroids	<ul style="list-style-type: none"> • fluticasone (ArmonAir Respiclick) • fluticasone (Flovent Diskus) • fluticasone (Flovent HFA) 	Treatment of asthma for patients age 12 and older	<ul style="list-style-type: none"> • Another fluticasone inhaler identical to the dry powder inhaler ArmonAir Respiclick but with App technology • Flovent HFA and Diskus are BCF and step preferred and contain the same ingredient as ArmonAir • No new clinical efficacy studies were undertaken for ArmonAir Digihaler approval • There is no evidence that the use of the App leads to improved clinical outcomes • The Digihaler device provides little to no clinical benefit relative to existing formulary agents or delivery devices 	<ul style="list-style-type: none"> • Tier 4/Not Covered
fluticasone/salmeterol (AirDuo Digihaler)	Pulmonary-1 Agents: Combinations	<ul style="list-style-type: none"> • Fluticasone/Salmeterol (AirDuo Respiclick) • Fluticasone/Salmeterol (Advair Diskus) • Fluticasone/Salmeterol (Advair HFA) 	Treatment of asthma for patients age 12 and older	<ul style="list-style-type: none"> • Another fluticasone/salmeterol inhaler identical to the dry powder inhaler AirDuo Respiclick but with App technology • Advair HFA and Diskus are BCF and step preferred and contain the same ingredients as AirDuo • There are no new clinical efficacy studies were undertaken for AirDuo Digihaler approval • There is no evidence that the use of the App leads to improved clinical outcomes • The Digihaler device provides little to no clinical benefit relative to existing formulary agents or delivery devices 	<ul style="list-style-type: none"> • Tier 4/Not Covered
fostemsavir (Rukobia)	Antiretrovirals: Other Agents	<ul style="list-style-type: none"> • Trogarzo (IV infusion) 	Human immunodeficiency virus (HIV)	<ul style="list-style-type: none"> • Rukobia is a first-in-class antiretroviral indicated for HIV in adults with treatment resistance who are failing their current regimen due to resistance, intolerance, or safety considerations • Rukobia has a novel mechanism of action and works by selectively inhibiting HIV-1 gp120 subunit • Rukobia is dosed orally twice daily • It should be taken in addition to continuing the current failing regimen • Rukobia offers another treatment option for treatment-resistant, treatment-experienced HIV in adults 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

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
insulin glargine (Semglee; Semglee Pen)	Insulins: Basal	<ul style="list-style-type: none"> • insulin glargine (Lantus) • insulin glargine (Basaglar) • insulin glargine U-300 (Toujeo) • insulin Detemir (Levemir) • insulin degludec (Tresiba) 	Type 1 and 2 diabetes mellitus in adults & pediatrics	<ul style="list-style-type: none"> • Semglee is another insulin glargine formulation approved for Type 1 and Type 2 DM in adults and pediatrics • 6th long acting basal insulin analog • Conducted 2 non-inferiority studies and 1 switching study • Showed non-inferiority in lowering A1c at 24 weeks • No differences in efficacy or safety compared to another insulin glargine • Provides no compelling clinical advantage over existing formulary agents 	<ul style="list-style-type: none"> • NF and non-step-preferred • Add to EMMPI list
levamlodipine (Conjupri)	Calcium channel blockers (CCBs)	<ul style="list-style-type: none"> • amlodipine • amlodipine oral suspension (Katerzia) • felodipine • isradipine • nifedipine ER tabs 	Used alone or in combination with other antihypertensive agents for the treatment of hypertension, to lower blood pressure for adults and pediatric patients 6 years and older	<ul style="list-style-type: none"> • New isomer of amlodipine for treating hypertension in adults and pediatric patients ≥ 6 years of age • FDA 5050b2 pathway approval using data from amlodipine besylate (Norvasc) • Levamlodipine is the pharmacologically active, anti-hypertensive isomer. • Conjupri 5 mg provides equivalent BP lowering as Norvasc 10 mg • Indication is limited to hypertension (HTN), compared to Norvasc which has indications for coronary artery disease (chronic stable angina and vasospastic angina) • No clinical efficacy studies were undertaken with Conjupri; approval based on efficacy/safety data with Norvasc • Offers no compelling advantages compared to amlodipine or the other formulary dihydropyridine CCBs, and has the risk of dosing errors, including excessive doses 	<ul style="list-style-type: none"> • Tier 4/Not covered

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
metoclopramide nasal spray (Gimoti)	Gastrointestinal -2 Agents	<ul style="list-style-type: none"> • metoclopramide oral tablet and oral solution (Reglan) • metoclopramide ODT (Reglan ODT) 	Relief of symptoms in adults with acute and recurrent diabetic gastroparesis	<ul style="list-style-type: none"> • Gimoti is another formulation of metoclopramide supplied as a nasal spray • Limited distribution requirements setup by manufacturer may delay patient receiving Gimoti • Although it's the only nasal formulation indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis, FDA-approval was based solely on pharmacokinetic studies comparing the nasal spray to the oral tablet formulation and relied on clinical studies that were done with oral formulation • Very limited clinical trial data available only in small numbers of patients that evaluated subjective outcomes, with varying results reported • Not recommended as initial therapy in adults ≥ 65 years of age, at all in pediatric patients, adult patients with hepatic or renal impairment, or adult patients on strong CYP2D6 inhibitors • Provides little to no compelling clinical advantages when compared to other available formulary agents 	<ul style="list-style-type: none"> • Tier 4/Not Covered
monomethyl fumarate (Bafiertam)	Multiple Sclerosis Agents	<ul style="list-style-type: none"> • dimethyl fumarate (Tecfidera, generics) • diroximel fumarate (Vumerity) 	Multiple sclerosis	<ul style="list-style-type: none"> • Bafiertam is the 3rd methyl fumarate product • Approval is based on bioequivalence to dimethyl fumarate (Tecfidera) • Bafiertam FDA package insert lists Tecfidera study data for both safety and efficacy • A study comparing GI adverse events between Bafiertam and Tecfidera showed no statistically significant differences • Dimethyl fumarate and diroximel fumarate rapidly convert to the active substrate monomethyl fumarate • Expect to see future competition with recently approved FDA generics for Tecfidera • Bafiertam provides little to no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> • NF • Do not add to EMMPI list

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
nifurtimox (Lampit)	Anti-infective: Miscellaneous	<ul style="list-style-type: none"> • benznidazole 	Chagas disease in pediatrics	<ul style="list-style-type: none"> • Lampit is the 2nd available agent for treating Chagas disease in pediatric patients • 1st FDA-approved option for children < 2 and > 12 years of age • Lampit has been used for treatment of Chagas disease outside of the US since 1965, and is included in the WHO List of Essential Medicines • Evaluated in 1 placebo-controlled trial which showed higher cure rate over historical placebo • Lampit provides another option in the treatment of a rare infectious disease 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
octreotide (Mycapssa)	Endocrine Agents Miscellaneous	<ul style="list-style-type: none"> • octreotide SQ/IV • octreotide SQ pen (Bynfezia Pen) • octreotide (Sandostatin LAR Depot) 	<ul style="list-style-type: none"> • Acromegaly 	<ul style="list-style-type: none"> • Mycapssa is a new formulation of octreotide acetate, available as an oral capsule FDA approved for acromegaly • Mycapssa is the first oral agent and the 4th octreotide formulation available • Evaluated in one small study showing statistical significance vs placebo in maintaining biochemical response at 9 months (58% vs 19%) • No head-to-head studies with other agents • Comparative statements about efficacy are difficult to make given the varying study durations which resulted in different responses at different time points • An indirect comparison of the LAR depot at 12 months and Mycapssa at 9 months showed similar efficacy • A switching study from Melmed, et al showed biochemical response of LAR depot at baseline (88.7%) compared to Mycapssa (62%) • Most common ADRs included nausea, vomiting, headache and diarrhea • Other than patient convenience of an oral dosage form, Mycapssa offers no compelling clinical advantage over existing formulary agents 	<ul style="list-style-type: none"> • NF • Do not add to EMMPI list

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
ofatumumab injection (Kesimpta)	Multiple Sclerosis Agents	<ul style="list-style-type: none"> • ocrelizumab IV (Ocrevus) – *medical benefit 	Relapsing forms of Multiple sclerosis	<ul style="list-style-type: none"> • Kesimpta is the 1st pharmacy benefit anti-CD20 B-cell cytolytic mAb for Multiple Sclerosis • Similar to the medical benefit drug Ocrevus, which guidelines recommend as a switching option for patients who need great efficacy • Study data shows improvements over Aubagio in annualized relapse rates, MRI lesions (T1 and T2), and in 3 month disability progression • Similar in efficacy to Ocrevus which is reserved for more serious disease due to its greater efficacy • Does not have BBW for PML like Arzerra does • Relatively mild side effects • Monthly injections are a disadvantage compared to Ocrevus (every 6 months administration) • Kesimpta adds an additional anti-CD20 cytolytic B-cell mAb option for treating Multiple Sclerosis 	<ul style="list-style-type: none"> • UF • Add to EMMPI list
opicapone (Ongentys)	Parkinson's Agents	<ul style="list-style-type: none"> • entacapone tab (Comtan) • tolcapone tab (Tasmar) 	Off episodes associated with Parkinson's	<ul style="list-style-type: none"> • Ongentys is the 3rd COMT inhibitor for Parkinson's patients experiencing "off episodes" while taking carbidopa/levodopa • Study trials showed modest efficacy as an adjunctive treatment to levodopa/carbidopa in • In the BIPARK-1 study, Ongentys showed non-inferiority compared to entacapone for absolute time in the "off" state • The safety profile appears similar to entacapone but Ongentys does not have the same black box warning for liver failure as tolcapone • Ongentys is given once daily at bedtime which is favorable to the concurrent administration of entacapone with each levodopa/carbidopa dosing or the TID with tolcapone • Ongentys provides a slight advantage over current COMT inhibitor therapy for treating Parkinson's patients experiencing "off episodes" by having once daily dosing and favorable adverse effects 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

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
oxymetazoline ophthalmic solution (Upneeq)	Ophthalmic Miscellaneous	<ul style="list-style-type: none"> Off-label Alpha-2 agonists short term 	Acquired blepharoptosis (droopy eyelid)	<ul style="list-style-type: none"> Upneeq is another formulation of oxymetazoline with a new indication for blepharoptosis Upneeq is currently the only FDA approved therapy for ptosis, as the current standard of care is surgery There is limited efficacy data showing a statistically significant difference from placebo on the primary outcome Leicester Peripheral Field Test (LPFT) at 2 hours and sustained to 6 hours Marginal reflex distance 1 (MRD1) was an endpoint in the unpublished trials, with results favoring Upneeq over vehicle at days 1 and 14. Specialists stated there may be a diminishing effect over time with alpha-adrenergic agonists Side effects seen with Upneeq compared to vehicle include punctate keratitis, conjunctival hyperemia, dry eye, and others. Providers feel these side effects may limit use Upneeq offers an additional option for the treatment of acquired blepharoptosis to the current standard of care of surgery 	<ul style="list-style-type: none"> NF Do not add to EMMPI list
pralsetinib (Gavreto)	Oncological Agents: Lung Cancer	<ul style="list-style-type: none"> selpercatinib (Retevmo) 	Non-small cell lung cancer (NSCLC)	<ul style="list-style-type: none"> Gavreto is a preferred agent indicated for RET-(+) NSCLC Gavreto achieves robust depths of response and response rates Poorly tolerated with high rate of dose-reductions Gavreto provides another treatment option for RET-(+) NSCLC 	<ul style="list-style-type: none"> UF Do not add to EMMPI

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
risdiplam injection (Evrysdi)	Neurological Agents Miscellaneous	<ul style="list-style-type: none"> • Spinraza (nusinersen)* • Zolgensma (onasemnogene abeparvovec-xioi)* <p>*medical benefit</p>	Spinal muscular atrophy (SMA)	<ul style="list-style-type: none"> • Risdiplam is the first oral agent approved for spinal muscular atrophy (SMA) • Risdiplam acts as a survival of motor neuron 2 (SMN2) splicing modifier • In Type 1 SMA, Phase 2 data suggest that patients have improved ability to sit without support for > 5 seconds and survival without permanent ventilation compared to the expected natural course of the disease • In Type 2 and 3 SMA, trial data showed a modest improvement in motor function and upper limb motor performance when compared to placebo • No head-to-head studies with medical benefit agents approved for spinal muscular atrophy, including Spinraza and Zolgensma • Risdiplam was well tolerated; most common ADRs included fever, diarrhea, rash, URI, pneumonia, constipation, and vomiting • Despite limited data available and uncertain place in therapy, risdiplam provides a novel oral treatment for spinal muscular atrophy 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
triheptanoin (Dojolvi)	Metabolic agents-misc.	<ul style="list-style-type: none"> • MCT Oil • Betaquik OTC • Liquigen OTC 	Long-chain fatty acid oxidation disorders (LC-FAOD)	<ul style="list-style-type: none"> • Dojolvi is a medium chain fatty acid FDA approved to treat pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD) • Dojolvi is a source of calories and fatty acids • <u>Most</u> medium chain fatty acids are considered nutritional supplements and are easily available to consumers online and in stores • Dojolvi was evaluated in one small study of 32 patients comparing Dojolvi to trioctanoin which showed a statistically significant improvement in left ventricular ejection fraction (LVEF) • Other than being a FDA approved product, Dojolvi provides no compelling clinical advantage over existing nutritional supplements available to consumers 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

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
satralizumab-mwge injection (Enspryng)	Neurological Agents Miscellaneous	<ul style="list-style-type: none"> • None 	Neuromyelitis optica spectrum disorder (NMOSD)	<ul style="list-style-type: none"> • Enspryng is the first self-administered agent approved to treat neuromyelitis optica spectrum disorder (NMOSD) • Enspryng was evaluated in two placebo-controlled studies • The primary end point was statistically significant in comparison to placebo (+/-) immunosuppressant treatment (IST) therapy • 22% vs 57% relapsed without IST in study 1; 11.5% vs 42.3% relapsed with IST in study 2 • Overall relapse free at 96 weeks in both studies were statistically significant to placebo (Study 1 76.5% v 41.1%) & (Study 2 91.1% vs 56.8%) • No significant change in visual analog scale (VAS) pain score was observed • No improvement or worsening in fatigue was seen in either group • No head-to-head studies with other agents • Most common ADRs: nasopharyngitis, headache, upper respiratory tract infection, gastritis, rash, arthralgia, extremity pain, fatigue, and nausea • Enspryng offers the first subcutaneous agent for NMOSD, however alternative agents are available 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)	Sleep disorders: wakefulness promoting agents	<ul style="list-style-type: none"> • armodafinil • modafinil • sodium oxybate (Xyrem) • solriamfetol (Sunosi) • pitolisant (Wakix) 	Narcolepsy with or without cataplexy	<ul style="list-style-type: none"> • Xywav is a new formulation of Xyrem which contains 92% less sodium (~1g to 1.5g per night) than Xyrem due to a unique composition of cations • FDA approved based on one phase 3 trial in patients with narcolepsy and cataplexy • Xywav demonstrated statistically and clinically significant differences compared to placebo in weekly # of cataplexy attacks and Epworth Sleepiness Scale scores • There are no head-to-head studies of Xywav with other agents indicated for narcolepsy • Most common ADRs included headache, nausea, dizziness, decreased appetite, parasomnia, diarrhea, hyperhidrosis, anxiety, and vomiting • Other than providing less sodium, Xywav has no compelling clinical advantage over existing agents 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 during the November 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)
November 2020	<p>ADHD Agents: Stimulants UF (brand maintenance only) <i>No reason to exempt from EMMPI requirement, pending any operational issues (e.g., sourcing at prime vendor, state laws)</i></p> <ul style="list-style-type: none"> ▪ lisdexamfetamine cap and chew tab (Vyvanse) ▪ Note that implementation for Vyvanse will occur 30 days after signing of the minutes <p>Respiratory Interleukins UF (brand maintenance only) <i>Maintain current status:</i></p> <ul style="list-style-type: none"> ▪ benralizumab (Fasenra) ▪ dupilumab (Dupixent) ▪ mepolizumab (Nucala) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Similar agents are already on list</i></p> <ul style="list-style-type: none"> ▪ ofatumumab (Kesimpta) <p><i>No reason for to exempt from EMMPI requirement:</i></p> <ul style="list-style-type: none"> ▪ decitabine/cedazuridine (Inqovi) <p>Designated NF: <i>No reason to exempt from NF-2-Mail requirement and similar agents are already on list:</i></p> <ul style="list-style-type: none"> ▪ insulin glargine (Semglee, Semglee Pen) <p>Designated NF (from Aug 2020 meeting) <i>Similar agents are already on list:</i></p> <ul style="list-style-type: none"> ▪ leuprolide acetate injection (Fensolvi) <p>Line Extensions Designated UF <i>Similar agents are already on list:</i></p> <ul style="list-style-type: none"> ▪ dulaglutide 3 mg, 4.5 mg injection (Trulicity) 	<p>ADHD Agents: Stimulants Designated NF <i>Maintain current status and exempt from NF-2-Mail requirement due to C-II status, as originally outlined in the August 2015 DoD P&T Committee meeting minutes:</i></p> <ul style="list-style-type: none"> • amphetamine XR-ODT (Adzenys XR-ODT) • amphetamine ER OS (Adzenys ER) • amphetamine XR OS (Dyanavel XR) • mixed amphetamine salts ER capsules triphasic release (Mydayis) • methylphenidate transdermal system (Daytrana) • methylphenidate ER chew tab (Quillichew ER) • methylphenidate XR-ODT (Cotempla XR-ODT) <p>ADHD Agents: Stimulants Designated UF <i>C-II Drugs</i></p> <ul style="list-style-type: none"> • amphetamine sulfate IR (Evekeo) • amphetamine sulfate ODT (Evekeo ODT) • dextroamphetamine IR tablets (Zenzedi) • methylphenidate ER oral suspension (Quillivant XR) • methylphenidate ER sprinkle capsules nighttime dosing (Jornay PM) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere) • opicapone (Ongentys) • satralizumab-mwge injection (Enspryng) <p><i>Drugs for limited duration use, similar agents not on list, and not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • nifurtimox (Lampit) <p><i>Drugs in class not currently represented on EMMPI List:</i></p> <ul style="list-style-type: none"> • Factor VIIa [recombinant]-jncw (Sevenfact) • fostemsavir (Rukobia) <p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • azacitidine (Onureg) • cysteamine 0.37% ophthalmic solution (Cystadrops) • pralsetinib (Gavreto)

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

		<ul style="list-style-type: none"> • risdiplam (Evrysdi) • triheptanoin (Dojolvi) <p>Designated NF: <i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • monomethyl fumarate (Bafiertam) • octreotide (Mycapssa) • oxymetazoline ophthalmic solution (Upneeq) <p>Line Extensions Designated UF <i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) <p>Designated NF <i>Drugs for acute or limited duration use:</i> doxycycline hyclate delayed release tablet (Doryx)</p>
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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
Nov 2020	Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants Subclass	UF Class Review Class last reviewed November 2015	<ul style="list-style-type: none"> ▪ mixed amphetamine salts XR (Adderall XR, generic) ▪ methylphenidate OROS and other (Concerta, generic) 	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ methylphenidate ER sprinkle caps (Adhansia XR) <ul style="list-style-type: none"> ▪ amphetamine sulfate (Evekeo, generic) ▪ amphetamine sulfate ODT (Evekeo ODT) ▪ dextroamphetamine (Dexedrine Spansule ER cap, generic, Dextrostat tab, ProCentra sol, generic) ▪ dextroamphetamine (Zenzedi tab) ▪ lisdexamfetamine capsule and chewable tablet (Vyvanse) ▪ methamphetamine HCL (Desoxyn, generic) ▪ mixed amphetamine salts IR (Adderall, generic) ▪ dexmethylphenidate IR (Focalin, generic) ▪ dexmethylphenidate ER (Focalin XR, generic) ▪ methylphenidate CD (Metadate CD, generic) ▪ methylphenidate chewable tablet and solution (Methylin, generic) ▪ methylphenidate ER (Metadate ER, Methylin ER, generic) ▪ methylphenidate ER (Aptensio, generic) ▪ methylphenidate ER OS (Quillivant XR) ▪ methylphenidate IR (Ritalin, generic) ▪ methylphenidate LA (Ritalin LA, generic) ▪ methylphenidate XR sprinkle capsule (Jornay PM) 	<ul style="list-style-type: none"> ▪ amphetamine ER-ODT (Adzenys XR-ODT) ▪ amphetamine ER OS (Adzenys ER) ▪ amphetamine XR OS (Dyanavel XR) ▪ mixed amphetamine salts ER triphasic release (Mydayis) ▪ methylphenidate ER chewable tablet (Quillichew ER) ▪ methylphenidate XR-ODT (Cotempla XR-ODT) ▪ methylphenidate patch (Daytrana) 	Pending signing of the minutes / 30 days The effective date is March 3, 2021	<ul style="list-style-type: none"> ▪ Maintained existing Manual PA criteria for Evekeo ODT, Mydayis, Cotempla XR-ODT, and Jornay PM ▪ Added new PA criteria for new users of Vyvanse. 	See Appendices B and C for MN and PA criteria.

Appendix G—Table of Implemented Status of UF Recommendations/Decision 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
Nov 2020	Respiratory Interleukin Class	UF Class Review	<p>Tier 4/Not Covered Medications</p> <p>MTFs must not have on formulary</p> <p>Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None 	<ul style="list-style-type: none"> ▪ benralizumab (Fasenra) ▪ dupilumab (Dupixent) ▪ mepolizumab (Nucala) 	<ul style="list-style-type: none"> ▪ None 	<p>Pending signing of the minutes/30 days</p> <p>The effective date is March 3, 2021</p>	<ul style="list-style-type: none"> ▪ PA updates apply to all new users ▪ New PA criteria for new Nucala indication of HES ▪ QLs updated across the class for 1 month supply at retail and 2 month at MTF and mail 	<p>No changes to current UF status and no changes to patients currently taking this medication</p>

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
Nov 2020	Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants	<ul style="list-style-type: none"> • methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> • 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) • dexamethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics) 	<ul style="list-style-type: none"> • Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	<ul style="list-style-type: none"> • budesonide ER 9 mg capsules (Ortikos) 	<ul style="list-style-type: none"> • budesonide ER tablets (Entocort EC, generics) • other corticosteroids 	<ul style="list-style-type: none"> • June 2 2021
Nov 2020	Corticosteroids	<ul style="list-style-type: none"> • dexamethasone 20 mg tablets (Hemady) 	<ul style="list-style-type: none"> • dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs 	<ul style="list-style-type: none"> • June 2 2021
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	<ul style="list-style-type: none"> • fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) 	<ul style="list-style-type: none"> • fluticasone (Flovent Diskus) • fluticasone (Flovent HFA) • fluticasone furoate (Arnuity Ellipta) [non formulary] • beclomethasone (QVAR) [non formulary] • budesonide (Pulmicort Flexhaler) [non formulary] • ciclesonide (Alvesco) [non formulary] • flunisolide (Aerospan) [non formulary] • mometasone (Asmanex Twisthaler) [non formulary] 	<ul style="list-style-type: none"> • June 2 2021

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
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	<ul style="list-style-type: none"> fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) 	<ul style="list-style-type: none"> fluticasone/salmeterol (Advair Diskus) fluticasone/salmeterol (Advair HFA) fluticasone/vilanterol (Breo Ellipta) [non formulary] mometasone/formoterol (Dulera) [non formulary] budesonide/formoterol (Symbicort) [non formulary] fluticasone/salmeterol (AirDuo Respiclick) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Calcium Channel Blockers	<ul style="list-style-type: none"> levamlodipine (Conjupri) 	<ul style="list-style-type: none"> amlodipine felodipine nifedipine diltiazem verapamil 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	GI-2 Agents	<ul style="list-style-type: none"> metoclopramide nasal spray (Gimoti) 	<ul style="list-style-type: none"> metoclopramide oral tablet (Reglan generics) metoclopramide oral solution (Reglan, generics) metoclopramide orally disintegrating tablet (Reglan ODT) 	<ul style="list-style-type: none"> June 2 2021
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% solution clobetasol 0.05% solution, shampoo fluocinonide 0.05% solution calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% ointment, cream, solution clobetasol 0.05% ointment, cream fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> February 24, 2021

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> • betamethasone propylene glycol 0.05% cream • clobetasol propionate 0.05% cream and ointment • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream and ointment • fluocinonide 0.05% cream and ointment • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% ointment 	<ul style="list-style-type: none"> • February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> • tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> • adapalene 0.1% lotion, gel, cream • adapalene 0.3% gel • clindamycin phosphate 1% gel, cream, lotion, and solution • clindamycin/ benzoyl peroxide 1.2% - 5% gel • tazarotene 0.1% cream • tretinoin 0.025%, 0.05%, and 0.1% cream • tretinoin 0.01% and 0.025% gel 	<ul style="list-style-type: none"> • February 24, 2021
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • amlodipine/celecoxib (Consensi) 	<ul style="list-style-type: none"> • Dihydropyridine calcium channel blockers: amlodipine, felodipine, nifedipine, isradipine <p style="text-align: center;">PLUS</p> <ul style="list-style-type: none"> • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • diclofenac potassium liquid-filled capsules (Zipsor) • diclofenac submicronized (Zorvolex) • fenoprofen capsules • indomethacin submicronized (Tivorbex) • meloxicam submicronized (Vivlodex) 	<ul style="list-style-type: none"> • celecoxib • diclofenac • ibuprofen • meloxicam • naproxen • Also includes other NSAIDs 	<ul style="list-style-type: none"> • August 26, 2020

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	<ul style="list-style-type: none"> • ibuprofen and famotidine tablets (Duexis) 	<ul style="list-style-type: none"> • H2 blockers: famotidine, ranitidine, cimetidine, nizatidine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • August 26, 2020
Feb 2020	Pain Agents – Combinations	<ul style="list-style-type: none"> • naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> • PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • diclofenac 1.3% patch (Flector) • diclofenac 2% solution (Pennsaid) 	<ul style="list-style-type: none"> • oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) • diclofenac 1.5% solution • diclofenac 1% gel 	<ul style="list-style-type: none"> • August 26, 2020
Feb 2020	Pain Agents Class; Pain Topical Subclass	<ul style="list-style-type: none"> • lidocaine 1.8% patch (ZTlido) 	<ul style="list-style-type: none"> • lidocaine 5% patch 	<ul style="list-style-type: none"> • August 26, 2020
Feb 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> • benzoyl peroxide 9.8% foam (Enzoclear) 	<ul style="list-style-type: none"> • clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) • clindamycin/benzoyl peroxide 1% - 5% gel (Benzacilin, generics) • clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit) 	<ul style="list-style-type: none"> • August 26, 2020
Feb 2020	Anti-Infectives: Miscellaneous	<ul style="list-style-type: none"> • omeprazole magnesium, amoxicillin and rifabutin (Talaria) 	<ul style="list-style-type: none"> • omeprazole PLUS amoxicillin PLUS rifabutin (given separately) • omeprazole PLUS clarithromycin PLUS amoxicillin • bismuth subsalicylate OTC PLUS metronidazole PLUS tetracycline PLUS PPI 	<ul style="list-style-type: none"> • August 26, 2020
Feb 2020	Pulmonary-1: Short Acting Beta2 Agonists (SABA)	<ul style="list-style-type: none"> • albuterol dry powder inhaler (ProAir Digihaler) 	<ul style="list-style-type: none"> • albuterol MDI (ProAir HFA) • albuterol DPI (ProAir Respiclick) • albuterol MDI (Proventil HFA) [Nonformulary] • albuterol MDI (Ventolin HFA) [Nonformulary] • levalbuterol MDI (Xopenex HFA) [Nonformulary] 	<ul style="list-style-type: none"> • August 26, 2020

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
Nov 2019	PDE-5 inhibitor	<ul style="list-style-type: none"> • avanafil tablet (Stendra) • brand Viagra tablet • brand Cialis tablet • vardenafil tablet (Levitra and generics) • vardenafil oral disintegrating tablet (ODT) (Staxyn and generics) 	<ul style="list-style-type: none"> • sildenafil tablet (generic Viagra only) • tadalafil tablet (generic Cialis only) 	<ul style="list-style-type: none"> • June 3, 2020
Nov 2019	Rapid Acting Insulins	<ul style="list-style-type: none"> • insulin plus niacinamide (Fiasp) 	<ul style="list-style-type: none"> • insulin aspart (Novolog) • insulin lispro (Humalog or authorized generic lispro) • insulin lispro (Admelog) [nonformulary] • insulin glulisine (Apidra) [nonformulary] 	<ul style="list-style-type: none"> • July 1, 2020
Nov 2019	Pulmonary-2 Agents: COPD	<ul style="list-style-type: none"> • formoterol/acclidinium (Duaklir Pressair) 	<ul style="list-style-type: none"> • umeclidinium/vilanterol (Anoro Ellipta) • tiotropium/olodaterol (Stiolto Respimat) • glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary] • glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary] 	<ul style="list-style-type: none"> • June 3, 2020
Nov 2019	Migraine Agents: Triptans	<ul style="list-style-type: none"> • sumatriptan nasal spray (Tosymra) 	<ul style="list-style-type: none"> • sumatriptan nasal spray (Imitrex, generics) • sumatriptan nasal powder (Onzetra Xsail) [nonformulary] • zolmitriptan nasal spray (Zomig) 	<ul style="list-style-type: none"> • June 3, 2020
Nov 2019	GI2 Agents: CIC and IBS-C	<ul style="list-style-type: none"> • tegaserod (Zelnorm) 	<ul style="list-style-type: none"> • linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Amitiza) • prucalopride (Motegrity) [nonformulary] 	<ul style="list-style-type: none"> • June 3, 2020

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	ADHD	<ul style="list-style-type: none"> • methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • clobetasol propionate 0.025% cream (Impoysz) • difflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog) 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • halcinonide 0.1% ointment (Halog) 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • March 4, 2020

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • clobetasol propionate 0.05% shampoo/ cleanser (kit) (Clodan kit) • halobetasol propionate 0.05% lotion (Ultravate) • halobetasol propionate 0.05% foam (authorized generic for Lexette) <i>(see Feb 2019 for brand Lexette)</i> • halobetasol propionate 0.01% lotion (Bryhali) 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • March 4, 2020
May 2019	PPIs	<ul style="list-style-type: none"> • dexlansoprazole (Dexilant) • esomeprazole strontium 	<ul style="list-style-type: none"> • esomeprazole • omeprazole • pantoprazole • rabeprazole 	<ul style="list-style-type: none"> • Nov 28, 2019 MTF Tier 4 implementation for Dexilant delayed to Jan 31, 2020
Feb 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • halobetasol propionate 0.05% foam (Lexette brand) 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Nov 2020: Lexette brand and generic remains Tier 4 • Aug 28, 2019 Note that Lexette reaffirmed as Tier 4 at the August 2019 High Potency Topical Steroid review
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	<ul style="list-style-type: none"> • metformin ER gastric retention 24 hours (Glumetza) 	<ul style="list-style-type: none"> • metformin IR (Glucophage generic) • metformin ER (Glucophage XR generic) 	<ul style="list-style-type: none"> • Nov 2020 Glumetza brand and generic remain Tier 4 • Aug 28, 2019
Feb 2019	Pain Agents – Combinations	<ul style="list-style-type: none"> • naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> • PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • Nov 2020 Vimovo brand and generic remain Tier 4 • Aug 28, 2019 • Note that Vimovo reaffirmed as Tier 4 at the February 2020 NSAID subclass review

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

* The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents, based on an interim final rule published on December 11, 2018. <https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms>. The Final Rule was published June 3, 2020 and is available at <https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms>. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service.

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
OTC Vaginal Antifungals (Azoles)		
November 2020	<p>Retain these GCNs:</p> <ul style="list-style-type: none"> ▪ 28360 – clotrimazole 1% cream (7-day) ▪ 28380 – miconazole 2% cream (7-day) ▪ 69380 – miconazole 200 mg supp/2% cream kit (3-day) 	<p>Remove these GCNs:</p> <ul style="list-style-type: none"> ▪ 28361 – clotrimazole 2% cream (3-day) ▪ 28390 – miconazole 100 mg suppository (7-day)

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

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
AAD	American Academy of Dermatology	LABA	Long acting beta agonist
ADR	Adverse reaction	LAMA	Long acting muscarinic antagonist
AE	Adverse event	LC-FAOD	Long-chain fatty acid oxidation disorder
AML	Acute myeloid leukemia	LPFT	Leicester Peripheral Field Test
BCF	Basic Core Formulary	mcL	Microliter
BIA	Budget impact analysis	MHS	Military Health System
CFR	Code of Federal Regulations	MN	Medical Necessity
CMA	Cost minimization analysis	MRD-1	Marginal Reflex Distance 1
CMML	Chronic myelomonocytic leukemia	MTF	Military Treatment Facility
COMT	Catechol-o-methyl transferase inhibitor	NCCN	National Comprehensive Cancer Network
COPD	Chronic obstructive pulmonary disease	NDA	National Defense Authorization Act
CRSwNP	Chronic rhinosinusitis with nasal polyposis	NDC	National Drug Codes
CV	Cardiovascular	NMOSD	Neuromyelitis optica spectrum disorder
DHA	Defense Health Agency	NSAID	Nonsteroidal anti-inflammatory drugs
DNRI	dopamine and norepinephrine reuptake inhibitor	ODT	Orally Disintegrating Tablet
DoD	Department of Defense	OSA	Obstructive Sleep Apnea
DR	Delayed release	OSDr	Optica spectrum disorder
EAACI	European Academy of Allergy and Clinical Immunology	OTC	Over the counter
ECF	Extended Core Formulary	PA	Prior authorization
EDS	Excessive daytime sleepiness	PBM	Pharmacy Benefit Manager
EGPA	Eosinophilic granulomatosis with polyangiitis	POD	Pharmacy Operations Division
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	POS	Point of service
EPOS	European Position Paper on Rhinosinusitis and Nasal Polyposis	PPI	Proton Pump Inhibitor
ER	Extended release	QL	Quantity limits
FDA	U.S. Food and Drug Administration	RET	metastatic rearranged during transfection
GINA	Global Initiative for Asthma	Rx	Medical Prescription
HES	Hypereosinophilic Syndrome	SC	Subcutaneous
IST	Immunosuppressive therapy	SMA	Spinal muscular atrophy
JNC	Joint National Contract	SMN2	Survival of motor neurons 2

**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, meclufenamate 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, meclufenamate, 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)
 - meclufenamate (*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, meclufenamate, 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 than 7 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 Akliief, 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 Akliief, Amzeeq, Fasentra 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, Ajoyv, 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, Fasentra 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, Ajoyv, 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

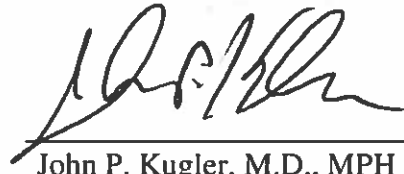
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

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
<ul style="list-style-type: none"> diclofenac potassium powder packets 50 mg (Cambia) <p>Pain Agents: NSAIDs</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from at least three formulary NSAIDs Use of at least 3 formulary NSAIDs has resulted in therapeutic failure <p>Formulary alternatives: celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)</p>
<ul style="list-style-type: none"> fenoprofen tablets ketoprofen ketorolac nasal (Sprix) meclofenamate naproxen sodium ER (Naprelan, generic) tolmetin <p>Pain Agents: NSAIDs</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from at least three formulary NSAIDs <p>Formulary alternatives: celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)</p>
<ul style="list-style-type: none"> indomethacin oral suspension <p>Pain Agents: NSAIDs</p>	<ul style="list-style-type: none"> No alternative formulary agent – patient requires an oral suspension formulation due to swallowing difficulties (e.g. stroke, developmental delay, etc.) <p>Formulary alternatives: celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)</p>
<ul style="list-style-type: none"> meloxicam ODT (Qmiiz) <p>Pain Agents: NSAIDs</p>	<ul style="list-style-type: none"> 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 <p>Formulary alternatives: naproxen oral suspension, celecoxib, diclofenac, ibuprofen, meloxicam, and naproxen (also includes other NSAIDs)</p>
<ul style="list-style-type: none"> trifarotene 0.005% cream (Aklief) <p>Acne Agents: Topical Acne and Rosacea</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from both tretinoin <u>and</u> 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 <p>Formulary Alternatives: adapalene (cream, gel, lotion), tazarotene (cream), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel)</p>

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> • asenapine patch (Secuado) <p>Antipsychotic Agents: Atypical</p>	<ul style="list-style-type: none"> • 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 <p>Formulary Alternatives: risperidone, quetiapine, aripiprazole, olanzapine, olanzapine/fluoxetine, ziprasidone, paliperidone, lurasidone</p>
<ul style="list-style-type: none"> • baclofen oral solution (Ozobax) <p>Skeletal Muscle Relaxants and Combinations</p>	<ul style="list-style-type: none"> • No alternative formulary agent. Patient cannot swallow and crushed tablets are not an option <p>Formulary Alternatives: baclofen tablets</p>
<ul style="list-style-type: none"> • colchicine oral solution (Gloperba) <p>Anti Gout Agents: Acute</p>	<ul style="list-style-type: none"> • No alternative formulary agent – Patient requires colchicine but cannot swallow colchicine tablets/capsules <p>Formulary Alternatives: colchicine capsules/tablets</p>
<ul style="list-style-type: none"> • diroximel fumarate (Vumerity) <p>Multiple Sclerosis Agents: Methyl Fumarate</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from formulary agents <p>Formulary Alternatives: dimethyl fumarate (Tecfidera)</p>
<ul style="list-style-type: none"> • minocycline 4% foam (Amzeeq) <p>Acne Agents: Topical Acne and Rosacea</p>	<ul style="list-style-type: none"> • 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 <p>Formulary Alternatives: adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel)</p>
<ul style="list-style-type: none"> • testosterone undecanoate capsules (Jatenzo) <p>Androgens-Anabolic Steroids: Testosterone Replacement Therapies</p>	<ul style="list-style-type: none"> • 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 <p>Formulary Agents: Androderm patch, testosterone 2% gel (Fortesta), testosterone 1% gel (generic to Androgel), and Testim 1% gel</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
<ul style="list-style-type: none"> • diclofenac potassium powder packets 50 mg (Cambia) <p>Pain Agents; NSAIDs</p>	<p>PA criteria apply to all new and current users of diclofenac potassium powder (Cambia)</p> <p>Note that multiple formulary NSAIDs and triptans are available without a PA including ibuprofen, indomethacin, naproxen, diclofenac potassium tablets, sumatriptan, rizatriptan, and zolmitriptan.</p> <p><u>Manual PA Criteria:</u> Cambia is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization expires in one year.</p> <p>No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.</p>
<ul style="list-style-type: none"> • meloxicam ODT (Qmiiz) <p>Pain Agents; NSAIDs</p>	<p>PA criteria apply to all new users of meloxicam ODT (Qmiiz)</p> <p>Note that multiple formulary NSAIDs, including meloxicam oral tablets, are available for DoD beneficiaries without a PA</p> <p><u>Manual PA Criteria:</u> Qmiiz is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider must explain why the patient requires meloxicam ODT and cannot take any of the formulary NSAIDs. <p>Non-FDA-approved uses are NOT approved. PA does not expire.</p>
<ul style="list-style-type: none"> • naproxen sodium ER (Naprelan brand and generic) <p>Pain Agents; NSAIDs</p>	<p>PA criteria apply to all new users of naproxen CR (Naprelan)</p> <p>Note that multiple formulary NSAIDs are available without a PA including ibuprofen, indomethacin, meloxicam, naproxen, and celecoxib.</p> <p><u>Manual PA Criteria:</u> naproxen CR is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider must provide clinical rationale of why patient cannot take any of the formulary NSAIDs. <p>Non-FDA-approved uses are NOT approved. PA does not expire</p>

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
<ul style="list-style-type: none"> • baclofen oral solution (Ozobax) <p>Skeletal Muscle Relaxants and Combinations</p>	<p>Manual PA is required for all new users of Ozobax.</p> <p><u>Manual PA Criteria:</u> Ozobax is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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 <p>Non-FDA-approved uses are not approved including nystagmus, trigeminal neuralgia, hiccups, GERD, alcohol abstinence in alcoholic liver disease, and low back pain.</p> <p>Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • benralizumab injection (Fasenra Pen) <p>Pulmonary 1-Agents: Pulmonary Miscellaneous</p>	<p>Manual PA is required for all new and current users of Fasentra Pen.</p> <p><u>Manual PA Criteria:</u> Fasentra Pen is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> – 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: <ul style="list-style-type: none"> – 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: <ul style="list-style-type: none"> – LABA (e.g., salmeterol), LAMA (tiotropium), or leukotriene receptor antagonist <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • colchicine oral solution (Gloperba) <p>Anti-Gout Agents: Acute</p>	<p>Manual PA is required for all new users of Gloperba.</p> <p>Note: other formulations of colchicine (e.g. Colcrys) do not require prior authorization.</p> <p><u>Manual PA Criteria:</u> Gloperba is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider must explain why the patient requires liquid colchicine and cannot take colchicine capsules or tablets <p>Non-FDA-approved uses are not approved. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • diroximel fumarate (Vumerity) <p>Multiple Sclerosis Agents: Methyl Fumarate</p>	<p>Manual PA criteria apply to all new and current users of Vumerity.</p> <p><u>Manual PA Criteria:</u> Vumerity is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Documented diagnosis of a relapsing form of Multiple Sclerosis (MS) • Patient must have had at least a two-week trial of Tecfidera and either <ul style="list-style-type: none"> – 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 <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> • elexacaftor/tezacaftor/ivacaftor (Trikafta) <p>Cystic Fibrosis Agents</p>	<p>Manual PA is required for all new and current users of Trikafta.</p> <p><u>Manual PA Criteria:</u> Trikafta is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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 <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> • minocycline 4% foam (Amzeeq) <p>Acne Agents: Topical Acne and Rosacea</p>	<p>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</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Amzeeq is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses (including rosacea) are not approved. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • testosterone undecanoate capsules (Jatenzo) <p>Androgens-Anabolic Steroids: Testosterone Replacement Therapies</p>	<p>Manual PA is required for all new and current users of Jatenzo</p> <p><u>Manual PA Criteria:</u> Jatenzo is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Patient is a male age \geq 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 <p>OR</p> <ul style="list-style-type: none"> • 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 <p>OR</p> <ul style="list-style-type: none"> • The requested medication is being used for female-to-male gender reassignment (endocrinologic masculinization) <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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. <p>Non-FDA-approved uses are not approved.</p> <p>PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • trifarotene 0.005% cream (Aklief) <p>Acne Agents: Topical Acne and Rosacea</p>	<p>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.</p> <p>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.</p> <p><u>Manual PA criteria:</u> Aklief is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are not approved. PA does not expire</p>
<ul style="list-style-type: none"> • voxelotor (Oxbryta) <p>Hematological Agents: Sickle Cell Anemia Agents</p>	<p>Manual PA criteria apply to all new and current users of Oxbryta.</p> <p><u>Manual PA criteria:</u> Oxbryta is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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.): <ul style="list-style-type: none"> – 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. <p>Non-FDA-approved uses are not approved.</p> <p>PA expires after 1 year.</p> <p><u>Renewal criteria:</u> PA will be approved indefinitely if</p> <ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • zanubrutinib (Brukinsa) <p>Oncologic Agents</p>	<p>Manual PA criteria apply to all new users of Brukinsa.</p> <p><u>Manual PA Criteria:</u> Brukinsa is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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: _____. <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
New PAs	
<ul style="list-style-type: none"> • epinephrine (Auvi-Q) auto-injector <p>Respiratory Agents Miscellaneous</p>	<p>Manual PA criteria apply to all new users of epinephrine (Auvi-Q) auto-injector.</p> <p>Note: Auvi-Q has been identified as having cost-effective alternatives including EpiPen, EpiPen generic, and Symjepi. These agents do not require prior authorization.</p> <p><u>Manual PA Criteria:</u> Coverage for Auvi-Q is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The provider documents a patient-specific reason as to why the patient cannot use the formulary alternatives (blank write-in) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • generic insulin aspart (authorized generic for Novolog) <p>Insulin: Rapid-Acting Agents</p>	<p>Manual PA criteria apply to new and current users of authorized generic insulin aspart.</p> <p>Note: Brand Novolog or brand Humalog are the preferred rapid acting insulins and do not require prior authorization.</p> <p><u>Manual PA Criteria:</u> Coverage for authorized generic insulin aspart is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider explains a patient-specific justification as to why the brand Novolog or brand Humalog product cannot be used (blank write-in) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • prenatal multivitamin (Zalvit) <p>Vitamins: Prenatal</p>	<p>Manual PA criteria apply to new and current users of Zalvit, regardless of the woman's age.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Coverage for Azesco or Zalvit is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • sulfacetamide and sulfacetamide/sulfur and combination products <p>Topical Acne and Rosacea Agents</p>	<p>Manual PA criteria apply to new and current users of sulfacetamide and sulfacetamide combination products.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Coverage for sulfacetamide and sulfacetamide combination products is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • venlafaxine HCL ER 24 hr. tablets <p>Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin-Norepinephrine Reuptake Inhibitors</p>	<p>Manual PA criteria apply to new and current users of venlafaxine HCL ER 24 hr. tablets.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Coverage for venlafaxine HCL ER 24 hr. tablets is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<p>Updated PAs (on next page)</p>	

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • deflazacort (Emflaza) <p>Corticosteroids- Immune Modulators</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p>Manual PA criteria applies to all new users of Emflaza.</p> <p><u>Manual PA Criteria:</u> Emflaza is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> – Unmanageable weight gain OR – Experienced severe behavioral adverse events that requires a reduction in prednisone dose <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • doxycycline (Oracea) <p>Acne Agents: Tetracyclines</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p>[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.]</p> <p>Manual PA criteria applies to all new and current users of Oracea.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Oracea is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization expires after 1 year.</p> <p><u>Renewal Criteria:</u> Coverage will be approved indefinitely for continuation of therapy if <u>all</u> of the following are met (Note that initial TRICARE PA approval is required for renewal):</p> <ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • erenumab-aooe (Aimovig) • fremanezumab-vfrm (Ajovy) • galcanezumab-gnlm (Emgality) <p>Migraine Agents: CGRP Preventative</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p>Manual PA criteria applies to all new users of Aimovig, Ajovy, and Emgality.</p> <p><u>Manual PA Criteria:</u> Aimovig, Ajovy, or Emgality is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> – 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, intolerance to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: <ul style="list-style-type: none"> – 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 <p>Non-FDA-approved uses are NOT approved. Prior authorization expires after 6 months.</p> <p><u>Renewal Criteria:</u> 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):</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> – Migraine Disability Assessment (MIDAS) <ul style="list-style-type: none"> • Reduction of ≥ 5 points when baseline score is 11–20 • Reduction of ≥ 30% when baseline score is > 20 – Headache Impact Test (HIT-6) <ul style="list-style-type: none"> • Reduction of ≥ 5 points – Migraine Physical Functional Impact Diary (MPFID) <ul style="list-style-type: none"> • Reduction of ≥ 5 points

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • icosapent ethyl (Vascepa) <p>Antilipidemic-2: Omega-3 Fatty Acids</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p><u>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.</u></p> <p>Manual PA criteria applies to all new users of Vascepa and Lovaza.</p> <p><u>Manual PA Criteria:</u> Vascepa is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient has a diagnosis of hypertriglyceridemia • The patient has a triglyceride (TG) level \geq 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 <p>OR</p> <ul style="list-style-type: none"> • 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 <p>OR (below only applies to Vascepa)</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> - 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 <p>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.</p> <p>Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • insulin glargine U-300 (Toujeo) <p>Insulin: Basal</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p>Manual PA criteria apply to new users of Toujeo.</p> <p><u>Manual PA Criteria:</u> Coverage for Toujeo is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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 <u>not acceptable</u> reasons for receiving Toujeo <ul style="list-style-type: none"> – 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 <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • mepolizumab (Nucala) <p>Pulmonary-1 Agents: Pulmonary Miscellaneous</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p>Manual PA criteria applies to new users of Nucala.</p> <p><u>Manual PA Criteria:</u> Coverage for Nucala is approved if <u>all</u> criteria are met:</p> <p>For <u>eosinophilic asthma</u>:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> – 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 <ul style="list-style-type: none"> – 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 <u>at least two</u> of the following while using a <u>high-dose inhaled corticosteroid</u>: <ul style="list-style-type: none"> – 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) <p>OR</p> <p>For <u>eosinophilic granulomatosis with polyangiitis (EGPA)</u>:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> – 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 <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • tofacitinib (Xeljanz, Xeljanz XR) <p>Targeted Immunomodulatory Biologics (TIBs): Miscellaneous</p>	<p><u>Changes from the February 2020 meeting are in BOLD and strikethrough.</u></p> <p>Step therapy and manual PA criteria apply to new users of Xeljanz, Xeljanz XR.</p> <p><u>Automated PA Criteria:</u> 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.</p> <p>AND</p> <p><u>Manual PA Criteria:</u> If automated criteria are not met, coverage for Xeljanz, Xeljanz XR is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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 <p>OR</p> <ul style="list-style-type: none"> • The patient has a contraindication to Humira • Age ≥ 18 years • Patient has a diagnosis of: <ul style="list-style-type: none"> ○ Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate <ul style="list-style-type: none"> ▪ The prescription is for 5 mg BID or 11 mg once a day ○ Active psoriatic arthritis (PsA) <ul style="list-style-type: none"> ▪ The prescription is for 5 mg BID or 11 mg once a day ○ Moderately to severely active ulcerative colitis (UC) <ul style="list-style-type: none"> ▪ Will allow doses up to 10 mg BID OR up to 22 mg once a day <ul style="list-style-type: none"> • Patient has no history of thromboembolic disease • Patient hemoglobin (Hgb) must be > 9 g/dL • Patient absolute neutrophil count (ANC) < 1,000/mm³ • Patient absolute lymphocyte count (ALC) < 500/ mm³ • 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 <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> Diclofenac potassium powder packets (Cambia) <p>Pain Agents: NSAIDs</p>	<ul style="list-style-type: none"> Retail: 18 packets/30 days MTF/Mail: 54 packets/90 days <p>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</p>
<ul style="list-style-type: none"> ketorolac nasal (Sprix) <p>Pain Agents: NSAIDs</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 5 bottles/30-day supply at all POS <p>Note that implementation will occur 2 weeks after signing of the minutes, along with the rest of the QLs in this table</p>
<ul style="list-style-type: none"> lidocaine 5% patch (Lidoderm generic) <p>Pain Agents: Pain Topical</p>	<ul style="list-style-type: none"> Retail: 90 patches per fill MTF/Mail: 270 patches per fill
<ul style="list-style-type: none"> benralizumab injection (Fasenra Pen) <p>Pulmonary-1 Agents: Pulmonary Miscellaneous</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 1 pen per fill at all POS
<ul style="list-style-type: none"> elexacaftor/tezacaftor/ivacaftor (Trikafta) <p>Cystic Fibrosis Agents</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 84 tabs/28 days at all POS
<ul style="list-style-type: none"> ivacaftor (Kalydeco) <p>Cystic Fibrosis Agents</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 60 tabs/30 days at all POS
<ul style="list-style-type: none"> Newly approved drugs <p>Cystic Fibrosis Agents</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: “x number” tabs/28 days or “y number” tabs/30 days (based on packaging) at all POS
<ul style="list-style-type: none"> pegfilgrastim-bmez (Ziextenzo) <p>White Blood Cell Stimulants: Pegfilgrastims</p>	<ul style="list-style-type: none"> Retail: 1 syringe per 21 days and a 21-day supply MTF/Mail: 2 syringes per 45 days and a 45-day supply
<ul style="list-style-type: none"> zanubrutinib (Brukinsa) <p>Oncological Agents</p>	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> amlodipine and celecoxib taken separately 	Adult patients for whom treatment with amlodipine for hypertension (HTN) and celecoxib for osteoarthritis (OA) are appropriate.	<ul style="list-style-type: none"> 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 alternative agents 	<ul style="list-style-type: none"> Tier 4/Not Covered (part of NSAID class review)
albuterol dry powder inhaler (ProAir Digihaler)	Pulmonary-1 Agents: Short Acting Beta Agonists	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Tier 4/Not Covered
asenapine transdermal system (Secuado)	Antipsychotic Agents: Atypical	<ul style="list-style-type: none"> aripiprazole oral liquid (Abilify, generics) asenapine sublingual tab (Saphris, generics) brexpiprazole (Rexulti) cariprazine (Vraylar) lurasidone (Latuda, generics) 	Schizophrenia in adults	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • NF • Do not add to EMMI list
benralizumab injection (Fasenra Pen)	Pulmonary 1-Agents: Pulmonary Miscellaneous	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 α pathway 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
benzoyl peroxide 9.8% foam (Enzoclear)	Keratolytics	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Tier 4/Not Covered
colchicine oral solution (Gloperba)	Anti Gout Agents: Acute	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> NF and non-step-preferred Do not add to EMMI list
elexacaftor/tezacaftor/ivacaftor (Trikafta)	Cystic Fibrosis (CF) Agents	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> UF Do not add to EMMPI list
minocycline 4% topical foam (Amzeeq)	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> omeprazole + amoxicillin + clarithromycin omeprazole + amoxicillin + rifabutin (given separately) 	For the treatment of <i>Helicobacter pylori</i> infection in adults	<ul style="list-style-type: none"> Talicia is fixed-dose combination of 3 drugs (omeprazole, amoxicillin, and rifabutin) to treat <i>H. pylori</i> 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 <i>H. pylori</i> 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 	<ul style="list-style-type: none"> Tier 4/Not Covered
pegfilgrastim-bmez injection (Ziextenzo)	Hematological Agents: White Blood Cell Stimulants	<ul style="list-style-type: none"> pegfilgrastim (Neulasta) pegfilgrastim-jmdb (Fulphila) pegfilgrastim-cbqv (Udenyca) 	To decrease the incidence of infection in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs	<ul style="list-style-type: none"> Ziextenzo is the 4th biosimilar of pegfilgrastim (Neulasta) No new clinical data exists Ziextenzo provides no compelling advantage or disadvantage over existing formulary agents 	<ul style="list-style-type: none"> UF Do not add to EMMPI list
pretomanid	Anti-tubercular agents	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • testosterone 2% gel (Fortesta, generics) • testosterone 1% gel (Testim, generics) • Striant buccal • Xyosted injection 	Primary hypogonadism, hypogonadotropic hypogonadism	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • NF and non-step-preferred • Add to EMMI list
trifarotene 0.005% cream (Aklief)	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
zanubrutinib (Brukinsa)	Oncological agents	<ul style="list-style-type: none"> • ibrutinib (Imbruvica) • acalabrutinib (Calquence) 	adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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	<p>Pain Agents: NSAIDs UF (brand maintenance only)</p> <ul style="list-style-type: none"> • add diclofenac /misoprostol • maintain Anaprox DS, Celebrex, Daypro, Feldene, Mobic, Nalfon, and Naprosyn <p>Pain Agents: NSAIDs Designated NF <i>No reason to exempt from EMMPI requirement</i></p> <ul style="list-style-type: none"> • add meloxicam ODT (Qmiiz ODT) and tolmetin <p>Newly Approved Drugs per 32 CFR 199.21 (g)(5)</p> <p>Designated UF: <i>Similar agents are already on list</i></p> <ul style="list-style-type: none"> ▪ benralizumab (Fasenra Pen) ▪ pegfilgrastim-bmez (Ziextenzo) <p>Designated NF: <i>No reason to exempt from EMMPI requirement:</i></p> <ul style="list-style-type: none"> ▪ baclofen oral solution (Ozobax) ▪ minocycline 4% foam (Amzeeq) ▪ testosterone undecanoate capsule (Jatenzo) ▪ trifarotene 0.005% cream (Aklief) <p><i>Similar agents are already on list:</i></p> <ul style="list-style-type: none"> ▪ diroximel fumarate (Vumerity) 	<p>Pain Agents: NSAIDs Designated NF <i>Drugs for acute or limited duration use - Do not add</i></p> <ul style="list-style-type: none"> • diclofenac potassium powder packets (Cambia), fenoprofen tabs, indomethacin oral susp, ketoprofen, ketorolac nasal (Sprix), meclufenamate, naproxen sodium ER (Naprelan) <p><i>Remove</i></p> <ul style="list-style-type: none"> • Voltaren, Voltaren XR (discontinued brand names) • Duexis and Vivlodex (due to Tier 4 status) <p>Pain Agents: Pain Topical UF (brand maintenance only) <i>Maintain current status and do not add any agents</i></p> <ul style="list-style-type: none"> • Lidoderm 5% patch, Pennsaid 1.5% solution, and Voltaren 1% gel <p>Newly Approved Drugs per 32 CFR 199.21 (g)(5)</p> <p>Designated UF: <i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • elexacaftor/tezacaftor/ivacaftor (Trikafta) • voxelotor (Oxbryta) • zanubrutinib (Brukinsa) <p><i>Drugs in classes not currently on the list</i></p> <ul style="list-style-type: none"> • pretomanid <p>Designated NF: <i>Antipsychotic exemption</i></p> <ul style="list-style-type: none"> • asenapine transdermal system (Secuado) <p><i>Acute use exception</i></p> <ul style="list-style-type: none"> • colchicine oral solution (Gloperba) <p>Pulmonary-1 Agents: Combinations Designated NF <i>Drugs for acute use</i></p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> ▪ 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) 	<p align="center">Tier 4/Not Covered Medications MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ 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) <ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ diclofenac potassium powder packets 50 mg (Cambia) ▪ fenoprofen tablets ▪ indomethacin oral suspension ▪ ketoprofen ▪ ketorolac nasal (Sprix) ▪ meclufenamate ▪ meloxicam ODT (Qmiiz) ▪ naproxen sodium ER (Naprelan, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card ▪ tolmetin 	<p>Pending signing of the minutes / 120 days</p> <p>The effective date is August 26, 2020.</p>	<ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ 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.

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

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: Topical Pain Subclass	UF Class Review Class previously reviewed February 2013	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ diclofenac 2% solution (Pennsaid) ▪ diclofenac 1.3% patch (Flector) ▪ lidocaine 1.8% patch (ZTlido) 	<ul style="list-style-type: none"> ▪ diclofenac 1% gel (added) ▪ lidocaine 5% patch (added) 	<ul style="list-style-type: none"> ▪ diclofenac 1% gel ▪ diclofenac 1.5% solution (Pennsaid) ▪ lidocaine 5% patch 	<ul style="list-style-type: none"> ▪ None 	<p>Pending signing of the minutes / 120 days</p> <p>The effective date is August 26, 2020</p>	<ul style="list-style-type: none"> ▪ 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. <p>Note that diclofenac 1% gel and lidocaine 5% patch were added to the BCF</p>

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	<ul style="list-style-type: none"> • amlodipine/celecoxib (Consensi) 	<ul style="list-style-type: none"> • Dihydropyridine calcium channel blockers: amlodipine, felodipine, nifedipine, isradipine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • diclofenac potassium liquid-filled capsules (Zipsor) • diclofenac submicronized (Zorvolex) • fenoprofen capsules • indomethacin submicronized (Tivorbex) • meloxicam submicronized (Vivlodex) 	<ul style="list-style-type: none"> • celecoxib • diclofenac • ibuprofen • meloxicam • naproxen • Also includes other NSAIDs 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • ibuprofen and famotidine tablets (Duexis) 	<ul style="list-style-type: none"> • H2 blockers: famotidine, ranitidine, cimetidine, nizatidine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents – Combinations	<ul style="list-style-type: none"> • naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> • PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • diclofenac 1.3% patch (Pennsaid) • diclofenac 2% solution (Pennsaid) 	<ul style="list-style-type: none"> • oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) • diclofenac 1.5% solution • diclofenac 1% gel 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; Pain Topical Subclass	<ul style="list-style-type: none"> • lidocaine 1.8% patch (ZTIldo) 	<ul style="list-style-type: none"> • lidocaine 5% patch 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> benzoyl peroxide 9.8% foam (Enzoclear) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Feb 2020	Anti-Infectives: Miscellaneous	<ul style="list-style-type: none"> omeprazole magnesium, amoxicillin and rifabutin (Talicia) 	<ul style="list-style-type: none"> omeprazole PLUS amoxicillin PLUS rifabutin (given separately) omeprazole PLUS clarithromycin PLUS amoxicillin bismuth subsalicylate OTC PLUS metronidazole PLUS tetracycline PLUS PPI 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Feb 2020	Pulmonary-1: Short Acting Beta2 Agonists (SABA)	<ul style="list-style-type: none"> albuterol dry powder inhaler (ProAir Digihaler) 	<ul style="list-style-type: none"> albuterol MDI (ProAir HFA) albuterol DPI (ProAir Respiclick) albuterol MDI (Proventil HFA) [Nonformulary] albuterol MDI (Ventolin HFA) [Nonformulary] levalbuterol MDI (Xopenex HFA) [Nonformulary] 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Nov 2019	PDE-5 inhibitor	<ul style="list-style-type: none"> avanafil tablet (Stendra) brand Viagra tablet brand Cialis tablet vardenafil tablet (Levitra and generics) vardenafil oral disintegrating tablet (ODT) (Staxyn and generics) 	<ul style="list-style-type: none"> sildenafil tablet (generic Viagra only) tadalafil tablet (generic Cialis only) 	<ul style="list-style-type: none"> June 3, 2020
Nov 2019	Rapid Acting Insulins	<ul style="list-style-type: none"> insulin plus niacinamide (Fiasp) 	<ul style="list-style-type: none"> insulin aspart (Novolog) insulin lispro (Humalog or authorized generic lispro) insulin lispro (Admelog) [nonformulary] insulin glulisine (Apidra) [nonformulary] 	<ul style="list-style-type: none"> July 1, 2020
Nov 2019	Pulmonary-2 Agents: COPD	<ul style="list-style-type: none"> formoterol/acclidinium (Duaklir Pressair) 	<ul style="list-style-type: none"> umeclidinium/vilanterol (Anoro Ellipta) tiotropium/olodaterol (Stiolto Respimat) glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary] glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary] 	<ul style="list-style-type: none"> June 3, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2019	Migraine Agents: Triptans	<ul style="list-style-type: none"> sumatriptan nasal spray (Tosymra) 	<ul style="list-style-type: none"> sumatriptan nasal spray (Imitrex, generics) sumatriptan nasal powder (Onzetra Xsail) [nonformulary] zolmitriptan nasal spray (Zomig) 	<ul style="list-style-type: none"> June 3, 2020
Nov 2019	GI2 Agents: CIC and IBS-C	<ul style="list-style-type: none"> tegaserod (Zelnorm) 	<ul style="list-style-type: none"> linaclotide (Linzess) plecanatide (Trulance) lubiprostone (Amitiza) prucalopride (Motegrity) [nonformulary] 	<ul style="list-style-type: none"> June 3, 2020
Aug 2019	ADHD	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> clobetasol propionate 0.025% cream (Impoyz) diflorasone diacetate/emollient 0.05% cream (Apexicon-E) halcinonide 0.1% cream (Halog) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% ointment (Halog) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit) halobetasol propionate 0.05% lotion (Ultravate) halobetasol propionate 0.05% foam (authorized generic for Lexette) <i>(see Feb 2019 for brand Lexette recommendation)</i> halobetasol propionate 0.01% lotion (Bryhali) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020
May 2019	PPIs	<ul style="list-style-type: none"> dexlansoprazole (Dexilant) esomeprazole strontium 	<ul style="list-style-type: none"> esomeprazole omeprazole pantoprazole rabeprazole 	<ul style="list-style-type: none"> Nov 28, 2019 MTF Tier 4 implementation for Dexilant delayed to Jan 31, 2020
Feb 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halobetasol propionate 0.05% foam (Lexette brand) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Aug 28, 2019
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	<ul style="list-style-type: none"> metformin ER gastric retention 24 hours (Glumetza) 	<ul style="list-style-type: none"> metformin IR (Glucophage generic) metformin ER (Glucophage XR generic) 	<ul style="list-style-type: none"> Aug 28, 2019
Feb 2019	Pain Agents – Combinations	<ul style="list-style-type: none"> naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> 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 H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

Minutes and Recommendations of the DoD P&T Committee Meeting February 5-6, 2020

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	<p>Retained GCNs</p> <ul style="list-style-type: none"> ▪ 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 <p>Added GCNs*</p> <ul style="list-style-type: none"> ▪ 46303/45889 psyllium husk (with sugar) ▪ 43199 psyllium husk/aspartame 3 G/5.8 G powder 	<p>Removed GCNs</p> <ul style="list-style-type: none"> ▪ 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	<p>Retained GCNs</p> <ul style="list-style-type: none"> ▪ 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 	<p>Removed GCNs</p> <ul style="list-style-type: none"> ▪ 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* <p>*Vit D2 (ergocalciferol) 50,000 unit cap remains available</p>

***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		

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

May 2020

I. CONVENING

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

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of February 2020 Minutes**—Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the February 2020 DoD P&T Committee meeting on April 27, 2020.
2. **Clarification of Previous Minutes**
 - a) **May 2019 and November 2019 Meetings—Rapid Acting Insulins (RAI): Authorized generic insulin lispro PA criteria:** Prior authorization (PA) criteria for authorized generic insulin lispro requiring a trial of Humalog first were recommended at the May 2019 P&T Committee meeting. The PA was recommended for removal at the November 2019 meeting during the RAI class review, with an implementation date of July 1 2020. Due to significant price reductions in the authorized generic insulin lispro, the PA was removed on April 21, 2020.
 - b) **November 2019 Meeting—Hematological Agents: Platelets: avatrombopag (Doptelet) Quantity Limits (QLs):** Avatrombopag was previously approved for pre-procedure use with a 5-day supply QL at all Points of Service (POS). It was subsequently approved for treating idiopathic thrombocytopenia (ITP) and the QLs were increased for this indication. However, QLs for avatrombopag will be set at a 30-day supply at all POS, since the QLs could not be operationalized by indication.
 - c) **February 2020 Meeting—MHS GENESIS OTC Test List implementation:** Starting with the February 2020 meeting, the implementation for any added GCNs will occur on signing, with the deletions occurring at 120 days. This will help alleviate situations where existing MHS GENESIS sites need to change from one product to another quickly.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 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 (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
 - antihemophilic factor (recombinant) glycoPEGylated-exei (Esperoct) injection – Antihemophilic Factor; new recombinant pegylated formulation of factor VIII
 - avapritinib (Ayvakit) – Oncological agent for gastrointestinal stromal tumors (GIST)
 - cenobamate (Xcopri) – Anticonvulsants-Antimania Agents; for partial-onset seizures
 - diazepam nasal spray (Valtoco) – Anticonvulsants-Antimania Agents; new nasal spray formulation of diazepam for seizures
 - metformin ER suspension (Riomet ER) – Diabetes Non-Insulin Drugs, Biguanides; new extended-release oral suspension formulation of metformin
 - peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia) – Miscellaneous Immunologic Agent for peanut allergy
 - rimegepant orally disintegrating tablet (Nurtec ODT) – Migraine agent for acute treatment of migraine
 - tazemetostat (Tazverik) – Oncological agent for epithelioid sarcoma

- NF:
 - bempedoic acid (Nexletol) – Antilipidemic I (LIP-1) approved as an adjunct to a statin to reduce low density lipoprotein (LDL) cholesterol
 - cetirizine 0.24% ophthalmic solution (Zerviate) – Ophthalmic Allergy Drugs; new ophthalmic formulation of cetirizine
 - lasmiditan (Reyvow) – Migraine Agent for acute treatment of migraine
 - lumateperone (Caplyta) – Atypical Antipsychotic for schizophrenia
 - teriparatide (Bonsity) injection – Osteoporosis Agents: Parathyroid Hormone, a biosimilar of Forteo for osteoporosis
 - ubrogepant (Ubrelvy) – Migraine Agent for acute treatment of migraine

B. COMMITTEE ACTION: MN CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Bonsity, Caplyta, Nexletol, Reyvow, Ubrelvy, and Zerviate. See Appendix B for the full criteria.

C. COMMITTEE ACTION: PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Applying the same manual PA criteria to new and current users of Bonsity that currently applies to Forteo and Tymlos.
- Applying manual PA criteria to new and current users of Reyvow and Zerviate.
- Applying manual PA criteria to new users of Ayvakit, Caplyta, Nexletol, Nurtec ODT, Palforzia, Tazverik, and Ubrelvy.

D. COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service, on August 5th, 2020.

V. UTILIZATION MANAGEMENT

A. Quantity Limits

1. **General QLS:** QLS were reviewed for eight newly approved drugs from drug classes where there are existing QLS, including the anticonvulsants-antimania agents, immunological agents miscellaneous, migraine agents, oncological agents, and osteoporosis agents.

COMMITTEE ACTION: QLS—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLS for Ayvakit, Bonsity, Nurtec ODT,

Palforzia, Reyvow, Tazverik, Ubrelyvy, and Valtoco. See Appendix D for the QLs.

B. QLs Implementation Periods

1. **COMMITTEE ACTION: QLs IMPLEMENTATION PERIOD**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for the eight drugs listed above and in Appendix D become effective the first Wednesday 2 weeks after signing of the minutes in all POS.

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

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

See Appendix F for the mail order status of medications designated UF or NF during the May 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 May 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 (16 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI List for the reasons outlined in the table. See Appendix F.

VII. ITEM FOR INFORMATION

Veteran's Administration Continuity of Care List

The P&T Committee was briefed on the updated DoD/VA Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715. Additions, deletions, and clarifications to the list were based on FY19 Active Duty prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The updated list will be posted on www.health.mil when finalized.

VIII. ADJOURNMENT

The meeting adjourned at 1400 hours on May 6, 2020. The next meeting will be in August 2020.

Appendix A—Attendance: May 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 May 2020 DoD P&T Committee Meeting

Appendix G—Tier 4/Not Covered Drugs and Therapeutic Alternatives

Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

The Director, DHA:

concurs with all recommendations.

concurs with the recommendations, with the following modifications:

- 1.
- 2.
- 3.

concurs with the recommendations, except for the following:



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

24 July 20
Date

Appendix A—Attendance: May 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
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
CDR Christopher Janik for CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Eugene Moore, PharmD, BCPS, for CDR Eric Parsons, MSC	COR Tricare Pharmacy Program

Appendix A—Attendance (continued)

Guests	
LCDR William Agbo, MSC	DLA Troop Support
Ms. Kimberlymae Wood	DHA Contracting Officer
Ms. Yvette Dluhos	DHA Contracting
Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Dr. Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Dr. Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Dr. Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
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

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> teriparatide injection (Bonsity) <p>Osteoporosis Agents: PTH Analogs</p>	<ul style="list-style-type: none"> No alternative formulary agent: Patient cannot use Forteo <p>Formulary alternatives: teriparatide (Forteo)</p>
<ul style="list-style-type: none"> lumateperone (Caplyta) <p>Antipsychotics: Atypical</p>	<ul style="list-style-type: none"> Use of formulary agents is contraindicated Patient has experienced significant adverse effects from formulary agents Formulary agents resulted in therapeutic failure Patient previously responded to the non-formulary agent and changing to a formulary agent would incur unacceptable risk <p>Formulary alternatives: aripiprazole (tablets, ODT, and solution), quetiapine IR and XR tablets, risperidone (tablets and ODT), olanzapine (tablets & ODT), olanzapine/fluoxetine, paliperidone, ziprasidone, and lurasidone (Latuda)</p>
<ul style="list-style-type: none"> bempedoic acid (Nexletol) <p>Antilipidemics-1</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse events from the preferred formulary statins. The preferred formulary statins have results in therapeutic failure <p>Formulary alternatives: atorvastatin, simvastatin, pravastatin, rosuvastatin, fluvastatin, lovastatin, evolocumab, alirocumab, ezetimibe</p>
<ul style="list-style-type: none"> cetirizine 0.24% ophthalmic solution (Zerviate) <p>Ophthalmic: Allergy</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from formulary agents <p>Formulary alternatives: olopatadine 0.1%, azelastine 0.05%, epinastine 0.05%, olopatadine 0.7% (Pazeo)</p>
<ul style="list-style-type: none"> lasmiditan (Reyvow) <p>Migraine Agents</p>	<ul style="list-style-type: none"> Use of formulary alternatives is contraindicated <p>Formulary alternatives: rizatriptan (Maxalt, Maxalt MLT, generics), sumatriptan (Imitrex, generics), zolmitriptan (Zomig, Zomig ZMT, generics), eletriptan (Relpax), naratriptan (Amerge), rimegepant (Nurtec ODT)</p>
<ul style="list-style-type: none"> ubrogepant (Ubrovelvy) <p>Migraine Agents</p>	<ul style="list-style-type: none"> Use of formulary alternatives is contraindicated <p>Formulary alternatives: rizatriptan (Maxalt, Maxalt MLT, generics), sumatriptan (Imitrex, generics), zolmitriptan (Zomig, Zomig ZMT, generics), eletriptan (Relpax), naratriptan (Amerge), rimegepant (Nurtec ODT)</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
<ul style="list-style-type: none"> • teriparatide injection (Bonsity) <p>Osteoporosis Agents: PTH Analogs</p>	<p>Manual PA is required for all new and current users of Bonsity.</p> <p><u>Manual PA Criteria:</u> Bonsity is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that Forteo is the Department of Defense's preferred osteoporosis parathyroid hormone (PTH) analog; the patient must try and fail Forteo prior to use of Bonsity • The patient is ≥ 18 years old • The drug is prescribed for treatment of osteoporosis and not for prevention of osteoporosis. • The patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ Patient is a postmenopausal female with osteoporosis; OR ○ Patient is a male with primary or hypogonadal osteoporosis; OR ○ Patient is a male or female with osteoporosis associated with sustained systemic glucocorticoid therapy (e.g., more than 6 months use of greater than 7.5 mg/day of prednisone or equivalent) AND • The patient has one of the following: <ul style="list-style-type: none"> ○ A high risk for fracture due to history of osteoporotic fracture, OR ○ Has multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) • Patient has a documented bone mineral density (BMD) with T-score of -2.5 or worse • Patient is able to take calcium and vitamin D supplements and will continue throughout therapy • Patient has tried and experienced an inadequate response to, has had therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) • Patient does not have an increased risk for osteosarcoma • Cumulative treatment with Bonsity, Tymlos, and/or Forteo must not exceed 24 months during the patient's lifetime <p>Non-FDA-approved uses are not approved. PA expires in 24 months.</p>
<ul style="list-style-type: none"> • lumateperone (Caplyta) <p>Antipsychotics: Atypical</p>	<p>Manual PA is required for all new users of Caplyta.</p> <p><u>Manual PA Criteria:</u> Caplyta is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Age ≥ 18 years • Patient has a diagnosis of schizophrenia • Patient has tried and failed at least TWO formulary atypical antipsychotics (e.g. risperidone, aripiprazole, lurasidone, quetiapine) • Drug is prescribed by or in consultation with a psychiatrist <p>Non-FDA approved uses are NOT approved including sleep disorders, depression, and other neuropsychiatric and neurological disorders. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • bempedoic acid (Nexletol) <p>Antilipidemics-1</p>	<p>Manual PA is required for all new users of Nexletol.</p> <p><u>Manual PA Criteria:</u> Note that the automation for the LIP-I step therapy will not apply for Nexletol.</p> <p>Nexletol is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The drug is prescribed by a cardiologist, endocrinologist or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization) AND • The patient has tried a Department of Defense preferred statin with similar LDL lowering (moderate or low intensity; including atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin) at maximal doses and has not reached LDL goal OR • The patient has tried a Department of Defense preferred statin with similar LDL lowering (moderate or low intensity; including atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin) at maximal doses and has been unable to tolerate it due to adverse effects AND • The patient will continue on statin therapy, consistent with the package labeling. <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> • cetirizine 0.24% ophthalmic solution (Zerviate) <p>Ophthalmic: Allergy</p>	<p>Manual PA is required for all new and current users of Zerviate.</p> <p><u>Manual PA Criteria:</u> Zerviate is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient has ocular symptoms of allergic conjunctivitis AND <ul style="list-style-type: none"> ○ The patient has tried and failed TWO of the following formulary alternatives in the last 90 days, olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine OR • The patient has experienced intolerable adverse effects to at least TWO of the following formulary alternatives, olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine <p>Non-FDA-approved uses are not approved. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • Peanut (<i>Arachis hypogaea</i>) Allergen Powder-dnfp (Palforzia) <p>Immunological agents miscellaneous</p>	<p>Manual PA criteria apply to all new users of Palforzia.</p> <p><u>Manual PA Criteria:</u> Palforzia is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Palforzia is prescribed by an allergist or immunologist , or in consultation with an allergist or immunologist, and the provider has satisfied the requirements of the REMS program • The patient is between the ages of 4 to 17 years • The patient has a documented history of peanut allergy • The patient has a history of diagnostic evidence of peanut allergy, including either serum IgE to peanut of ≥ 0.35 kUA/L (serum testing) and/or positive skin prick test (SPT) for peanut ≥ 3 mm greater than negative control • The patient does not have uncontrolled asthma; eosinophilic esophagitis or other eosinophilic gastrointestinal diseases • The patient has not had severe or life-threatening anaphylaxis within the previous 60 days prior to starting therapy • Provider acknowledges that the patient will be counseled on the following: <ul style="list-style-type: none"> ○ Avoiding peanut ingestion ○ The need for access to an epinephrine injector ○ Palforzia is not intended to treat emergencies <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> • lasmiditan (Reyvow) <p>Migraine Agents</p>	<p>Changes are in strikethrough below</p> <p>Manual PA is required for all new and current users of Reyvow.</p> <p><u>Manual PA Criteria:</u> Reyvow is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Age ≥ 18 • Reyvow is prescribed by or in consultation with a neurologist • Reyvow is not approved for patients who have history of hemorrhagic stroke • Reyvow is not approved for patients with a history of epilepsy or any other condition with increased risk of seizure • The patient has a contraindication to, intolerance to, or has failed a 2-month trial of at least TWO of the following medications <ul style="list-style-type: none"> ○ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • The patient has had a contraindication to, intolerance to, or has failed a 2-month trial of Nurtec ODT • Concurrent use with monoclonal CGRP antagonists are not allowed • If Reyvow is used with a triptan, provider acknowledges Reyvow and the triptan should not be used within 24 hours of each other • Reyvow will be used with caution in patients with low heart rate and/or those using beta blockers, such as propranolol <p>Non-FDA-approved uses are not approved. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • rimegepant orally disintegrating tablet (Nurtec ODT) <p>Migraine Agents</p>	<p>Changes are in bold and strikethrough below</p> <p>Manual PA is required for all new users of Nurtec ODT.</p> <p><u>Manual PA Criteria:</u> Nurtec ODT is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Age ≥ 18 • Nurtec ODT is prescribed by or in consultation with a neurologist • Patient has had a diagnosis of migraine for at least 1 year with an onset before 50 years of age • Patient has fewer than 15 migraine headaches per month • Nurtec ODT is not approved for patients who have clinically significant or unstable cardiovascular disease • The patient has a contraindication to, intolerance to, or has failed a 2-month trial of at least TWO of the following medications <ul style="list-style-type: none"> – sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • Concurrent use with monoclonal CGRP antagonists are not allowed • Concurrent use with any other small molecule CGRP targeted medication (i.e., including Ubrelvy or another “gepant”) is not allowed <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> • ubrogepant (Ubrelvy) <p>Migraine Agents</p>	<p>Changes are in bold and strikethrough below</p> <p>Manual PA is required for all new users of Ubrelvy.</p> <p><u>Manual PA Criteria:</u> Ubrelvy is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Age ≥ 18 • Ubrelvy is prescribed by or in consultation with a neurologist • Patient has had a diagnosis of migraine for at least 1 year with an onset before 50 years of age • Patient has fewer than 15 migraine headaches per month • Ubrelvy is not approved for patients who have clinically significant or unstable cardiovascular disease • The patient has a contraindication to, intolerance to, or has failed a 2-month trial of at least TWO of the following medications <ul style="list-style-type: none"> ○ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • Patient has had a contraindication to, intolerance to, or has failed a 2-month trial of Nurtec ODT • Concurrent use with monoclonal CGRP antagonists are not allowed • Concurrent use with any other small molecule CGRP targeted medication (i.e., including Nurtec ODT or another “gepant”) is not allowed <p>Non-FDA-approved uses are not approved. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • avapritinib (Ayvakit) <p style="text-align: center;">Oncological Agents</p>	<p>Manual PA is required for all new users of Ayvakit.</p> <p><u>Manual PA Criteria:</u> Ayvakit is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient must be ≥ 18 years • Ayvakit is prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation with or without the D842V mutation • Provider agrees to monitor for intracranial bleeding and other central nervous system (CNS) adverse effects • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy • 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: _____. <p>Non-FDA-approved uses are not approved, except as noted above. PA does not expire.</p>
<ul style="list-style-type: none"> • tazemetostat (Tazverik) <p style="text-align: center;">Oncological Agents</p>	<p>Manual PA is required for all new users of Tazverik.</p> <p><u>Manual PA Criteria:</u> Tazverik is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient must be ≥ 16 years • Tazverik is prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed metastatic or locally advanced epithelioid sarcoma not eligible for complete resection • Patient will be monitored for secondary malignancies (especially, T-cell lymphoblastic lymphoma, myelodysplastic syndrome, and acute myeloid leukemia) • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 months after cessation of therapy for males and 6 months for females • 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: _____. <p>Non-FDA-approved uses are not approved except as noted above. PA does not expire.</p>

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> avapritinib (Ayvakit) <p>Oncological Agents</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 30 day supply at all POS
<ul style="list-style-type: none"> tazemetostat (Tazverik) <p>Oncological Agents</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 30 day supply at all POS
<ul style="list-style-type: none"> diazepam nasal spray (Valtoco) <p>Anticonvulsants-Antimania Agents</p>	<ul style="list-style-type: none"> Retail: 5 cartons/30 days MTF/Mail: 15 cartons/90 days <p>Note that Valtoco is packaged in cartons of 2 nasal sprays per carton</p>
<ul style="list-style-type: none"> lasmiditan (Reyvow) <p>Migraine Agents</p>	<ul style="list-style-type: none"> Retail: 8 tabs/30 days MTF/Mail: 24 tabs/90 days
<ul style="list-style-type: none"> rimegepant (Nurtec ODT) <p>Migraine Agents</p>	<ul style="list-style-type: none"> Retail: 8 ODTs/30 days MTF/Mail: 24 ODTs/90 days
<ul style="list-style-type: none"> ubrogepant (Ubrelyv) <p>Migraine Agents</p>	<ul style="list-style-type: none"> Retail: 10 tabs/30 days MTF/Mail: 30 tabs/90 days <p>Note that Ubrelyv is currently available only as cartons containing 10 tablets per carton</p>
<ul style="list-style-type: none"> peanut (<i>Arachis hypogaea</i>) allergen powder-dnfp (Palforzia) <p>Immunological Agents Miscellaneous</p>	<ul style="list-style-type: none"> Retail/MTF/Mail: 30 day supply at all POS
<ul style="list-style-type: none"> teriparatide injection (Bonsity) <p>Osteoporosis Agents: PTH Analogs</p>	<ul style="list-style-type: none"> Retail: 1 pen/28 days and 28 day supply MTF/Mail: 3 pens/84 days and 84 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
antihemophilic factor (recombinant) glycoPEGylated-exei (Esperoct)	Antihemophilic Factors	<ul style="list-style-type: none"> • Recombinate • Hemofil M • Koate DVI • Kogenate FS • ReFacto • Advate • Afstyla • Obizur • Kovaltry • Novoeight • Nuwiq • Eloctate • Adynovate • Jivi 	Hemophilia A	<ul style="list-style-type: none"> • Esperoct is the 15th antihemophilic factor indicated for the treatment of Hemophilia A • Esperoct is the 3rd pegylated formulation and is dosed every four days in adults and twice weekly in pediatrics • Esperoct was evaluated in five multinational open-label trials in patients with severe Hemophilia A and demonstrated efficacy in preventing and treating bleeding episodes consistent with other Factor VIII products • Esperoct’s glycopegylated formulation and slightly longer half-life did not translate into a clinically relevant differences in dosing or effect compared to the other antihemophilic factors 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
avapritinib (Ayvakit)	Oncological Agents	<ul style="list-style-type: none"> • imatinib (Gleevac) • sunitinib (Sutent) • regorafenib (Stivarga) 	GI stromal tumors (GIST)	<ul style="list-style-type: none"> • Ayvakit is the 4th option for metastatic unresectable GIST but the only option when patients carry the D842V mutation • Indicated only for GIST with PDGFRA exon 18 mutations (not for all GIST) • Highly effective as judged by depth and duration of response • Poorly tolerated with high rates of dose-reduction and discontinuation 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
bempedoic acid (Nexletol)	Antilipidemics-1	<ul style="list-style-type: none"> • simvastatin • atorvastatin • rosuvastatin • ezetimibe • PSC-K9 inhibitors 	Treatment of established ASCVD or HeFH, as an adjunct to diet and maximally tolerated statin therapy in patients who require additional LDL lowering	<ul style="list-style-type: none"> • Antilipidemic with a new mechanism of action: adenosine triphosphate-citrate lyase (ACL) inhibitor • Reduces LDL an additional 18%-20% when added onto statins • Minimal impact on TG or HDL • Also available in a fixed dose combination with ezetimibe (Nexlizet); not launched yet • Long-term adverse event profile unknown • Potential place in therapy as an add-on option if patient has had an inadequate response on statin plus ezetimibe and an oral med is preferred over injectable PCSK-9 • Limited place in therapy due to lack of CV outcomes studies 	<ul style="list-style-type: none"> • NF and non-step-preferred • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
cenobamate (Xcopri)	Anticonvulsants-Antimania agents	<ul style="list-style-type: none"> • brivaracetam (Briviact) • carbamazepine ER • eslicarbazepine • perampanel (Fycompa) • plus other formulary anticonvulsants 	Partial-onset seizures	<ul style="list-style-type: none"> • Xcopri is the 18th antiepileptic drug approved for used in partial-onset seizures in adults • Efficacy is based on limited data, it is only indicated in adults, it is a controlled substance, and there are concerns with Xcopri use due to risk of drug rash with eosinophilia and systemic symptoms (DRESS) syndrome • No head-to-head studies with other anticonvulsants are available and professional treatment guidelines have not been updated to reflect its place in therapy • Most common ADRs included CNS effects (somnolence, dizziness, and fatigue) which occur at an increased incidence with increasing dose • Xcopri provides an additional option for adults with partial onset seizures, but provides no compelling advantage over existing anticonvulsants 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
cetirizine 0.24% ophthalmic solution (Zerviate)	Ophthalmic: Allergy	<ul style="list-style-type: none"> • olopatadine 0.1% (Patanol) • azelastine 0.05% (Optivar) • epinastine 0.05% (Elestat) • olopatadine 0.7% (Pazeo) 	Ocular itching associated with allergic conjunctivitis in patients 2 years of age and older	<ul style="list-style-type: none"> • Zerviate is the first ophthalmic formulation of the antihistamine cetirizine • Zerviate was evaluated in three studies and demonstrated a statistically significant reduction in ocular itching and redness compared to vehicle at 15 minutes and 8 hours after treatment. <ul style="list-style-type: none"> ▪ Results at 15 minutes met the minimally clinically important difference (MCID), but not at 8 hours ▪ Redness scores did not meet MCID • Adverse events were relatively mild • There are no head-to-head trials with Zerviate and other ocular antihistamines • Indirect comparisons with other ocular antihistamines show that Zerviate is similar in efficacy in relieving ocular itching • Despite the advantage of a new mechanisms of action, Zerviate offers little to no clinical benefit relative to existing formulary agents and requires twice daily dosing 	<ul style="list-style-type: none"> • NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
diazepam nasal spray (Valtoco)	Anticonvulsants-Antimania agents	<ul style="list-style-type: none"> • diazepam rectal (Diastat) • midazolam nasal spray (Nayzilam) 	For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older	<ul style="list-style-type: none"> • Valtoco is a nasal spray formulation of diazepam for acute intermittent seizures or seizure clusters • Valtoco was FDA approved through the 505(b)(2) pathway showing bioequivalence to diazepam (Diastat) for rectal administration • Both midazolam (Nayzilam) and diazepam (Valtoco) are nasal sprays for the same indication. Some differences include: <ul style="list-style-type: none"> ▪ Valtoco has a longer duration of action and requires fewer repeat doses ▪ Valtoco is approved in patients as young 6 years of age while Nayzilam is approved for 12 and older ▪ Valtoco has a range of available doses based on weight • Valtoco provides a clinically meaningful addition to the pharmacy benefit in the treatment of acute intermittent seizures or seizure clusters 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
lasmiditan (Reyvow)	Migraine Agents	<ul style="list-style-type: none"> • sumatriptan (Imitrex) • rizatriptan (Maxalt) • zolmitriptan (Zomig) • eletriptan (Relpax) • rimegepant (Nurtec ODT) • ubrogepant (Ubrelvy) 	For the acute treatment of migraine with or without aura in adults Limitation: not indicated for the preventive treatment of migraine	<ul style="list-style-type: none"> • Reyvow is the first selective 5-HT_{1f} agonist for acute migraine • Clinical trials show that Reyvow is superior to placebo for the endpoint of pain-free at 2 hours and relief of the most bothersome symptom at 2 hours • A 2020 ICER analysis evaluating acute migraine treatments concluded that Reyvow is incrementally better than or superior to placebo when patients cannot take triptans. If triptans are an option then Reyvow is comparable or inferior to triptans. • Unlike triptans, Reyvow is not contraindicated in patients with a history of cardiovascular disease. <i>In-vitro</i> data shows that Reyvow does not have vasoconstrictive effects, however, the patient population in the clinical trials excluded patients with clinically significant cardiovascular or cerebrovascular disease • Limitations to Reyvow include its C-V controlled substance status, and its warning regarding driving impairment. Patients should not drive for 8 hours after dosing. Studies showed that these patients are unaware of their impairment. • Reyvow provides an additional option for treating acute migraine for those unable to take triptans, but its place in therapy is limited due to the driving restriction and C-V status. 	<ul style="list-style-type: none"> • NF and non-step-preferred • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lumateperone (Caplyta)	Antipsychotics: Atypical	<ul style="list-style-type: none"> risperidone (tablets and ODT) quetiapine IR and ER aripiprazole lurasidone (Latuda) brexipiprazole (Rexulti) 	Schizophrenia in adults	<ul style="list-style-type: none"> Lumateperone is the 13th FDA-approved oral atypical antipsychotic and is approved for once daily use in adults It was evaluated in 3 placebo-controlled trials with 2 studies using risperidone as an active-control Conflicting results were seen in that only 2 of 3 the studies showed statistically significant results. Only the 42 mg dose showed statistical significance, and not 28 mg and 84 mg. No study met the minimal clinically important difference (MCID) of at least a 20% reduction in positive and negative syndrome scale (PANSS) score from baseline Caplyta is currently under investigation for other indications including bipolar depression, behavioral disorders associated with dementia in Alzheimer's, and other depressive disorders Caplyta provides another treatment option in schizophrenia but has no compelling advantages over existing formulary atypical antipsychotics 	<ul style="list-style-type: none"> NF Do not add to EMMPI list
metformin ER suspension (Riomet ER)	Diabetes non-insulin: Biguanides	<ul style="list-style-type: none"> metformin 500 mg/5 mL liquid (Riomet, generics) metformin IR 500, 850, 1000 mg tablets (generics) metformin ER 500, 750 mg tablets (generics) 	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years with T2DM	<ul style="list-style-type: none"> New formulation of metformin liquid in an extended-release suspension Glucophage IR and XR were used as the reference listed drugs Performed bioequivalence study with Glucophage XR No new clinical data to review Generic formulations of the IR solution are available Aside from reduced dosing of the IR solution from twice daily to once daily, Riomet ER offers little to no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> UF Do not add to EMMPI list
peanut (<i>Arachis hypogaea</i>) Allergen Powder-dnfp (Palforzia)	Immunological agents miscellaneous	<ul style="list-style-type: none"> No formulary alternatives 	Peanut allergy	<ul style="list-style-type: none"> 1st FDA-approved oral agent for mitigation of allergic reactions that may occur with accidental exposure to peanuts in patients with a history of peanut allergy Dosing consists of 11 titration levels followed by maintenance dosing. Initial: days 1-5 gradually increasing doses (0.5-6 mg); escalation: up-titration every 2 weeks and maintenance of 300 mg daily indefinitely Requires patient monitoring for 1 hour after each dose for all 11 titration levels; administered in a healthcare setting In the PALISADE trial, Palforzia was superior to placebo, with 67.2% vs 4.0% of patient's age 4-17 years able to tolerate 600 mg peanut protein during exit evaluation. Limitations include lack of statistical significance in pts 18-55 years old Requires continuous treatment, EpiPen availability, and continued avoidance of peanuts Is currently unknown how maintenance treatment with other peanut products or with exposure to actual peanuts would compare to Palforzia 	<ul style="list-style-type: none"> UF Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
<p>rimegepant orally disintegrating tablet (Nurtec ODT)</p> <p>ubrogepant (Ubrelvy)</p>	Migraine agents	<ul style="list-style-type: none"> • sumatriptan (Imitrex) • rizatriptan (Maxalt) • zolmitriptan (Zomig) • eletriptan (Relpax) • lasmiditan (Reyvow) • ubrogepant (Ubrelvy) 	<p>For the acute treatment of migraine with or without aura in adults</p> <p>Limitation: not indicated for the preventive treatment of migraine</p>	<ul style="list-style-type: none"> • Ubrelvy is the first oral calcitonin gene-related peptide (CGRP) antagonist for acute migraine • Nurtec ODT is the 2nd oral CGRP antagonist, and the first in the class available as an alternate dosage form (ODT formulation) • Clinical trials show that Nurtec ODT and Ubrelvy are superior to placebo for the endpoint of pain-free at 2 hours and relief of the most bothersome symptom at 2 hours • A 2020 ICER analysis evaluating acute migraine treatments concluded that Nurtec ODT and Ubrelvy are incrementally better than or superior to placebo when patients cannot take triptans. If triptans are an option then Nurtec ODT and Ubrelvy are comparable or inferior to triptans • Unlike triptans, Nurtec ODT and Ubrelvy are not contraindicated in patients with a history of cardiovascular disease. <i>In-vitro</i> data shows that Nurtec ODT and Ubrelvy do not exhibit vasoconstrictive effects, however, they were not studied in patients with clinically significant cardiovascular or cerebrovascular disease • Nurtec ODT has mild side effects to include nausea, while Ubrelvy can cause mild nausea and somnolence. Both drugs have strong warnings regarding drug interactions with CYP3A4 inducers and inhibitors • Nurtec ODT is the only alternate dosage form within the newer migraine agents but the triptans are available in ODT and nasal spray formulations • Nurtec ODT is not approved for re-dosing, while Ubrelvy can have repeat dosing • Nurtec ODT and Ubrelvy provide additional option for treating acute migraine for those unable to take triptans, but head-to-head trials with other therapies are lacking 	<p><u>Nurtec ODT</u></p> <ul style="list-style-type: none"> • UF • Do not add to EMMPI list <p><u>Ubrelvy</u></p> <ul style="list-style-type: none"> • NF and non-step-preferred • Do not add to EMMPI list
tazemetostat (Tazverik)	Oncological Agents	<ul style="list-style-type: none"> • None 	Epithelioid sarcoma	<ul style="list-style-type: none"> • Tazverik is the only non-chemotherapeutic option for epithelioid sarcoma • Accelerated approval was based on a comparable response rate to chemotherapeutic options but for those in whom it is effective, significantly longer duration of response • Limited confidence in study results due to low power 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
teriparatide injection (Bonsity)	Osteoporosis Agents: PTH Analogs	<ul style="list-style-type: none"> • teriparatide (Forteo) • abaloparatide (Tymlos) 	<ul style="list-style-type: none"> • Postmenopausal women with osteoporosis at high risk for fracture • Men with primary or hypogonadal osteoporosis at high risk for fracture to increase bone mass • Men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture 	<ul style="list-style-type: none"> • Bonsity is a new formulation of teriparatide approved as a biosimilar via the 505(b)2 pathway to Forteo • It is a recombinant human parathyroid hormone analog (PTH 1-34) • Efficacy was established using Forteo's trials and Bonsity was evaluated in a comparative study, NCT03002428 • No new clinical data to review • Most common ADRs included arthralgia, pain, and nausea • Bonsity is available in an autoinjector pen, requiring storage in the refrigerator • Duration of treatment is not recommended for more than 2 years, similar to Forteo and Tymlos • Provides no compelling clinical advantage over existing formulary agents 	<ul style="list-style-type: none"> • NF and non-step-preferred • Add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 during the May 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)
May 2020	<p>Newly Approved Drugs per 32 CFR 199.21 (g)(5)</p> <p>Designated UF: <i>Similar agents are already on list</i></p> <ul style="list-style-type: none"> ▪ None <p>Designated NF: <i>Similar agents are already on list:</i></p> <ul style="list-style-type: none"> ▪ bempedoic acid (Nexletol) ▪ teriparatide injection (Bonsity) 	<p>Newly Approved Drugs per 32 CFR 199.21 (g)(5)</p> <p>Designated UF: <i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • cenobamate (Xcopri) • rimegepant (Nurtec ODT) <p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • avapritinib (Ayvakit) • metformin ER suspension (Riomet ER) • peanut (<i>Arachis hypogaea</i>) allergen powder-dnfp (Palforzia) • tazemetostat (Tazverik) <p><i>Drugs in classes not currently on the list:</i></p> <ul style="list-style-type: none"> • antihemophilic factor (recombinant) glycoPEGylated-exei (Esperoct) • diazepam nasal spray (Valtoco) <p>Designated NF: <i>Antipsychotic exemption:</i></p> <ul style="list-style-type: none"> • lumateperone (Caplyta) <p><i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • lasmiditan (Reyvow) • ubrogepant (Ubrelyvy) <p><i>Drugs for acute use or limited duration use:</i></p> <ul style="list-style-type: none"> • cetirizine 0.24% ophthalmic solution (Zerviate)

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • amlodipine/celecoxib (Consensi) 	<ul style="list-style-type: none"> • Dihydropyridine calcium channel blockers: amlodipine, felodipine, nifedipine, isradipine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • diclofenac potassium liquid-filled capsules (Zipsor) • diclofenac submicronized (Zorvolex) • fenoprofen capsules • indomethacin submicronized (Tivorbex) • meloxicam submicronized (Vivlodex) 	<ul style="list-style-type: none"> • celecoxib • diclofenac • ibuprofen • meloxicam • naproxen • Also includes other NSAIDs 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • ibuprofen and famotidine tablets (Duexis) 	<ul style="list-style-type: none"> • H2 blockers: famotidine, ranitidine, cimetidine, nizatidine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020
Feb 2020	Pain Agents – Combinations	<ul style="list-style-type: none"> • naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> • PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 18669037258 • 75262416 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • diclofenac 1.3% patch (Pennsaid) • diclofenac 2% solution (Pennsaid) 	<ul style="list-style-type: none"> • oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) • diclofenac 1.5% solution • diclofenac 1% gel 	<ul style="list-style-type: none"> • 120 days after signing • August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2020	Pain Agents Class; Pain Topical Subclass	<ul style="list-style-type: none"> lidocaine 1.8% patch (ZTlido) 	<ul style="list-style-type: none"> lidocaine 5% patch 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Feb 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> benzoyl peroxide 9.8% foam (Enzoclear) 	<ul style="list-style-type: none"> clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) clindamycin/benzoyl peroxide 1% - 5% gel (Benzacilin, generics) clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit) 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Feb 2020	Anti-Infectives: Miscellaneous	<ul style="list-style-type: none"> omeprazole magnesium, amoxicillin and rifabutin (Talicea) 	<ul style="list-style-type: none"> omeprazole PLUS amoxicillin PLUS rifabutin (given separately) omeprazole PLUS clarithromycin PLUS amoxicillin bismuth subsalicylate OTC PLUS metronidazole PLUS tetracycline PLUS PPI 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Feb 2020	Pulmonary-1: Short Acting Beta2 Agonists (SABA)	<ul style="list-style-type: none"> albuterol dry powder inhaler (ProAir Digihaler) 	<ul style="list-style-type: none"> albuterol MDI (ProAir HFA) albuterol DPI (ProAir Respiclick) albuterol MDI (Proventil HFA) [Nonformulary] albuterol MDI (Ventolin HFA) [Nonformulary] levalbuterol MDI (Xopenex HFA) [Nonformulary] 	<ul style="list-style-type: none"> 120 days after signing August 26, 2020
Nov 2019	PDE-5 inhibitor	<ul style="list-style-type: none"> avanafil tablet (Stendra) brand Viagra tablet brand Cialis tablet ildenafil tablet (Levitra and generics) ildenafil oral disintegrating tablet (ODT) (Staxyn and generics) 	<ul style="list-style-type: none"> sildenafil tablet (generic Viagra only) tadalafil tablet (generic Cialis only) 	<ul style="list-style-type: none"> June 3, 2020
Nov 2019	Rapid Acting Insulins	<ul style="list-style-type: none"> insulin plus niacinamide (Fiasp) 	<ul style="list-style-type: none"> insulin aspart (Novolog) insulin lispro (Humalog or authorized generic lispro) insulin lispro (Admelog) [nonformulary] insulin glulisine (Apidra) [nonformulary] 	<ul style="list-style-type: none"> July 1, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2019	Pulmonary-2 Agents: COPD	<ul style="list-style-type: none"> • formoterol/aclidinium (Duaklir Pressair) 	<ul style="list-style-type: none"> • umecclidinium/vilanterol (Anoro Ellipta) • tiotropium/olodaterol (Stiolto Respimat) • glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary] • glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary] 	<ul style="list-style-type: none"> • June 3, 2020
Nov 2019	Migraine Agents: Triptans	<ul style="list-style-type: none"> • sumatriptan nasal spray (Tosymra) 	<ul style="list-style-type: none"> • sumatriptan nasal spray (Imitrex, generics) • sumatriptan nasal powder (Onzetra Xsail) [nonformulary] • zolmitriptan nasal spray (Zomig) 	<ul style="list-style-type: none"> • June 3, 2020
Nov 2019	GI2 Agents: CIC and IBS-C	<ul style="list-style-type: none"> • tegaserod (Zelnorm) 	<ul style="list-style-type: none"> • linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Amitiza) • prucalopride (Motegrity) [nonformulary] 	<p>June 3, 2020</p>
Aug 2019	ADHD	<ul style="list-style-type: none"> • methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • clobetasol propionate 0.025% cream (Impoyz) • diflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog) 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% ointment (Halog) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit) halobetasol propionate 0.05% lotion (Ultravate) halobetasol propionate 0.05% foam (authorized generic for Lexette) <i>(see Feb 2019 for brand Lexette recommendation)</i> halobetasol propionate 0.01% lotion (Bryhali) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020
May 2019	PPIs	<ul style="list-style-type: none"> dexlansoprazole (Dexilant) esomeprazole strontium 	<ul style="list-style-type: none"> esomeprazole omeprazole pantoprazole rabeprazole 	<ul style="list-style-type: none"> Nov 28, 2019 MTF Tier 4 implementation for Dexilant delayed to Jan 31, 2020
Feb 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halobetasol propionate 0.05% foam (Lexette brand) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Aug 28, 2019
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	<ul style="list-style-type: none"> metformin ER gastric retention 24 hours (Glumetza) 	<ul style="list-style-type: none"> metformin IR (Glucophage generic) metformin ER (Glucophage XR generic) 	<ul style="list-style-type: none"> Aug 28, 2019

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2019	Pain Agents – Combinations	<ul style="list-style-type: none"> naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> 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 H—Table of Abbreviations

Term	Definition	Term	Definition
ADR	Adverse reaction	MCID	Minimally Clinically Important Difference
AE	Adverse event	MIDAS	Migraine Disability Assessment
AHRQ	Agency for Healthcare Research and Quality	MHS	Military Health System
ASCVD	Atherosclerotic cardiovascular disease	MN	Medical Necessity
BCF	Basic Core Formulary	MTF	Military Treatment Facility
BIA	Budget impact analysis	NCCN	National Comprehensive Cancer Network
CFR	Code of Federal Regulations	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	ODT	Orally dissolving tablet
DHA	Defense Health Agency	OIT	Oral Immune Therapy
DoD	Department of Defense	OTC	Over the counter
DR	Delayed release	P&T	Pharmacy and Therapeutics
DRESS	drug rash with eosinophilia and systemic symptoms	PA	Prior authorization
ECF	Extended Core Formulary	PANSS	Positive and Negative Syndrome Scale
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	PDGFRA	Platelet-derived growth factor receptor alpha
ER	Extended release	POD	Pharmacy Operations Division
FDA	U.S. Food and Drug Administration	POS	Point of service
FMB	Formulary Management Branch	QL	Quantity limits
FY	Fiscal year	Rx	Medical Prescription
GCN	Generic code number	RAI	Rapid Acting Insulin drug class
GI	Gastrointestinal	SPT	Skin prick test
HCL	Hydrochloride	TIB	Targeted immunomodulatory biologic
HeFH	Heterozygous familial hypercholesterolemia	UF	Uniform Formulary
HFA	Hydroxyfluoroalkane	XR	Extended release
ICER	Institute for Clinical and Economic Review		
IR	Immediate release		
LDL	Low Density Lipoprotein		

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

August 2020

I. CONVENING

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

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

- 1. Approval of May 2020 Minutes**—Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the May 2020 DoD P&T Committee meeting on July 24, 2020.
- 2. Clarification of Previous Minutes**
 - a) February 2020 Meeting—Re-evaluation of nonformulary (NF) generics: Antidepressant-1s (AD-1s) and Non-Opioid Pain Syndrome Drugs: pregabalin controlled release (Lyrica CR):** Generic pregabalin (Lyrica) was returned to UF, status, the step-therapy and manual Prior Authorization (PA) that had previously required a trial of other AD-1 drugs including gabapentin was removed, and the medical necessity (MN) criteria were removed. However, Lyrica CR remains NF, with step-therapy and manual PA required. Slight modifications were made to the Lyrica CR PA and MN forms, to list generic pregabalin as a formulary alternative.
 - b) November 2019 Meeting—OTC Test List: OTC Artificial Tear Products:** Some OTC ophthalmic Artificial Tear products originally added to the list are no longer available in sufficient quantities. Clinically similar replacement products that have consistent availability that currently are not on the list were added in addition to the original products (Refresh PM, Refresh Lacri-lube, Systane Overnight Lubricating Eye). Implementation occurred in early June 2020.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at <https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits->

program-reforms. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018. MN criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

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

IV. UF DRUG CLASS REVIEWS

A. Sleep Disorders: Wakefulness Promoting Agents Subclass

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

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

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

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

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

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

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

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

- UF
 - armodafinil
 - modafinil
 - sodium oxybate (Xyrem)
- NF
 - solriamfetol (Sunosi)
 - pitolisant (Wakix)

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

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

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

4. **COMMITTEE ACTION: MN RECOMMENDATION**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current MN criteria for solriamfetol and pitolisant. See Appendix B for the full criteria.
5. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent), maintaining Sunosi on the EMMPI list, and excluding Xyrem and Wakix (limited distribution requirements).
6. **COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent): an effective date of the first Wednesday one week after signing of the P&T minutes at all points of service (POS); Based on the P&T Committee’s recommendation, the effective date is November 4, 2020.

B. White Blood Cell Stimulants — Filgrastims and Pegfilgrastims

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

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

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

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

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

Filgrastims

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

Pegfilgrastims

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

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

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

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

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

1. **COMMITTEE ACTION: UF and STEP THERAPY**

RECOMMENDATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

FILGRASTIMS

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

PEG FILGRASTIMS

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

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

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

3. **COMMITTEE ACTION: MANUAL PA CRITERIA**— The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the non-step-preferred WBC stimulants, requiring the step-preferred products first, unless the patient has had an inadequate response or could not tolerate the preferred WBC stimulants. For new users of Neupogen and Zarxio, a trial of Granix and Nivestym is required. New users of Neulasta, Neulasta OnPro, or Ziextenzo are required to try Udenyca and Fulphila first. Patients requiring a pegfilgrastim who cannot self-inject will be able to receive Neulasta OnPro. See Appendix C for the full criteria.
4. **COMMITTEE ACTION: QLS**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the current QLS for the pegfilgrastims (Neulasta, Neulasta OnPro, Fulphila, Udenyca, and Ziextenzo), as there is a low risk of inappropriate quantities being prescribed. The filgrastims do not currently require QLS. See Appendix D for the full criteria.
5. **EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS**—The filgrastims and pegfilgrastims are used for limited treatment durations. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing Neupogen, Granix syringe, Neulasta, Neulasta OnPro, and Udenyca from the program. Granix vials, Zarxio, Nivestym, Fulphila, and Ziextenzo are not currently on the EMMPI program. In summary, neither the filgrastims nor pegfilgrastims are included on the program.
6. **COMMITTEE ACTION: TIER 1 COST SHARE**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) lowering the current Tier 2 cost-share for the filgrastim Granix (both syringe and vial) and the pegfilgrastim Udenyca (both syringe and vial) to the generic Tier 1 cost-share.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states “in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes.” Lowering the cost-share for both Granix and Udenyca will provide a greater incentive for beneficiaries to use the most cost-effective WBC stimulant for the filgrastims and pegfilgrastims, in the purchased care points of service.

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

C. Psoriasis Agents

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

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

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

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

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

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

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

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

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

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

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

- tazarotene 0.05% gel (Tazorac)
- Tier 4/Not Covered:
 - calcipotriene 0.005%/betamethasone 0.064% suspension (Taclonex) (*moves from UF to Tier 4 status*)

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

2. **COMMITTEE ACTION: BASIC CORE FORMULARY (BCF)**

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

3. **COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION**

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

4. **COMMITTEE ACTION: MEDICAL NECESSITY (MN)**

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

5. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI)**

PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1

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

6. **COMMITTEE ACTION: UF/TIER 4, PA, MN, AND EMMPI**

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

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent), and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2020 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

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

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

- nimodipine oral syringe (Nymalize) – new oral syringe formulation of nimodipine
 - octreotide acetate injection (Bynfezia Pen) – new formulation of octreotide in a pre-filled pen
 - osilodrostat (Isturisa) – miscellaneous endocrine agent for Cushing’s disease
 - ozanimod (Zeposia) – Multiple Sclerosis agent
 - pemigatinib (Pemazyre) – oncological agent for cholangiocarcinoma
 - ripretinib (Qinlock) – oncological agent for gastrointestinal stromal tumors (GIST)
 - selpercatinib (Retevmo) – oncological agent for NSCLC and thyroid cancer
 - selumetinib (Koselugo) – oncological agent for Neurofibromatosis type 1
 - tucatinib (Tukysa) – oncological agent for breast cancer
- NF:
 - bempedoic acid/ezetimibe (Nexlizet) – antilipidemic-1 fixed dose combination for atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH)
 - diclofenac epolamine 1.3% patch (Licart) – NSAID patch for acute pain
 - lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi) – miscellaneous contraceptive vaginal gel for on-demand contraception
 - leuprolide acetate injection (Fensolvi) – leuprolide formulation for central precocious puberty
 - levonorgestrel/ethinyl estradiol transdermal system (Twirla) – Miscellaneous contraceptive
 - minocycline 1.5% topical foam (Zilxi) – topical formulation of minocycline for rosacea
- Tier 4/Not Covered:
 - halcinonide 0.1% topical solution (Halog) – high potency topical corticosteroid
 - Halog topical solution was recommended for Tier 4 status as it has no clinical benefit relative to other high potency topical corticosteroids, and the needs of TRICARE beneficiaries are met by alternative agents.

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

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

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

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

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

D. COMMITTEE ACTION: UF, TIER 4/NOT COVERED, MN, AND PA

IMPLEMENTATION PERIOD—The P&T Committee recommended group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- **New Drugs Recommended for UF or NF Status, MN and PA criteria:** An effective date of the first Wednesday upon two weeks after signing of the minutes in all POS, on November 11, 2020.
- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date of the first Wednesday after a 120-day implementation period at all POS, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation on February 24, 2021.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

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

- 1) **Narcotic Analgesics and Combinations—tramadol 100 mg IR tablet**—Cost-effective formulations of tramadol IR 50 mg tablets have been widely available from several manufacturers. The branded Ultram 100 mg tablets have been discontinued. A single manufacturer is now marketing a 100 mg IR tablet that is not cost-effective. The Committee recommended manual PA to encourage use of tramadol 50 mg IR tablets and to discourage the use of the 100 mg strength.
- 2) **Vitamins: Prenatal—prenatal multivitamin (Trinaz)**—Trinaz is a prenatal dietary supplement manufactured by a single company and requires a prescription prior to dispensing. The primary ingredients of Trinaz are similar to that found in Azesco and Zalvit, which require manual PA. Several prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria. Manual PA criteria were recommended for all new and current users of Trinaz, to require a trial of cost-effective formulary prenatal vitamins first.

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

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

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

c) Gastrointestinal-2 Agents—teduglutide (Gattex)

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

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

2. Updated PA Criteria

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

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

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

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

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

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

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

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

- 1) **Acne Agents: Topical Acne and Rosacea—dapson 5% and 7.5% gel (Aczone)**—Aczone 7.5% gel is only available in a proprietary formulation; however, generic dapsone 5% gel was first marketed in October 2017. Aczone 7.5% recently received approval for treating acne in patients as young as 9 years of age. Generic dapsone 5% has not been studied in patients younger than age 12. After reviewing clinical trial data, the Committee agreed to remove the age restrictions for both dapsone formulations. The committee also agreed that dapsone was unlikely to be used in children younger than 9, as acne is not commonly seen in this age group. Providers can therefore use the more cost-effective generic dapsone 5% rather than Aczone 7.5% for children. The PA criteria still requires a diagnosis of acne vulgaris and a trial of at least 3 step preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.
- 2) **Respiratory Interleukins—dupilumab injection (Dupixent)**—Manual PA criteria for Dupixent were updated to reflect a lowered age indication for pediatric patients with moderate to severe atopic dermatitis 6 years of age or older; the previous age was 12 years. Note that the current age requirements for the other indications are not changed, including patients older than 18 years for chronic sinusitis and for patients as young as 12 years for asthma.
- 3) **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)—nintedanib (Ofev)**—The IPF drugs were reviewed for formulary status in May 2017, with step therapy requiring a trial of pirfenidone (Esbriet) prior to Ofev. Ofev recently gained a new indication for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. Esbriet lacks this indication, therefore the step therapy requirements for a trial of Esbriet first will not apply here. The renewal criteria from the May 2017 class review was also clarified to exclude concomitant use of Esbriet and Ofev.
- 4) **Oncologic Agents: ovarian cancer [niraparib (Zejula), olaparib (Lynparza), and rucaparib (Rubraca)]; melanoma [encorafenib**

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

- **niraparib (Zejula)**—Allow use for the new FDA-approved indication as a first-line treatment for ovarian cancer
- **olaparib (Lynparza) and rucaparib (Rubraca)**—Updated for the new FDA-approved indications for treating prostate cancer, and added a urologist as an allowable prescriber, in addition to a hematologist/oncologist. The Lynparza criteria was also updated to allow use for a new pancreatic cancer indication.
- **encorafenib (Braftovi)**—Allow use for the new FDA-approved indication for treating colorectal cancer
- **selinexor (Xpovio)**—Allow use for the new FDA-approved indication for treating diffuse large B-cell lymphoma

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

- **adalimumab (Humira)**—Allow off-label use for moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids, based on supporting clinical data. Additionally, patients with PG or fistulizing Crohn’s Disease (CD) can use Humira without a trial of non-biologic systemic therapy (e.g., methotrexate, azathioprine, sulfasalazine, mesalamine, or corticosteroids) first.
- **ustekinumab (Stelara)**—Updated the PA to include the new indication for pediatric patients down to the age of 6 years for plaque psoriasis; the previous indication was down to the age of 12 years. A trial of Humira is not required in pediatric patients 6 to 17 years old with a diagnosis of plaque psoriasis, since Humira is not indicated for children for this condition.
- **ixekizumab (Taltz)**—Updated the criteria to allow use in adults with non-radiographic axial spondyloarthritis (nr-axSpA); a trial of both Humira and Cosentyx are required first for this indication. The criteria were also updated for the new indication of plaque psoriasis in pediatric patients 6 to 17 years old. Note that a trial of Humira and

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

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

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

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

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

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

B. Quantity Limits

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

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

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

C. PA and QLs Implementation Periods

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

- (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for tramadol 100 mg IR tablets and Trinaz will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.
- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Absorica, Absorica LD, and Solodyn in new and current users will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to the beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.
- (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for Striverdi Respimat and Gattex in new users will become effective the first Wednesday 60-days after the signing of the minutes.
- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Aczone, Addyi, Dupixent, Ofev, and the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs, Humira, Stelara, Taltz, and Cosentyx in new users will become effective the first Wednesday 60-days after the signing of the minutes.
- (16 for, 0 opposed, 0 abstained, 2 absent) QLs listed in Appendix D will become effective the first Wednesday 2 weeks after the signing of the minutes in all POS.

VII. LINE EXTENSIONS

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

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION—

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA) criteria, QLs, and EMMI List status, and specialty status for

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

- **ADHD Agents: Stimulants**—designating the **authorized generic methylphenidate ER capsules** as UF, similar to the brand Aptensio XR from the same manufacturer.
- **Antiretrovirals: Combinations**—designating **dolutegravir 5 mg tablets for suspension for children (Tivicay PD)** as UF, similar to Tivicay 10 mg, 25 mg and 50 mg oral tablets.
- **Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**—**empagliflozin/linagliptin/metformin extended release (Trijardy XR)** is a new triple fixed-dose combination product containing an SGLT-2 inhibitor, DPP-4 inhibitor and metformin. Empagliflozin-containing products (Jardiance, Glyxambi, Synjardy XR) are currently the step-preferred SGLT-2 inhibitor. The P&T Committee recommended designating Trijardy XR as UF, with the same step-therapy and PA criteria requirements as Jardiance, Glyxambi, and Synjardy XR.
- **Hepatitis Agents: Direct Acting Agents**—designating **ledipasvir/sofosbuvir 33.75 mg/150 mg oral pellet pack (Harvoni) and sofosbuvir 150 mg oral pellet pack (Sovaldi)** as UF, with the same manual PA requirements, QLs, and specialty reporting requirements similar to Harvoni 45 mg/200 mg pellet pack and Sovaldi 200 mg pellet pack, respectively.
- **Immunological Agents Miscellaneous**—designating **immune globulin SQ syringe (Hizentra)** as UF, similar to the Hizentra vials.
- **Migraine Agents: CGRP Preventative**—designating **fremanezumab autoinjector (Ajovy)** as UF, with the same manual PA requirements, and QLs as the Ajovy prefilled syringe.
- **Oncological Agents: Breast Cancer**—designating **palbociclib (Ibrance) 75 mg, 100 mg, and 125 mg tablets** as UF, with the same manual PA requirements, and same QLs as Ibrance capsules.
- **Pain Agents: NSAIDS**—designating the **authorized generic ketorolac nasal spray** as NF, with the same MN criteria, and QLs as brand ketorolac nasal spray (Sprix) from the same manufacturer.
- **Pulmonary-1 Agents: Inhaled Corticosteroids**—designating **mometasone furoate oral inhaler (Asmanex HFA 50 mcg/actuation)** as UF and non-step preferred, with the same manual PA requirements, and QLs as Asmanex HFA 100 mcg/actuation and 200 mcg/actuation.

- **Targeted Immunomodulatory Biologics**—designating **tofacitinib 22 mg tablets (Xeljanz XR)** as UF, with the same step therapy and PA criteria, EMMI status, and QLS as Xeljanz XR 11 mg.
- **Urinary Agents Miscellaneous**—**cysteamine bitartrate (Procysbi) is now available in 75 mg and 300 mg delayed release (DR) granule packets.** Previously, it was only available as oral DR sprinkle capsules in strengths of 25 mg and 75 mg. The P&T Committee recommended designating the new DR granule packets as UF. Procysbi DR sprinkle capsules have not been previously reviewed by the Committee but were FDA-approved prior to the Innovator Rule in August 2015 and are UF by default.

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

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

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

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

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

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

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

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

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

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

- **OTC Aspirin:** The most common aspirin formulations dispensed at MTFs are 81 and 325 mg, with enteric-coated options preferred for chronic use in order to alleviate gastrointestinal adverse events. There is minimal to no outpatient dispensing of other available formulations, including 300 and 600 mg suppositories.
- **Artificial Tears (Overnight Treatment):** The ophthalmology leaders requested a review of hypromellose 0.3% ophthalmic gel (Gentel Tears Severe, Systane Gel) due to its use in neonates for retinopathy of prematurity; the product is also used for laser procedures and for neonatal examinations. The MHS GENESIS OTC List also includes a number of formulations of mineral oil/petrolatum ointments (due to intermittent shortage issues).
- **Pyrantel pamoate for hookworm/pinworm:** The P&T Committee reviewed pyrantel pamoate oral suspension (e.g., Reese's Pinworm, Pin-X) due to an MTF request as it is a cost effective treatment for pinworm/hookworm, particularly in small children, compared to the two legend alternatives (albendazole and mebendazole).

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

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

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

XI. ADJOURNMENT

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

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

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

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

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

Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

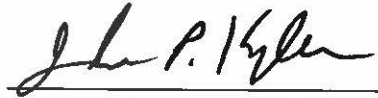
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

Appendix I—MHS GENESIS OTC Test List

Appendix J—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

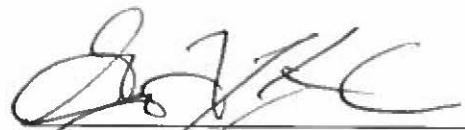
The Director, DHA:

concurs with all recommendations.

concurs with the recommendations, with the following modifications:

1.
- 2.
- 3.

concurs with the recommendations, except for the following:



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

2 NOV 2

Date

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

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

Appendix A—Attendance (continued)

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

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> • pitolisant (Wakix) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<ul style="list-style-type: none"> • Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure <p>Formulary Alternatives: armodafinil, modafinil, methylphenidate, amphetamine</p>
<ul style="list-style-type: none"> • solriamfetol (Sunosi) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<ul style="list-style-type: none"> • Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure <p>Formulary Alternatives: armodafinil, modafinil, methylphenidate, amphetamine</p>
<ul style="list-style-type: none"> • calcipotriene 0.005% foam (Sorilux) • calcitriol 3 mcg/g ointment <p>Psoriasis Drugs: Vitamin D Analogs</p>	<ul style="list-style-type: none"> • Patient has experienced adverse effects from one formulary Vitamin D analog agent <p>Formulary alternatives: calcipotriene 0.005% ointment, cream, solution</p>
<ul style="list-style-type: none"> • tazarotene 0.05% cream (Tazorac) • tazarotene 0.05% gel (Tazorac) • tazarotene 0.1% gel (Tazorac) <p>Psoriasis Drugs: Retinoids</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from tazarotene 0.1% cream • No alternative formulary agent: patient has scalp psoriasis and requires tazarotene gel. <p>Formulary alternative: tazarotene 0.1% cream</p>
<ul style="list-style-type: none"> • calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) • calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex, generic) <p>Psoriasis Drugs: Vitamin D Analog Combinations</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from at least one formulary Vitamin D analog AND at least one formulary high-potency topical corticosteroid agent <p>Formulary alternatives: Vitamin D analogs: calcipotriene 0.005% cream, ointment, and solution High-potency topical corticosteroid: clobetasol propionate 0.05% ointment, cream, solution and gel; fluocinonide 0.05% ointment, cream, and solution</p>
<ul style="list-style-type: none"> • bempedoic acid/ezetimibe (Nexlizet) • bempedoic acid (<i>Nexletol</i>) (updated from May 2020) <p>Antilipidemics-1</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from at least 2 formulary alternatives, including at least one statin and ezetimibe • At least 2 formulary alternatives, including at least one statin and ezetimibe have resulted in therapeutic failure <p>Formulary alternatives: atorvastatin, simvastatin 10, 20, 40 mg, pravastatin rosuvastatin, alirocumab, evolocumab, ezetimibe</p>
<ul style="list-style-type: none"> • diclofenac epolamine 1.3% patch (Licart) <p>Pain Agents: Pain Topical</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from at least 2 oral NSAIDs that are not expected to occur with Licart • Formulary alternatives: all oral NSAIDs,

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi) <p>Contraceptive Agents: Miscellaneous</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from a nonoxynol-9 spermicide plus one other formulary contraceptive agent (e.g. norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, and medroxyprogesterone injection) <p>Formulary and non-formulary alternatives: nonoxynol-9 spermicide, norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, medroxyprogesterone injection, or any other formulary contraceptive agent</p>
<ul style="list-style-type: none"> leuprolide acetate injection (Fensolvi) <p>Luteinizing Hormone-Releasing Hormone Agonists-Antagonists</p>	<ul style="list-style-type: none"> No alternative formulary agent: patient is not able to use short-acting leuprolide formulations OR is not able to use leuprolide via the intramuscular route or implant <p>Formulary alternatives: leuprolide acetate injection (Lupron Depot-Ped), histrelin (Supprelin LA), triptorelin (Triptodur)</p>
<ul style="list-style-type: none"> levonorgestrel/ethinyl estradiol (Twirla) <p>Contraceptive Agents: Miscellaneous</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from the Xulane patch that are not likely to occur with Twirla <p>Formulary alternatives: norelgestromin/ethinyl estradiol transdermal system (Xulane) and etonogestrel/ethinyl estradiol vaginal ring (NuvaRing), other combined hormonal contraceptives</p>
<ul style="list-style-type: none"> minocycline 1.5% topical foam (Zilxi) <p>Acne Agents: Topical Acne and Rosacea</p>	<ul style="list-style-type: none"> Use of metronidazole and azelaic acid are contraindicated Patient has experienced significant adverse effects from metronidazole and azelaic acid Metronidazole and azelaic acid have resulted in therapeutic failure <p>Formulary alternatives: metronidazole (1% gel; 0.75% lotion, and 0.75% cream) and azelaic acid 15%</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
<ul style="list-style-type: none"> • pitolisant (Wakix) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<p>Updates from the August 2020 meeting are in bold.</p> <p>Manual PA is required for all new users of Wakix.</p> <p><u>Manual PA Criteria:</u> Wakix is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that PA is not required for modafinil or armodafinil. • Patient is 18 years of age or older • Wakix is not approved for use in children, adolescents, or pregnant patients. • Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy and an Epworth Sleepiness Scale (ESS) score ≥ 14 • Narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing • Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Patient is not concurrently taking any of the following: <ul style="list-style-type: none"> • Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • Patient must have tried and failed and had an inadequate response to modafinil • Patient must have tried and failed and had an inadequate response to armodafinil • Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient does not have a history of severe hepatic impairment • Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea <p>Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, cataplexy, obstructive sleep apnea, major depression, ADHD, or shift work disorder).</p> <p>PA expires in 1 year.</p> <p><u>Renewal PA criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • solriamfetol (Sunosi) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<p><u>Updates from the August 2020 meeting are in bold.</u></p> <p>Manual PA is required for all new users of Sunosi.</p> <p><u>Manual PA Criteria:</u> Sunosi is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that PA is not required for modafinil or armodafinil. • Patient is 18 years of age or older • Sunosi is not approved for use in children, adolescents, or pregnant patients. • Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy or a documented diagnosis of obstructive sleep apnea (OSA) and an Epworth Sleepiness Scale (ESS) score \geq 10 • <u>For narcolepsy:</u> narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing • <u>For narcolepsy:</u> Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea • <u>For OSA:</u> Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least 1 month prior to initiation, and the patient demonstrated adherence to therapy during this time • <u>For OSA:</u> Patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of treatment • Sunosi is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • The patient is not concurrently taking any of the following: <ul style="list-style-type: none"> • Central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic • Monoamine oxidase inhibitor (MAOI) within the past 14 days • Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • The patient must have tried and failed and had an inadequate response to modafinil • The patient must have tried and failed and had an inadequate response to armodafinil • The patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient and provider agree to monitor blood pressure and heart rate at baseline and periodically throughout treatment. If the patient has hypertension, the blood pressure is controlled. • Patient does not have unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems <p>Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, major depression, ADHD, or shift work disorder).</p> <p>Prior authorization expires in 1 year.</p> <p><u>Renewal PA criteria:</u> No renewal allowed. A new prescription will require a new PA to be submitted.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • sodium oxybate (Xyrem) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<p>Note that there were no changes to the PA criteria from Xyrem made at the November 2019 meeting. PA included for completeness.</p> <p><u>Manual PA Criteria:</u> Coverage of Xyrem is approved if the following criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic • Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. <ul style="list-style-type: none"> • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND <ul style="list-style-type: none"> • The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) <p>OR</p> <ul style="list-style-type: none"> • Patient is child 7 years of age or older AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. <ul style="list-style-type: none"> • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND <ul style="list-style-type: none"> • The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders) <p>Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.</p> <p>PA expires after 1 year.</p> <p><u>Renewal PA criteria:</u> Renewal not allowed. A new prescription will require a new PA to be submitted.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • filgrastim (Neupogen) • filgrastim-sndz (Zarxio) <p>WBC Stimulants Class: Filgrastim subclass</p>	<p>Manual PA criteria apply to all new users of filgrastim (Neupogen) and filgrastim-sndz (Zarxio)</p> <p>Note that Granix is available at the Tier 1 copay at the Mail Order and Retail Network pharmacies.</p> <p><u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met</p> <ul style="list-style-type: none"> • Provider acknowledges that tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) are the TRICARE preferred filgrastims and are available without a PA. • Drug is prescribed by or in consultation with a hematologist or oncologist • Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio) • Patient has experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio) <p>PA does not expire</p>
<ul style="list-style-type: none"> • pegfilgrastim (Neulasta) • pegfilgrastim (Neulasta Onpro) • pegfilgrastim-bmez (Ziextenzo) <p>WBC Stimulants Class: Pegfilgrastim subclass</p>	<p>Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo)</p> <p>Note that Udenyca is available at the Tier 1 copay at the Mail Order and Retail Network pharmacies.</p> <p><u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that pegfilgrastim-cbqv (Udenyca) and pegfilgrastim-jmdb (Fulphila) are the TRICARE preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist or oncologist • For Neulasta OnPro: Patient requires use of an on-body injector because the patient and/or caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration <p>OR</p> <ul style="list-style-type: none"> • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-cbqv (Udenyca) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) <p>PA does not expire</p>

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

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • tazarotene 0.05% cream (Tazorac) • tazarotene 0.05% gel (Tazorac) • tazarotene 0.1% gel (Tazorac) <p>Psoriasis Agents</p>	<p>Manual PA is required for all new and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel.</p> <p><u>Manual PA Criteria:</u> Coverage approved if ALL criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that tazarotene 0.1% cream is a cost effective alternative that does not require a PA. • The patient has a diagnosis of acne vulgaris or plaque psoriasis • For acne vulgaris: <ul style="list-style-type: none"> • Patient is 12 years of age or older • The patient must have tried and failed, have a contraindication to, or have had an adverse reaction to tazarotene 0.1% cream. • For scalp psoriasis <ul style="list-style-type: none"> • Patient is 18 years of age or older • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% solution, shampoo; fluocinonide 0.05% solution) • For plaque psoriasis in other body areas: <ul style="list-style-type: none"> • Patient is 18 years of age or older • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution) AND • The patient must have tried and failed or have had an adverse reaction to tazarotene 0.1% cream. <p>Non-FDA-approved uses are NOT approved. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
<ul style="list-style-type: none"> • bempedoic acid/ezetimibe (Nexlizet) • bempedoic acid (Nexletol) <i>(updated from May 2020)</i> <p>Antilipidemics-1</p>	<p>Manual PA is required for all new users of Nexletol and Nexlizet.</p> <p><u>Manual PA Criteria:</u> Nexletol or Nexlizet is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization) • Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following: <ul style="list-style-type: none"> • History of clinical (ASCVD), including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA), peripheral artery disease (PAD) OR • Heterozygous Familial Hypercholesterolemia (HeFH) • For Nexletol: <ul style="list-style-type: none"> • Patient is taking concurrent ezetimibe and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR • Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR • For Nexlizet: <ul style="list-style-type: none"> • Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started, and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) OR • Patient is statin intolerant based on one of the following: <ul style="list-style-type: none"> • Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, cramp) with at least 2 statins OR • History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR • History of statin-associated rhabdomyolysis OR • Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) <p>Non-FDA-approved uses other than use without concurrent statin not allowed. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • capmatinib (Tabrecta) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Tabrecta</p> <p><u>Manual PA Criteria:</u> Tabrecta is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test. • Patient is 18 years of age or older • Must be prescribed by or in consultation with a hematologist/oncologist • Patient will be monitored for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity • Provider is aware and has counseled patient that capmatinib can cause photosensitivity and has counseled patients to avoid direct UV exposure • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment. • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy. • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. <p>Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • diclofenac epolamine 1.3% patch (Licart) <p>Pain Agents: Pain Topical</p>	<p>Manual PA is required for all new users of Licart.</p> <p><u>Manual PA Criteria:</u> Licart is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has acute pain due to minor strains, sprains, and/or contusions • Patient is 18 years of age or older • Patient cannot tolerate an oral NSAID due to renal insufficiency, history of gastrointestinal bleed, or other adverse events OR • Patient has tried and failed TWO oral NSAIDs <p>Non-FDA-approved uses are not approved. PA expires after 6 months.</p> <p><u>Renewal PA criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • elagolix/estradiol/norethindrone (Oriahnn) <p>Luteinizing Hormone-Releasing Hormone Agonists-Antagonists</p>	<p>Manual PA is required for all new users of Oriahnn.</p> <p><u>Manual PA Criteria:</u> Oriahnn is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD) • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant confirmed by (-) HCG • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 years • Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs; or if the patient has a sudden unexplained partial or complete loss of vision, proptosis (abnormal protrusion of the eye), diplopia (double vision), papilledema (optic disc swelling), or retinal vascular lesions • Patient does not have uncontrolled hypertension • Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly • Patient does not have osteoporosis • Provider agrees to assess baseline and periodic bone mineral density • Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes • Patient does not have a history of breast cancer or other hormonally-sensitive malignancies • Patient does not have known liver impairment or disease • Provider agrees to counsel patients on the signs and symptoms of liver injury • Patient does not have undiagnosed abnormal uterine bleeding • Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors <p>Non-FDA-approved uses are not approved including pain associated with endometriosis. Prior authorization expires after 24 months (lifetime expiration).</p>
<ul style="list-style-type: none"> • fenfluramine oral solution (Fintepla) <p>Anticonvulsants-Antimania Agents</p>	<p>Manual PA is required for all new users of Fintepla.</p> <p><u>Manual PA Criteria:</u> Fintepla is approved if all criteria are met.</p> <ul style="list-style-type: none"> • Must be prescribed by a neurologist • Patient has a diagnosis of Dravet Syndrome • Must be used as adjunct therapy with other anticonvulsant medications • Prescriber must abide by and the patient has been informed of the REMS program including safety risks and requirements of regular echocardiogram (ECHO) monitoring for valvular heart disease and pulmonary hypertension <p>Non-FDA-approved uses are not approved including for weight loss. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi) <p>Contraceptive Agents: Miscellaneous</p>	<p>Manual PA applies to new users of Phexxi.</p> <p>Manual PA Criteria: Phexxi is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that numerous contraceptives are available without a PA and are more effective than Phexxi (e.g. norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, and medroxyprogesterone injection); providers are encouraged to consider changing the prescription to a formulary contraceptive. • Phexxi is being used for contraceptive purposes • Patient has tried a nonoxynol-9 spermicide and has experienced significant adverse effects <p>Non-FDA approved uses are NOT approved PA does not expire</p>
<ul style="list-style-type: none"> • lemborexant (Dayvigo) <p>Sleep Disorders: Insomnia</p>	<p>Manual PA criteria apply to all new and current users of Dayvigo.</p> <p>Manual PA Criteria: Dayvigo is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release • Patient has tried and failed or had clinically significant adverse effects to eszopiclone • Patient has no current or previous history of narcolepsy • Patient has no current or previous history of drug abuse <p>Non FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> levonorgestrel/ethinyl estradiol transdermal system (Twirla) <p>Contraceptive Agents: Miscellaneous</p>	<p>Manual PA is required for all new users of Twirla.</p> <p><u>Manual PA Criteria:</u> Twirla is approved if all criteria are met:</p> <ul style="list-style-type: none"> The provider acknowledges that norelgestromin/ethinyl estradiol transdermal system (Xulane) and numerous other contraceptives are available for TRICARE patients that do not require a PA. Providers are encouraged to consider changing the prescription to Xulane or another formulary contraceptive. The patient has had an adverse reaction to Xulane that is not expected to occur with Twirla. OR The patient has tried Xulane and could not tolerate it. The patient does not have a contraindication to an estrogen-containing contraceptive (e.g., history of estrogen-dependent neoplasia, breast cancer, deep venous thrombosis (DVT)/ pulmonary embolism (PE), etc.) The patient's body mass index (BMI) is less than 30 kg/m²; note that Twirla is contraindicated in patients with a BMI ≥ 30 kg/m² Provider acknowledges that patients with a BMI between 25 to 30 kg/m² have decreased contraceptive effectiveness per the FDA label. <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> minocycline 1.5% topical foam (Zilxi) <p>Acne Agents: Topical Acne and Rosacea</p>	<p>All new and current users of Zilxi are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream), which is the current step therapy requirements for Soolantra and Mirvaso.</p> <p><u>Automated PA Criteria:</u></p> <ul style="list-style-type: none"> The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. <p><u>Manual PA Criteria:</u> If automated PA criteria is not met, Zilxi is approved if all criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older and has the following diagnosis: <ul style="list-style-type: none"> For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea For Soolantra and Zilxi: Patient has inflammatory lesions (papulopustular) of rosacea AND Patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) AND Patient has tried and failed topical azelaic acid <p>Non-FDA-approved uses are not approved. Prior authorization expires in 365 days. <u>Renewal criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • osilodrostat (Isturisa) <p>Endocrine Agents Miscellaneous</p>	<p>Manual PA is required for all new users of Isturisa.</p> <p><u>Manual PA Criteria:</u> Isturisa is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Documented diagnosis of Cushing's disease • Patient has persistent or recurrent Cushing's disease despite pituitary surgery <p>OR</p> <ul style="list-style-type: none"> • Patient in whom pituitary surgery is not indicated • Drug is prescribed by an Endocrinologist, Oncologist, or Neurosurgeon • Provider agrees to correct hypokalemia or hypomagnesemia prior to starting Isturisa • Provider agrees to obtain baseline electrocardiogram (ECG) prior to starting Isturisa and use with caution in patients with risk factors for QTc prolongation • Patient will be monitored closely for hypocortisolism and potentially life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary • Patient will be monitored for hypokalemia, worsening of hypertension, edema, and hirsutism <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • ozanimod (Zeposia) <p>Multiple Sclerosis Agents</p>	<p>Manual PA is required for all new users of Zeposia.</p> <p><u>Manual PA Criteria:</u> Zeposia is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by a neurologist • Patient has a documented diagnosis of relapsing forms of multiple sclerosis (MS) • Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroxime fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunamide [Aubagio]) • Patient has not previously failed a treatment course of fingolimod (Gilenya) and • Patient has not previously failed a treatment course of siponimod (Mayzent) • Provider acknowledges that all recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes complete blood count (CBC), liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), and macular edema screening as indicated. • Zeposia will not be used in patients with significant cardiac history, including: <ul style="list-style-type: none"> • Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization • Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • pemigatinib (Pemazyre) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Pemazyre.</p> <p><u>Manual PA Criteria:</u> Pemazyre is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient has a diagnosis of pathologically confirmed unresectable or advanced/metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient will be monitored for ophthalmologic disorders including pre-treatment screening for retinal disorders. • Patient will be monitored for hyperphosphatemia. • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment. • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy. • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. <p>Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • ripretinib (Qinlock) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Qinlock.</p> <p><u>Manual PA Criteria:</u> Qinlock is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed advanced gastrointestinal stromal tumor (GIST) • Patient has experienced disease progression on or had documented intolerance to imatinib (Gleevec) • Patient has experienced disease progression on or had documented intolerance to sunitinib (Sutent) • Patient has experienced disease progression on or had documented intolerance to regorafenib (Stivarga) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. <p>Non-FDA-approved uses are not approved, except as noted above. PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • selpercatinib (Retevmo) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Retevmo.</p> <p><u>Manual PA Criteria:</u> Retevmo is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following indications: <ul style="list-style-type: none"> • Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) • Patients 12 years and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy • Patients 12 years and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) • Patient will be monitored for hepatotoxicity and QT prolongation • Patient does not have uncontrolled hypertension • Provider is aware and has counseled patient that selpercatinib can cause life-threatening hemorrhage and allergic reactions • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. <p>Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • selumetinib (Koselugo) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Koselugo.</p> <p><u>Manual PA Criteria:</u> Koselugo is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by or in consultation with a hematologist/oncologist • Patient is diagnosed with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas • Patient will be monitored for cardiomyopathy including a left ventricular functional assessment prior to initiation and at regular intervals during treatment • Patient will be monitored for ocular toxicity including retinal vein occlusion and retinal detachment via ophthalmic exams prior to initiation and at regular intervals during treatment • Patient will be monitored for gastrointestinal toxicity and will receive co-administration of an anti-diarrheal if patient develops loose stools • Patient will be monitored for severe skin rashes • Patient will be monitored for rhabdomyolysis • Provider is aware that Koselugo contains Vitamin E, which can increase bleeding risk if co-administered with a Vitamin K antagonist (e.g., warfarin) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation <p>Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • tucatinib (Tukysa) <p>Oncological Agents</p>	<p>Manual PA is required for all new users of Tukysa.</p> <p><u>Manual PA Criteria:</u> Tukysa is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting. • Patient is 18 years of age or older • Medication is prescribed by or consultation with a hematologist or oncologist • Tucatinib will be used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda) • Provider agrees to monitor for hepatotoxicity • Patient has been counseled on risk of diarrhea • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. <p>Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
New PAs	
<ul style="list-style-type: none"> tramadol 100 mg IR tab <p>Narcotic Analgesic and Combinations</p>	<p>Manual PA criteria applies to all new and current users of tramadol 100mg IR.</p> <p><u>Manual PA Criteria:</u> tramadol 100 mg IR is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider is aware and acknowledges that tramadol 50 mg IR is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred tramadol 50 mg immediate release tablets. The provider must explain why the patient requires tramadol 100 mg IR tablets and cannot take the cost-effective tramadol 50 mg IR tablets. <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> prenatal multivitamin (Trinaz) <p>Vitamins: Prenatal</p>	<p>Manual PA criteria applies to new and current users of Trinaz, regardless of the woman's age.</p> <p><u>Manual PA Criteria:</u> Azesco, Zalvit, or Trinaz is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, and Prenatal Plus DHA are the preferred products and are covered without a prior authorization for women who are under the age of 45 years and planning to become pregnant or who are pregnant. The provider is encouraged to consider changing the prescription to one of these agents. The provider must explain why the patient requires Azesco, Zalvit or Trinaz and cannot take the available alternatives. <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> olodaterol (Striverdi Respimat) <p>Pulmonary-2 Agents: Long Acting Beta Agonists</p>	<p>Manual PA criteria applies to all new users of Striverdi Respimat.</p> <p><u>Manual PA Criteria:</u> Striverdi Respimat is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> The patient has tried and failed salmeterol (Serevent Diskus) OR The patient is unable to produce inspiratory flow necessary to use a dry powder inhaler <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • teduglutide (Gattex) <p>Gastrointestinal-2 Agents</p>	<p>Manual PA criteria applies to all new users of Gattex.</p> <p><u>Manual PA Criteria:</u> Gattex is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is at least 1 year of age or older • Gattex is prescribed by or in consultation with a gastroenterologist • Patient has a documented diagnosis of Short Bowel Syndrome • The patient is currently receiving parenteral nutrition on 3 or more days per week <p>Non-FDA-approved uses are NOT approved including patients not receiving parenteral nutrition.</p> <p>PA expires after 6 months. Renewal PA criteria: expires in one year.</p> <p><u>Renewal Criteria:</u> (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • Documented improvement (a decrease from baseline) in the weekly volume of parenteral nutrition or a reduction in the number of days requiring parenteral support
Updated PAs	
<ul style="list-style-type: none"> • flibanserin (Addyi) <p>Gynecological Agents Miscellaneous</p>	<p><u>Changes from the August 2020 meeting are BOLD and strikethrough.</u></p> <p>Manual PA criteria applies to all new users of Addyi.</p> <p><u>Manual PA Criteria:</u> Addyi is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • The drug is prescribed for a premenopausal female with hypoactive sexual desire disorder (HSDD) not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance • Patient has been counseled to wait 2 hours after consuming 1 or 2 standard alcoholic drinks before taking Addyi at bedtime or to skip their Addyi dose if they have consumed 3 or more standard alcoholic drinks that evening. After taking Addyi, the patient should not use alcohol until the following day • Patient does not have hepatic impairment (Child-Pugh score > 6) • Patient not on a concomitant moderate or strong CYP3A4 inhibitor (e.g. ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil) • Prescription written from provider who is certified/enrolled in the flibanserin REMS program • The patient has been informed that other treatment options such as cognitive-behavior therapy, sexual therapy, or couples therapy, may provide benefit without risk of side effects <p>Non-FDA-approved uses are NOT approved.</p> <p>PA expires after 3 months. Renewal PA criteria: will be approved indefinitely.</p> <p><u>Renewal Criteria:</u> (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • Patient has documented improvement in symptoms without serious side effects and continues to abstain from alcohol

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • isotretinoin (Absorica, Absorica LD) <p>Acne Agents: Isotretinoids</p>	<p><u>Changes from the August 2020 meeting are BOLD.</u></p> <p>Manual PA criteria applies to all new and current users of Absorica and Absorica LD.</p> <p><u>Manual PA Criteria:</u> Absorica and Absorica LD are approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that generic isotretinoin products (Amnesteem, Claravis, Myorisan) are available without a PA. Providers are encouraged to consider changing the prescription to one of these agents • Patient has tried and failed at least one of the following oral isotretinoin products: Amnesteem, Claravis, or Myorisan, AND • Patient is unable to comply with the dietary requirements of an AB-rated generic oral isotretinoin (e.g, Amnesteem, Claravis or Myorisan) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • minocycline ER (Solodyn, generics) <p>Antibiotics: Tetracyclines</p>	<p><u>Changes from the August 2020 meeting are BOLD and strikethrough.</u></p> <p>The previous automation requirements for generic minocycline ER and brand Solodyn will no longer apply, and will be replaced with the manual PA criteria described below. The previous renewal criteria will no longer apply.</p> <p>Manual PA criteria applies to all new and current users of generic minocycline ER and brand Solodyn.</p> <p><u>Automated PA Criteria:</u></p> <ul style="list-style-type: none"> • The patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) AND one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 <p><u>Manual PA Criteria:</u> Solodyn is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that minocycline immediate release (IR) is available to DoD beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to minocycline IR. • Patient has acne with inflammatory lesions AND • Patient is unable to tolerate generic minocycline IR due to gastrointestinal adverse events • The provider must describe why the patient requires minocycline extended release and cannot be treated with minocycline immediate release. <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p> <p>PA expires after 12 months. Renewal PA criteria: expires after 12 months.</p> <p><u>Renewal Criteria:</u> (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • Patient's therapy has been re-evaluated within the last 12 months • Patient is tolerating treatment and there continues to be a medical need for the medication • Patient has disease stabilization or improvement in disease while on therapy

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • pitolisant (Wakix) • solriamfetol (Sunosi) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply at all POS <p>Note that the QL for Sunosi was updated; no changes to the existing QL for Wakix.</p>
<ul style="list-style-type: none"> • pegfilgrastims (Fulphila, Neulasta, Neulasta OnPro, Udenyca, Ziextenzo) <p>WBC Stimulants</p>	<ul style="list-style-type: none"> ▪ Existing QLs for the pegfilgrastims will be removed the first Wednesday 60 days after signing of the minutes.
<ul style="list-style-type: none"> • lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi) <p>Contraceptive Agents: Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 12 applicators (1 box)/30 days at all POS <p>Note that Phexxi is packaged as a box of 12 applicators per box</p>
<ul style="list-style-type: none"> • diclofenac epolamine 1.3% patch (Licart) <p>Pain Agents: Pain Topical</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 patches/30 days at all POS
<ul style="list-style-type: none"> • osilodrostat (Isturisa) <p>Endocrine Agents Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • pemigatinib (Pemazyre) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 42 day supply ▪ MTF/Mail: 63 day supply <p>Note that Pemazyre is packaged as 14 tabs for a 21 day supply</p>
<ul style="list-style-type: none"> • tramadol 100 mg IR tablets <p>Narcotic Analgesics and Combinations</p>	<ul style="list-style-type: none"> ▪ Retail: 120 tabs/30 days ▪ MTF/Mail: 360 tabs/90 days
<ul style="list-style-type: none"> • capmatinib (Tabrecta) • ripretinib (Qinlock) • rucaparib (Rubraca) • selumetinib (Koselugo) • tucatinib (Tukysa) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply at all POS
<ul style="list-style-type: none"> • selpercatinib (Retevmo) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • mometasone furoate (AsmanexHFA) <p>Pulmonary-1 Agents: Inhaled Corticosteroids</p>	<ul style="list-style-type: none"> ▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
apomorphine sublingual film (Kynmobi)	Parkinson's Agents	<ul style="list-style-type: none"> • apomorphine SQ (Apokyn) • levodopa inhaled (Inbrija) 	For the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease	<ul style="list-style-type: none"> • Kynmobi is the 1st sublingual (SL) apomorphine for acutely treating "off" episodes in Parkinson's patients • It is the 3rd as needed treatment of acute "off" episodes • Kynmobi showed superiority over placebo on the Movement Disorder Society-Unified Parkinson's Disease Rating Scale, Part III showing improvement in motor dysfunction typical in patients experiencing "off" episodes • Kynmobi vs Apokyn <ul style="list-style-type: none"> ▪ Advantages – SL film rather than SQ Injection; easier to administer vs injection; no injection site reactions ▪ Neutral – still requires anti-nausea medication (e.g., trimethobenzamide), and has several adverse events (AEs), in particular hypotension ▪ Disadvantages – significant oropharyngeal adverse events • Kynmobi vs Inbrija <ul style="list-style-type: none"> ▪ Advantages – SL film is easier to administer than an inhaled powder, which is an advantage in asthma and COPD; and has a faster onset of action. An indirect comparison showed improved efficacy compared to Inbrija ▪ Disadvantages – oral AEs lead to high discontinuation rate; still requires anti-nausea medication (e.g., trimethobenzamide), and has several AEs, in particular hypotension • Kynmobi is another dosage form of apomorphine that will be useful for Parkinson's patients experiencing "off" episodes, with the convenience of an easily administered SL film. 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
bempedoic acid/ezetimibe (Nexlizet)	Antilipidemics-1	<ul style="list-style-type: none"> • simvastatin • atorvastatin • rosuvastatin • ezetimibe • alirocumab (Praluent) • evolocumab (Repatha) 	Tx of established atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH), as an adjunct to diet and maximally tolerated statin therapy in patients who require additional LDL lowering	<ul style="list-style-type: none"> • Antilipidemic with a new mechanism of action: adenosine triphosphate-citrate lyase (ACL) inhibitor • Bempedoic acid alone reduces low density lipoprotein (LDL) an additional 18%-20% when added onto statins • In patients taking statins, bempedoic acid plus ezetimibe reduced LDL levels by about 36% • Minimal impact on triglycerides (TG) or high-density lipoprotein (HDL) • Single ingredient bempedoic acid (Nexletol) evaluated at May 2020 meeting and designated NF • Long-term adverse event profile unknown • Potential place in therapy as an add-on option if patient has had an inadequate response to statin plus ezetimibe and an oral med is preferred over injectable PCSK-9 • Should not replace statins as first-line therapy • Limited place in therapy due to lack of CV outcomes studies; CLEAR OUTCOMES results not expected until 2022 	<ul style="list-style-type: none"> • NF and non-step-preferred • Add to EMMI list
capmatinib (Tabrecta)	Oncological agents: Lung Cancer	<ul style="list-style-type: none"> • Crizotinib (Xalkori) 	Adults with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test	<ul style="list-style-type: none"> • Tabrecta is the preferred agent for patients with NSCLC with a MET exon 14 skipping mutation per the NCCN guidelines • Tabrecta is the first drug FDA-approved for the treatment of patients with NSCLC and a mutation that leads to MET exon 14 skipping. • FDA-approval and recommendations based on limited available data; no published clinical data. • Available data shows Tabrecta has more favorable response rates in treatment-naïve patients compared with those in previously treated patients. • Serious adverse events occurred in 50% of the patients treated with Tabrecta. • MET exon 14 skipping mutations occur in 3% to 4% of patients with adenocarcinoma and the approval of Tabrecta fulfills an unmet need for treatment of patients with these tumors. 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
diclofenac epolamine 1.3% patch (Licart)	Pain agents: Pain topical	<ul style="list-style-type: none"> diclofenac 1% gel (Voltaren, generics) diclofenac 1.3% patch (Flector, generics) 	For the topical treatment of acute pain due to minor strains, sprains, and contusions	<ul style="list-style-type: none"> Licart is the 2nd FDA approved diclofenac 1.3% patch Licart is only FDA approved for acute pain of minor strains, sprains, and contusions; it is not approved for arthritis pain Licart was superior to placebo in clinical trials on the pain visual analog scale at 3 days, the onset of action is unknown, and the comparison to Flector patch did not have valid conclusions due to incorrect administration Flector is dosed twice daily while Licart is dosed once daily Licart offers little to no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> NF Do not add to EMMI list
elagolix/estradiol/norethindrone (OriaHnn)	Luteinizing hormone-releasing hormone agonists-antagonists	<ul style="list-style-type: none"> Lupron Depot IM (leuprolide) 	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	<ul style="list-style-type: none"> OriaHnn is an oral gonadotropin-releasing hormone (GnRH) antagonist approved for the treatment of heavy menstrual bleeding associated with uterine fibroids OriaHnn was evaluated in two phase III studies and was effective at decreasing heavy menstrual bleeding in more women than placebo OriaHnn treatment is limited to 24 months due to bone mineral density loss OriaHnn is contraindicated in patients with a high risk of arterial, venous thrombotic, or thromboembolic disorders, pregnancy, osteoporosis, current or history of breast cancer or other hormonally-sensitive malignancies, known liver impairment or disease, undiagnosed abnormal uterine bleeding, or known hypersensitivity to ingredients of OriaHnn including FD&C Yellow #5 OriaHnn is the first agent approved for treatment of heavy menstrual bleeding associated with uterine fibroids for longer than three months; however, other surgical and medical options exist and it is associated with a significant adverse event profile 	<ul style="list-style-type: none"> UF Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
fenfluramine oral soln (Fintepla)	Anticonvulsant/ Antimanic	<ul style="list-style-type: none"> • cannabidiol oral soln (Epidiolex) • clobazam (Onfi) • stiripentol (Diacomit) 	Dravet Syndrome	<ul style="list-style-type: none"> • Fintepla is another formulation of fenfluramine and is now approved as an antiepileptic drug to treat Dravet Syndrome in patients ≥ 2 years • Fenfluramine was previously used as a weight loss agent and was removed from the US market in 1997 due to valvular heart disease and pulmonary hypertension risks. There is now a REMS program requiring regular echocardiogram (ECHO) monitoring • Efficacy is based on limited data but Fintepla is more effective than placebo as adjunct therapy with other anticonvulsants • Limitations include that no head-to-head studies with other agents are available, and treatment guidelines have not yet been updated to reflect its place in therapy • Fintepla is another agent that can be used as adjunct therapy for patients with Dravet Syndrome 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
halcinonide 0.1% topical solution (Halog)	Corticosteroids-immune modulators: High potency	<ul style="list-style-type: none"> • betamethasone/propylene glycol 0.05% cream • clobetasol propionate 0.05% cream/oint • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream/oint • fluocinonide 0.05% cream/oint • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% oint 	Steroid-responsive dermatoses	<ul style="list-style-type: none"> • Halog topical solution was originally FDA-approved in 1977 • Ownership changed several times however the last label update was in 2004 • Class review of High-Potency Topical Corticosteroids was in August 2019; halcinonide 0.1% ointment and cream (Halog) made Tier 4 • Numerous alternatives identified • No new data • Same manufacturer as Halog cream and ointment (Sun), which are Tier 4 • Provides no additional benefit relative to the other high-potency topical corticosteroids 	<ul style="list-style-type: none"> • Tier 4 (not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
insulin lispro-aabc (Lyumjev)	Insulins: Rapid-acting agents	<ul style="list-style-type: none"> Insulin lispro (Admelog, Humalog, authorized generic insulin lispro) Insulin aspart (Novolog, Fiasp) 	Rapid-acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus	<ul style="list-style-type: none"> Lyumjev is a new formulation of insulin lispro that that may be injected at the start of a meal or up to 20 minutes after the start Approved by the BLA 351(a) pathway Evaluated in 2 non-inferiority, active comparator studies with Humalog (PRONTO-T1D and PRONTO-T2D) <ul style="list-style-type: none"> Lyumjev was non-inferior to Humalog in both studies at reducing A1c as both a mealtime and post-meal agent Lyumjev was statistically but not clinically significant compared to Humalog in post-prandial glucose reduction at 1-hour and 2-hours post-meal Similar adverse effect profile to Humalog No compelling advantage over existing formulary agents 	<ul style="list-style-type: none"> UF Add to EMMI list
lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi)	Contraceptive agents: Miscellaneous	<ul style="list-style-type: none"> nonoxynol-9 spermicide 	For prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception; limitation: not effective when administered after intercourse	<ul style="list-style-type: none"> Phexxi is a non-hormonal, on-demand contraceptive inserted vaginally prior to intercourse Less effective at preventing pregnancy than any other formulary contraceptive with a Pearl Index of 27.5 pregnancies/100 women-years of use (Pearl Index of less than 5 associated with oral combined hormonal contraceptives) > 20% of women using Phexxi and ~10% of male partners had local adverse reactions, but < 2% discontinued due to adverse reactions Can be used concomitantly with other vaginal medications and other methods of contraception including OCPs and condoms Nonoxynol-9 based spermicides have similar efficacy and side effects and are available OTC in a variety of formulations At this time, Phexxi has no compelling clinical advantages over existing formulary and OTC contraceptive agents 	<ul style="list-style-type: none"> NF Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
<p>lemborexant (Dayigo)</p>	<p>Sleep disorders: Insomnia</p>	<ul style="list-style-type: none"> • suvorexant (Belsomra) • zolpidem ER • eszopiclone 	<p>Insomnia characterized by difficulties with sleep onset and/or maintenance</p>	<ul style="list-style-type: none"> • Lemborexant is the 2nd FDA-approved orexin receptor antagonist indicated for insomnia associated with sleep onset and maintenance • Evaluated in 2 placebo-controlled studies with zolpidem ER as an active comparator in one study <ul style="list-style-type: none"> ▪ Lemborexant was statistically significant in all measures providing an additional 5-14 minute difference in sleep onset from placebo and an additional 13-28 min difference from placebo in sleep maintenance ▪ The 10 mg strength conferred no additional efficacy but had more adverse effects ▪ No clinically significant differences in any efficacy measure in an indirect comparison to suvorexant or zolpidem ER • The most common adverse effect is somnolence; patients taking 10 mg should be cautioned against driving the next day due to daytime somnolence • Similar to other agents in the class and suvorexant, lemborexant is a controlled medication, has several drug interactions, and has the same extensive warnings regarding sleep-related behaviors • Lemborexant is contraindicated in patients with narcolepsy; same as suvorexant • Patients should only take Dayigo if they can stay in bed for a full night (at least 7 hours) before being active again and food may delay the effect of Dayigo • Lemborexant provides another treatment option for insomnia but has no compelling advantages over suvorexant or older “z” drugs 	<ul style="list-style-type: none"> • UF and non-step-preferred • Add to EMMI list
<p>leuprolide acetate injection (Fensolvi)</p>	<p>Luteinizing hormone-releasing hormone (LHRH) agonists-antagonists</p>	<ul style="list-style-type: none"> • leuprolide acetate IM (Lupron Depot-Ped) • histrelin implant (Supprelin LA) – not a pharmacy benefit • triptorelin IM (Triptodur) – not a pharmacy benefit 	<p>Treatment of pediatric patients ≥ 2 years of age with central precocious puberty</p>	<ul style="list-style-type: none"> • Another formulation of leuprolide acetate supplied in a kit for subcutaneous (SQ) injection however it must be administered by a healthcare professional • Only SQ formulation indicated for treatment of pediatric patients ≥ 2 years with central precocious puberty (CPP) • Other than patient convenience in the administration route and the duration of action (long-acting formulation), provides no additional compelling advantages compared to other available agents 	<ul style="list-style-type: none"> • NF • Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
levonorgestrel/ ethinyl estradiol transdermal system (Twirla)	Contraceptive Agents: Miscellaneous	<ul style="list-style-type: none"> norelgestromin/ ethinyl estradiol (EE) transdermal system (Xulane) 	<p>Contraception in women of reproductive potential with a BMI < 30 kg/m² for whom a combined hormonal contraceptive is appropriate;</p> <p>Limitations: decreased effectiveness in women with a BMI ≥ 25 to < 30 kg/m²</p>	<ul style="list-style-type: none"> Twirla is the second available contraceptive patch in the US Contains less estrogen than Xulane, the other contraceptive patch (30 mcg/day vs. 35 mcg/day) Decreased effectiveness in women with a BMI ≥ 25 kg/m² and contraindicated in women with a BMI ≥ 30 kg/m² Indirectly compared to Xulane, Twirla has a higher Pearl Index and a higher rate of venous thromboembolism (VTEs) Support for FDA approval was not unanimous Post-marketing trials are required to assess thrombotic risk and residual drug content in the patch Twirla is less effective and less safe than other available contraceptive agents 	<ul style="list-style-type: none"> NF Do not add to EMMI list
minocycline 1.5% topical foam (Zilxi)	Acne agents: Topical acne and rosacea	<ul style="list-style-type: none"> minocycline 50 mg capsule minocycline 4% foam (Amzeeq) metronidazole 1% gel (MetroGel) azelaic acid 15% foam (Finacea) brimonidine tartrate 0.33% gel (Mirvaso) ivermectin 1% cream (Soolantra) 	For the treatment of inflammatory lesions of rosacea in adults	<ul style="list-style-type: none"> Zilxi is the 2nd FDA-approved topical minocycline and 1st with an indication for rosacea It has not yet been incorporated into rosacea treatment guidelines Only compared to vehicle in pivotal clinical trials Zilxi was well-tolerated; warnings and precautions are identical to that of oral minocycline except flammability Storage requirements represent a disadvantage compared to other available topical rosacea treatments There are many other available topical and oral rosacea medications that can be used first-line that do not have flammability concerns and storage constraints 	<ul style="list-style-type: none"> NF and non-step-preferred Add to EMMI list
nimodipine oral syringe (Nymalize)	Calcium Channel Blocker	<ul style="list-style-type: none"> nimodipine oral dosing cups (Nymalize) nimodipine liquid-filled capsule (Nimotop) – discontinued 	subarachnoid hemorrhage (SAH)	<ul style="list-style-type: none"> nimodipine (Nimotop) liquid-filled capsules were first approved for subarachnoid hemorrhage (SAH) in 1988 Nimotop was withdrawn from the market due to frequent administration and dosing errors nimodipine oral solution (Nymalize) was approved in 2013 in unit-dose oral dosing cups, then a multi-dose bottle of the oral syrup; 6 mg/mL and 3 mg/mL (discontinued) nimodipine oral syringe (Nymalize) is a new formulation of nimodipine available in 60 mg/20 mL or 30 mg/10 mL prefilled oral syringes that decrease the risk of dosing/administration errors 	<ul style="list-style-type: none"> UF Do not add to EMMI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
octreotide acetate injection (Bynfezia Pen)	Endocrine agents miscellaneous	<ul style="list-style-type: none"> • octreotide (Sandostatin, generics) • octreotide (Sandostatin LAR Depot) Kit – not a pharmacy benefit 	<ul style="list-style-type: none"> • Acromegaly • Carcinoid tumors • Vasoactive intestinal peptide secreting tumors (VIPomas) in adults 	<ul style="list-style-type: none"> • Bynfezia Pen is a new immediate-release formulation of octreotide acetate in a prefilled syringe • No new data • Other than providing patient convenience in a pre-filled multi-dose syringe, Bynfezia Pen provides no compelling advantage over existing formulary agents 	<ul style="list-style-type: none"> • UF • Add to EMMI list
osilodrostat (Isturisa)	Endocrine agents miscellaneous	<ul style="list-style-type: none"> • Signifor/Signifor LAR • Korlym • Ketoconazole • Metyrapone • Mitotane 	Treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative	<ul style="list-style-type: none"> • Isturisa is the 1st drug FDA-approved to prevent cortisol synthesis in patients with Cushing's disease (CD) for whom pituitary surgery is not an option or has not been curative • A single, multi-center, double-blind, randomized withdrawal study following a 24-week, single arm, open-label dose titration period demonstrated that treatment with osilodrostat in patients with non-surgical or recurrent CD is effective in reducing mean 24-hour urinary free cortisol levels from baseline • Osilodrostat is effective in approximately 52% of all treatment-naïve patients and the response can be maintained in ~ 80% of patients who responded to and tolerated the drug after 6 months of treatment • Patients must be monitored for hypocortisolism and potentially life-threatening adrenal insufficiency, QTc prolongation, and hypokalemia, worsening of hypertension, edema, and hirsutism • Limitations: data are not fully-published and no head-to-head trials with other agents are available • Osilodrostat adds to the armamentarium in treating patients with Cushing's disease 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
ripretinib (Qinlock)	Oncological Agents	<ul style="list-style-type: none"> • imatinib (generics) • sunitinib (Sutent) • regorafenib (Stivarga) • avapritinib (Ayvakit) 	For advanced GI stromal tumors (GIST) with disease progression after tx w/ ≥3 kinase inhibitors	<ul style="list-style-type: none"> • Ripretinib is a tyrosine kinase inhibitor (TKI) FDA-approved for 4th line therapy of unresectable or metastatic GIST, evaluated in one phase 3 study for FDA approval • The primary endpoint of progression-free survival (PFS) resulted in a statistically-significant median PFS of 6.3 months v. 1 month for placebo • The secondary endpoints included overall response rate (ORR) and overall survival (OS); ORR was not statistically significant and OS was statistically significant • Most common AEs include alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhea, decreased appetite, palmar-plantar erythrodyesthesia (PPES), and vomiting • Utility in practice: 4th line option for unresectable or metastatic GIST 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
selpercatinib (Retevmo)	Oncological Agents: Lung Cancer	<ul style="list-style-type: none"> • cabozantinib (various, generics) • vandetanib (Caprelsa) 	Adults with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) 12+ years with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy 12+ years with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory	<ul style="list-style-type: none"> • Retevmo is indicated for RET-(+) NSCLC and MTC • Retevmo is the preferred agent for RET-(+) NSCLC 	<ul style="list-style-type: none"> • UF • Add to EMMI list

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tucatinib (Tukysa)	Oncological agents: Breast cancer	<ul style="list-style-type: none"> • trastuzumab (various brands; generic) • pertuzumab (Perjeta) • lapatinib (Tykerb) 	In combination with trastuzumab and capecitabine for adults with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting	<ul style="list-style-type: none"> • Tukysa is the 3rd available tyrosine kinase inhibitor (TKI) available for advanced HER2-(+) breast cancer refractory to 1st line treatment • Tukysa improves survival, including survival in patients with brain metastatic disease • Adverse events are common but serious adverse events are less so. • Tukysa is an additional treatment option for patients with advanced disease 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list

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

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

		<p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> ▪ fenfluramine (Fintepla) ▪ osilodrostat (Isturisa) ▪ pemigatinib (Pemazyre) ▪ ripretinib (Qinlock) ▪ selumetinib (Koselugo) ▪ tucatinib (Tukysa) <p>Designated NF:</p> <p><i>Drugs for acute or limited duration use:</i></p> <ul style="list-style-type: none"> ▪ diclofenac epolamine 1.3% patch (Licart) <p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> ▪ leuprolide acetate injection (Fensolvi) (<i>limited distribution</i>) <p><i>Contraceptive exception/existing exclusion applies:</i></p> <ul style="list-style-type: none"> ▪ levonorgestrel/ethinyl estradiol (Twirla) ▪ lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi)
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Appendix G—Table of Implementation Status of UF Recommendations/Decisions Summary

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

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2020	WBC Stimulants: Filgrastim Subclass and Pegfilgrastim Subclass	UF Class Review Class not previously reviewed	<p>Tier 4/Not Covered Medications</p> <p>MTFs <u>must not</u> have on formulary</p> <p>Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None 	<p><u>UF step-preferred</u></p> <p><i>filgrastims</i></p> <ul style="list-style-type: none"> ▪ filgrastim-aafi (Nivestym) <p><i>pegfilgrastims</i></p> <ul style="list-style-type: none"> ▪ pegfilgrastim-jmdb (Fulphila) <p><u>UF non-step-preferred</u></p> <p><i>filgrastims</i></p> <ul style="list-style-type: none"> • filgrastim (Neupogen) • filgrastim-sndz (Zarxio) <p><i>pegfilgrastims</i></p> <ul style="list-style-type: none"> • pegfilgrastim (Neulasta) • pegfilgrastim (Neulasta OnPro) • pegfilgrastim-bmez (Ziextenzo) 	<p>▪ None</p>	<p>Pending signing of the minutes / 60 days</p> <p>The effective date is December 30, 2020</p>	<p>PA applies to non-step-preferred agents</p> <p>The UF step-preferred agents do not have a PA</p> <p>No QLs for these agents</p>	<p>This is the first biosimilar review</p> <p>See Appendix C for PA criteria.</p>

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2020	Psoriasis Agents	UF Class Review	<p style="text-align: center;">Tier 4/Not Covered Medications</p> <p style="text-align: center;">MTFs <u>must not</u> have on formulary</p> <p style="text-align: center;">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex) 			Pending signing of the minutes / 120 days The effective date is February 24, 2021	<ul style="list-style-type: none"> ▪ 	<ul style="list-style-type: none"> ▪ Manual PA criteria applies to all users of the NF drugs, except for Vectical ▪ See Appendices B and C for MN and PA Criteria. ▪ One Tier 4 product
			<ul style="list-style-type: none"> ▪ calcipotriene 0.005% cream (Dovenex, generics) 	<ul style="list-style-type: none"> ▪ calcipotriene 0.005% ointment (Calcitrene, generics) ▪ calcipotriene 0.005% solution (generics) ▪ tazarotene 0.1% cream (Tazorac, generics) 	<ul style="list-style-type: none"> ▪ calcipotriene 0.005% foam (Sorilux) ▪ calcitriol 3 mcg/g ointment (Vectical, generics) ▪ calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex) ▪ calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) ▪ tazarotene 0.1% gel (Tazorac) ▪ tazarotene 0.05% cream (Tazorac) ▪ tazarotene 0.05% gel (Tazorac) 			

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> • calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> • calcipotriene 0.005% solution • clobetasol 0.05% solution, shampoo • fluocinonide 0.05% solution • calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> • calcipotriene 0.005% ointment, cream, solution • clobetasol 0.05% ointment, cream • fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> • 120 days after signing • February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> • halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> • betamethasone propylene glycol 0.05% cream • clobetasol propionate 0.05% cream and ointment • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream and ointment • fluocinonide 0.05% cream and ointment • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% ointment 	<ul style="list-style-type: none"> • 120 days after signing • February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> • tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> • adapalene 0.1% lotion, gel, cream • adapalene 0.3% gel • clindamycin phosphate 1% gel, cream, lotion, and solution • clindamycin/benzoyl peroxide 1.2% - 5% gel • tazarotene 0.1% cream • tretinoin 0.025%, 0.05%, and 0.1% cream • tretinoin 0.01% and 0.025% gel 	<ul style="list-style-type: none"> • 120 days after signing • February 24, 2021
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> • amlodipine/celecoxib (Consensi) 	<ul style="list-style-type: none"> • Dihydropyridine calcium channel blockers: amlodipine, felodipine, nifedipine, isradipine <p>PLUS</p> <ul style="list-style-type: none"> • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> • August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> diclofenac potassium liquid-filled capsules (Zipsor) diclofenac submicronized (Zorvolex) fenoprofen capsules indomethacin submicronized (Tivorbex) meloxicam submicronized (Vivlodex) 	<ul style="list-style-type: none"> celecoxib diclofenac ibuprofen meloxicam naproxen Also includes other NSAIDs 	<ul style="list-style-type: none"> August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	<ul style="list-style-type: none"> ibuprofen and famotidine tablets (Duexis) 	<ul style="list-style-type: none"> H2 blockers: famotidine, ranitidine, cimetidine, nizatidine PLUS NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> August 26, 2020
Feb 2020	Pain Agents – Combinations	<ul style="list-style-type: none"> naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> diclofenac 1.3% patch (Flector) diclofenac 2% solution (Pennsaid) 	<ul style="list-style-type: none"> oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) diclofenac 1.5% solution diclofenac 1% gel 	<ul style="list-style-type: none"> August 26, 2020
Feb 2020	Pain Agents Class; Pain Topical Subclass	<ul style="list-style-type: none"> lidocaine 1.8% patch (ZTIido) 	<ul style="list-style-type: none"> lidocaine 5% patch 	<ul style="list-style-type: none"> August 26, 2020
Feb 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> benzoyl peroxide 9.8% foam (Enzoclear) 	<ul style="list-style-type: none"> clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) clindamycin/benzoyl peroxide 1% - 5% gel (Benzacilin, generics) clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit) 	<ul style="list-style-type: none"> August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2020	Anti-Infectives: Miscellaneous	<ul style="list-style-type: none"> omeprazole magnesium, amoxicillin and rifabutin (Talcia) 	<ul style="list-style-type: none"> omeprazole PLUS amoxicillin PLUS rifabutin (given separately) omeprazole PLUS clarithromycin PLUS amoxicillin bismuth subsalicylate OTC PLUS metronidazole PLUS tetracycline PLUS PPI 	<ul style="list-style-type: none"> August 26, 2020
Feb 2020	Pulmonary-1: Short Acting Beta2 Agonists (SABA)	<ul style="list-style-type: none"> albuterol dry powder inhaler (ProAir Digihaler) 	<ul style="list-style-type: none"> albuterol MDI (ProAir HFA) albuterol DPI (ProAir Respiclick) albuterol MDI (Proventil HFA) [Nonformulary] albuterol MDI (Ventolin HFA) [Nonformulary] levalbuterol MDI (Xopenex HFA) [Nonformulary] 	<ul style="list-style-type: none"> August 26, 2020
Nov 2019	PDE-5 inhibitor	<ul style="list-style-type: none"> avanafil tablet (Stendra) brand Viagra tablet brand Cialis tablet ildenafil tablet (Levitra and generics) ildenafil oral disintegrating tablet (ODT) (Staxyn and generics) 	<ul style="list-style-type: none"> sildenafil tablet (generic Viagra only) tadalafil tablet (generic Cialis only) 	<ul style="list-style-type: none"> June 3, 2020
Nov 2019	Rapid Acting Insulins	<ul style="list-style-type: none"> insulin plus niacinamide (Fiasp) 	<ul style="list-style-type: none"> insulin aspart (Novolog) insulin lispro (Humalog or authorized generic lispro) insulin lispro (Admelog) [nonformulary] insulin glulisine (Apidra) [nonformulary] 	<ul style="list-style-type: none"> July 1, 2020
Nov 2019	Pulmonary-2 Agents: COPD	<ul style="list-style-type: none"> formoterol/acclidinium (Duaklir Pressair) 	<ul style="list-style-type: none"> umeclidinium/vilanterol (Anoro Ellipta) tiotropium/olodaterol (Stiolto Respimat) glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary] (discontinued from market March 2020) glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary] 	<ul style="list-style-type: none"> June 3, 2020
Nov 2019	Migraine Agents: Triptans	<ul style="list-style-type: none"> sumatriptan nasal spray (Tosymra) 	<ul style="list-style-type: none"> sumatriptan nasal spray (Imitrex, generics) sumatriptan nasal powder (Onzetra Xsail) [nonformulary] zolmitriptan nasal spray (Zomig) 	<ul style="list-style-type: none"> June 3, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2019	GI2 Agents: CIC and IBS-C	<ul style="list-style-type: none"> tegaserod (Zelnorm) 	<ul style="list-style-type: none"> linaclotide (Linzess) plecanatide (Trulance) lubiprostone (Amitiza) prucalopride (Motegrity) [nonformulary] 	June 3, 2020
Aug 2019	ADHD	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> clobetasol propionate 0.025% cream (Impoiz) diflorasone diacetate/emollient 0.05% cream (Apexicon-E) halcinonide 0.1% cream (Halog) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% ointment (Halog) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit) halobetasol propionate 0.05% lotion (Ultravate) halobetasol propionate 0.05% foam (authorized generic for Lexette) (see Feb 2019 for brand Lexette) halobetasol propionate 0.01% lotion (Bryhali) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> March 4, 2020
May 2019	PPIs	<ul style="list-style-type: none"> dexlansoprazole (Dexilant) esomeprazole strontium 	<ul style="list-style-type: none"> esomeprazole omeprazole pantoprazole rabeprazole 	<ul style="list-style-type: none"> Nov 28, 2019 MTF Tier 4 implementation for Dexilant delayed to Jan 31, 2020
Feb 2019	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halobetasol propionate 0.05% foam (Lexette brand) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Aug 28, 2019 Note that Lexette reaffirmed as Tier 4 at the August 20219 High Potency Topical Steroid review
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	<ul style="list-style-type: none"> metformin ER gastric retention 24 hours (Glumetza) 	<ul style="list-style-type: none"> metformin IR (Glucophage generic) metformin ER (Glucophage XR generic) 	<ul style="list-style-type: none"> Aug 28, 2019
Feb 2019	Pain Agents – Combinations	<ul style="list-style-type: none"> naproxen / esomeprazole (Vimovo) 	<ul style="list-style-type: none"> PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 	<ul style="list-style-type: none"> Aug 28, 2019 Note that Vimovo reaffirmed as Tier 4 at the February 2020 NSAID subclass review

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents, based on an interim final rule published on December 11, 2018. <https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms>. The Final Rule was published June 3, 2020 and is available at <https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms>. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service.

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

Minutes and Recommendations of the DoD P&T Committee Meeting August 5-6, 2020

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
Aspirin		
August 2020	<p>Retain these GCNs</p> <ul style="list-style-type: none"> ▪ 16713 – aspirin 81 mg chewable tab ▪ 00161 – aspirin 81 mg delayed release tab (enteric-coated) ▪ 16701 – aspirin 325 mg tab ▪ 16720 – aspirin 325 mg delayed release tab (enteric-coated) 	<p>Remove these GCNs:</p> <ul style="list-style-type: none"> ▪ 26911 – aspirin suspension
Artificial Tears (Overnight Treatment)		
August 2020	<p>Retain these GCNs</p> <ul style="list-style-type: none"> ▪ 98935 – mineral oil/petrolatum 15%-83% ointment (Artificial tears) ▪ 99250 – mineral oil/petrolatum 20%-80% ointment (Retaine PM, Soothe) ▪ 99952 – mineral oil/petrolatum 3%-94% ointment (Overnight Lubricating Eye, Systane) ▪ 99222 – mineral oil/petrolatum 42.5%-56.8% ointment (Refresh Lacri-Lube) ▪ 28068 – mineral oil/petrolatum 42.5%-57.3% ointment (Refresh PM) <p>Add these GCNs</p> <ul style="list-style-type: none"> ▪ 27956 – hypromellose 0.3% gel (Genteal Tears Severe, Systane Gel) 	
Anthelmintics		
August 2020	<p>Add these GCNs</p> <ul style="list-style-type: none"> ▪ 43170 – pyrantel pamoate 50 mg/mL suspension 	

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

Appendix J—Table of Abbreviations

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