DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2019

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 7 and 8, 2019, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May 2019 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the May 2019 DoD P&T Committee meeting on July 26, 2019.

2. **Clarification of Previous Minutes**

   a) **May 2019 Meeting—Brand over Generic Requirement for ambrisentan (Letairis):** The brand over generic authorization and Tier 1 copay for Letairis was not implemented, as cost-effective generic ambrisentan formulations were widely available after the meeting.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. All Uniform Formulary (UF), Basic Core Formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year 2018. Medical necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a nonformulary (NF) medication.

Nonformulary 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. High-Potency Topical Corticosteroids

Background—The full Topical Corticosteroid class was previously reviewed in August 2013. The current review was limited to only the high-potency corticosteroids. The subclass is comprised of 9 parent drugs, amcinonide, fluocinonide, halcinonide, flurandrenolide,

desoximetasone, betamethasone dipropionate, clobetasol propionate, halobetasol propionate, and diflorasone diacetate. These nine drugs are distributed across three Coopman structural classes (B, C, and D_1), and two Stoughton-Cornell potency groups (super high-potent and high-potent). Nine different potential vehicles are available: ointments, creams, lotions, solutions, foams, gels, sprays, shampoos, and tape. No one drug is available in all nine vehicles. Based on parent compound and vehicle, there are 39 total products in the subclass. Generic formulations are available for several of the products.

The clinical effectiveness review considered Coopman structural class, Stoughton-Cornell potency group, and vehicle, among other factors, when comparing the individual products, along with clinical effectiveness and safety.

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

- There were no major changes to the previous conclusions from the 2013 review for the following:
  - Issues of efficacy and safety within the Topical Corticosteroid class are considered class effects.
  - No particular agent within the same Stoughton-Cornell potency group and vehicle demonstrates a compelling advantage or disadvantage in either efficacy or safety compared to other agents in that same potency and vehicle group.
  - Topical corticosteroids within a potency group and vehicle are clinically interchangeable.
  - At least one product from each Coopman structural class is required on the formulary.
- Coopman Class C agents have the lowest cross-reactivity compared to products in the Coopman Class B and D_1 structural classes. Desoximetasone is the only Coopman C agent in the high-potency topical corticosteroid subclass.
- Both super high-potent and high-potent agents are necessary on the formulary, as patients refractory to less potent (Stoughton-Cornell Group 2) agents may still respond to super-high potent (Stoughton-Cornell Group 1) agents. There are currently 21 super high-potent and 18 high-potent products marketed, and there is no inherent additional clinical value to retaining all 39 products on the formulary.
- In addition to the parent structure and drug concentration, the type of vehicle also contributes to the potency classification of an individual topical corticosteroid. With regard to specific vehicle, the P&T Committee concluded the following:
  - Ointments and creams are individually unique vehicles and remain necessary options to include on the formulary. There are 9 ointments and 12 creams commercially available, and not all these products are required for Military Health System (MHS) beneficiaries.
  - Lotions, solutions, foams, and gels have overlapping utility and are advantageous for treating the scalp and large body surface areas. Foams and solutions are the preferred

vehicles for scalp use. Although hair-friendly products are necessary on the formulary, not all of the commercially available lotion, foams, and solutions are necessary for MHS beneficiaries.

  - Sprays and tape have unique features, in that sprays offer patients the convenience of treating hard-to-reach body locations (e.g., the back) while the tape offers a physical barrier.
  - The primary advantage offered by gels, sprays, shampoos, and tape is patient convenience, and none are absolutely clinically necessary components of the benefit.

- With regard to efficacy, clinical trials conducted with the high-potency topical steroids are all of low quality. There is no robust phase III clinical trial evidence available. Clobetasol continues to be the high-potency topical corticosteroid with the largest amount of literature available.
- A comprehensive updated review of safety found no major differences from the conclusions reached in 2013, except for potential issues with inactive ingredients. Inactive ingredients, including propylene glycol, can cause allergic contact dermatitis. However, there are representative members within each Coopman class (B, C, and D_1) that do not contain propylene glycol.
- Professional treatment guidelines continue to support the use of high-potency topical corticosteroids across a wide array of dermatoses, with varying levels of evidence and recommendation strengths.
- Overall, the P&T Committee agreed that there were several candidates for Tier 4/not covered status due to the clinical conclusions discussed above and the numerous representatives from each Coopman structural class, Stoughton-Cornell potency classification, and vehicle.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the High-Potency Topical Corticosteroids. For the cost analysis, branded high-potency topical steroids without generic equivalents were evaluated in detail. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results for the subclass showed the following branded products were substantially less cost-effective than the remainder of the class: halobetasol propionate 0.01% lotion (Bryhali), flurandrenolide 4 mcg/sq. cm tape (Cordran), clobetasol propionate 0.025% cream (Impoyz), halobetasol propionate 0.05% lotion (Ultravate), and halobetasol propionate 0.05% foam (Lexette) respectively.
- BIA was performed for the subclass to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that the following designations demonstrated cost avoidance for the Military Health System (MHS):
  - Designating halobetasol propionate 0.05% cream (Ultravate & generic), clobetasol propionate/emollient 0.05% foam (Olux-E & generic),

flurandrenolide 4 mcg/sq. cm tape (Cordran), and desoximetasone 0.05% gel (Topicort & generic) as NF

- Designating clobetasol propionate 0.025% cream (Impoyz), diflorasone diacetate/emollient 0.05% cream (Apexicon-E & generic), halcinonide 0.1% cream (Halog), halobetasol propionate 0.05% foam (Lexette and authorized generic), clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan Kit), halobetasol propionate 0.01% lotion (Bryhali), halobetasol propionate 0.05% lotion (Ultravate), and halcinonide 0.1% ointment (Halog) as Tier 4

1. ***COMMITTEE ACTION: HIGH-POTENCY TOPICAL CORTICOSTEROIDS UF/TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent for all the members of the class, except for Cordran Tape: 14 for, 2 opposed, 0 abstained, 1 absent) the following formulary recommendations for the High-Potency Topical Corticosteroids as outlined below, based on clinical and cost-effectiveness.

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

   - UF
     - betamethasone dipropionate 0.05% ointment
     - betamethasone/propylene glycol 0.05% ointment, cream, lotion, gel
     - clobetasol propionate 0.05% ointment, cream, solution, lotion, shampoo, spray, gel, foam
     - clobetasol propionate/emollient 0.05% cream
     - clobetasol propionate/emollient 0.05% emulsion foam
     - desoximetasone 0.25% ointment, cream
     - fluocinonide 0.05% ointment, cream, solution, gel
     - fluocinonide/emollient base 0.05% cream
     - halobetasol propionate 0.05% ointment
     - *Note that all the agents recommended for UF status are currently on the formulary.*
   - NF
     - amcinonide 0.1% ointment (Cyclocort, generics)

- clobetasol propionate/emollient 0.05% foam (Olux-E, generics) *(moves from UF to NF status)*
- desoximetasone 0.05% gel (Topicort, generic) *(moves from UF to NF status)*
- diflorasone diacetate 0.05% ointment (Psorcon, Apexicon, generics)
- diflorasone diacetate 0.05% cream (Psorcon, Apexicon, generics)
- fluocinonide 0.1% cream (Vanos, generics)
- flurandrenolide 4 mcg/sq. cm tape (Cordran) *(moves from UF to NF status)*
- halobetasol propionate 0.05% cream (Ultravate, generics) *(moves from UF to NF status)*

- Tier 4/Not Covered
  - clobetasol propionate 0.025% cream (Impoyz)
  - clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit)
  - diflorasone diacetate/emollient 0.05% cream (Apexicon-E)
  - halcinonide 0.1% ointment (Halog)
  - halcinonide 0.1% cream (Halog)
  - halobetasol propionate 0.05% lotion (Ultravate)
  - halobetasol propionate 0.05% foam (Lexette and authorized generic) *(note that Lexette foam was previously recommended for Tier 4 status in February 2019, with implemented scheduled for August 28, 2019)*
  - halobetasol propionate 0.01% lotion (Bryhali)

  For all eight products recommended for Tier 4/Not Covered status, the P&T Committee concluded that Impoyz, Clodan kit, Apexicon-E, Halog ointment and cream, Ultravate, Lexette and authorized generic, and Bryali provide very little to no additional clinical effectiveness relative to the other high-potency topical corticosteroids. Overall, the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other high-potency topical steroids. See Appendix H for the formulary alternatives for the Tier 4 drugs.

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) maintaining clobetasol 0.05% ointment, clobetasol 0.05% cream, fluocinonide 0.05% ointment, and fluocinonide 0.05% cream on the BCF and adding fluocinonide 0.05% solution to the BCF.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for amcinonide 0.1% and diflorasone diacetate 0.05% ointments, diflorasone diacetate 0.05% cream, clobetasol propionate/emollient 0.05% foam, desoximetasone 0.05% gel, and flurandrenolide 4 mcg/sq. cm (Cordran) tape in all new and current users, due to the large number of clinically and cost-effective formulary alternatives available. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for amcinonide 0.1% ointment, diflorasone diacetate 0.05% ointment, diflorasone diacetate 0.05% cream, fluocinonide 0.1% cream, halobetasol propionate 0.05% cream, clobetasol propionate/emollient 0.05% foam, desoximetasone 0.05% gel, and flurandrenolide 4 mcg/sq. cm (Cordran) tape. See Appendix B for full requirements.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—*** The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing halobetasol (Ultravate) from the EMMPI list and excluding the NF topical corticosteroids from the NF to mail requirement due to acute use. See Appendix F for details.

6. ***COMMITTEE ACTION: UF/TIER 4, PA, MN, AND EMMPI IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of 120 days from signing of the minutes in all points of service (POS), and 2) DHA send letters to beneficiaries who are affected by the Tier 4 decision and those affected by a change from UF to NF status. Based on the P&T Committee's recommendation, the effective date is March 4, 2020.

B. Multiple Sclerosis: Interferons and Methyl Fumarate

Background—The full Multiple Sclerosis (MS) drug class was previously evaluated for formulary status at the November 2014 P&T Committee meeting. However, this review focused on two subclasses, the Interferons and Methyl Fumarate. The other MS subclasses, including glatiramer, symptomatic agents, and oral miscellaneous drugs, were not reviewed and will maintain their current formulary status.

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

Background

- The interferons and dimethyl fumarate, along with glatiramer and the oral miscellaneous drugs, are all considered disease-modifying therapies (DMTs). DMTs are not prescribed for symptom improvement but for reducing relapses and new lesions on MRI.
- Professional treatment guidelines and MS organizations recommend availability of all DMTs without limitations and recommend choosing the appropriate MS therapy based on efficacy, safety, and individualized patient factors.

Interferons

- The five products in the subclass include the interferon beta-1b subcutaneous (SC) products (Betaseron and Extavia) and the interferon beta-1a products, Avonex intramuscular (IM), Rebif/Rebif Rebidose SC, and Plegridy IM.
- There were no significant changes from the November 2014 previous clinical conclusions which stated no one individual interferon is preferred over another in terms of efficacy or safety.
- Professional treatment guidelines from the American Academy of Neurology also do not give preference to one product over another.
- A 2017 network meta-analysis from the Institute for Clinical and Economic Review (ICER) stated the interferons are relatively similar in terms of efficacy for the relative risk of relapse rate and disability progression. Compared to placebo, the interferons have a 17%-36% reduction in the relative risk of relapse rate and a 19%-34% reduction in the relative risk of disability progression.
- The interferons have similar rates of serious adverse events and discontinuation due to adverse events. For the class, flulike symptoms are most common.
- The peginterferon beta-1a product Plegridy is similar to Avonex and Rebif, with the exception that it is a pegylated formulation. Plegridy may be associated with more serious adverse events than other interferons but shows a similar discontinuation rate with the other products.
- Interferons generally have fewer adverse events compared to other DMTs.
- Although Betaseron and Extavia utilized the same registration studies to gain FDA approval and contain the same active ingredient, the two products are not interchangeable at the pharmacy.
- There is a high degree of therapeutic interchangeability between the interferons.

Methyl Fumarate

- Dimethyl fumarate (Tecfidera) is an oral tablet and is currently the only product in the methyl fumarate subclass.
- There are no head-to-head trials comparing dimethyl fumarate and other DMTs.

- The 2017 ICER network meta-analysis showed that compared to placebo, treatment with dimethyl fumarate resulted in a 47% reduction in the relative risk of relapse rate and a 38% reduction in the relative risk of disability progression.
- Dimethyl fumarate (Tecfidera) has more serious adverse events and a greater discontinuation rate compared to the interferons.
- Dimethyl fumarate requires monitoring of the complete blood count and lymphocytes, due to the potential risk of developing progressive multifocal leukoencephalopathy (PML)
- At least two methyl fumarate products are pending FDA approval for late 2019 and mid-2020.

Overall Conclusion

- Patients with MS who are stable on an individual DMT should continue their current therapy unless the patient and provider decide a trial off therapy is warranted.
- In order to meet the needs of MHS beneficiaries, at least one interferon and one methyl fumarate product are required on the UF.
- The other DMT MS classes will remain on the UF.

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

Interferon Subclass

- CMA results for the Interferon subclass showed that Extavia and Betaseron were the most cost effective products, followed by the interferon beta-1a products.
- BIA was performed for the Interferon subclass to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating interferon beta-1a SQ (Rebif and Rebif Rebidose), interferon beta-1a IM (Avonex IM), interferon beta-1b SC (Betaseron), and interferon beta-1b SC (Extavia) as UF and peginterferon beta-1a SC (Plegridy) as NF demonstrated cost avoidance for the Military Health System (MHS).

Methyl Fumarate Subclass

- BIA results for the Methyl Fumarate subclass showed that designating dimethyl fumarate (Tecfidera) as UF demonstrated cost avoidance for the MHS.

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

Interferons

- UF
    - interferon beta-1a IM (Avonex)
    - interferon beta-1a SC (Rebif, Rebif Rebidose)
    - interferon beta-1b SC (Betaseron)
    - interferon beta-1b (Extavia)
- NF:
    - peginterferon beta-1a SC (Plegridy)

Methyl Fumarate

- UF
    - dimethyl fumarate (Tecfidera)
- NF
    - None

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing Betaseron from the BCF; as a result there will not be an MS drug on the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—For dimethyl fumarate (Tecfidera) PA criteria have been in place since November 2013 to ensure appropriate safety monitoring. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updating the current manual PA criteria for dimethyl fumarate (Tecfidera) in new users to only allow use for the FDA-labeled indication of MS. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current MN criteria for peginterferon beta-1a (Plegridy), which have been in place since May 2015. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: MAIL ORDER REQUIREMENTS FOR INTERFERON AGENTS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) adding dimethyl fumarate (Tecfidera) to the EMMPI program.

6. ***COMMITTEE ACTION: SPECIALTY CARE DRUG LIST—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) adding Plegridy to the Specialty Care Drug List, since the other MS drugs are in the program.

7. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) implementation effective the first Wednesday one week after signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is November 6, 2019.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 2019 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF/TIER 4/NOT COVERED RECOMMENDATION—*** The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
  - alpelisib (Piqray) – Oncological Agent for breast cancer
  - amifampridine (Ruzurgi) – Miscellaneous Neurological Agent for Lambert-Eaton myasthenic syndrome (LEMS)
  - amphetamine sulfate orally disintegrating IR tablet (Evekeo ODT) – Attention Deficit Hyperactivity Disorder (ADHD)
  - dolutegravir/lamivudine (Dovato) – Single-tablet regimen (STR) antiretroviral for Human Immunodeficiency Virus (HIV)
  - erdafitinib (Balversa) – Oral Oncological Agent for urothelial cancer
  - halobetasol propionate 0.01%/tazarotene 0.045% lotion (Duobrii) – Combination product for Plaque Psoriasis
  - immunoglobulin subcutaneous injection (Cutaquig) – Immunoglobulin for Immune Deficiency Disorders
  - mepolizumab injection (Nucala) – Miscellaneous Pulmonary I Agent severe asthma and eosinophilic granulomatosis with polyangiitis (EGPA) *(note refers to self-administered syringe and auto-injector, not the vial)*
  - methylphenidate extended-release sprinkle capsules nighttime dosing (Jornay PM) – ADHD

        - tafamidis (Vyndaqel) – Miscellaneous Neurological Agents cardiomyopathy associated with hereditary transthyretin-mediated amyloidosis (ATTR-CM)
        - triclabendazole (Egaten) – Antiinfectives: Anthelmintics for fascioliasis
    - NF:
        - drospirenone (Slynd) – Progestogen-only contraceptive agent
        - galcanezumab-gnlm 100 mg injection (Emgality) – Migraine Agents: Calcitonin gene-related peptide (CGRP) inhibitors for cluster headache. *Note that the Emgality 120 mg injection formulation for prevention of migraine headache remains on the UF.*
        - risankizumab-rzaa injection (Skyrizi) – Targeted Immunomodulatory Biologic (TIB) for Plaque Psoriasis
        - rosuvastatin sprinkle capsules (Ezallor Sprinkle) – Antilipidemics-I
        - solriamfetol (Sunosi) –Wakefulness Promoting Agent
    - Tier 4 (Not Covered):
        - methylphenidate extended-release sprinkle capsules (Adhansia XR) – ADHD
            - Adhansia XR was recommended for Tier 4 status as it has very little to no additional clinical effectiveness relative to similar ADHD drugs; there is a significant safety risk due to its very long duration of action (particularly in children for insomnia and weight loss) relative to other ADHD drugs; and the needs of TRICARE beneficiaries are met by alternative agents.
                - Formulary methylphenidate ER alternatives to Adhansia XR include Aptensio XR sprinkle cap and Quillivant XR suspension for patients with swallowing difficulties; Concerta, generics; Ritalin LA, generics; Metadate CD, generics; dexmethylphenidate ER (Focalin XR, generics) and mixed amphetamine salts (Adderall XR, generics). (See Appendix H.)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Sunosi, Ezallor Sprinkle, Slynd, Skyrizi, and Emgality 100 mg injection. See Appendix B for the full criteria.

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

- ADHD: Applying manual PA criteria to new and current users of Jornay PM, requiring a trial of other clinically efficacious, safe, and cost-effective methylphenidate ER formulations with long durations of action first,

including branded products targeted for patients with swallowing difficulties (i.e., Quillivant XR suspension or Aptensio XR sprinkle capsule).

- TIBs: Applying the same manual PA criteria in new users of Skyrizi that is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally for Skyrizi a trial of both secukinumab (Stelara) and ustekinumab (Cosentyx) is required if the patient cannot be treated with Humira.
- Migraine Agents: CGRP Inhibitors for Cluster Headache: Manual PA criteria apply to the CGRP Inhibitors that are approved for prevention of migraine headache, including Emgality 120 mg injection. PA criteria will apply to new users of Emgality 100 mg syringe for cluster headache, requiring a trial of traditional preventive therapies, including verapamil, topiramate or lithium. Use of Emgality 100 mg will not be allowed for prevention of migraine headache.
- Applying manual PA criteria to new and current users of Sunosi and Nucala.
- Applying manual PA criteria to new users of Ruzurgi, Ezallor Sprinkle, Piqray, Balversa, Vyndaqel, and Evekeo ODT.

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

- **New Drugs Recommended for UF or NF Status:** an effective date upon two weeks after signing of the minutes in all points of service, on November 13, 2019.

- **New Drugs Recommended for Tier 4 Status methylphenidate extended-release capsules (Adhansia XR):** 1) an effective date of the first Wednesday after a 120-day implementation period at 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. Based on the P&T Committee's recommendation, the effective date is March 4, 2020.

VI. BCF CLARIFICATION: POTASSIUM CHLORIDE (KCl) PRODUCTS

The BCF currently includes several potassium chloride (KCl) formulations. The P&T Committee responded to an MTF request to delete KCl 20 mEq packets from the BCF, based on cost. A lower-cost alternative product, 20 mEq dispersible tablets (generic Klor-Con M20 tablets), which can be mixed with water to form a suspension, is currently on the BCF and commonly dispensed by the MTFs. A review of all the KCl BCF formulations found the

20 mEq packet and 20 mEq/15 mL (10%) liquid are significantly more costly than the other KCl formulations.

A. ***COMMITTEE ACTION: POTASSIUM CHLORIDE (KCl) PRODUCTS ON THE BCF—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing both the KCl 20 mEq packets (GCN 03404) and 20 mEq/15 mL (10%) liquid (GCN 03443) from the BCF. The KCl products remaining on the BCF are the 10 mEq ER tablets (generic K-Tab ER) (GCN 03510), 20 mEq dispersible tablets (generic Klor-Con M20) (GCN 03513), and 10 mEq ER caps (GCN 03321).

VII. UTILIZATION MANAGEMENT

A. PA Criteria and Step Therapy

1. New Manual PA Criteria—New manual PA criteria were recommended by the P&T Committee due to a variety of reasons. The new manual PAs outlined below will apply to new users for the oncology drugs Alecensa, Alunbrig, Zykadia, and Xalkori, the orthostatic hypotension product Northera and to new and current users for the prescription multivitamin Azesco and tetracycline product doxycycline hyclate ER 80 mg. See Appendix C for the full criteria of the drugs with new manual PA criteria.

a) Antibiotics: Tetracyclines – Doxycycline hyclate extended-release 80 mg – Oral tetracycline antibiotic for acne vulgaris or rosacea

PA criteria were recommended for this new 80 mg ER doxycycline hyclate available from a single manufacturer. The P&T Committee reviewed the oral tetracycline class in February 2017 and agreed there is little evidence to support advantages of the newer doxycycline products over the traditional generic formulations in terms of salt (monohydrate versus hyclate), dosage form (tablet versus capsule versus scored tablets), or release mechanisms (IR versus ER versus DR). Cost-effective generic formulations of doxycycline hyclate (i.e., 50 mg and 100 mg immediate release) are available on the UF without a PA required.

COMMITTEE ACTION: DOXYCYCLINE HYCLATE EXTENDED-RELEASE 80 MG MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of doxycycline hyclate ER 80 mg tablets. See Appendix C for the full criteria.

b) Oral Oncologic Agents: alectinib (Alecensa), brigatinib (Alunbrig), ceritinib (Zykadia), and crizotinib (Xalkori)

PA criteria have not previously been required for the non-small cell lung cancer (NSCLC) drugs; however, PA is in place for several oncological drug classes. The P&T Committee reviewed four oral oncologic agents, Alecensa, Alunbrig, Zykadia,

and Xalkori. PA criteria were recommended for these four products in new users in order to ensure prescribing in accordance with FDA-approved indications or National Comprehensive Cancer Network (NCCN) Guideline-endorsed off-label indications.

COMMITTEE ACTION: ALECTINIB (ALECENSA), BRIGATINIB (ALUNBRIG), CERITINIB (ZYKADIA), AND CRIZOTINIB (XALKORI) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users. See Appendix C for the full criteria.

c) Vitamins: Prenatal – Prenatal multivitamin (Azesco)

Azesco is a prenatal multivitamin manufactured by a single manufacturer and requires a prescription prior to dispensing. The primary ingredients of Azesco are 13 mg of iron and 1 mg of folic acid. Prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than age 45. This agent was identified as having numerous cost-effective alternatives (including Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA) that are available on the UF, where a PA is not required.

COMMITTEE ACTION: PRENATAL MULTIVITAMIN (AZESCO) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of Azesco, regardless of the woman's age. See Appendix C for the full criteria.

d) Cardiovascular Agents Miscellaneous: Droxidopa (Northera)

Droxidopa (Northera) is an alpha/beta agonist approved in February 2014 for neurogenic orthostatic hypotension (NOH). The product labeling for Northera contains a black box warning that it may cause or exacerbate supine hypertension. A consensus statement from the American Autonomic Society and the National Parkinson Foundation for NOH was published in 2017 and recommends treatments include midodrine, fludrocortisone, and pyridostigmine, in addition to droxidopa. No one pharmacologic treatment is preferred over another in the guidelines. PA criteria were recommended for Northera to ensure appropriate use of clinically and cost-effective alternative therapies for neurogenic orthostatic hypotension first.

COMMITTEE ACTION: DROXIDOPA (NORTHERA) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for droxidopa in new users. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria and Step Therapy**—Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications, pediatric uses, clinical trial data or to be consistent with existing PAs for the drug class. The updated manual PAs outlined below will apply to new users. See Appendix C for the full criteria of the drugs with updated manual PA criteria.

   a) Updated Criteria for reasons other than new FDA indications

   - Gastrointestinal-2 Agents: telotristat ethyl (Xermelo) – Manual PA criteria for Xermelo were first recommended in May 2017. Manual PA criteria for Xermelo were updated to reflect the TELECAST trial, which allowed for use in carcinoid syndrome diarrhea in persons having fewer than 4 bowel movements per day with or without concurrent somatostatin analog therapy.
   - Neurological Agents Miscellaneous: amifampridine (Firdapse) – Manual PA criteria for Firdapse for treating LEMS were first recommended in May 2019. Ruzurgi is another amifampridine formulation (see section V, A on page 10). Although the package labeling for Ruzurgi states it is approved for pediatric patients, the clinical trial used to gain FDA approval was conducted in adult patients with a mean age of 52 years, and the maximal dosing is higher with Ruzurgi than Firdapse (100 mg vs. 80 mg, respectively). Ruzurgi is cost-effective compared to Firdapse. Manual PA criteria for Firdapse were updated to require a trial of the cost-effective amifampridine agent Ruzurgi first in new patients.
   - Parkinson's Agents: levodopa inhalation powder (Inbrija) – Manual PA criteria for Inbrija were first recommended in May 2019. Manual PA criteria were updated to remove the 1-year expiration date and renewal criteria, as the other Parkinson's drugs have PAs that do not expire.

   b) New FDA-Approved Indications or Age Ranges

   - ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents: sodium oxybate (Xyrem) – Manual PA criteria were updated to reflect a new FDA-approved indication for use in children ≥ 7 years of age for the treatment of cataplexy in patients with narcolepsy.
   - Corticosteroids – Immune Modulators: Atopic Dermatitis: dupilumab (Dupixent) – Manual PA criteria were updated for the new indication for add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.
   - Cystic Fibrosis Agents: tezacaftor/ivacaftor (Symdeko) – Manual PA criteria were updated to reflect a new indication for treatment of patients ≥ 6 years of age in the treatment of cystic fibrosis.
   - Hematological agents: Platelets: avatrombopag (Doptelet) – Manual PA criteria were updated to reflect a new indication for thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

- Immunosuppressives: belimumab (Benlysta) – Manual PA criteria were updated to reflect a new indication for the treatment of patients as young as 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.
- Oncological Agents: Acute Myelogenous Leukemia: ivosidenib (Tibsovo) – Manual PA criteria were updated to reflect a new indication for the treatment of adult patients with newly diagnosed acute myelogenous leukemia (AML) who are aged 75 years and older or who have comorbidities that preclude use of intensive induction chemotherapy.
- Targeted Immunomodulatory Biologics (TIBs) – Non-Tumor Necrosis Factor (TNF) Inhibitors: apremilast (Otezla) – Manual PA criteria were updated to reflect a new indication for treatment of adult patients with oral ulcers associated with Behçet's disease. Note that for Behçet's disease, a trial of adalimumab (Humira) is not required first.
- Targeted Immunomodulatory Biologics (TIBs) – Tumor Necrosis Factor (TNF) Inhibitors: adalimumab (Humira) – Manual PA criteria for Humira were updated to allow for off-label use in pediatric patients for plaque psoriasis. In the European Union, Humira is approved in the pediatric population for plaque psoriasis, and data exists to support its use in this age group. Note that pediatric patients are not required to use the DoD's step-preferred Humira first for plaque psoriasis given that it is currently off-label in the United States.

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 Xyrem, Dupixent, Symdeko, Doptelet, Benlysta, Tibsovo, Otezla, Humira, Xermelo, Firdapse, and Inbrija. See Appendix C for the full criteria.

c) Weight Loss Agents—The P&T Committee was briefed on trends in the current utilization and spend for the weight loss agents, which were reviewed in November 2017. Generic phentermine is the most utilized weight loss agent, while liraglutide 3 mg injection (Saxenda) is the second most utilized weight loss agent, but ranks first in total cost per patient. A review of Saxenda claims data found that the majority of patients did not meet the criteria for a trial of other branded weight loss drugs first. The P&T Committee recommended updating the manual PA criteria for liraglutide 3 mg (Saxenda) to streamline the PA form and more closely reflect the original intent of the November 2017 P&T Committee meeting

A. ***COMMITTEE ACTION: LIRAGLUTIDE 3 MG (SAXENDA) MANUAL PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) updating the manual PA criteria for new and current users of Saxenda who do not have a diagnosis of diabetes. Affected patients will receive letters notifying them of this

decision. Previous trials of other weight loss drugs must be documented prior to use of Saxenda. See Appendix C for the full criteria.

B. COMMITTEE ACTION: LIRAGLUTIDE 3 MG (SAXENDA) PA IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date 60 days after the signing of the minutes in all points of service, on January 8, 2020.

B. Quantity Limits (QLs)

1. General QLs: QLs were reviewed for 28 drugs from several classes, including 8 newly approved drugs, 3 drugs where existing QLs were either updated or new QLs placed, and 17 nasal steroid inhalers for allergic rhinitis.

COMMITTEE ACTION: QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for Vyndaqel, Skyrizi, Balversa, Piqray, Emgality 100 mg syringe, Nucala, Ruzurgi, Sunosi, Northera, Lucemyra, Doptelet, and nasal steroids including Astepro, Atrovent 0.03%, Atrovent 0.03% 15 mL, Atrovent 0.06%, Beconase AQ, Qnasl 40 mcg and 80 mcg, Rhinocort Aqua, Dymista, flunisolide, Nasonex, Patanase, Omnaris, Zetonna, Nasacort AQ, Flonase, Veramyst, and Xhance. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

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

- (16 for, 0 opposed, 0 abstained, 1 absent) New PAs for Alecensa, Alunbrig, Zykadia, Xalkori, Azesco, Northera, and doxycycline hyclate ER 80 mg become effective 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for Azesco and doxycycline hyclate extended-release 80 mg if applicable, as new and current users will be subject to the PA.
- (15 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Firdapse, Xermelo, Inbrija, Xyrem, Symdeko, Benlysta, Otezla, Tibsovo, Dupixent, Doptelet, and Humira in new users become effective 30 days after the signing of the minutes.
- (16 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 28 drugs listed in section VI B above, and in Appendix D, become effective on the first Wednesday two weeks after the signing of the minutes in all POS.

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for 2 product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following 2 products to reflect the current formulary status and applicable step therapy, PA criteria, MN criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- Neurological Agents Miscellaneous: Movement Disorders – Valbenazine (Ingrezza) initiation pack is now available. Previously, Ingrezza was only available in 40 mg and 80 mg capsules. The P&T Committee recommended designating the Ingrezza initiation pack as UF with the same manual PA requirements as the Ingrezza capsules.

- Oncological Agents: Lung Cancer – Ceritinib (Zykadia) tablets are now available whereas they were previously available only in capsules. The P&T Committee recommended designating Zykadia tablets as UF with the same PA and QL requirements as the Zykadia capsules.

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

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

See Appendix F for the mail order status of medications designated UF, NF, or Tier 4/Not Covered during the August 2019 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 non-formulary to mail requirement. The implementation date for all of the recommendations from the August 2019 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 (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 1 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI program for the reasons outlined in the table. See Appendix F.

B. Drugs Selected for Removal from the Program

The P&T Committee reviewed the status of three products currently included on the EMMPI List: conjugated estrogens vaginal cream (Premarin cream), estradiol vaginal cream (Estrace), and leuprolide depot injection for 4-month administration (Lupron Depot 4-month kit). Dosing for all three of these drugs exceeds (Lupron Depot 4-month kit) or potentially may exceed (Premarin and Estrace creams) a duration of use longer than 30 days. Express Scripts maintains these agents on specialized adjudication lists that allow pharmacies to enter the correct days' supply; however, this logic conflicts with the 30-day-per-fill rule for the EMMPI program (which allows two 30-day fills at retail before the branded maintenance medications included on the EMMPI list must be filled at MTFs or Mail).

2. ***COMMITTEE ACTION: CHANGES TO THE EXPANDED MTF/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) removing conjugated estrogens (Premarin) cream, estradiol (Estrace) cream, and leuprolide depot injection for 4-month administration (Lupron Depot 4-month kit) from the EMMPI List.

X. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OVER-THE-COUNTER (OTC) FORMULARIES AT MTFS: TOPICAL CORTICOSTEROIDS AND TOPICAL ANTIFUNGALS

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 DoD P&T Committee meeting minutes, found at http://health.mil/PandT. Factors influencing whether a particular OTC product was retained or removed from the MHS GENESIS OTC List included such things as volume and utilization across multiple MTFs; feedback from MTF providers to include the Primary Care Clinical Communities, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

1) *OTC Topical Corticosteroids: hydrocortisone*

- The OTC topical steroids category includes only topical products, and not those intended for rectal use, which will be reviewed at a future meeting.
- The most commonly dispensed OTC hydrocortisone products at the MTFs were for the 1% cream and 1% ointment. The hydrocortisone 1% cream with aloe vera and 1% lotion were infrequently dispensed. Hydrocortisone 1% lotion is about 8 times more costly than the cream or ointment.
- There is relatively low utilization of OTC hydrocortisone 0.5% products, and feedback revealed that the 0.5% strength is seen as generally less effective or unnecessary compared to the 1% strength.
- Hydrocortisone cream, ointment, and lotion are also available in a 2.5% concentration as legend products, with hydrocortisone 2.5% cream accounting for the bulk of legend use at the MTFs.

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

- removing the following products from the MHS GENESIS OTC List: hydrocortisone 0.5% cream, lotion, and ointment; hydrocortisone 1% lotion; and hydrocortisone 1% cream with aloe vera;
- retaining hydrocortisone 1% cream (GCN 30942) and 1% ointment (GCN 30951) on the MHS GENESIS OTC list.
- The P&T Committee did not recommend adding or retaining any other OTC hydrocortisone product on the list.

B. COMMITTEE ACTION: IMPLEMENTATION—Removal of the above items from the MHS GENESIS OTC List is expected to have relatively little impact at the current GENESIS sites or the next wave sites expected to implement MHS GENESIS in September 2019 (Mountain Home, Lemoore, Monterey, and Travis). The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 120 days following signing of the minutes. Letters were not recommended due to the limited duration of use for these products.

2) *OTC Topical Antifungals*

- *Azole antifungals*
  - This category includes only topical OTC clotrimazole, miconazole, and ketoconazole products, with vaginal products to be reviewed by the P&T Committee at a later date.
  - Products in this category are most commonly used for cutaneous candidiasis; the non-azole antifungals appear more effective for tinea infections.
  - The most commonly dispensed OTC antifungals at the MTFs include clotrimazole 1% cream, miconazole 2% cream, clotrimazole 1% solution, miconazole 2% powder, miconazole 2% tincture, and miconazole 2% aerosolized powder.
  - OTC ketoconazole 1% shampoo was not dispensed at the MTFs, in contrast to the prescription 2% concentration, which had a significant amount of use.
- *Non-azole antifungals*
  - The majority of MTF utilization of the OTC non-azole antifungals included terbinafine 1% cream and tolnaftate 1% powder. There was relatively little use of tolnaftate 1% cream, OTC butenafine 1% cream, and tolnaftate 1% solution.
  - MTF feedback indicated a preference for terbinafine (when a preference was expressed), with several respondents expressing support for a powder formulation (i.e., tolnaftate powder). Tolnaftate 1% powder is less costly on a per package basis, relative to terbinafine 1% cream.
- *Gentian violet*

- Gentian violet is an antiseptic dye with antifungal and weak antibacterial effects; it can be used on minor cuts and scrapes to prevent infection. It also may be used for *tinea corporis* and oral candidiasis, but it is not the preferred treatment for either condition.
- There may be a potential association of gentian violet with cancer development, but supporting data are sparse and primarily based on studies in rats and mice. There is also some evidence suggesting potential efficacy of gentian violet as an anti-cancer agent.
- MTF feedback indicated that it is used primarily as a back-up if nystatin suspension is unavailable and that overall Gentian violet is rarely used.

- *Need for provider group feedback*–Having feedback from a wider community of providers is desirable when changes are recommended to the OTC MHS GENESIS test list. The P&T Committee requested that input from the relevant clinical communities of MTF providers established under DHA be routinely sought.

A. *COMMITTEE ACTION: STATUS OF TOPICAL ANTIFUNGALS ON THE MHS GENESIS OTC LIST*—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- removing clotrimazole 1% solution; miconazole 2% cream, powder, aerosolized powder, and tincture;
- removing tolnaftate 1% cream;
- removing gentian violet 1% and 2% solution; and
- retaining clotrimazole 1% cream (GCN 30370), terbinafine 1% cream (GCN 62498), and tolnaftate 1% powder (GCN 30310) on the MHS GENESIS OTC List.
- The P&T Committee did not recommend adding or retaining any other OTC antifungal product on the list.

B. *COMMITTEE ACTION: IMPLEMENTATION*—Removal of the above OTC antifungals from the MHS GENESIS OTC List is expected to have relatively little impact at the current GENESIS sites or the next wave sites expected to implement MHS GENESIS in September 2019 (Mountain Home, Lemoore, Monterey, and Travis). The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 120 days following signing of the minutes. Letters were not recommended due to the limited duration of use for these products.

Note that the Primary Care Clinical Communities that serve to advise DHA on various matters that affect providers and the patients served by those providers provided feedback that concurred with the conclusions of the P&T Committee.

XI. 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.

The cost of branded specialty medications is typically higher at retail pharmacies than at MTFs or Mail Order; however, availability of specialty medications at Mail Order depends on a number of factors, including manufacturer access programs (e.g., limited distribution agreements), drug safety program requirements, and prime vendor availability. In some cases, Express Scripts is able to work with manufacturers and the prime vendor to establish mail order availability for specialty products.

Drugs Added to the Specialty Care Program

Oral Oncologic Agents for Non-Small Cell Lung Cancer: alectinib (Alecensa) —The P&T Committee reviewed alectinib (Alecensa), an oral medication for advanced non-small cell lung cancer, for addition to the EMMPI and Specialty Care programs. Alectinib is both feasible to provide at Mail Order according to Express Scripts and more costly to provide at retail than at MTFs or Mail Order. Adding a drug to the Specialty Care Program provides additional clinical services and ensures an expedited and scheduled delivery. The P&T Committee requested that the impact of adding alectinib to the two programs should be monitored by Express Scripts for review by the P&T Committee, prior to considering further additions to the program.

A. ***COMMITTEE ACTION: SPECIALTY CARE DRUG LIST***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) adding alectinib (Alecensa) to the Specialty Care Drug List and the EMMPI program, with implementation as soon as feasible following signing of the minutes. No specific letters are necessary since, under the EMMPI program, beneficiaries filling prescriptions for alectinib at retail will receive letters following each of

their next two retail prescription fills. Beneficiaries will also receive an introductory mailing from the Specialty Care program.

Note that Plegridy was also added to the Specialty Care Drug List (see p. 9).

XII. ITEMS FOR INFORMATION

A. Prior Authorization, Step Therapy, and Utilization Management Effects

The P&T Committee was briefed on the effects of previous drug class formulary recommendations, including step therapy, prior authorization requirements, and QLs, on utilization and cost patterns in the MHS.

XIII. ADJOURNMENT

The meeting adjourned at 1600 hours on August 8, 2019. The next meeting will be in November 2019.

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

30 OCT 19
Date

Appendix A—Attendance: August 2019 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Mr. David Bobb	Chief, DHA Pharmacy Operations Division (POD)
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder) POD
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Peter Cole, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
LCDR Christopher Janik, USCG for CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Col Melissa Howard, BSC	Air Force, 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
Kelly Echevarria, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Erik Troff	DHA, Deputy General Counsel
Lt Col Derek Underhill, BSC	DLA Troop Support
Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Ms. Kimberlymae Wood	DHA Contracting Office
Mr. James Berns	Chief, DHA Contracting Office
Ms. Viktoria Reed	DHA Contracting
CAPT Chris Lamer	Indian Health Service
Maj Rachel Copeland, BSC	Director of Pharmacy, Lackland AFB

Appendix A—Attendance (continued)

Guests Continued	
LCDR Garret Hand, MSC	NAS Corpus Christi
MAJ Allison Sternberg, MSC	Chief, Pharmacy Branch, Ft Sam Houston
CDR Marisol Martinez	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program
Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
MAJ Matthew Krull	DHA Formulary 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. Cortney Raymond	DHA Formulary Management Branch Contractor
LT Danielle Kerr	Naval Medical Center San Diego Pharmacy Resident
Alana Coleman	University of Texas at Austin Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• amcinonide 0.1% ointment • diflorasone diacetate 0.05% ointment **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** betamethasone dipropionate 0.05%, betamethasone/propylene glycol 0.05%, clobetasol propionate 0.05%, desoximetasone 0.25%, fluocinonide 0.05%, halobetasol propionate 0.05% ointments
• clobetasol propionate/emollient 0.05% foam • desoximetasone 0.05% gel **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** fluocinonide 0.05% solution and gel, clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo, betamethasone/propylene glycol 0.05% lotion, betamethasone dipropionate 0.05% gel, and clobetasol propionate/emollient 0.05% (emulsion) foam
• diflorasone diacetate 0.05% cream • fluocinonide 0.1% cream • halobetasol propionate 0.05% cream **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** betamethasone/propylene glycol 0.05%, clobetasol propionate 0.05%, clobetasol propionate/emollient 0.05%, desoximetasone 0.25%, fluocinonide 0.05%, and fluocinonide/emollient base 0.05% creams
• flurandrenolide 4 mcg/sq. cm (Cordran) tape **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** fluocinonide 0.05% ointment, solution, and gel, clobetasol propionate 0.05% ointment, cream, solution, lotion, gel, foam, spray, and shampoo, betamethasone/propylene glycol 0.05% ointment, cream, and lotion, betamethasone dipropionate 0.05% ointment and gel, clobetasol propionate/emollient 0.05% (emulsion) foam, clobetasol propionate/emollient 0.05% cream, desoximetasone 0.25% ointment and cream, fluocinonide/emollient 0.05% cream, and halobetasol propionate 0.05% ointment
• Peginterferon beta-1a (Plegridy) **Multiple Sclerosis: Injectable – Interferons**	• No alternative formulary agent: patient requires Plegridy and cannot be treated with Avonex or Rebif. **Formulary Alternatives:** interferon beta-1a (Rebif), interferon beta-1a (Avonex), Copaxone, Betaseron, Extavia, and the oral agents
• drospirenone (Slynd) **Contraceptive Agents: Progestogen-Only**	• Patient has experienced significant adverse effects from formulary agent **Formulary Alternative:** norethindrone (Nor-QD, Jolivette, generics)
• galcanezumab-gnlm injection (Emgality 100 mg) **Migraine Agents: CGRP Cluster Headache**	• Other drugs for cluster headache have resulted in therapeutic failure **Formulary Alternatives:** verapamil, topiramate, lithium

Drug / Drug Class	Medical Necessity Criteria
• risankizumab-rzaa injection (Skyrizi) **TIBs**	• Use of adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) is contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) • Adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) result or are likely to result in therapeutic failure. **Formulary Alternative:** Adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara)
• rosuvastatin sprinkle (Ezallor Sprinkle) **Antilipidemics-1**	• No alternative formulary agent: Patient requires simvastatin, atorvastatin, or rosuvastatin and cannot swallow tablets **Formulary alternatives:** rosuvastatin, simvastatin, atorvastatin
• solriamfetol (Sunosi) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	• Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure **Formulary Alternatives:** armodafinil, modafinil, methylphenidate, amphetamine

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• amcinonide 0.1% ointment • diflorasone diacetate 0.05% ointment **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of amcinonide 0.1% ointment and diflorasone diacetate 0.05% ointment. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives, including clobetasol propionate 0.05% and fluocinonide 0.05% ointments. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to fluocinonide 0.05% AND desoximetasone 0.25% AND betamethasone dipropionate 0.05% ointments. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time
• clobetasol propionate/emollient 0.05% foam **High-Potency Topical Corticosteroids**	PA apply to all new and current users of clobetasol propionate/emollient 0.05% foam. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives, including fluocinonide 0.05% solution and clobetasol propionate 0.05% solution. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to clobetasol propionate 0.05% solution, lotion, gel, AND foam. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time
• desoximetasone 0.05% gel **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of desoximetasone 0.05% gel. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives including fluocinonide 0.05% solution and clobetasol propionate 0.05% solution. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to fluocinonide 0.05% solution AND gel. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days. No PA renewals allowed; patients must fill out a new PA each time
• diflorasone diacetate 0.05% cream **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of diflorasone diacetate 0.05% cream. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives, including fluocinonide 0.05% and betamethasone/propylene glycol 0.05% creams. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to fluocinonide 0.05% AND betamethasone/propylene glycol (augmented) 0.05% AND desoximetasone 0.25% creams. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time

Drug / Drug Class	Prior Authorization Criteria
• flurandrenolide 4 mcg/sq. cm (Cordran) tape **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of Cordran tape. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • Written by a dermatologist or plastic surgeon • The provider acknowledges that this agent has been identified as having cost-effective alternatives, including clobetasol propionate 0.05% ointment and fluocinonide 0.05% cream and solution. These agents do not require a PA. • The provider acknowledges that barrier function can be accomplished by using an alternative agent (e.g., fluocinonide 0.05% cream) with an occlusive dressing. Please note occlusion increases transmission (i.e., potency); a lower potency agent should be used as an alternative to flurandrenolide tape if used with a barrier. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to clobetasol propionate 0.05% ointment OR halobetasol propionate 0.05% ointment OR betamethasone dipropionate 0.05% ointment. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time
• dimethyl fumarate (Tecfidera) **Multiple Sclerosis: Methyl Fumarate**	**Changes from August 2019 are in BOLD** Manual PA criteria apply to new users of Tecfidera. Manual PA Criteria: Coverage approved for patients with: • Documented diagnosis of relapsing forms of multiple sclerosis (MS). • 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 **Non-FDA-approved uses are not approved.** PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• alpelisib (Piqray) **Oncological Agents: Breast Cancer**	Manual PA is required for all new users of Piqray. Manual PA Criteria: Piqray is approved if all criteria are met: • Patient must be ≥18 years. • Patient is diagnosed with advanced or metastatic HR positive, HER2 negative breast cancer with PIK3CA mutation as confirmed by an FDA-approved test. • Drug is prescribed by, or in consultation with, an oncologist/hematologist. • Female patients are post-menopausal, or if pre-menopausal, they are receiving ovarian ablation/suppression. • Female patients of reproductive potential will use effective contraception during therapy and for one week after the last dose. • Patient has tried and failed, or is not a candidate for, adjuvant or neoadjuvant chemotherapy. • Patient has had disease progression while on or after endocrine-based therapy. • Patient will receive fulvestrant injection (Faslodex) therapy along with alpelisib (Piqray). • Patient has no history of Stevens Johnson Syndrome, Erythema Multiforme, or Toxic Epidermal Necrolysis. • Provider is aware and has informed patient of risk of serious, life-threatening skin reactions, including Stevens Johnson Syndrome; severe hyperglycemia; gastrointestinal toxicity, including severe diarrhea; kidney injury; lung injury including pneumonitis; pancreatitis; and severe hypersensitivity reactions. • Provider is aware and has informed patient that safety has not been established in type 1 or uncontrolled type 2 diabetic patients. • Male patients with female partners of reproductive potential should use condoms and effective contraception during therapy and for one week after last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis:_____ Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• amifampridine (Ruzurgi) **Neurological Agents Miscellaneous**	Manual PA is required for all new users of Ruzurgi. Manual PA Criteria: Ruzurgi is approved if all criteria are met: • Patient has Lambert-Eaton myasthenic syndrome (LEMS) Non-FDA-approved uses other than LEMS in adults are not approved. PA does not expire.
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	**Updates from the August 2019 meeting are in bold.** Manual PA applies to all new users of Firdapse. Manual PA Criteria: Firdapse is approved if: • **Provider acknowledges that amifampridine (Ruzurgi) is a cost-effective alternative to Firdapse and is the preferred amifampridine agent. The provider should consider writing a new prescription for Ruzurgi.** • Age ≥ 18 years old • Firdapse is prescribed by an oncologist or neurologist • The patient has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS) • **The patient must try amifampridine (Ruzurgi) first** Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT) **ADHD-Wakefulness Promoting Agents: Stimulants**	Manual PA is required for all new users of Evekeo ODT. Manual PA Criteria: Evekeo ODT is approved if ALL criteria are met: • Patient is 6-17 years of age with 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 tabs (generic) • Patient has tried for at least two months and failed or the patient has a contraindication to IR methylphenidate tablets or solution Non-FDA-approved uses are not approved. PA does not expire.
• erdafitinib (Balversa) **Oncological Agents**	Manual PA criteria apply to all new uses of Balversa. Manual PA Criteria: Erdafitinib (Balversa) is approved if all criteria are met: • Age ≥ 18 • Patient has locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR3 or FGFR2 mutation confirmed with an FDA-approved test • The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy) • Prescribed by or in consultation with an oncologist • The patient will be evaluated by an ophthalmologist before starting treatment and every month for the first 4 months; every 3 months thereafter • The patient will be advised to seek emergent evaluation for new ocular symptoms • The patient will be monitored for hyperphosphatemia. (Note that 33% of patients required a phosphate binder in the trial supporting FDA approval for erdafitinib) • If the patient is female, she is not pregnant or planning to become pregnant. • Female patients will not breastfeed. • All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• galcanezumab-gnlm 100 mg injection (Emgality) **Migraine Agents: CGRP Cluster Headache**	Note that this PA applies to the Emgality 100 mg cluster headache formulation. The Emgality 120 mg migraine prophylaxis indication PA criteria is on a separate form. Manual PA criteria apply to all new users of Emgality for episodic cluster headaches. Manual PA Criteria: Emgality 100 mg at a dosage of 300 mg/month is approved if all criteria are met: • Patient ≥ 18 years old and not pregnant • The drug must be prescribed by or in consultation with a neurologist • Patient has a diagnosis of episodic cluster headaches • Patient has a contraindication to, intolerability to, or has failed an adequate trial of: – Verapamil, topiramate, or lithium • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Emgality 120 mg, Ajovy) is not allowed Non-FDA-approved uses, including for migraine prophylaxis, chronic cluster headache, medication overuse headache, etc., are not approved. PA expires after 6 months. Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if there is a clinically appropriate reduction in weekly attacks (≥ 50% reduction in weekly cluster headache attack frequency) during an episode as reported by the patient.
• mepolizumab injection (syringe and autoinjector) (Nucala) **Pulmonary-1 Agents: Pulmonary Miscellaneous**	Manual PA is required for all new and current users of Nucala. Manual PA Criteria: Nucala is approved if all criteria are met: For eosinophilic asthma: • The patient has a diagnosis of severe persistent eosinophilic asthma • Patient must be ≥ 12 years • The drug is prescribed by an allergist, immunologist, or pulmonologist • Patient has an eosinophilic phenotype asthma as defined as either • blood eosinophil count of > 150 cells/mcL within the past month while on oral corticosteroids OR • ≥ 300 cells/mcL within the past year • The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen, with uncontrolled asthma defined as • Hospitalization for asthma in the past year OR • Required course of oral corticosteroids twice in the past year OR • Daily high-dose inhaled corticosteroid (ICS) with inability to taper off the ICS • The patient has tried and failed an adequate course (3 months) of at least two of the following while using a high-dose inhaled corticosteroid: • Inhaled long-acting beta agonist (LABA) (e.g., Serevent, Striverdi), long-acting muscarinic antagonist (LAMA) (e.g., Spiriva, Incruse), leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) For eosinophilic granulomatosis with polyangiitis (EGPA): • Patient must have diagnosis of EGPA • The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist, or hematologist • Patient must be ≥ 18 years • The patient has had an adequate trial of at least 3 months of one of the following with either an inadequate response to therapy or significant side effects/toxicity or the patient has a contraindication to therapy with • Corticosteroids, cyclophosphamide, azathioprine, or methotrexate • An quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication only Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• methylphenidate extended-release capsules nighttime dosing (Jornay PM) **ADHD-Wakefulness Promoting Agents: Stimulants**	Manual PA is required for all new and current users of Jornay PM. Manual PA Criteria: Jornay PM is approved if all criteria are met: • Patient is 6 years and older with a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record • The patient must have tried for at least two months and failed Concerta (generic) or have difficulty swallowing pills • The patient must have tried for at least two months and failed another long-acting methylphenidate (Methylphenidate ER/CD/LA, Quillivant XR, Aptensio XR) • The patient must have tried for at least two months and failed or have a contraindication to Adderall XR (generic) • Must have tried for at least two months an immediate release formulation methylphenidate product in conjunction with Concerta or another long-acting methylphenidate • Please explain why the patient needs Jornay PM. Non-FDA-approved uses are not approved. PA does not expire.
• risankizumab-rzaa injection (Skyrizi) **TIBs: Non-Tumor Necrosis Factor Inhibitors**	PA criteria apply to all new users of Skyrizi. The patient must have tried Humira, Stelara, and Cosentyx. Manual PA Criteria: Skyrizi is approved if ALL criteria are met: • The patient has a contraindication or has had an inadequate response to Humira, Cosentyx, AND Stelara OR • The patient has had an adverse reaction to Humira, Cosentyx, AND Stelara that is not expected with the requested non-step-preferred TIB AND • Patient ≥ 18 years old • The patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy • Patient has tried and had an inadequate response to non-biologic systemic therapy (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) • Coverage NOT provided for concomitant use with other TIBs • The patient has had a negative TB test result in past 12 months (or TB is adequately managed) Non-FDA-approved uses are not approved. PA does not expire.
• rosuvastatin sprinkle capsules (Ezallor Sprinkle) **Antilipidemics-1**	**PA does not apply to patients 12 years of age and younger (age edit)** PA criteria apply to all new users of Ezallor Sprinkle older than 12 years of age. Manual PA Criteria: Ezallor Sprinkle is approved if all criteria are met: • Provider must explain why the patient requires rosuvastatin sprinkle capsules and cannot take simvastatin, atorvastatin, OR rosuvastatin tablets. Non-FDA-approved uses are not approved. PA does not expire.

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

Drug / Drug Class	Prior Authorization Criteria
• tafamidis meglumine (Vyndaqel) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Vyndaqel. Manual PA Criteria: Tafamidis (Vyndaqel) is approved if all criteria are met: • Age ≥ 18 • Patient has a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis • Prescribed by or in consultation with a specialist who manages hereditary transthyretin amyloidosis (e.g., cardiologist, geneticist, neurologist) • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed • Female patients of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose Non-FDA-approved uses (other than ATTR disease manifestations) are not approved. PA does not expire.
• alectinib (Alecensa) • brigatinib (Alunbrig) • ceritinib (Zykadia) **Oncological Agents: Lung Cancer**	Manual PA applies to new users of Alecensa, Alunbrig, and Zykadia. Manual PA Criteria: Alecensa, Alunbrig, or Zykadia is approved if all criteria are met: • The patient has *metastatic* anaplastic lymphoma kinase (*ALK*)-positive NSCLC as detected by an FDA-approved test AND ▪ The drug is prescribed by or in consultation with a hematologist/oncologist OR ▪ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• crizotinib (Xalkori) **Oncological Agents: Lung Cancer**	Manual PA applies to new users of Xalkori. Manual PA Criteria: Xalkori is approved if all criteria are met: • Patient has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an FDA-approved test OR • Patient has NSCLC with ROS1 rearrangement AND ▪ The drug is prescribed by or in consultation with a hematologist/oncologist OR ▪ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• doxycycline hyclate extended-release 80 mg **Antibiotics: Tetracyclines**	Manual PA applies to new and current users of doxycycline hyclate extended-release 80 mg. Note: Generic doxycycline hyclate immediate-release (IR) 50 mg and 100 mg tablets and capsules are available without a PA; providers are encouraged to consider changing the prescription to generic IR doxycycline hyclate 50 mg or 100 mg tablets or capsules. Manual PA Criteria: doxycycline hyclate extended-release 80 mg is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this drug is required as opposed to available alternatives._____ Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• droxidopa (Northera) **Cardiovascular Agents Miscellaneous**	Manual PA applies to new users of Northera. <u>Manual PA Criteria:</u> Northera is approved if all criteria are met: • Patient is ≥ 18 years of age • Patient has been diagnosed with symptomatic Neurogenic Orthostatic Hypotension (NOH) due to primary autonomic failure (Parkinson's disease [PD], multiple system atrophy [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy • The drug is prescribed by or in consultation with a cardiologist or a neurologist • The patient has tried two other medications (e.g., fludrocortisone, pyridostigmine, or midodrine) and failed to respond to therapy • Patient has initiated non-pharmacological measures including but not limited to elevation of the head of the bed, orthostatic compression garments, increased salt intake, and appropriate physical training Non-FDA-approved uses are not approved. PA does not expire.
• prenatal multivitamin (Azesco) **Vitamins: Prenatal**	Manual PA applies to new and current users of Azesco, regardless of the woman's age. Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA are all available without a PA. Providers are encouraged to consider changing the prescription to Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin + Low Iron, or Prenatal Plus DHA. <u>Manual PA Criteria:</u> Azesco is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this drug is required as opposed to available alternatives._____ Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors**	**<u>Updates from the August 2019 meeting are in bold.</u>** Manual PA criteria apply to all new users of Humira. <u>Manual PA Criteria</u>: Coverage is approved for Humira if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy. • Moderate to severely active Crohn's disease (CD). • Moderate to severely active ulcerative colitis (UC). • Moderate to severe hidradenitis suppurativa (HS). • Non-infectious intermediate, posterior, and panuveitis. • Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation. Coverage approved for pediatric patients ≥ 6 years with: • Moderate to severely active Crohn's disease. Coverage approved for pediatric patients ≥ 12 years with: • Moderate to severe hidradenitis suppurativa (HS) **Coverage approved for pediatric patients 4-17 years with:** • **Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate** Coverage approved for pediatric patients 2-17 years with: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA). • Non-infectious intermediate, posterior, and panuveitis. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? (applies to adults for all indications except for ophthalmic uses, and applies for pediatric patients with plaque psoriasis or Crohn's disease) • AS only: Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Coverage for non-FDA-approved uses not listed above. Please provide diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Drug / Drug Class	Prior Authorization Criteria
• apremilast (Otezla) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**<u>Updates from the August 2019 meeting are in bold.</u>** Step therapy and manual PA criteria apply to all new users of Otezla. <u>Automated PA Criteria</u>: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria</u>: If automated criteria are not met, coverage is approved for Otezla if: • Contraindications exist to Humira. • Inadequate response to Humira. • Adverse reactions to Humira not expected with requested non-step-preferred TIB. AND Coverage approved for patients ≥ 18 years with: • **Oral ulcers associated with Behçet's disease (Please note: A trial of Humira first is not required for Behçet's disease.)** • Active psoriatic arthritis (PsA). • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR? • If yes: Fill in the blank write-in referencing literature to support combination, and patient will be monitored closely for adverse effects. Has the patient had an inadequate response to non-biologic systemic therapy? (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? Patient has negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**<u>Updates from the August 2019 meeting are in bold.</u>** Manual PA criteria apply to all new users of Doptelet. <u>Manual PA Criteria</u>: Avatrombopag (Doptelet) is approved if all criteria are met: **Patients with chronic liver disease who are scheduled to undergo a procedure** • Age ≥ 18 • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 10^9/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • Prescribed by or in consultation with a gastroenterologist **Or** **<u>Chronic immune thrombocytopenia (ITP)</u>** • **Age <u>></u> 18** • **The patient has a diagnosis of chronic immune thrombocytopenia (ITP) and has had an insignificant response to previous therapy** • **The patient has tried and failed or has a contraindication to Nplate or Promacta OR** • **The patient is anticipated to have an adverse effect to both Nplate and Promacta that would not be anticipated with avatrombopag (Doptelet)** • **The drug is prescribed by or in consultation with a hematologist/oncologist** • **Doptelet is not being used concomitantly with other chronic ITP therapy** Non-FDA-approved uses are not approved. For thrombocytopenia associated with liver disease: PA expires in 60 days. **For ITP: PA does not expire.**

• dupilumab (Dupixent)
 	
Corticosteroids – Immune Modulators: Atopic Dermatitis
	<u>Updates from the August 2019 meeting are in bold.</u>
	
	Manual PA criteria apply to all new users of Dupixent.
	
	<u>Manual PA Criteria:</u> Coverage will be approved for initial therapy for 6 months if all criteria are met:
	Atopic Dermatitis
	• Patient has moderate to severe or uncontrolled atopic dermatitis
	• Patient must be 12 years of age or older
	• Prescribed by a dermatologist, allergist, or immunologist
	• Patient has a contraindication to, intolerability to, or failed treatment with at least ONE high potency/class 1 topical corticosteroid
	• Patient has a contraindication to, intolerability to, or failed treatment with at least ONE systemic immunosuppressant
	• Patient has a contraindication to, intolerability to, inability to access treatment, or failed treatment with Narrowband UVB phototherapy
	OR
	Asthma
	• Patient has moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma
	• Patient must be 12 years of age or older
	• Prescribed by a pulmonologist, asthma specialist, allergist, or immunologist
	• Patient has baseline eosinophils ≥ 150 cells/mcL
	• 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
	• Will not be used for relief of acute bronchospasm or status asthmaticus
	• Dupixent will be only used as add-on therapy to other asthma controller medications
	OR
	Chronic rhinosinusitis with nasal polyposis
	• **Patient has chronic rhinosinusitis with nasal polyposis and is refractory to treatment with other therapies**
	• **Patient must be 18 years of age or older**
	• **Written by or in consultation with an allergist, immunologist, pulmonologist, or otolaryngologist**
	• **Nasal polyposis is confirmed by imaging or direct visualization**
	• **Dupixent will only be used as <u>add-on</u> therapy**
	• **The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following maximized treatments**
	  • **Adequate duration of at least two different high-dose intranasal corticosteroids AND**
	  • **Nasal saline irrigation AND**
	  • **The patient has failed 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**
	• **Patient is not currently taking any other type-2 allergic immunobiologics (mepolizumab, omalizumab, etc.)**
	• **Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength**
	
	Non-FDA-approved uses are not approved.
	PA expires after 6 months.
	
	<u>Renewal PA Criteria:</u> Coverage will be approved indefinitely for continuation of therapy if:
	1. Atopic Dermatitis: The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1)
	2. Asthma: The patient has had a positive response to therapy with a decrease in exacerbations, improvements in FEV_1, or decrease in oral corticosteroid use.

Drug / Drug Class	Prior Authorization Criteria
	3. Chronic rhinosinusitis with nasal polyposis : Evidence of effectiveness as documented by decrease in nasal polyps score (NPS) or nasal congestion score (NC)
• ivosidenib (Tibsovo) **Oncological Agents: Acute Myelogenous Leukemia**	**<u>Updates from the August 2019 meeting are in bold.</u>** Manual PA criteria apply to all new users of Tibsovo. <u>Manual PA Criteria</u>: Tibsovo is approved if all criteria are met: • Patient ≥ 18 years old • ~~Has laboratory evidence of relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test~~ • **Patient has a diagnosis of acute myeloid leukemia with a susceptible IDH1 mutation as detected by an FDA-approved test** ▪ **Patient has relapsed or refractory acute myeloid leukemia OR** ▪ **Patient has newly diagnosed AML and is aged 75 years and older or who has comorbidities that preclude use of intensive induction chemotherapy OR** ▪ **The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.** • The patient will be monitored for differentiation syndrome • The patient will be monitored for Guillain-Barre syndrome • Prescribed by or in consultation with a hematologist/oncologist **Other** non-FDA-approved uses, please cite supporting literature. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	**<u>Updates from the August 2019 meeting are in bold</u>** Manual PA criteria apply to all new and current users of Saxenda. <u>Manual PA Criteria</u>—Saxenda is approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • **Patient has tried and failed all 5 weight loss medications (generic phentermine, Qsymia, Xenical, Contrave, and Belviq or Belviq XR) or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** • **Phentermine: Date_____ Duration of therapy _____** • **Qsymia: Date_____ Duration of therapy _____** • **Xenical: Date _____ Duration of therapy _____** • **Contrave: Date _____ Duration of therapy _____** • **Belviq/Belviq XR: Date _____ Duration of therapy _____** • If the patient is diabetic, they must have tried and failed metformin and the preferred GLP1-RAs (Bydureon **and Trulicity**) • Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, **Trulicity**, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy AND will remain engaged throughout course of therapy. • Patient is not pregnant. Non-FDA-approved uses are not approved, including Diabetes Mellitus. Prior authorization expires after 4 months and then annually. <u>Renewal PA Criteria:</u> Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.

Drug / Drug Class	Prior Authorization Criteria
• sodium oxybate (Xyrem) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	**Updates from the August 2019 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Xyrem. Manual PA Criteria: Coverage of Xyrem is approved if the following criteria are met: • **Patient is 18 years of age** AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND • The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) **OR** • **Patient is child ≥ 7 years AND** • **The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND** • **Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND** • **Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.** ▪ **Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR** • **Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND** ▪ **The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND** • **Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders)** Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy. PA expires after 1 year**. Renewal not allowed; patient must fill out a new PA.** ~~PA Renewal criteria: Xyrem will be renewed on a yearly basis if:~~ • ~~There is documentation demonstrating the patient has had a reduction in frequency of cataplexy attacks associated with Xyrem therapy OR~~ • ~~There is documentation demonstrating the patient has had a reduction in the symptoms of excessive daytime sleepiness associated with Xyrem therapy AND~~ • ~~Patient is not receiving a concomitant CNS depressant~~

Drug / Drug Class	Prior Authorization Criteria
• telotristat ethyl (Xermelo) **Gastrointestinal-2 Agents**	**Updates from the August 2019 meeting are in bold.** Manual PA criteria apply to all new users of Xermelo. Manual PA Criteria: Coverage approved for one year if all criteria are met: • Patient has diagnosis of carcinoid syndrome diarrhea. • Patient has had an inadequate treatment response to at least a 3-month trial of somatostatin analog (SSA) therapy. • Telotristat must be used in combination with an SSA (i.e., octreotide or lanreotide). • Patient has > 4 bowel movements daily **or** • **Patient has < 4 bowel movements/day while receiving somatostatin analogs (SSAs) or patient has ≥ 1 symptom or ≥ 4 bowel movements/day if not receiving concurrent SSAs** **Non-FDA-approved** uses are not approved. PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Xermelo will be approved when a) used in combination with a somatostatin analog, b) decrease from baseline in amount of average daily bowel movements, c) prescriber agrees to continue to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops, d) no severe constipation or abdominal pain develops. • Renewal PA criteria is limited to one year.
• tezacaftor/ivacaftor (Symdeko) **Cystic Fibrosis Agents**	**Updates from the August 2019 meeting are in bold and strikethrough.** Manual PA criteria apply to new users of Symdeko. Manual PA Criteria—Symdeko is approved if ALL of the following criteria are met: • Symdeko is prescribed for the treatment of cystic fibrosis ~~in patient ages 12 years and older.~~ **The patient's age is appropriate according to the FDA-approved indication for Symdeko. AND** • The patient meets the following criteria: a. The patient is homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test. OR b. The patient has at least one specific gene mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Symdeko as detected by an FDA-approved CF mutation test. AND c. Please enter the CF-related gene mutation based on FDA-approved testing. (write in below): _____ • Symdeko is not approved for use in combination with other CFTR modulators (e.g., Orkambi, Kalydeko). Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• alpelisib (Piqray) **Oncological Agents: Breast Cancer**	▪ Retail/MTF/Mail: 28-day supply at all POS, due to packaging
• amifampridine (Ruzurgi) **Neurological Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply at all POS
• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**August 2019 updates are in BOLD.** **For Idiopathic Thrombocytopenia (ITP):** ▪ **30-day supply** at Mail/MTF/Retail
• droxidopa (Northera) **Cardiovascular Agents Miscellaneous**	▪ Retail/MTF/Mail: 180 capsules per fill at all POS
• erdafitinib (Balversa) **Oncological Agents**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• galcanezumab-gnlm (Emgality) 100 mg injection **Migraine Agents: CGRP Cluster**	▪ Retail: 1 package (3 syringes) per fill ▪ MTF/Mail: 3 packages (9 syringes) per fill
• lofexidine (Lucemyra) **Narcotic Analgesics and Combinations**	**August 2019 updates are in BOLD.** ▪ Retail/MTF/Mail: **108 tablets per fill at all POS**
• mepolizumab injection (Nucala) **Pulmonary-1 Agents: Pulmonary Miscellaneous**	For asthma ▪ Retail: 1 syringe per fill ▪ MTF/Mail: 3 syringes per fill For EGPA ▪ Quantity limit overrides for the 300 mg EGPA dose are provided for in the Prior Authorization
• risankizumab-rzaa (Skyrizi) **TIBs**	▪ Retail: 30-day supply ▪ MTF/Mail: 90-day supply to allow for loading doses at initiation, 4 weeks, and 12 weeks
• solriamfetol (Sunosi) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	▪ Retail/MTF/Mail: 30 tablets per fill at all POS
• Tafamidis (Vyndaqel) **Neurological Agents Miscellaneous**	▪ Retail/MTF/Mail: 30-day supply all POS

Drug / Drug Class	Quantity Limits
• azelastine and fluticasone nasal (Dymista) **Nasal Allergy Agents: Antihistamines**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• azelastine nasal (Astepro 0.15%, generics) **Nasal Allergy Agents: Antihistamines**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• beclomethasone nasal (Beconase AQ) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 4 inhalers per fill
• beclomethasone nasal (Qnasl 40 mcg and 80 mcg) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• budesonide nasal (Rhinocort Aqua, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• ciclesonide 50 mcg nasal (Omnaris) • ciclesonide37 mcg nasal (Zetonna) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• fluticasone furoate nasal (Veramyst) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• fluticasone propionate nasal (Flonase, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• fluticasone propionate 93 mcg nasal (Xhance) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• flunisolide nasal inhaler **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 3 inhalers per fill ▪ MTF/Mail: 7 inhalers per fill

Drug / Drug Class	Quantity Limits
• ipratropium 0.03% nasal (Atrovent 0.03%, generics) • ipratropium 0.03% Nasal Spray (Atrovent 0.03%, generics), pack size 15 mL • ipratropium 0.06% Nasal Spray (Atrovent 0.06%) **Nasal Allergy Agents: Anticholinergics**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 4 inhalers per fill
• mometasone nasal (Nasonex, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• olopatadine 0.06% (Patanase 0.06%, generics) **Nasal Allergy Agents: Antihistamines**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• triamcinolone Acetonide (Nasacort AQ, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
alpelisib (Piqray)	Oncological agents: breast cancer	• abemaciclib (Verzenio) • palbociclib (Ibrance) • ribociclib (Kisqali)	Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, PIK3CA-mutated advanced or metastatic breast cancer in combination with fulvestrant	• 1st PI3K Inhibitor and is the only drug indicated for breast cancer with the specific PIK3CA mutation • Must be used in combination with fulvestrant (medical benefit) • The CDK 4/6 inhibitors (Verzenio, Ibrance, and Kisqali) are also approved for advanced metastatic breast cancer. • No head-to-head trials are available. • The primary endpoint of progression-free survival was statistically significant compared to placebo, with a difference of about 5 months. • Is also associated with severe hypersensitivity reactions including anaphylaxis and pulmonary toxicity. • Safety has not been evaluated in Type 1 or uncontrolled Type 2 diabetic patients. • Severe AEs include Stevens Johnson Syndrome, severe hyperglycemia, severe diarrhea and kidney injury, lung injury including pneumonitis, pancreatitis, and severe hypersensitivity reactions. • Almost 70% of patients required dose interruption with 62% needing dose reduction due to adverse events. • The most recent NCCN guidelines rate Piqray as a category 1 drug, which is the lowest level of recommendation. • Compared to placebo, alpelisib provided benefit in the treatment of advanced breast cancer in patients with the specific PIK3CA mutation who have failed previous therapy, based on the limited data available.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
amifampridine (Ruzurgi)	Neurological agents miscellaneous	• Firdapse	Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to 17 years of age	• Ruzurgi is the first FDA-approved drug for LEMS in pediatric patients in the U.S.; however, in the clinical trial used to gain FDA approval, the average patient age was 52 years, with only adults enrolled. • Ruzurgi is available in the exact same formulation as Firdapse, the adult version which was approved earlier in 2019. • Amifampridine was approved by the European Commission as an orphan drug in December of 2002. • Amifampridine was previously available in a compounded formulation through compassionate use; however, this will no longer be an option. The company marketing Ruzurgi was previously compounding the original formulation. • Apart from the AEs listed, amifampridine may cause seizures, including seizures in patients with no prior history. • Dosing for adults can be obtained by using the Ruzurgi formulation, since both Firdapse and Ruzurgi are 10 mg scored tablets. Ruzurgi's package insert states the maximal dose is 100 mg daily, compared to Firdapse's max dose of 80 mg daily. • Ruzurgi provides the first available FDA-approved pediatric therapy to treat this very rare disorder in a more cost-effective manner than Firdapse, with dosing and clinical trial data based on adults.	• UF • Do not add to EMMPI list
amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT)	ADHD – Wakefulness Promoting Agents: Stimulants	• Adzenys XR ODT, Adderall XR, Vyvanse, Dyanavel XR, Mydayis	ADHD in pediatric patients 6-17 years old	• 2nd Evekeo formulation on the market with an ADHD indication • Evekeo ODT was approved through a 505(b)(2) pathway, with no new clinical studies. • Immediate release dosage formulation • There are many alternatives available in this crowded therapeutic space – including multiple amphetamine ODTs, multiple agents with the same duration of action for those with difficulties swallowing, and multiple stimulants that are also approved for this age group. • Effects 4-6 hours, similar to other short-acting stimulants in the class. • Evekeo carries the same black box warning as all other stimulant agents for potential abuse, dependency, and sudden cardiac death. • Clinically, children who experience adverse events to Adderall are more commonly switched to dexedrine, rather than an amphetamine product. • There are no compelling clinical advantages over other formulary products at this time.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
dolutegravir/ lamivudine (Dovato)	Antiretrovirals: Combinations	• Tivicay + Truvada • Biktarvy • Triumeq	Human immuno-deficiency virus (HIV) treatment	• Dovato is a 2-drug antiretroviral combination of dolutegravir and lamivudine FDA approved for initial therapy of HIV in adults. • Based on HIV guidelines, Dovato provides another second-line single-tablet regimen (STR) treatment option for HIV. • Dovato was non-inferior to the combination of Tivicay + Truvada in two phase III, non-inferiority trials (GEMINI 1 & 2). • Side effects are generally mild and include nausea, headache, diarrhea, fatigue, and insomnia. • Additional data on long-term efficacy, studies in pediatric and geriatric populations, safety, and viral suppression sustainability are needed to better characterize strengths and weaknesses. • Dovato provides an additional single-tablet regimen option for patients who cannot take abacavir or tenofovir disoproxil fumarate (TDF)/tenofovir alafenamide (TAF).	• UF • Do not add to EMMPI list
drospirenone (Slynd)	Contraceptive agents: progestogen-only	• norethindrone 0.35 mg	Progestogen-only contraceptive tablet	• 2nd Progestin-only pill (POP) for contraception • Compared to norethindrone, Slynd has an extended window for allowable late dose without need for back-up protection. • POPs are commonly used when contraindications or adverse reactions (severe nausea, headache, etc.) exist to combined oral contraceptives (COCs). • Progestin-only pills are often used in breastfeeding patients. • Many contraindications to COCs are related to thromboembolic potential of estrogen. • Drospirenone unlike other progestins has some likely thromboembolic risk. • Additional lab monitoring may be needed with drospirenone. • Slynd has no compelling clinical advantages over existing progestogen-only formulary agents.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
erdafitinib (Balversa)	Oncological agents	• None	Locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR mutation and has progressed during or following at least one line of prior platinum-containing chemotherapy	• 1st drug with FDA approval for FGFR gene-altered metastatic urothelial carcinoma • Superior overall response rate (ORR) but unknown survival advantage • Better tolerated than National Comprehensive Cancer Network (NCCN)-directed comparator chemotherapy regimens • Very limited data, but progression-free survival of about 5 months, which can be significant for this particular cancer which has a high mortality rate. • Risk of severe ophthalmic AEs, including central serous retinopathy/retinal pigment epithelial detachment. • AE profile is less severe than pembrolizumab (Keytruda) chemotherapy. NCCN guidelines recommend Balversa as an alternative preferred regimen behind pembrolizumab (Keytruda – medical benefit "checkpoint inhibitor") for recurrent invasive or metastatic disease.	• UF • Do not add to EMMPI list
galcanezumab injection 100 mg (Emgality)	Migraine Agents: CGRP Cluster	• topiramate • lithium • verapamil • galcanezumab (Emgality 120 mg)	Treatment of episodic cluster headache	• New formulation of galcanezumab approved for episodic cluster headache. • 1st calcitonin gene-related peptide (CGRP) approved for cluster headache; others are in the pipeline. • Galcanezumab 120 mg is approved for migraine headache prophylaxis. • One clinical trial showed a reduction in the frequency of weekly cluster headaches compared to placebo. • Unpublished data provides conflicting results. • Verapamil is the agent of choice for preventive therapy of cluster headache, with glucocorticoids, lithium, and topiramate also showing efficacy. • Limited data (1 small trial in 100 patients with an 8-week duration vs. placebo) showed efficacy of this formulation for prevention of cluster headache. How it compares to other treatments, including verapamil, is unknown.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
halobetasol propionate 0.01%/ tazarotene 0.045% lotion (Duobrii)	Psoriasis Agents	• Enstilar • Taclonex • Tazarotene	Plaque psoriasis	• Duobrii is the 3rd topical combination agent for the treatment of plaque psoriasis, but it is the first to combine a high-potency topical corticosteroid with a retinoid (tazarotene). • Guidelines recommend the combination of a topical corticosteroid with a retinoid only after a full treatment course of an individual high-potency topical corticosteroid treatment has failed. • The combination of a high-potency topical corticosteroid and a topical non-corticosteroid (either a vitamin D analogue or a retinoid) offers improved clinical efficacy over either agent alone and is supported by Level 1 evidence with a strength A recommendation from the American Academy of Dermatology (AAD). • However, Duobrii offers no compelling clinical advantage over concomitant use of individual topical components (halobetasol and tazarotene).	• UF • Do not add to EMMPI list
immunoglobulin SC injection (Cutaquig)	Immunological agents miscellaneous	• Gammagard • Gamunex-C • Cuvitru • Hizentra • Hyqvia	Treatment of primary humoral immuno-deficiency (PI) in adults	• 6th subcutaneous (SC) human immune globulin indicated for the treatment of primary humoral immunodeficiency (PI) in adults. • Cutaquig was evaluated in one open-label, non-controlled study that demonstrated efficacy in preventing serious bacterial infections. • No head-to-head studies with other human immune globulin products were conducted. • Most common ADRs included local reaction (46%), headache (11.5%), fever (8.2%), diarrhea (8.2%), dermatitis (8.2%), asthma (6.6%), and skin abrasion (6.6%). • The large injection volume required will likely result in patients needing a pump for administration. • Cutaquig provides little to no clinical benefit relative to existing formulary agents.	• UF • Do not add to EMMPI list
mepolizumab injection (Nucala)	Pulmonary 1-Agents: Pulmonary Miscellaneous	• dupilumab (Dupixent) • benralizumab (Fasenra) • reslizumab (Cinqair) • omalizumab (Xolair)	Add-on maintenance treatment of severe asthma in patients ≥ 12 yo with an eosinophilic phenotype or for adults with eosinophilic granulomatosis with polyangiitis (EGPA)	• Nucala is the 2nd biologic for asthma that is part of the TRICARE pharmacy benefit (after Dupixent). • With the introduction of Nucala, there are now 5 approved biologics for type 2 inflammatory asthma. • In a network meta-analysis (NMA) and randomized controlled trial (RCT), there was statistically significant and clinically relevant benefits of Nucala over placebo in treating eosinophilic asthma and EGPA. • Indirect comparison of Nucala with the other biologics for asthma (Dupixent, Fasenra, Cinqair, and Xolair) did not show statistically significant differences in efficacy. • Nucala provides a clinically meaningful addition to pharmacy benefit in the treatment of type 2 inflammatory asthma over placebo via a mechanism of acting through the IL-5 pathway.	• UF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
methylphenidate ER sprinkle capsule (Adhansia XR)	ADHD – Wakefulness Promoting Agents: Stimulants	• methylphenidate ER tab (Concerta) • methylphenidate ER sprinkle (Aptensio XR) • methylphenidate ER suspension (Quilivant XR • methylphenidate ER (Metadate CD, Ritalin LA, • dexmethylphenidate XR (Focalin XR) • Mixed amphetamine salts XR (Adderall XR)	ADHD in patients 6 years and older	• Adhansia XR was approved under a 505(b)(2) application and is indicated for treating ADHD in patients 6 years and older. • Multiple current formulary agents cover the same age range. • Adhansia XR is the 11th long-acting methylphenidate available on the market. • Several long-acting methylphenidate products are on the UF, including two products that are formulary alternatives for those who have difficulty swallowing (Quillivant XR, Aptensio XR). • Effects can last 16 hours, which is the "marketing claim" for this agent – this may be more useful for adults, as children rarely need to concentrate for 16 hours. • Other methylphenidate ER formulations have 10-14 hour durations of action (e.g., Concerta, Aptensio XR sprinkle, Jornay PM). • Adhansia XR carries the same Black Box Warning as other methylphenidates for abuse potential, dependency, and sudden cardiac death. • The long duration of action is concerning for adverse effects of insomnia and weight loss in children • Adhansia XR has little to no additional clinical effectiveness relative to similar drugs in the class.	• Tier 4/Not Covered • Do not add to EMMPI list
methylphenidate ER capsule nighttime dosing (Jornay PM)	ADHD – Wakefulness Promoting Agents: Stimulants	• methylphenidate ER tab (Concerta) • methylphenidate ER sprinkle (Aptensio XR)	ADHD in patients 6 years and older	• Jornay PM is the 12th long-acting methylphenidate approved via 505(b)(2) pathway for ADHD in patients ≥ 6 years. • Jornay is administered at night before bedtime; it has a delayed onset of action so that therapeutic effects occur 8 hours after administration; stimulating effects may last 14 hours. • Rates of insomnia (up to 41%) were twice that of placebo. • Jornay PM has the same Black Box Warning as other methylphenidates for abuse potential, dependency, and sudden cardiac death. • Jornay PM shows no clinical advantage when compared to current formulary alternatives and showed a higher rate of insomnia versus other agents in this class.	• UF • Do not add to EMMPI list
risankizumab-rzaa injection (Skyrizi)	Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor Inhibitors	• adalimumab (Humira) • ustekinumab (Stelara) • guselkumab (Tremfya) • tildrakizumab (Ilumya)	Patients with moderate to severe plaque psoriasis who are candidates for systemic or phototherapy	• Skyrizi is the 3rd IL-23 antagonist and the 7th agent in the IL-17/23 subclass. • Same manufacturer as Humira • Solely indicated for plaque psoriasis • Head-to-head trials with appropriate comparators (e.g., Stelara) show superiority for psoriasis; however, higher neutralizing antibody rate with corollary efficacy impact, due to reduced drug concentration • No unique safety concerns • Skyrizi provides an additional robust option in the management of plaque psoriasis but has fewer indications than Humira or Stelara and a higher neutralizing antibody rate.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
rosuvastatin sprinkle capsules (Ezallor Sprinkle)	Antilipidemics-1	• rosuvastatin • atorvastatin • simvastatin oral suspension (FloLipid)	• Increased triglycerides • Type III hyper-lipoproteinemia • Homozygous Familial Hypercholesterolemia (HoFH) • To reduce total cholesterol, LDL-C, and ApoB	• Approved via 505(b)(2) application using clinical safety and efficacy data from rosuvastatin calcium (Crestor). • No clinical efficacy studies were conducted. • No cardiovascular (CV) outcome data • Can swallow capsules whole, open the contents of the granules/sprinkles and mix with applesauce, or administer in an NG tube. • Targeted for patients with swallowing difficulties or those who require NG tube feedings (nursing home patients) • Rosuvastatin tablets are not on the Institute for Safe Medication Practices (ISMP) Do Not Crush list, but all manufacturers recommend swallowing tablets whole due to bitter taste when crushed/chewed. • Moderate to high intensity (LDL lowering ≥ 50%) statin with same active ingredient as Crestor just in a sprinkle capsule formulation instead of tablets (convenience formulation) • No compelling advantages over formulary statins other than a convenience to patients with swallowing difficulties.	• NF • Add to EMMPI list
solriamfetol (Sunosi)	ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents	• modafinil • armodafinil • sodium oxybate (Xyrem)	Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)	• Sunosi is a new dopamine and norepinephrine reuptake inhibitor (DNRI) indicated for wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). • Sunosi was evaluated in 4 pivotal trials and demonstrated modest efficacy on a patient's ability to remain awake and their perceived likelihood of falling asleep during usual daily activities when compared to placebo. • No head-to-head studies with similar agents are available; indirect comparisons are confounded by differences in test methodology and baseline patient populations. • ADRs for Sunosi are similar to modafinil and armodafinil; however, drug interactions, warnings, and precautions differ since Sunosi may cause increases in blood pressure and heart rate. The 300 mg formulation was not approved due to AEs. • Sunosi may cause psychiatric symptoms including anxiety, insomnia, and irritability. Caution is advised in patients with a history of psychosis or bipolar disorders. • Sunosi is a CIV scheduled drug. • Sunosi provides no compelling clinical advantages over existing formulary agents.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status

Tafamidis (Vyndaqel)	Neurological agents miscellaneous	• inotersen (Tegsedi)
		• patisiran (Onpattro)
			Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce CV mortality and CV-related hospitalization	• 1st agent FDA-approved for transthyretin amyloid cardiomyopathy (ATTR-CM)
				• Statistically and clinically meaningful clinical efficacy in New York Heart Association (NYHA) Class 1 and 2 patients was seen for the following:
				  • All-Cause Mortality
				  • CV-related Hospitalizations
				  • Function (6-minute walk test [6MWT])
				  • Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS)
				• Non-statistically significant mortality benefit in NYHA Class 3, but statistically significant higher CV-related hospitalization rate in this sub-group
				• Favorable safety profile (especially in indirect comparison to Tegsedi)
				• Use in polyneuropathy is supported by weaker evidence.
				• Tafamidis is approved for transthyretin amyloid polyneuropathy (ATTR-PN) in 41 other countries, but the FDA denied approval.
				• Guidelines recommend tafamidis in ATTR and ATTR-PN.
					• UF
					• Do not add to EMMPI list

triclabendazole (Egaten)	Antiinfectives: Anthelmintics	• praziquantel • mebendazole • albendazole • ivermectin	Fascioliasis (liver flukes)	• Egaten is an anthelmintic and the first drug approved for the treatment of fascioliasis (liver flukes). • A dosage of 20 mg/kg was studied in seven relatively small open-label trials and found higher efficacy compared with artesunate and lower doses of Egaten. • The Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) recommend Egaten as the drug of choice for fascioliasis and as an option for paragonimus (lung flukes). • Most common ADRs included abdominal pain, hyperhidrosis, nausea, decreased appetite, headache, urticaria, diarrhea, vomiting, musculoskeletal chest pain, and pruritus. • Egaten demonstrated efficacy against fascioliasis and has a unique place in therapy for a neglected and rare tropical disease.	• UF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 During the August 2019 DoD P&T Committee Meeting

<table>
<tr><th>DoD P&T Meeting</th><th>ADD to the Select Maintenance List
(if Formulary, Add to EMMPI Program;
if NF, NOT Excepted from Mail Order Requirement)</th><th>Do NOT Add to the Select Maintenance List
(if Formulary, Do Not Add to EMMPI Program;
if NF, Excepted from Mail Order Requirement)</th></tr>
<tr><td rowspan="2">August 2019</td><td>Multiple Sclerosis drugs:
Note that the interferon products for MS, as well as glatiramer (Copaxone), will remain on the list.
▪ dimethyl fumarate (Tecfidera)

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

Designated UF:
▪ Other Pulmonary-1 agents are on the program: mepolizumab (Nucala)

Designated NF:
No reason to exempt from EMMPI requirement:
▪ risankizumab-rzaa (Skyrizi)
▪ rosuvastatin sprinkle caps (Ezallor)
▪ solriamfetol (Sunosi)</td><td>High-Potency Topical Steroids Designated NF:
Drugs for acute or limited duration use
▪ None of the high-potency topical steroids should be added to the EMMPI program.

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

Designated UF:
Not yet clear if feasible to provide through mail order:
▪ amifampridine (Ruzurgi)
▪ triclabendazole (Egaten)
▪ tafamidis meglumine (Vyndaqel)

Drugs in classes not currently represented on the EMMPI list:
▪ alpelisib (Piqray)
▪ dolutegravir/lamivudine (Dovato)
▪ erdafitinib (Balversa)
▪ halobetasol/tazarotene (Duobrii)
▪ immunoglobulin SQ (Cutaquig)

C-II drugs:
▪ methylphenidate ER caps (Jornay PM)
▪ amphetamine sulfate IR ODT (Evekeo ODT)

Designated NF:
Acute use exception applies:
▪ galcanezumab-gnlm 100 mg (Emgality)

Existing exclusion for contraceptives applies:
▪ drospirenone (Slynd)</td></tr>
<tr><td colspan="2">Remove from Select Maintenance List due to dosing exceeding or potentially exceeding 30 days duration of use
▪ conjugated estrogens vaginal cream (Premarin cream)
▪ estradiol vaginal cream (Estrace)
▪ leuprolide depot injection for 4-month administration (Lupron Depot 4-month kit)
Remove from Select Maintenance List due to limited duration of use
▪ halobetasol (Ultravate) Note that none of the other high-potency topical steroids are on the EMMPI program</td></tr>
</table>

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

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

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

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

MTFs may not have on formulary</th><th>Decision Date / Implement Date</th><th>PA and QL Issues</th><th>Comments</th></tr>
<tr><td rowspan="2">Aug 2019</td><td rowspan="2">High-Potency Topical Corticosteroids</td><td rowspan="2">UF Sub-Class Review; full class previously reviewed in August 2013</td><td colspan="3">Tier 4/Not Covered Medications

MTFs <u>must not</u> have on formulary
Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies

▪ clobetasol propionate 0.025% cream (Impoyz)
▪ clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit)
▪ diflorasone diacetate/emollient 0.05% cream (Apexicon-E)
▪ halcinonide 0.1% ointment (Halog)
▪ halcinonide 0.1% cream (Halog)
▪ halobetasol propionate 0.05% lotion (Ultravate)
▪ halobetasol propionate 0.05% foam (Lexette & authorized generic)
▪ halobetasol propionate 0.01% lotion (Bryhali)</td><td rowspan="2">Pending signing of the minutes / 120 days

The effective date is March 4, 2020</td><td rowspan="2">▪ Manual PA criteria applies to all new and current users for the following products:
▪ amcinonide 0.1% ointment
▪ diflorasone diacetate 0.05% ointments
▪ diflorasone diacetate 0.05% cream
▪ clobetasol propionate/ emollient 0.05% foam
▪ desoximetasone 0.05% gel
▪ flurandrenolide 4 mcg/sq. cm (Cordran) tape</td><td rowspan="2">▪ See Appendix C for PA criteria
▪ Note the Lexette foam was previously rec for Tier 4 status at the February 2019 meeting, which will implement on August 28, 2019.</td></tr>
<tr><td>▪ clobetasol 0.05% ointment & cream
▪ fluocinonide 0.05% ointment, cream & solution</td><td>Note that all are currently UF
▪ betamethasone dipropionate 0.05% ointment
▪ betamethasone/propylene glycol 0.05%, ointment, cream, lotion, gel
▪ clobetasol propionate 0.05% ointment, cream, solution, lotion, shampoo, spray, gel, foam
▪ clobetasol propionate/emollient 0.05% cream
▪ clobetasol propionate/emollient 0.05% emulsion foam
▪ desoximetasone 0.25% ointment, cream
▪ fluocinonide 0.05% ointment, cream, solution, gel
▪ fluocinonide/emollient base 0.05% cream
▪ halobetasol propionate 0.05% ointment</td><td>▪ amcinonide 0.1% ointment (Cyclocort, generics)
▪ clobetasol propionate/emollient 0.05% foam (Olux-E, generics) moves from UF to NF
▪ desoximetasone 0.05% gel (Topicort, generic) moves from UF to NF
▪ diflorasone diacetate 0.05% ointment, cream (Psorcon, Apexicon, generics)
▪ fluocinonide 0.1% cream (Vanos, generics)
▪ flurandrenolide 4 mcg/sq. cm (Cordran) tape moves from UF to NF
▪ halobetasol propionate 0.05% cream (Ultravate, generics) moves from UF to NF</td></tr>
</table>

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2019	**Multiple Sclerosis: Interferons and Methyl Fumarate**	UF Class Review Class previously reviewed in November 2014.	Note that no BCF selection was made for the Interferons and Methyl Fumarate subclasses.	**Interferons** ▪ Interferon beta-1a (Avonex) ▪ Interferon beta-1a (Rebif, RebifRebidose) ▪ Interferon beta-1b (Betaseron) ▪ Interferon beta-1b (Extavia) **Methyl Fumarate** ▪ dimethyl fumarate (Tecfidera)	**Interferons** ▪ peginterferon beta-1a (Plegridy)	Upon signing of the minutes The effective date is November 6, 2019	▪ Updated manual PA criteria for all users of dimethyl fumarate (Tecfidera); off-label uses are not allowed	▪ The MS subclasses of Glatiramer, symptomatic agents, and Oral Miscellaneous were not reviewed ▪ Betaseron removed from BCF ▪ See Appendices B and C for MN and PA criteria.

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

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	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule) for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension) for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.025% cream (Impoyz) • diflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog)	• betamethasone/propylene glycol 0.05% cream • clobetasol propionate 0.05% cream • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream • fluocinonide 0.05% cream • fluocinonide/emollient base 0.05% cream	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• halcinonide 0.1% ointment (Halog)	• betamethasone dipropionate 0.05% ointment • betamethasone/propylene glycol 0.05% ointment • clobetasol propionate 0.05% ointment • desoximetasone 0.25% ointment • fluocinonide 0.05% ointment • halobetasol propionate 0.05% ointment	• March 4, 2020

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

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents, based on an interim final rule published on December 11, 2018. https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms .

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

Appendix I—Table of Abbreviations

Term	Definition	Term	Definition
6MWT	6-minute walk test	COPD	Chronic obstructive pulmonary disease
AAD	American Academy of Dermatology	CPAP	continuous positive airway pressure
AAN	American Academy of Neurology	CV	Cardiovascular
ADHD	Attention Deficit Hyperactivity Disorder	DHA	Defense Health Agency; docosahexaenoic acid
ADR	adverse reaction	DMT	Disease-modifying therapy
AE	adverse event	DNRI	dopamine and norepinephrine reuptake inhibitor
ALK	anaplastic lymphoma kinase	DoD	Department of Defense
AML	Acute Myelogenous Leukemia	DR	Delayed release
ANA	antinuclear antibodies	ECF	Extended Core Formulary
Anti-dsDNA	anti-double-stranded DNA	EGPA	eosinophilic granulomatosis with polyangiitis
AS	ankylosing spondylitis	EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ATTR-CM	transthyretin-mediated amyloidosis	ER	extended release
ATTR-PN	transthyretin amyloid polyneuropathy	FDA	U.S. Food and Drug Administration
BCF	Basic Core Formulary	FEV_1	forced expiratory volume in one second
BIA	budget impact analysis	FY	fiscal year
BMI	Body mass index	GCN	Generic code number
CBC	Complete blood count	GLP1RA	Glucagon-Like Peptide-1 Receptor Agonists
CD	Crohn's Disease; continuous delivery	HER2	human epidermal growth factor receptor 2
CDC	Centers for Disease Control and Prevention	HIV	human immunodeficiency virus
CDK	Cyclin-dependent kinase	HoFH	Homozygous Familial Hypercholesterolemia
CF	Cystic Fibrosis	HR	Hormone receptor
CFR	Code of Federal Regulations	HS	hidradenitis suppurativa
CFTR	cystic fibrosis transmembrane conductance regulator	ICER	Institute for Clinical and Economic Review
CGRP	calcitonin gene-related peptide	ICS	Inhaled corticosteroids
CHCS	Composite Health Care System	IDH1	isocitrate dehydrogenase-1
CHF	chronic/congestive heart failure	IR	Immediate release
CMA	cost minimization analysis	ISGA	Investigator's Static Global Assessment
CMP	Complete metabolic panel	ISMP	Institute for Safe Medication Practices
COC	Combined oral contraceptive	ITP	immune thrombocytopenia

Term	Definition	Term	Definition
JC	John Cunningham	OSA	obstructive sleep apnea
KCCQ-OS	Kansas City Cardiomyopathy Questionnaire - Overall Summary	OTC	Over the counter
KCl	Potassium chloride	P&T	Pharmacy and Therapeutics
LA	long acting	PA	Prior authorization
LABA	Long-acting beta agonist	PAF	pure autonomic failure
LAMA	Long-acting muscarinic antagonist	PD	Parkinson's Disease
LEMS	Lambert-Eaton myasthenic syndrome	PI	primary humoral immunodeficiency
LFT	Liver function tests	pJIA	Polyarticular juvenile idiopathic arthritis
MAOI	Monoamine oxidase inhibitor	PML	progressive multifocal leukoencephalopathy
MHS	Military Health System	POD	Pharmacy Operations Division
MN	Medical Necessity	POP	Progestin-only pill
MOA	Mechanism of action	POS	Point of service
MRI	Magnetic resonance imaging	Ps	Plaque psoriasis
MS	Multiple Sclerosis	PsA	Psoriatic arthritis
MSA	multiple system atrophy	QL	Quantity limits
MSLT	mean sleep latency time	RA	Rheumatoid arthritis
MTF	Military Treatment Facility	RCT	Randomized controlled trial
NC	nasal congestion score	SC	subcutaneous
NCCN	National Comprehensive Cancer Network	SLE	systemic lupus erythematosus
NDAA	National Defense Authorization Act	SQ	subcutaneous
NF	Nonformulary	SSA	somatostatin analog
NG	nasogastric	STR	Single-tablet regimen
NMA	Network meta-analysis	TAF	tenofovir alafenamide
NOH	Neurogenic Orthostatic Hypotension	TB	tuberculosis
NPS	nasal polyps score	TDF	tenofovir disoproxil fumarate
nr-axSpA	non-radiographic axial spondyloarthritis	TIB	Targeted immunomodulatory biologic
NSAID	Nonsteroidal anti-inflammatory drug	TNF	Tumor Necrosis Factor
NSCLC	Non-Small Cell Lung Cancer	UC	Ulcerative colitis
NYHA	New York Heart Association	UF	Uniform Formulary
ODT	Orally dissolving tablet	WHO	World Health Organization
ORR	overall response rate	XR	Extended release