DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA), on formulary or Tier 4/not covered status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) or Tier 4 status are received from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. UF CLASS REVIEWS—HIGH-POTENCY TOPICAL CORTICOSTEROIDS

P&T Comments

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.

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 sub-class.
- 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 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 Military Health System (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 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.

B. High-Potency Topical Corticosteroids—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 & branded 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

C. 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 & branded generic) *(note that Lexette foam was previously recommended for Tier 4 status in February 2019, with implementation 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 branded generic, and Bryhali 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.

D. High-Potency Topical Corticosteroids—Manual Prior Authorization (PA) 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.

The PA criteria are as follows:

1. amcinonide 0.1% ointment and diflorasone diacetate 0.05% ointment

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:

- The provider acknowledges that 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

2. clobetasol propionate/emollient 0.05% foam

PA criteria 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:

- The provider acknowledges that 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

3. desoximetasone 0.05% gel

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:

- The provider acknowledges that 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

4. diflorasone diacetate 0.05% cream

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:

- The provider acknowledges that 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

5. flurandrenolide 4 mcg/sq. cm (Cordran) tape

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

E. High-Potency Topical Corticosteroids—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of 120 days from signing of the minutes in all points of service (POS), and that DHA send letters to beneficiaries who are affected by the Tier 4 decision and those affected by a change from UF to NF status.

III. UF CLASS REVIEWS—HIGH-POTENCY TOPICAL CORTICOSTEROIDS

BAP Comments

A. High-Potency Topical Corticosteroids—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended the formulary status for the High-Potency Topical Corticosteroid agents as discussed above.

- 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
- NF
  - Cyclocort ointment, generics
  - Olux-E foam, generics
  - Topicort gel, generic
  - Psorcon ointment, Apexicon ointment, generics
  - Psorcon cream, Apexicon cream, generics
  - Vanos cream, generics
  - Cordran tape

    - Ultravate cream, generics
- Tier 4/Not Covered
    - Impoyz cream
    - Clodan shampoo/cleanser kit
    - Apexicon-E cream
    - Halog ointment
    - Halog cream
    - Ultravate lotion
    - Lexette foam & branded generic
    - Bryhali lotion

BAP Comment: ☐ Concur ☐ Non-concur

B. High-Potency Topical Corticosteroids—Manual PA Criteria

The P&T Committee recommended 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 Cordran tape in all new and current users, as discussed previously.

BAP Comment: ☐ Concur ☐ Non-concur

C. High-Potency Topical Corticosteroids—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of 120 days from signing of the minutes in all points of service (POS) and that DHA send letters to beneficiaries who are affected by the Tier 4 decision and those affected by a change from UF to NF status.

BAP Comment: ☐ Concur ☐ Non-concur

IV. MULTIPLE SCLEROSIS – INTERFERONS AND METHYL FUMARATE

P&T Comments

A. Multiple Sclerosis – Interferons and Methyl Fumarate—Relative Clinical Effectiveness Analysis and Conclusion

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.

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 it 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 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.

B. Multiple Sclerosis – Interferons and Methyl Fumarate—Relative Cost-Effectiveness Analysis and Conclusion

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.

C. Multiple Sclerosis – Interferons and Methyl Fumarate—UF Recommendation

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following for the Multiple Sclerosis agents, as outlined below, based on clinical and cost-effectiveness:

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

D. Multiple Sclerosis – Interferons and Methyl Fumarate—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.

1. **dimethyl fumarate (Tecfidera)**
   Changes from August 2019 are in BOLD.
   Manual PA criteria apply to all 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.

E. Multiple Sclerosis – Interferons and Methyl Fumarate—UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) implementation effective upon signing of the minutes in all points of service (POS).

V. MULTIPLE SCLEROSIS – INTERFERONS AND METHYL FUMARATE

BAP Comments

A. Multiple Sclerosis – Interferons and Methyl Fumarate—UF Recommendation

The P&T Committee recommended the formulary status, as stated above.

Interferons

- UF
  - Avonex
  - Rebif, Rebif Rebidose
  - Betaseron
  - Extavia
- NF
  - Plegridy

Methyl Fumarate

- UF
  - Tecfidera
- NF
  - None

BAP Comment: ☐ Concur ☐ Non-concur

B. Multiple Sclerosis – Interferons and Methyl Fumarate—Manual PA Criteria

The P&T Committee recommended updating the current manual PA criteria for dimethyl fumarate (Tecfidera) in new users to only allow use for the FDA-labeled indication of MS.

BAP Comment: ☐ Concur ☐ Non-concur

C. Multiple Sclerosis – Interferons and Methyl Fumarate—UF and PA Implementation Plan

The P&T Committee recommended implementation effective upon signing of the minutes in all points of service (POS).

BAP Comment: ☐ Concur ☐ Non-concur

VI. NEWLY APPROVED DRUGS PER 32 CFR 199.21(G)(5)

P&T Comments

A. 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).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—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 for severe asthma and eosinophilic granulomatosis with polyangiitis (EGPA)
- methylphenidate extended-release sprinkle capsules (Jornay PM) – ADHD
- tafamidis (Vyndaqel) – Miscellaneous Neurological Agents for 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 alternatives to Adhansia XR include methylphenidate ER (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).

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—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:

- 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.

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5)

1. alpelisib (Piqray)

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 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.

2. amifampridine (Ruzurgi)

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.

3. amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT)

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.

4. erdafitinib (Balversa)

Manual PA criteria apply to all new users 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 1 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.

5. galcanezumab-gnlm 100 mg injection (Emgality)

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 (≥ 50% reduction in weekly cluster headache attack frequency) in weekly attacks during an episode as reported by the patient.

6. mepolizumab injection (Nucala)

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 past year
  - Required course of oral corticosteroids twice in past year
  - 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 an 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
- A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for EGPA indication only

Non-FDA-approved uses are not approved.
Prior authorization does not expire.

7. methylphenidate extended-release capsules (Jornay PM)

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.

8. risankizumab-rzaa injection (Skyrizi)

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 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.

9. rosuvastatin sprinkle capsules (Ezallor Sprinkle)
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.

10. solriamfetol (Sunosi)

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.

11. tafamidis meglumine (Vyndaqel)

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.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

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 signing of the minutes in all points of service.
- **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.

VII. NEWLY APPROVED DRUGS PER 32 CFR 199.21(G)(5)

BAP Comments

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

The P&T Committee recommended the formulary status for the new drugs as stated previously.

- UF:
  - Piqray
  - Ruzurgi
  - Evekeo ODT
  - Dovato
  - Balversa
  - Duobrii
  - Cutaquig injection
  - Nucala injection
  - Jornay PM
  - Vyndaqel
  - Egaten
- NF:
  - Slynd

- Emgality 100 mg injection
- Skyrizi injection
- Ezallor Sprinkle
- Sunosi

- Tier 4 (Not Covered):
  - Adhansia XR

BAP Comment:	☐ Concur	☐ Non-concur

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended the PA criteria for the new drugs as stated previously.

BAP Comment:	☐ Concur	☐ Non-concur

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended an effective date upon signing of the minutes in all points of service for all drugs recommended for UF or NF status, and for Adhansia XR (recommended for Tier 4 status), an effective date of the first Wednesday after a 120-day implementation period and that DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation.

BAP Comment:	☐ Concur	☐ Non-concur

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. New 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 and the orthostatic hypotension product Northera and to new and current users for the prescription multivitamin Azesco and the tetracycline product doxycycline hyclate ER 80 mg.

1. **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.

   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.

   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.

2. **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.

   The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users.

   a) **alectinib (Alecensa), brigatinib (Alunbrig), and ceritinib (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.

b) crizotinib (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.

3. Vitamins: Prenatal – Prenatal multivitamin (Azesco)

Azesco is a prenatal multivitamin manufactured by a single manufacturer that 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.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of Azesco.

Manual PA Criteria: 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.

4. 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 including 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.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for droxidopa in new users.

Manual PA Criteria: 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.

B. New PA Criteria—PA Implementation

The P&T Committee recommended (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.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. New Manual PA Criteria

The P&T Committee recommended new manual PA criteria for the drugs discussed above.

BAP Comment: □ Concur □ Non-concur

B. New Manual PA Criteria—PA Implementation Plan

The P&T Committee recommended the new PA criteria for the drugs discussed above become effective 90 days after the signing of the minutes.

BAP Comment: □ Concur □ Non-concur

X. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

P&T Comments

A. Updated PA Criteria

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.

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.

The updates are as follows:

Updated Criteria for reasons other than new FDA indications

1. **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 less than 4 bowel movements per day with or without concurrent somatostatin analog therapy.

2. **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 VI B on page 13). 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.

3. **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.

New FDA-Approved Indications or Age Ranges

1. **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.

2. **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.

3. **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.

4. **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.

5. **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.

6. **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 or who have comorbidities that preclude use of intensive induction chemotherapy.

7. **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.

8. **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.

B. Updated PA Criteria—Implementation Plan

The P&T Committee recommended (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 after the signing of the minutes.

C. Weight Loss Agents: liraglutide 3 mg (Saxenda)—Updated PA Criteria

The P&T Committee was briefed on trends in the current utilization and spend for the weight loss agents, which were reviewed in November 2018. 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.

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. Previous trials of other weight loss drugs must be documented prior to use of Saxenda.

D. Weight Loss Agents: liraglutide 3 mg (Saxenda)—Implementation Plan

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.

XI. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

BAP Comments

A. Updated Manual PA Criteria

The P&T Committee recommended updates to the manual PA criteria for the drugs discussed above.

BAP Comment: □ Concur □ Non-concur

B. Updated Manual PA Criteria—PA Implementation Plan

The P&T Committee recommended the updates to the PA criteria for the drugs discussed above become effective 30 days after the signing of the minutes.

BAP Comment: ☐ Concur ☐ Non-concur

C. Weight Loss Agents—Updated Manual PA Criteria

The P&T Committee recommended updates to the PA criteria for Saxenda as discussed above.

BAP Comment: ☐ Concur ☐ Non-concur

D. Weight Loss Agents—PA Implementation Plan

The P&T Committee recommended the updates to the PA criteria for Saxenda become effective 60 days after the signing of the minutes.

BAP Comment: ☐ Concur ☐ Non-concur

XII. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT AUGUST 2019

Table of Implementation Status of UF Recommendations/Decisions Summary

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
High-Potency Topical Corticosteroids	*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	▪ 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*	▪ 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 & branded generic) ▪ halobetasol propionate 0.01% lotion (Bryhali)	Pending signing of the minutes / 120 days	▪ Manual PA criteria applies to all new and current users for the following products: ▪ amcinonide 0.1% ointment ▪ diflorasone diacetate 0.05% ointment ▪ diflorasone diacetate 0.05% cream ▪ clobetasol propionate/emollient 0.05% foam ▪ desoximetasone 0.05% gel ▪ flurandrenolide 4 mcg/sq. cm (Cordran) tape ▪ Note the Lexette foam was previously recommended for Tier 4 status at the February 2019 meeting, which was implemented on August 28, 2019. <u>Unique Users Affected (Tier 4 candidates)</u> Mail – 195 MTF – 18 Retail – 502 Total – 715 (UF to NF changes) Mail – 1,061 MTF – 1,318 Retail – 2,533 Total 4,912
Multiple Sclerosis: Interferons and Methyl Fumarate	**<u>Interferons</u>** ▪ Interferon beta-1a (Avonex) ▪ Interferon beta-1a (Rebif, Rebif Rebidose) ▪ Interferon beta-1b (Betaseron) ▪ Interferon beta-1b (Extavia) **<u>Methyl Fumarate</u>** ▪ dimethyl fumarate (Tecfidera)	**<u>Interferons</u>** peginterferon beta-1a (Plegridy)	▪ None	Upon signing of the minutes	▪ The MS subclasses of Glatiramer, symptomatic agents, and Oral Miscellaneous were not reviewed ▪ Updated manual PA criteria for all users of dimethyl fumarate (Tecfidera); off label uses are not allowed <u>Unique Users Affected</u> – Not applicable, no change to formulary status.

Drugs with Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Weight Loss Agents – liraglutide 3 mg injection (Saxenda)	45	177	575	786
Vitamins: Prenatal – Prenatal multivitamin (Azesco)	0	0	0	0
Antibiotics: Tetracyclines – Doxycycline hyclate extended-release 80 mg	0	0	0	0