

**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 Fasenra 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 Fasenra, 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 (Fasenra), 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, QIs, 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

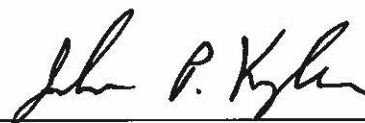
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

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

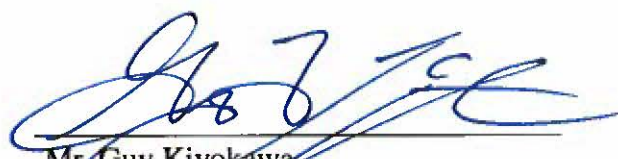
The Director, DHA:

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 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>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>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>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>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 (Impoyz) • 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	NDAA	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