

**DEPARTMENT OF DEFENSE  
PHARMACY AND THERAPEUTICS COMMITTEE  
MINUTES AND RECOMMENDATIONS  
May 2022**

**I. CONVENING**

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on May 4-5, 2022.

**II. ATTENDANCE**

The attendance roster is listed in Appendix A.

**A. Approval of February 2022 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the February 2022 DoD P&T Committee meeting on April 25, 2022.**

**B. Clarification of Previous Minutes: February 2022 Meeting—Oncological Drugs class review: No new updates for prior authorizations (PAs) or quantity limits (QLs) were made for the five subclasses reviewed at the February 2022 meeting. Refer to the previous DoD P&T Committee meeting minutes for information on existing PA and QL requirements, rather than the TRICARE Formulary Search Tool.**

**III. REQUIREMENTS**

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at <https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms>. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/Not Covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018. Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

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

**IV. UF DRUG CLASS REVIEWS**

**A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass**

*Background*—The GLP1RAs were most recently reviewed in February 2018 when dulaglutide (Trulicity) replaced albiglutide (Tanzeum) on the formulary, due to market withdrawal. Exenatide once weekly (Bydureon BCise) and Trulicity have been the formulary step-preferred agents since 2018, with the remainder of the products nonformulary and non-step-preferred. This review focused primarily on systematic reviews and meta-analyses of the cardiovascular outcomes trials (CVOTs) with the GLP1As. Oral semaglutide (Rybelsus) was not part of this review, but remains UF.

*Relative Clinical Effectiveness Conclusion*—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- Metformin has an established place in therapy and remains first-line in most patients unless there are contraindication for use.
- The previous clinical conclusions from February 2018 remain largely unchanged with regard to GLP1RA effects on glycemic control, lipids, blood pressure, and body weight as well as safety and tolerability in patients with type 2 diabetes (T2DM).
- The GLP1RAs have a comparable range of efficacy across a broad population of patients with T2DM.
- Active comparator studies are available that evaluate the changes in hemoglobin A1c between the once weekly agents, semaglutide (Ozempic), dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise).
  - Ozempic vs. Bydureon: In the open-label, active comparator SUSTAIN-3 study, Ozempic was statistically and clinically superior to Bydureon BCise in glycemic control, as semaglutide lowered A1c by 1.5% from baseline compared to 0.9% with exenatide. Limitations to the SUSTAIN-3 study include its open label, active comparator design; it was not designed to show superiority.
  - Ozempic vs. Trulicity: In the open-label, active comparator SUSTAIN-7 study, semaglutide (Ozempic) was statistically superior to dulaglutide (Trulicity) in glycemic control, as it reduced A1c by 1.5-1.8% from baseline compared to 1.1-1.4% with dulaglutide. However, the differences in change in A1c between semaglutide and dulaglutide were not considered clinically relevant, as the change in A1c between the two drugs was less than 0.5% in respective treatment arms. Additionally, SUSTAIN-7 did not include the highest doses of dulaglutide (3 mg and 4 mg) which are now available.
- One recent systematic review (Giugliano, 2021) included approximately 60,000 patients with T2DM, where approximately 14,800 patients did not have established CV disease.

- Overall, the results showed the GLP1RAs have a moderate benefit on major adverse cardiovascular events (MACE), including a reduction in hospitalization from heart failure, all-cause mortality, and the incidence of macroalbuminuria.
- A greater effect was shown in those patients with known cardiovascular (CV) disease compared to those without.
- Individual clinical trials have shown a neutral or beneficial effect of the GLP1RAs in reducing CV events. The package inserts of Victoza, Ozempic, and Trulicity have an additional indication for CV risk reduction in those with established CV disease or who have multiple CV risk factors.
- Ozempic and Trulicity have warnings regarding diabetic retinopathy in their package inserts. However, studies are not powered to adequately assess this adverse effect. Additional studies are needed to definitively determine the long term effects of GLP1RAs on diabetic retinopathy.

#### *Overall Conclusions*

- Trulicity and Ozempic have a high degree of therapeutic interchangeability with regard to once weekly administration, cardiovascular benefits, ease of administration, indications, warnings, and adverse reactions.
- Victoza, Adlyxin, Bydureon BCise, and Byetta are less advantageous and have less clinical utility compared to Trulicity and Ozempic, due to such factors as the results of CVOT trials, increased frequency of dosing, and user-friendliness of the device.

*Relative Cost Effectiveness Analysis and Conclusion*—The Committee reviewed the solicited bids from manufacturers and also conducted a budget impact analysis (BIA). The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- Cost minimization analysis (CMA) results showed that dulaglutide (Trulicity), exenatide (Byetta), exenatide once weekly (Bydureon BCise), liraglutide (Victoza), lixisenatide (Adlyxin), and semaglutide (Ozempic) were all cost effective agents.
- Budget Impact Analysis (BIA) and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Trulicity as UF, and Byetta, Bydureon BCise, Victoza, Adlyxin, and Ozempic as NF demonstrated significant cost avoidance for the MHS.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:
  - UF
    - dulaglutide (Trulicity)
  - NF
    - semaglutide (Ozempic)
    - exenatide once weekly (Bydureon BCise) *moves from UF/BCF to NF*
    - exenatide twice daily (Byetta)
    - liraglutide (Victoza)
    - lixisenatide (Adlyxin)
    - Note that for Bydureon BCise, Byetta, Victoza and Adlyxin, a trial of both Trulicity and Ozempic are required
  - Tier 4 (Not covered) - None
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA criteria have applied to the GLP1RAs for several years, requiring a trial of metformin first, unless the patient has had an adverse event, inadequate response or a contraindication. Currently a trial of dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise) are required, prior to use of one of the non-step-preferred products.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the GLP1RA class. Metformin will still be required in all new users of a GLP1RA, consistent with professional treatment guidelines. For Ozempic, a trial of dulaglutide will no longer be required in new patients.

All new and current users of Bydureon BCise (which is now moving to NF status), Byetta, Victoza and Adlyxin will now require a trial of both Trulicity and Ozempic. Children as young as 10 years can receive Victoza or Bydureon BCise without a trial of Trulicity and Ozempic, as these two products are the only GLP1RAs approved for children. *(Note that after the May 2022 meeting a clinical trial evaluating use of Trulicity in adolescents was published; even though Trulicity is not currently approved for use in adolescents, the PA will allow use of Trulicity for children.)* See Appendix C for the full criteria.
3. **COMMITTEE ACTION: BCF RECOMMENATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) adding dulaglutide (Trulicity) to the Basic Core Formulary (BCF) and removing exenatide once weekly (Bydureon BCise) from the BCF.

4. **COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) medical necessity criteria for Adlyxin, Byetta, Bydureon BCise, Ozempic, and Victoza. See Appendix B for the full criteria.
5. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the GLP1RAs on the EMMPI list.
6. **COMMITTEE ACTION: UF, BCF, MN, PA, EMMPI and IMPLEMENTATION PERIOD**—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service.; and 2) DHA send letters to beneficiaries who are affected by the formulary decision. (See Appendix G for the actual implementation dates.)

## **B. Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass**

*Background*—The P&T Committee evaluated the relative clinical effectiveness of the oral CGRP antagonists. The drugs in the subclass include ubrogepant (Ubrelvy), rimegepant (Nurtec), and atogepant (Qulipta). The CGRP antagonists are available as tablets (Ubrelvy, Qulipta) and as an oral disintegrating tablet (ODT) (Nurtec).

Ubrelvy and Nurtec ODT were reviewed as new drugs during the May 2020 P&T committee meeting, while Qulipta was reviewed in February 2022. The injectable CGRP agents for migraine headache prevention [erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality)] were reviewed for formulary status in February 2019.

The drugs in the subclass differ in their FDA-approved indications. Ubrelvy is approved for the acute treatment of migraine, Qulipta is labeled for prevention of episodic migraine, and Nurtec ODT is approved for both acute treatment of migraine and prevention of episodic migraine.

*Relative Clinical Effectiveness Conclusion*—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

### *Professional Treatment Guidelines*

- *Acute treatment:* Medications with established efficacy for acute migraine treatment should be considered prior to initiation of the oral CGRP agents.

Specifically, oral CGRP medications may be considered after a trial of two or more oral triptans, or in patients with a contraindication to or intolerability to triptans. These recommendations are based on the 2021 American Headache Society (AHS) consensus statement for integrating new migraine treatments into clinical practice.

- *Preventive treatment:* Medications including antiepileptics (e.g., valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol) and antidepressants (e.g., amitriptyline, nortriptyline), are first-line treatment options for episodic migraine prevention. This is based on the 2012/2015 American Academy of Neurology/American Headache Society migraine prevention guidelines. The 2021 AHS consensus statement for instituting new migraine treatments into clinical practice expands on the use of injectable CGRP antagonists for episodic migraine prevention. However, there is no specific guidance for oral CGRPs, citing the need for additional evidence and data.

### *Efficacy*

- *Acute treatment vs. other therapies:* A 2020 network meta-analysis (NMA) from the Institute for Clinical and Economic Review (ICER) found that the oral CGRP antagonists (Ubrovelvy, Nurtec ODT) are less efficacious than triptans when assessing pain freedom at 2 hours post treatment of migraine. A 2020 Cochrane Network Meta-analysis (NMA) similarly reported that Ubrovelvy and Nurtec ODT are less efficacious than sumatriptan, ibuprofen, diclofenac, and acetylsalicylic acid when assessing pain freedom at 2 hours post treatment of migraine.
- *Preventive treatment vs other therapies:* There are no head-to-head trials comparing Nurtec ODT and Qulipta to other standard migraine preventive treatments, or to their injectable CGRPs counterparts. Of note, the injectable CGRPs are only indicated for prevention of migraine, not acute treatment. Clinical trials demonstrate that the oral CGRP antagonists (Nurtec ODT, Qulipta) decrease monthly migraine days (MMD) by 0.7 to 1.7 days from baseline, compared to placebo. A 2018 ICER NMA found that the injectable CGRP antagonists (Aimovig, Emgality, Ajovy), decreased MMDs by 1.2 to 1.9 days from baseline, compared to placebo.
- *Oral CGRPs vs. Oral CGRPs:* There are no head-to-head trials between the oral CGRP antagonists for either acute treatment or prevention of migraine headache. The high placebo response rate limits the ability to determine if there are clinically relevant differences in efficacy between the Qulipta, Nurtec ODT and Ubrovelvy.

### *Safety*

- The oral CGRP agents all have a relatively mild side effect profile. The most frequently reported adverse events for all the products include nausea,

nasopharyngitis, urinary tract infection, and upper respiratory tract infection. Constipation and fatigue have been reported with Qulipta.

- There is limited long term data to understand the risks with chronic CGRP antagonism. CGRP is a known vasodilator; there is a theoretical risk of increased ischemic events with CGRP antagonism. However, the 2021 FDA review for Qulipta states that based on available data, this medication does not require CV restrictions in labeling. The AHS in 2021 states that oral CGRPs (i.e. Nurtec ODT) may have a role in patients with CV contraindications to triptans. Extension studies out to 52 weeks with Ubrelvy report no significant CV outcomes.

#### *Distinguishing Characteristics*

- *atogepant (Qulipta)* has multiple strengths available, allows for dosage adjustment in end stage renal disease; however it only carries a single indication (preventive treatment) and has more reported side effects than its competitor, Nurtec ODT.
- *rimegepant (Nurtec ODT)* has dual indications (acute and preventive treatment of migraine), and fewer reported side effects when compared to both Ubrelvy and Qulipta. However it only allows for once daily dosing in 24 hours with acute treatment, and must be avoided in patients with renal and hepatic failure. Indirect comparisons suggest Nurtec ODT has fewer reported adverse effects than Qulipta and Ubrelvy. Nurtec ODT has not been associated with rebound headache for acute migraine treatment.
- *ubrogepant (Ubrelvy)* allows for repeat doses for acute migraine treatment, and dosage adjustment in hepatic failure; however it only carries a single indication for use (acute treatment). Ubrelvy has not been associated with rebound headache for acute migraine treatment.

#### *Overall Conclusions*

- In terms of efficacy, there is a high degree of interchangeability between the oral CGRP antagonists when compared across the same clinical indication. In terms of safety, there is a moderate degree of therapeutic interchangeability as each medication carries a few unique adverse events. However, the side effects are mild and the oral agents are considered well tolerated.
- In order to meet the needs of MHS beneficiaries, at least one oral CGRP agent is required for treatment of each indication, acute migraine treatment and episodic migraine prevention.

*Relative Cost-Effectiveness Analysis and Conclusion*—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that atogepant (Qulipta) was the most cost-effective oral CGRP antagonist, followed by rimegepant (Nurtec ODT), and then ubrogepant (Ubrelvy).
- BIA was performed to evaluate the potential impact of designating the three oral CGRP agents as UF, NF, or Tier 4 on the formulary. BIA results found that designating Ubrelvy, Nurtec ODT, and Qulipta as UF demonstrated significant cost avoidance for the Military Health System (MHS).

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - atogepant (Qulipta) *moves from NF to UF*
  - rimegepant (Nurtec ODT)
  - ubrogepant (Ubrelvy) *moves from NF to UF*
- NF - None
- Tier 4 (Not covered) – None

2. **COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA**— PA criteria were originally recommended when the individual oral CGRP medications were first evaluated as new drugs. The current PA criteria require a trial of first-line medications for both acute and preventive indications. For Ubrelvy, currently a trial of Nurtec ODT is required.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) minor updates to the current manual PA criteria in new users. The PA criteria and updates reflect the recommendations from the 2021 AHS Consensus Statement regarding candidates for a CGRP and assessment of response. For episodic migraine prevention, a trial of two standard therapies (antiepileptics, beta blockers, or antidepressants) as well as one injectable CGRP agent (Aimovig, Ajovy, or Emgality) will continue to be required first, before an oral CGRP agent. Additionally, for acute migraine treatment, a trial of two triptans are still required. Consultation with or evaluation by a neurologist is also still required for the oral CGRP agents.

For Ubrelvy and Nurtec ODT, the exclusion for patients with underlying cardiovascular disease has been removed. Additionally, a trial of Nurtec ODT is no longer required in new patients receiving Ubrelvy. There were no changes made to the PA criteria for Qulipta (the CV exclusion was removed at the February 2022 meeting). (See Appendix C for the full criteria.)



3. **COMMITTEE ACTION: QUANTITY LIMITS**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the quantity limits for Ubrelvy and Qulipta, and updating the QLs for Nurtec ODT, to allow for the migraine prevention indication (which will be approved in the PA criteria). See Appendix D for the full QLs.
4. **EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining excluding the three oral CGRP antagonists from the EMMPI program.
5. **COMMITTEE ACTION: UF, PA, QUANTITY LIMITS, EMMPI IMPLEMENTATION PERIOD**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. (See Appendix G for the actual implementation date.)

## 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: 15 for, 0 opposed, 0 abstained, 1 absent; and Group 2: 16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 2022 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.

1. **COMMITTEE ACTION: UF RECOMMENDATION**— The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following:
  - UF
    - filgrastim-ayow injection (Releuko) – White Blood Cell Stimulants - filgrastims. Note that as part of this recommendation Releuko will be designated as non-step-preferred.
    - mitapivat (Pyrukynd) – Miscellaneous metabolic agent for pyruvate kinase deficiency
    - naloxone 5 mg/0.5mL injection (Zimhi) – Narcotic Antagonist
    - pacritinib (Vonjo) – Oncologic agent for myelofibrosis
  - NF

- abrocitinib (Cibinqo) – Atopy drug class; oral Janus kinase (JAK) inhibitor for atopic dermatitis
- baclofen oral suspension (Fleqsuvy) – Skeletal Muscle Relaxant spasticity associated with multiple sclerosis
- tenapanor (Ibsrela) – Gastrointestinal-2 Agent for Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
- tralokinumab-ldrm injection (Adbry) – Atopy drug class; injectable agent for atopic dermatitis
- Tier 4 (Not covered): The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents. See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
  - budesonide delayed release (DR) capsules (Tarpeyo) – Miscellaneous nephrology agent; an extended-release formulation of budesonide approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN)
    - Alternatives include prednisone, methylprednisolone, and budesonide DR capsules (Entocort EC, generics).
  - celecoxib/tramadol (Seglentsis) – Narcotic Analgesics and Combinations; a fixed-dose combination of celecoxib and tramadol for acute pain
    - Alternatives include tramadol and celecoxib individual components.
  - glycopyrrolate orally disintegrating tablet (Dartisla ODT) – Anti-cholinergic/Antispasmodic Agents; another formulation of glycopyrrolate approved to reduce the symptoms of peptic ulcer as an adjunct to treatment of peptic ulcer
    - Alternatives include glycopyrrolate tablets, glycopyrrolate oral solution (Cuvposa), omeprazole, and famotidine.
  - levoketoconazole (Recorlev) – Miscellaneous endocrine agent; a ketoconazole formulation approved to treat Cushing’s disease for whom pituitary surgery is not an option or has not been curative
    - Alternatives ketoconazole, osilodrostat (Isturisa), metyrapone, mitotane, and pasireotide SQ (Signifor LAR injection, available under the medical benefit).
  - torsemide 20 mg and 60 mg tablets (Soaanz) – Diuretics; another formulation of torsemide approved to treat patients with heart failure or renal disease with edema who have concerns with excessive urination or hypokalemia

- Alternatives include torsemide tablets, bumetanide, furosemide, and ethacrynic acid.
  - tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twynéo) – Acne Agent; combination of tretinoin and benzoyl peroxide approved for acne vulgaris in 9 years of age and older
    - Alternatives include the individual components of tretinoin and benzoyl peroxide, Epiduo, Epiduo Forte
- 2. **COMMITTEE ACTION: MN CRITERIA**— The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for criteria for Adbry, Cibinqo, Fleqsuvy, and Ibsrela (see Appendix B for the full criteria.)
- 3. **COMMITTEE ACTION: PA CRITERIA**— The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):
  - Releuko will be non-step-preferred, requiring a trial of both Granix and Nivestym prior to use. The same manual PA criteria that currently applies to the non-step-preferred filgrastims Neupogen and Zarxio will apply to new users of Releuko.
  - Applying manual PA criteria to new users of Adbry and Cibinqo, requiring a trial of topical corticosteroids and topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus), similar to the requirements for other products approved for atopic dermatitis, including Dupixent, Opzelura cream and Rinvoq (*see Utilization Management section*).
  - Applying manual PA criteria to new users of Fleqsuvy, similar to the current PA for baclofen oral solution (Ozobax).
  - Applying manual PA criteria to new users of Ibsrela, similar to the current PA for prucalopride (Motegrity).
  - Applying manual PA criteria to new users of Pyrukynd, consistent with the FDA indications and monitoring requirements.
- 4. **COMMITTEE ACTION: EMMPI**— The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

**5. COMMITTEE ACTION: UF, TIER 4, MN, AND PA**

**IMPLEMENTATION PERIOD**—The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following

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

**VI. UTILIZATION MANAGEMENT**

**A. PA Criteria**

**1. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**

Manual PA criteria were recommended for several recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. These drugs all have numerous cost-effective formulary alternatives available that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users, requiring a trial of cost effective generic formulary medications first.

- a) **Antiemetic/Antivertigo Agents—meclizine 25 mg chewable tablet (Antivert)**—Meclizine is an older antiemetic widely available in 12.5 mg and 25 mg tablets in prescription and over-the-counter (OTC) formulations. A new 25 mg chewable tablet has come to market manufactured by a single company which requires a prescription prior to dispensing.
- b) **Endocrine Agents Miscellaneous—lanreotide 120 mg injection**—Lanreotide 120 mg injection is a new Somatuline Depot formulation only available in this one dosage strength. Somatuline Depot is more cost-effective than the lanreotide 120 mg injection made by a sole manufacturer.
- c) **Selective Serotonin Reuptake Inhibitors (SSRIs)—citalopram 30 mg capsule**—Citalopram 30 mg capsules are manufactured by a single company and are markedly not cost-effective relative to other generic SSRIs. All other formulations of citalopram and various other SSRIs are included on the TRICARE pharmacy benefit and do not require prior authorization criteria.

- d) **Pain Agents: NSAIDs—ketoprofen 25 mg capsule**—Ketoprofen 25 mg capsule is manufactured by a single company which requires a prescription prior to dispensing. Numerous cost-effective ketoprofen formulations are available without prior authorization in addition to other formulary cost-effective NSAIDs.

***COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PLAN***—

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for citalopram 30 mg capsule, lanreotide 120 mg injection, ketoprofen 25 mg capsule, and meclizine 25 mg chewable tablet (Antivert) in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

**2. Updated PA Criteria for New FDA-Approved Indications**

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications. The updated PA criteria outlined below will apply to new users. The most current PA criteria is found on the TRICARE Formulary Search Tool at: <https://www.esrx.com/tform>.

- a) **Anticonvulsants-Antimania Agents—fenfluramine oral solution (Fintepla)**—The manual PA criteria were updated to expand use for Lennox-Gastaut syndrome.
- b) **Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)**—The manual PA criteria were updated to expand use for adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.
- c) **Targeted Immunomodulatory Biologics (TIBs)**
- **ustekinumab (Stelara)**—The manual PA criteria were updated to expand use for moderate to severe ulcerative colitis (UC). Patients must first try adalimumab (Humira) before use of Stelara for UC. Alternatively, the medical benefit drug infliximab (Remicade) may be used first in lieu of Humira.
  - **upadacitinib (Rinvoq)**—The manual PA criteria were updated for Rinvoq to expand use for atopic dermatitis (AD) and moderately to severely active ulcerative colitis (UC). For AD, patients must first try a high potency topical corticosteroid and a topical calcineurin inhibitor similar to other agents approved for AD. For UC, patients must first try adalimumab (Humira) before use of Rinvoq. Additionally, other non-

biologics (e.g., azathioprine, sulfasalazine) are well established therapies for UC, and are more cost effective than Rinvoq.

**COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Lynparza, Fintepla, Stelara, and Rinvoq in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

### 3. Updated PA Criteria for Removal of Indication

**Oncological Agents: idelalisib (Zydelig)**—Zydelig was reviewed as a newly approved drug in November 2019. PA criteria was implemented at that time. Recently the FDA determined that two previously-approved indications were no longer merited, including relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL). The indication of chronic lymphocytic leukemia (CLL) will remain.

**COMMITTEE ACTION: ZYDELIG UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) to remove the FL and SLL indications for new users but will allow current users to consult their provider as to whether continued treatment is clinically appropriate. The other FDA-approved indication for CLL for Zydelig is not affected and will remain on the PA. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

### 4. Updated PA Criteria for Reasons other than new FDA indications

a) **Neurological Agents Miscellaneous: amifampridine (Firdapse)**—Manual PA criteria for Firdapse for treating Lambert-Eaton myasthenic syndrome (LEMS) were first recommended in May 2019. Ruzurgi is another amifampridine formulation approved for ALS. In May 2019, manual PA criteria for Firdapse required a trial of the cost-effective amifampridine agent Ruzurgi first in new patients. The FDA deemed Ruzurgi's license in pediatric patients as no longer valid in February 2022 therefore the manual PA criteria for Firdapse was updated to allow use for LEMS without a trial of Ruzurgi.

b) **Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy—testosterone cypionate and testosterone enanthate**—PA criteria were recommended for the injectable testosterone products at the February 2022 meeting. Based on current policies and guidelines for treating gender dysphoria, the Committee recommended removal of the requirement of 3 months of real life experience (RLE) and/or 3 months of psychotherapy prior to PA approval. These changes will also apply to the

testosterone replacement therapy formulations. (see February 2022 minutes for other information)

- c) **Anti-Inflammatory Immunomodulatory Ophthalmic Agents: cenegermin-bkbj ophthalmic solution (Oxervate)**—Oxervate was reviewed as a new drug in February 2019 and is FDA-approved to treat neurotrophic keratitis. Manual PA criteria currently allow for an indefinite duration of use. PA Criteria were updated to expire after 6 months to ensure an appropriate duration of therapy, consistent with the product labeling for Oxervate.
- d) **Miscellaneous Insulin Devices: Omnipod, Omnipod DASH**—Manual PA criteria and quantity limits were recommended for Omnipod and Omnipod DASH in November 2021. These devices may be used for up to 72 hours but could be changed every 48 hours. The renewal PA criteria were updated to remove the previously listed limit for duration of use. QLs were updated to reflect the change as well (See section below on QLs and Appendix C).

**COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the PA for Ruzurgi, IM testosterone products, Oxervate and the Omnipod products. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

## B. Quantity Limits

**Newly approved drugs:** QLs were reviewed for the newly approved drugs where there are existing QLs for the class, including the Myelogenous Leukemia, Narcotic Antagonists, and agents for Atopy. QLs were also recommended for the oncology drugs, Alecensa and Inlyta.

**Omnipod and Omnipod DASH**—Omnipod was reviewed for PA and QLs at the August 2021 meeting, with implementation set to occur on May 18, 2022. The QLs were updated to allow for 15 pods/30 days at Retail, and for 45 pods/90 days at TRICARE Mail Order and MTF pharmacies. This will allow replacing the pod every 48 hours. The PA was also updated accordingly (see above section).

**COMMITTEE ACTION: QLs AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) QLs for Adbry, Alecensa, Cibinqo, Inlyta, Omnipod/Omnipod DASH, Vonjo, and Zimhi with implementation occurring the first Wednesday two weeks after signing of the minutes. See Appendix D for the QLs.

## C. Line Extensions

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

- a) **Anticoagulants**—designating **rivaroxaban 1 mg/mL oral solution (Xarelto)** as UF, with the same formulary status and EMMPI List status as Xarelto tablets
- b) **Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis**—designating **lanadelumab-flyo (Takhzyro) 300 mg/2 mL syringe** as UF, with the same manual PA criteria requirements, QL, and specialty status as Takhzyro vials

**COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS AND IMPLEMENTATION**—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the formulary status for the line extension products as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

## **VII. BRAND OVER GENERIC AUTHORIZATION FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE-DOSE VIALS (RESTASIS) AND TIER 1 COPAY**

*Background*—The Ophthalmic Immunomodulatory Agents subclass was reviewed in February 2018. This class includes cyclosporine 0.05% ophthalmic emulsion (Restasis) and lifitegrast 5% ophthalmic solution (Xiidra). Since then, generic formulations of Restasis have come to market however these generics are less cost-effective compared to brand Restasis at the MTFs and Mail Order points of service.

Brand Restasis will now be required prior to receiving generic cyclosporine 0.05% ophthalmic emulsion at the MTFs and Mail Order. This brand over generic PA will not apply at the retail point of service. Additionally, the requirement only applies to the Restasis single dose formulation, and not the multi-dose formulation. The Tier 1 copay for brand Restasis single dose is recommended and Restasis will also remain on the EMMI list.

**COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE-DOSE, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) requiring brand Restasis over generic cyclosporine 0.05% ophthalmic emulsion in all new and current users at MTF and mail, based on cost effectiveness. The prescriber will provide patient-specific justification as to why brand cannot be used. The Tier 1 (generic) copayment will apply to brand Restasis. The effective date will be two weeks after signing of the minutes at MTF and mail. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. See Appendix C for the full PA criteria for generic cyclosporine 0.05% ophthalmic emulsion.



The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3):  
When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

#### **VIII. BCF CLARIFICATION: ANTIRETROVIRAL AGENTS: NUCLEOSIDE/NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)**

*Background*—The Antiretroviral Agents were reviewed in August 2017. At that time, all agents were designated UF with no agent added to the BCF. Some of the reasons against selecting a BCF product included limited treatment choices in a disease where resistance is a concern, rapidly changing treatment guidelines, patient comorbidities, and individual drug-drug interaction profiles, among others.

The NNRTIs emtricitabine/tenofovir disoproxil fumarate (Truvada) and emtricitabine/tenofovir alafenamide (Descovy) are both oral options for HIV pre-exposure prophylaxis (PrEP). Truvada is now available as a cost-effective generic. Professional treatment guidelines from the Centers for Disease Control and the US Preventive Services Task Force, along with DoD infectious disease provider feedback, support use of Truvada for PrEP for most patients.

***COMMITTEE ACTION: ADDITION OF GENERIC TRUVADA ON THE BCF***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding generic emtricitabine/tenofovir disoproxil fumarate (Truvada) to the BCF, based on cost-effectiveness, guideline endorsement for PrEP, and provider feedback. Implementation will occur on the first Wednesday two weeks after signing of the minutes. (See Appendix G for the actual implementation dates.)

#### **IX. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFs: BROAD REVIEW OF REMAINING CLASSES**

*Background*—The DoD P&T Committee reviewed two categories of OTC medications that were tabled at the February 2022 P&T Committee meeting, the probiotics and rectal skin preps (hemorrhoidal) agents. Additionally the status of OTC versions of olopatadine 0.1% ophthalmic solution were also discussed.

For a full description of the origin and purpose of the MHS GENESIS OTC list, please refer to the February 2022, August 2019, and May 2019 DoD P&T Committee meeting minutes, found at <http://health.mil/PandT>. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

**COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC**

**LIST/IMPLEMENTATION**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- For **probiotics**, retaining or adding products based on provider recommendations, clinical evidence support, and current MTF utilization. This included specific recommendations for liquid formulations of *Lactobacillus reuteri* (e.g., Biogaia) and *Lactobacillus reuteri*/vitamin D for treatment of colic in infants, *Bifidobacterium infantis* (Align) and *Lactobacillus rhamnosus* GG (Culturelle) for irritable bowel syndrome, *Saccharomyces boulardii* (e.g., Florastor) for recurrent *C. difficile* infection, and *Lactobacillus 2/Bifido 1/S thermo* (VSL#3, Visbiome) for the treatment of pouchitis and recurrent *C. difficile*. The P&T Committee also recommended addition of three additional *Lactobacillus acidophilus* products based on MTF utilization.
- For the **skin preps: rectal hemorrhoidal agents**:
  - Removing cream and ointment combination agents containing phenylephrine (e.g., Preparation H) due to low utilization
  - Retaining the Preparation H rectal suppository, adding pramoxine foam, and retaining dibucaine ointment (Nupercainal), which was recommended due to obstetric use.
  - The P&T Committee noted that it was likely that the majority of products prescribed for hemorrhoids were legend or OTC versions of hydrocortisone.
  - Note that witch hazel medicated pads were reviewed in February 2022 and retained on the MHS GENESIS OTC list.
- For **olopatadine 0.1% ophthalmic solution**: Confirming the April 6, 2022 addition of OTC versions of olopatadine solution to the MHS GENESIS OTC list.
  - Olopatadine 0.1% ophthalmic solution products were switched from legend status to OTC in mid-March 2022. Olopatadine 0.1% ophthalmic solution is the most commonly used and most cost effective ophthalmic antihistamine dispensed at all points of services. Although there are legend versions currently in use at the retail and mail order points of service, they are not readily available at MTFs.
- **Fluoride products**: The P&T Committee also noted that fluoride products, including creams, drops, gels, pastes, solutions, and chewable tabs, are not included on the MHS GENESIS List, but are available at MTFs and will adjudicate through PDTS.
- Implementation dates of 120 days following signing of the minutes for the products removed from the list, and two weeks for products added to the list were recommended. No patient letters are required based on current MTF utilization and typical use.

## **X. ITEMS FOR INFORMATION**

### **A. DoD Pharmacy and Commercial Trends and Focus on Specialty Pharmacy**

Information on MHS prescribing, including overall trends and spends, the effect of co-pay changes on utilization patterns, the top 25 drug classes, and the continued increases in use and cost of specialty drugs was presented to the Committee. Comparisons between the MHS and commercial health plans in these trends was discussed. Other information included the forecast for biosimilars and a review of technology trends.

### **B. Post-Implementation Review: Utilization Management Actions: The Committee reviewed utilization and cost trends for several drugs where utilization management actions were taken during 2020. The effects of implementing PA criteria or designating Tier 1 status for drugs from 10 different drug classes were evaluated. Utilization management actions show a variety of effects in cost avoidance and utilization, driven mostly on the nature of the PA and the specific agent or class.**

### **C. Pulmonary I Agents: The Committee was briefed on various aspects of the class to include up-to-date clinical practice guideline recommendations and current PA requirements.**

### **D. Veteran's Affairs Continuity of Care List: The Committee updated the DoD/VA Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715. Additions, deletions, and clarifications to the list were based on FY21 Active Duty prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The updated list will now go to the VA for review and will be posted on [www.health.mil](http://www.health.mil) when finalized.**

### **E. Specialty Pharmacy (TPharm5) Discussion: The 5th generation TRICARE Pharmacy Service (TPharm5) contract was awarded to Express Script, Inc. on August 5, 2021, with the implementation set to occur on January 1, 2023. Several key components of the program, including the new specialty pharmacy program, were presented to the Committee.**

## **XI. ADJOURNMENT**

The meeting adjourned at 1445 hours on May 5, 2022. The next meeting will be in August 2022.

**Appendix A—Attendance: May 4-5, 2022 DoD P&T Committee Meeting:**

**Appendix B—Table of Medical Necessity Criteria**

**Appendix C—Table of Prior Authorization Criteria**

**Appendix D—Table of Quantity Limits**

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

**Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 2022 DoD P&T Committee Meeting**

**Appendix G—Implementation Dates**

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

**Appendix I—MHS GENESIS OTC Text List**

## DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

The Director, DHA:



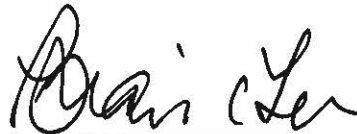
concurs with all recommendations.



concurs with the recommendations, with the following modifications:



concurs with the recommendations, except for the following:



Brian C. Lein, MD  
Assistant Director,  
Healthcare Administration  
for Ronald J. Place  
LTG, MC, USA  
Director

27 Jul 2022

Date

## Appendix A—Attendance

<b>Voting Members Present</b>	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Col Markus Gmehlin BSC	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Consultant
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, COL (Ret.) MC, USA	Army, Family Medicine Physician
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Lt Col Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
LTC Jason Burris, MC	Army, Oncologist
Beth Days, PharmD	Oncology Pharmacist
<b>Nonvoting Members Present</b>	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
Lt Col Matt Cowan, BSC	Defense Logistics Agency

Appendix A—Attendance

<b>Guests</b>	
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Tracy Banks	DHA Contracting Officer
<b>Others Present</b>	
CDR Scott Raisor, USPHS	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
LCDR Todd Hansen, MC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
David Folmar, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, RPh	DHA Formulary Management Branch Contractor
Michael Lee, RPh	DHA Formulary Management Branch Contractor
Dean Valibhai, PharmD	DHA Purchased Care Branch
Sarah Bandy, Pharm D	University of Texas at Austin/UTHSCSA pharmacy resident
Yufeng Zhai	University of Texas at Austin/UTHSCSA pharmacy student

## Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
<b>Drug Class Reviews MN Criteria</b>	
<ul style="list-style-type: none"> <li>semaglutide (Ozempic)</li> </ul> <p><b>Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)</b></p>	<ul style="list-style-type: none"> <li>Patient has experienced significant adverse effects from dulaglutide (Trulicity) which is not expected to occur with semaglutide (Ozempic)</li> </ul> <p><b>Formulary alternatives:</b> dulaglutide (Trulicity)</p>
<ul style="list-style-type: none"> <li>exenatide once weekly (Bydureon BCise)</li> <li>exenatide twice daily (Byetta)</li> <li>liraglutide (Victoza)</li> <li>lixisenatide (Adlyxin)</li> </ul> <p><b>Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)</b></p>	<ul style="list-style-type: none"> <li>Patient has experienced significant adverse effects from dulaglutide (Trulicity) and semaglutide (Ozempic) which is not expected with the non-preferred products.</li> <li>No alternative formulary agent - for Victoza and Bydureon BCise only: patient is between the ages of 10 to less than 18 years</li> </ul> <p><b>Formulary and non-formulary alternatives:</b> dulaglutide (Trulicity) and semaglutide (Ozempic)</p>
<b>Newly Approved Drugs MN Criteria</b>	
<ul style="list-style-type: none"> <li>abrocitinib (Cibinqo)</li> </ul> <p><b>Atopy</b></p>	<ul style="list-style-type: none"> <li>Use of formulary agents is contraindicated</li> <li>Patient has experienced significant adverse effects from formulary agents</li> <li>Formulary agents resulted in therapeutic failure</li> </ul> <p><b>Formulary alternatives:</b> dupilumab (Dupixent), topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus), high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)</p>
<ul style="list-style-type: none"> <li>baclofen oral suspension (Fleqsuvy)</li> </ul> <p><b>Skeletal Muscle Relaxants &amp; Combinations</b></p>	<ul style="list-style-type: none"> <li>No alternative formulary agent. Patient cannot swallow and crushed tablets are not an option.</li> </ul> <p><b>Formulary alternatives:</b> baclofen tablets</p>
<ul style="list-style-type: none"> <li>tenapanor (Ibsrela)</li> </ul> <p><b>Gastrointestinal-2: CIC &amp; IBS-C</b></p>	<ul style="list-style-type: none"> <li>Use of formulary agents is contraindicated</li> <li>Patient has experienced significant adverse effects from formulary agents</li> <li>Formulary agents resulted in therapeutic failure</li> </ul> <p><b>Formulary alternatives:</b> Linzess, Trulance, Amitiza</p>
<ul style="list-style-type: none"> <li>tralokinumab injection (Adbry)</li> </ul> <p><b>Atopy</b></p>	<ul style="list-style-type: none"> <li>Use of formulary agents is contraindicated</li> <li>Patient has experienced significant adverse effects from formulary agents</li> <li>Formulary agents resulted in therapeutic failure</li> </ul> <p><b>Formulary alternatives:</b> dupilumab (Dupixent), topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus), high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)</p>



# Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<b>Drug Class Review PAs</b>	
<ul style="list-style-type: none"> <li>dulaglutide (Trulicity)</li> <li>semaglutide (Ozempic)</li> </ul> <p><b>Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)</b></p>	<p><b>The only change from the May 2022 meeting is new patients receiving Ozempic do not require a trial of Trulicity first.</b></p> <p>All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.</p> <p><u>Manual PA criteria</u>—Trulicity or Ozempic are approved (i.e., a trial of metformin is NOT required) if:</p> <ul style="list-style-type: none"> <li>The patient has a confirmed diagnosis of Type 2 diabetes mellitus.</li> <li>The patient has experienced any of the following issues on metformin: <ul style="list-style-type: none"> <li>impaired renal function precluding treatment with metformin</li> <li>history of lactic acidosis</li> </ul> </li> <li>The patient has had inadequate response to metformin</li> <li>The patient has a contraindication to metformin</li> </ul> <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> <li>exenatide once weekly (Bydureon BCise)</li> <li>exenatide twice daily (Byetta)</li> <li>liraglutide (Victoza)</li> <li>lixisenatide (Adlyxin)</li> </ul> <p><b>Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)</b></p>	<p><b>Changes from the May 2022 meeting are in bold and strikethrough.</b></p> <p>All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.</p> <p><b>New and current users of Bydureon BCise, Byetta, Victoza, or Adlyxin, must try <del>Bydureon/Bydureon BCise</del> Trulicity and Ozempic first.</b></p> <p><u>Manual PA criteria</u>—Bydureon BCise, Byetta, Victoza, or Adlyxin is approved (i.e., a trial of metformin is NOT required) if:</p> <ul style="list-style-type: none"> <li>The patient has a confirmed diagnosis of Type 2 diabetes mellitus.</li> <li>The patient has experienced any of the following issues on metformin: <ul style="list-style-type: none"> <li>impaired renal function precluding treatment with metformin</li> <li>history of lactic acidosis</li> </ul> </li> <li>The patient has had inadequate response to metformin</li> <li>The patient has a contraindication to metformin</li> </ul> <p>AND</p> <p><b>In addition to the above criteria regarding metformin the following PA criteria would apply specifically to new and current users of Bydureon BCise, Byetta, Victoza, and Adlyxin:</b></p> <ul style="list-style-type: none"> <li>The patient has had an inadequate response to Trulicity and <del>Bydureon BCise</del> <b>Ozempic OR</b></li> <li><b>For Victoza and Bydureon BCise, patient is age 10 years to &lt; 18 years.</b></li> </ul> <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire</p>

<ul style="list-style-type: none"> <li>• atogepant (Qulipta)</li> </ul> <p><b>Migraine Agents oral CGRP</b></p>	<p><b>There were no changes made at the May 2022 meeting</b></p> <p>Manual PA criteria apply to all new users of Qulipta.</p> <p><u>Manual PA criteria:</u> Qulipta is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Patient is 18 years of age or older</li> <li>• Medication is prescribed by or in consultation with neurologist</li> <li>• Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed</li> <li>• Patient has Episodic Migraine as defined by the following: <ul style="list-style-type: none"> <li>○ 4 to 7 migraine days per month for 3 months AND has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score &gt; 11 or Headache Impact Test-6 (HIT-6) score &gt; 50 OR</li> <li>○ 8 to 14 migraine days per month for 3 months</li> </ul> </li> <li>• Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: <ul style="list-style-type: none"> <li>○ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate</li> <li>○ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol</li> <li>○ Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine</li> </ul> </li> <li>• Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents <ul style="list-style-type: none"> <li>○ erenumab-aooe (Aimovig)</li> <li>○ fremanezumab-vfrm (Ajovy)</li> <li>○ galcanezumab-gnlm (Emgality)</li> </ul> </li> </ul> <p>Non-FDA-approved uses are not approved. Prior Authorization expires after 6 months.</p> <p><u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:</p> <ul style="list-style-type: none"> <li>• The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR</li> <li>• The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: <ul style="list-style-type: none"> <li>• Migraine Disability Assessment (MIDAS) <ul style="list-style-type: none"> <li>- Reduction of ≥ 5 points when baseline score is 11–20</li> <li>- Reduction of ≥ 30% when baseline score is &gt; 20</li> </ul> </li> <li>• Headache Impact Test (HIT-6) <ul style="list-style-type: none"> <li>- Reduction of ≥ 5 points</li> </ul> </li> <li>• Migraine Physical Functional Impact Diary (MPFID) <ul style="list-style-type: none"> <li>- Reduction of ≥ 5 points</li> </ul> </li> </ul> </li> </ul>
---	--

<ul style="list-style-type: none"> <li>• rimegepant (Nurtec ODT)</li> </ul> <p><b>Migraine Agents oral CGRP</b></p>	<p><b><u>Updates from the May 2022 meeting are in bold and strikethrough.</u></b> Manual PA criteria apply to all new users of rimegepant (Nurtec ODT).</p> <p><u>Manual PA criteria:</u> Nurtec ODT is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• The patient is 18 years of age or older</li> <li>• Medication is prescribed by or in consultation with neurologist</li> <li>• Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrelvy or another gepant) is not allowed</li> <li>• <del>Not approved for patients who have clinically significant or unstable cardiovascular disease</del></li> </ul> <p><u>For Acute Treatment</u></p> <ul style="list-style-type: none"> <li>• Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications <ul style="list-style-type: none"> <li>○ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)</li> </ul> </li> </ul> <p><u>For Prevention of Episodic Migraine</u></p> <ul style="list-style-type: none"> <li>• The patient has episodic migraine as defined by one of the following: <ul style="list-style-type: none"> <li>○ Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score &gt; 11 or Headache Impact Test-6 (HIT-6) score &gt; 50 <b>OR</b></li> <li>○ Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months</li> </ul> </li> <li>• Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: <ul style="list-style-type: none"> <li>○ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate</li> <li>○ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol</li> <li>○ Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine</li> </ul> </li> <li>• Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents <ul style="list-style-type: none"> <li>○ erenumab-aooe (Aimovig)</li> <li>○ fremanezumab-vfrm (Ajovy)</li> <li>○ galcanezumab-gnlm (Emgality)</li> </ul> </li> <li>• <b>If approved for prevention: authorized quantity limit is 16 ODT for 30 days or 48 ODT for 90 days</b></li> </ul> <p>Non-FDA-approved uses are NOT approved. PA expires after 6 months.</p> <p><u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:</p> <p><u>Acute Treatment</u></p> <ul style="list-style-type: none"> <li>• Patient has a documented positive clinical response to therapy</li> </ul> <p><u>Preventive Treatment</u></p> <ul style="list-style-type: none"> <li>• The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) <b>OR</b></li> <li>• The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: <ul style="list-style-type: none"> <li>• Migraine Disability Assessment (MIDAS) <ul style="list-style-type: none"> <li>- Reduction of ≥ 5 points when baseline score is 11–20</li> <li>- Reduction of ≥ 30% when baseline score is &gt; 20</li> </ul> </li> <li>• Headache Impact Test (HIT-6): Reduction of ≥ 5 points</li> <li>• Migraine Physical Functional Impact Diary (MPFID): Reduction of ≥ 5 points</li> </ul> </li> </ul>
---	--

## Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> <li>ubrogepant (Ubrelyvy)</li> </ul> <p><b>Migraine Agents oral CGRP</b></p>	<p><b>Updates from the May 2022 Meeting are in strikethrough.</b></p> <p>Manual PA criteria apply to all new users of ubrogepant (Ubrelyvy).</p> <p><u>Manual PA criteria:</u> Ubrelyvy is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>The patient is 18 years of age or older</li> <li>Medication is prescribed by or in consultation with neurologist</li> <li>Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or another gepant) is not allowed</li> <li><del>Not approved for patients who have clinically significant or unstable cardiovascular disease</del></li> <li>Patient has a contraindication to, intolerance to, or has failed a trial of at least TWO of the following medications</li> <li>sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)</li> <li><del>Patient has had a contraindication to, intolerance to, or has failed a 2-month trial of Nurtec ODT</del></li> </ul> <p>Non-FDA-approved uses are not approved. PA expires after 6 months</p> <p>Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met (Note that initial TRICARE PA approval is required for renewal):</p> <p>Acute Treatment: Patient has a documented positive clinical response to therapy</p>
<p><b>Newly Approved Drug PAs</b></p>	
<ul style="list-style-type: none"> <li>abrocitinib (Cibinqo)</li> </ul> <p><b>Atopy</b></p>	<p>Manual PA criteria apply to all new users of abrocitinib (Cibinqo).</p> <p><u>Manual PA criteria:</u> abrocitinib (Cibinqo) is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>Patient is 18 years of age or older</li> <li>Medication is prescribed by an allergist, dermatologist, or immunologist</li> <li>Drug is used to treat moderate to severe atopic dermatitis</li> <li>Patient failed, has a contraindication, or intolerance to one medication in EACH of the following two categories: <ul style="list-style-type: none"> <li>Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND</li> <li>Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)</li> </ul> </li> <li>Patient is unable to access, has a contraindication to, or intolerance to UVB phototherapy</li> <li>Patient has had a negative TB test in the last 12 months (or is adequately managed)</li> <li>Patient has no history of venous thromboembolism (VTE)</li> <li>Provider is aware of the boxed FDA warnings</li> <li>Patient does not have neutropenia (ANC &lt; 1000)</li> <li>Patient does not have lymphocytopenia (ALC &lt; 500)</li> <li>Patient does not have anemia (Hgb &lt; 8)</li> <li>Patient is not taking a concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulatorys</li> </ul> <p>Non-FDA-approved uses are not approved. PA expires in 1 year. Renewal PA criteria will be approved indefinitely.</p> <p><u>Renewal criteria:</u> The patient's disease severity has improved and stabilized to warrant continued therapy</p>

## Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> <li>• baclofen oral suspension (Fleqsuvy)</li> </ul> <p><b>Skeletal Muscle Relaxants &amp; Combinations</b></p>	<p>Manual PA criteria apply to all new users of baclofen oral solution (Ozobax) and <b>baclofen oral suspension (Fleqsuvy)</b>.</p> <p><u>Manual PA criteria:</u> baclofen oral solution (Ozobax) or <b>baclofen oral suspension (Fleqsuvy)</b> is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Baclofen will be used for spasticity</li> <li>• Patient requires baclofen and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience</li> </ul> <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>• filgrastim-ayow injection (Releuko)</li> </ul> <p><b>WBC Stimulants: Filgrastims</b></p>	<p>Manual PA criteria apply to all new users of filgrastim (Neupogen), <b>filgrastim-ayow (Releuko)</b>, and filgrastim-sndz (Zarxio).</p> <p><u>Manual PA criteria:</u> filgrastim (Neupogen), <b>filgrastim-ayow (Releuko)</b>, or filgrastim-sndz (Zarxio) is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Provider acknowledges that tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) are the preferred filgrastims and are available without a PA</li> <li>• Drug is prescribed by or in consultation with a hematologist/oncologist</li> <li>• Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen), filgrastim-sndz (Zarxio), or filgrastim-ayow (Releuko)</li> <li>• Patient has experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen), filgrastim-sndz (Zarxio), or filgrastim-ayow (Releuko)</li> </ul> <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>• tenapanor (Ibsrela)</li> </ul> <p><b>Gastrointestinal-2: CIC &amp; IBS-C</b></p>	<p>Manual PA criteria apply to all new users of Ibsrela.</p> <p><u>Manual PA criteria:</u> Ibsrela is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Patient is 18 years of age or older</li> <li>• Patient has had documented symptoms for ≥ 3 months</li> <li>• Patient has diagnosis of IBS-C</li> <li>• Patient has tried and failed all formulary agents including Linzess, Amitiza, and Trulance</li> <li>• Patient does not have GI obstruction</li> <li>• Patient has documentation of failure of an increase in dietary fiber/dietary modification</li> <li>• Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes defined as: <ul style="list-style-type: none"> <li>• osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)</li> <li>• bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids;</li> <li>• stool softener (e.g., docusate)</li> <li>• stimulant laxative (e.g., bisacodyl, sennosides)</li> </ul> </li> <li>• Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Trulance, Zelnorm, Motegrity, Symproic, Relistor, or Movantik)</li> </ul> <p>Non-FDA-approved uses are not approved including opioid-induced constipation (OIC), chronic idiopathic constipation (CIC), and hyperphosphatemia. Prior authorization expires in 1 year.</p> <p><u>Renewal criteria:</u> (Initial TRICARE PA approval required for renewal) Coverage will be approved for an additional year if both of the following applies:</p> <ul style="list-style-type: none"> <li>• Patient has had improvement in constipation symptoms</li> <li>• Patient is not taking any of these agents concomitantly Amitiza, Linzess, Trulance, Motegrity, Zelnorm, Symproic, Relistor, Movantik</li> </ul>

## Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> <li>• tralokinumab-ldrm injection (Adbry)</li> </ul> <p><b>Atopy</b></p>	<p>Manual PA criteria apply to all new users of Adbry.</p> <p><u>Manual PA criteria:</u> Adbry is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Patient is 18 years of age or older</li> <li>• The drug is prescribed by a dermatologist, allergist, or immunologist</li> <li>• The patient has moderate to severe atopic dermatitis</li> <li>• The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: <ul style="list-style-type: none"> <li>• Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND</li> <li>• Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)</li> </ul> </li> <li>• The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy</li> </ul> <p>Non-FDA-approved uses are not approved. PA expires in 1 year</p> <p><u>Renewal criteria:</u> (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:</p> <ul style="list-style-type: none"> <li>• The patient's disease severity has improved and stabilized to warrant continued therapy.</li> </ul>
<ul style="list-style-type: none"> <li>• mitapivat (Pyrukynd)</li> </ul> <p><b>Metabolic Agents- Miscellaneous: Replacement Enzymes</b></p>	<p>Manual PA criteria apply to all new users of Pyrukynd.</p> <p><u>Manual PA criteria:</u> Pyrukynd is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Patient is 18 years of age or older</li> <li>• Patient has a documented diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency</li> <li>• Patient has a documented presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, at least one of which is a missense variant</li> <li>• Patient has a hemoglobin less than or equal to 10 g/dL</li> <li>• Patient and provider are aware that abrupt discontinuation may lead to acute hemolysis</li> </ul> <p>Non-FDA-approved uses are not approved including patients who were homozygous for the c.1436G&gt;A (p.R479H) variant or had 2 non-missense variants (without the presence of another missense variant) in the PKLR gene.</p> <p>Prior authorization expires in 6 months.</p> <p><u>Renewal criteria:</u> (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:</p> <ul style="list-style-type: none"> <li>• Patient has experienced a <math>\geq 1.5</math> g/dL sustained increase in Hgb from baseline after 24 weeks of therapy.</li> </ul>

## Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management New PAs	
<ul style="list-style-type: none"> <li>citalopram 30 mg capsule</li> </ul> <p><b>Antidepressants and Non-Opioid Pain Syndromes: SSRIs</b></p>	<p>Manual PA criteria apply to all new and current users of citalopram 30 mg capsules.</p> <p><u>Manual PA criteria:</u> Citalopram 30 mg capsule is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>Provider acknowledges other strengths of citalopram and other formulary SSRIs are available without prior authorization.</li> <li>Provider must explain why the patient cannot take a combination of lower strengths to achieve the desired dose.</li> </ul> <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>ketoprofen 25 mg capsule</li> <li><b>Pain Agents: NSAIDs</b></li> </ul>	<p>Manual PA criteria apply to new and current users of ketoprofen 25 mg capsule.</p> <p><u>Manual PA criteria:</u> Ketoprofen 25 mg capsule is approved if all criteria are met:</p> <ul style="list-style-type: none"> <li>Provider acknowledges that other strengths of ketoprofen and other formulary NSAIDs are available without the need of prior authorization.</li> <li>The provider must explain why the patient requires ketoprofen 25 mg capsule and cannot take the cost-effective generic ketoprofen or other formulary NSAIDs</li> </ul> <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>lanreotide acetate 120 mg injection</li> </ul> <p><b>Endocrine Agents Misc</b></p>	<p>Manual PA criteria apply to all new and current users of lanreotide acetate 120 mg injection.</p> <p><u>Manual PA criteria:</u> Lanreotide acetate 120 mg injection is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization.</li> <li>Provider must explain why the patient cannot use the 120 mg Somatuline Depot brand.</li> </ul> <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>meclizine 25 mg chewable tab (Antivert)</li> </ul> <p><b>Anti-Emetic/ Antivertigo Agents</b></p>	<p>Manual PA criteria apply to new and current users of meclizine 25 mg chewable tablet (Antivert).</p> <p><u>Manual PA criteria:</u> Meclizine 25 mg chewable tablet (Antivert) is approved if all criteria are met:</p> <ul style="list-style-type: none"> <li>Provider is aware and acknowledges that meclizine 25 mg tablet is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred meclizine 25 mg tablet</li> <li>The provider must explain why the patient requires meclizine 25 mg chewable tablet (Antivert) and cannot take the cost-effective meclizine 25 mg tablet (fill-in blank)</li> </ul> <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

## Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> <li>amifampridine (Firdapse)</li> </ul> <p><b>Neurological Agents Miscellaneous</b></p>	<p><b>Updates from the May 2022 meeting are in strikethrough.</b></p> <p>Manual PA applies to all new users of Firdapse.</p> <p><u>Manual PA Criteria:</u> Firdapse is approved if:</p> <ul style="list-style-type: none"> <li><del>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.</del></li> <li>Patient is 18 years of age or older</li> <li>Firdapse is prescribed by an oncologist or neurologist</li> <li>The patient has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS)</li> <li><del>The patient must try amifampridine (Ruzurgi) first</del></li> </ul> <p>Non-FDA-approved uses are not approved. PA does not expire.</p>
<ul style="list-style-type: none"> <li>cenegermin-bkbj ophthalmic solution (Oxervate)</li> </ul> <p><b>Anti-inflammatory Immunomodulatory Ophthalmic Agents</b></p>	<p><b>Updates from the May 2022 meeting are in bold and strikethrough.</b></p> <p>Manual PA criteria apply to all new users of Oxervate.</p> <p><u>Manual PA Criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> <li>Age ≥ 2 years</li> <li>Patient has a documented diagnosis of neurotrophic keratitis</li> <li>Drug is prescribed by a cornea specialist or ophthalmologist</li> <li>Patient does not wear contact lenses during treatment course</li> </ul> <p>Non-FDA-approved uses are NOT approved. <del>PA does not expire</del> <b>expires after 6 months.</b></p>
<ul style="list-style-type: none"> <li>cyclosporine 0.05% ophthalmic emulsion single-dose</li> </ul> <p><b>Anti-Inflammatory Immunomodulatory Ophthalmics: Ophthalmic Immunomodulatory Agents Subclass</b></p>	<p>Manual PA criteria applies to new and current users (at MTF and Mail) of generic cyclosporine 0.05% ophthalmic emulsion.</p> <p><u>Manual PA criteria</u> – Cyclosporine 0.05% ophthalmic emulsion generics are approved if all criteria are met:</p> <ul style="list-style-type: none"> <li>The brand Restasis single-dose formulation is DoD's preferred product over generic single-dose cyclosporine 0.05% ophthalmic emulsion and is covered at the lowest copayment, which is the generic formulary copayment for non-Active Duty patients, and at no cost share for Active Duty patients. (Although Restasis is a branded product, it will be covered at the generic formulary copayment or cost share.)</li> <li>Please provide a patient-specific justification as to why the generic single-dose cyclosporine 0.05% ophthalmic emulsion product must be used in this patient: _____ (fill in the blank)</li> </ul> <p>Non-FDA approved uses are not approved. Prior Authorization does not expire.</p>



## Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> <li>fenfluramine oral solution (Fintepla)</li> </ul> <p><b>Anticonvulsants- Antimania Agents</b></p>	<p><b>Changes from the May 2022 meeting are in bold.</b></p> <p>Manual PA is required for all new users of Fintepla.</p> <p><u>Manual PA Criteria:</u> Fintepla is approved if all criteria are met.</p> <ul style="list-style-type: none"> <li>Must be prescribed by a neurologist</li> <li>Patient has a diagnosis of Dravet Syndrome <b>or Lennox-Gastaut syndrome</b></li> <li>Must be used as adjunct therapy with other anticonvulsant medications</li> <li>Prescriber must abide by and the patient has been informed of the REMS program including safety risks and requirements of regular echocardiogram (ECHO) monitoring for valvular heart disease and pulmonary hypertension</li> </ul> <p>Non-FDA-approved uses are not approved including for weight loss. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>Omnipod and Omnipod DASH</li> </ul> <p><b>Insulins: Miscellaneous Insulin Device</b></p>	<p><b>Updates from the May 2022 meeting are in bold and strikethrough.</b></p> <p>Manual PA applies to new and current users of Omnipod/Omnipod DASH</p> <p><u>Manual PA criteria</u>—Omnipod/Omnipod DASH is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>The patient has diabetes mellitus AND requires insulin therapy</li> <li>The patient is on an insulin regimen of 3 or more injections per day and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy</li> <li>The patient performs 4 or more blood glucose tests per day or is using a Continuous Glucose Monitoring (CGM) system</li> <li>The patient has completed a comprehensive diabetes education program</li> <li>The patient has demonstrated willingness and ability to play an active role in diabetes self-management</li> </ul> <p>Initial prior authorization expires after 1 year.</p> <p><u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Omnipod or Omnipod DASH is approved for 1 year for continuation of therapy if all criteria are met:</p> <ul style="list-style-type: none"> <li>Patient has been successful with therapy</li> </ul> <p><b><del>Patient does not require changing the Omnipod DASH unit more frequently than every 72 hours (e.g., changing the unit every 48 hours is not allowed)</del></b></p>

<ul style="list-style-type: none"> <li>• upadacitinib (Rinvoq)</li> </ul> <p><b>Targeted Immunomodulatory Biologics (TIBs):</b> <b>Miscellaneous</b></p>	<p><b>Updates from the May 2022 meeting are in bold.</b></p> <p>Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq ER).</p> <p><u>Manual PA Criteria:</u> Rinvoq is approved if all criteria are met:</p> <p><i>For Rheumatoid Arthritis</i></p> <ul style="list-style-type: none"> <li>• Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis</li> <li>• The provider also acknowledges that for rheumatoid arthritis a trial of Xeljanz or Olumiant is required before Rinvoq.</li> <li>• The patient is 18 years of age or older</li> <li>• The patient has a diagnosis of active rheumatoid arthritis (RA)</li> <li>• Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs)</li> <li>• Patient has had an inadequate response to Humira OR</li> <li>• Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR</li> <li>• Patient has a contraindication to Humira AND</li> <li>• Patient has had an inadequate response to Xeljanz or Olumiant OR</li> <li>• Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with Rinvoq OR</li> <li>• Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq</li> </ul> <p><i>For Psoriatic Arthritis</i></p> <ul style="list-style-type: none"> <li>• Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for psoriatic arthritis.</li> <li>• The provider also acknowledges that for psoriatic arthritis a trial of Xeljanz is required before Rinvoq.</li> <li>• The patient has a diagnosis of active psoriatic arthritis (PsA)</li> <li>• The patient is 18 years of age or older</li> <li>• Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs)</li> <li>• Patient has had an inadequate response to Humira OR</li> <li>• Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR</li> <li>• Patient has a contraindication to Humira AND</li> <li>• Patient has had an inadequate response to Xeljanz OR</li> <li>• Patient has experienced an adverse reaction to Xeljanz or OR</li> <li>• Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq</li> </ul> <p><i>For Atopic Dermatitis</i></p> <ul style="list-style-type: none"> <li>• The patient is 12 years of age or older</li> <li>• The drug is prescribed by a dermatologist, allergist, or immunologist</li> <li>• The patient has moderate to severe atopic dermatitis</li> <li>• The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent)</li> <li>• The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: <ul style="list-style-type: none"> <li>▪ Topical Corticosteroids:</li> </ul> </li> </ul>
--	--

	<ul style="list-style-type: none"> <li>○ For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)</li> <li>○ For patients 12 to 17 year of age: any topical corticosteroid AND <ul style="list-style-type: none"> <li>▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)</li> </ul> </li> <li>• The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy</li> </ul> <p><b>For Ulcerative Colitis</b></p> <ul style="list-style-type: none"> <li>• Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis</li> <li>• The patient is 18 years of age or older</li> <li>• The patient has moderately to severely active ulcerative colitis</li> <li>• Patient has had an inadequate response to Humira OR</li> <li>• Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR</li> <li>• Patient has a contraindication to Humira</li> <li>• The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)</li> </ul> <p><b>For all indications</b></p> <ul style="list-style-type: none"> <li>• Patient has no evidence of active TB infection within the past 12 months</li> <li>• Patient has no history of venous thromboembolic (VTE) disease</li> <li>• Provider is aware of the FDA safety alerts AND Boxed Warnings</li> <li>• Patient has no evidence of neutropenia (ANC &lt; 1000)</li> <li>• Patient has no evidence of lymphocytopenia (ALC &lt; 500)</li> <li>• Patient has no evidence of anemia (Hgb &lt; 8)</li> <li>• Patient is not receiving other targeted immunobiologics with Rinvoq ER except for Otezla, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Talz, Xeljanz or Xeljanz XR or Tremfya?</li> </ul> <p>Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, or ulcerative colitis <b>For atopic dermatitis, PA expires in 1 year</b></p> <p><b>Renewal criteria:</b> initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if the following apply:</p> <ul style="list-style-type: none"> <li>• Atopic Dermatitis - The patient's disease severity has improved and stabilized to warrant continued therapy</li> </ul>
--	--

## Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> <li>ustekinumab (Stelara)</li> </ul> <p><b>Targeted Immunomodulatory Biologics (TIBs): Non-TNF Inhibitors</b></p>	<p><b>Updates from the May 2022 meeting are in bold.</b></p> <p>Note that Humira is the Department of Defense's preferred targeted biologic agent.</p> <p><u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</p> <p>AND</p> <p><u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved for Stelara if:</p> <ul style="list-style-type: none"> <li>Contraindications exist to Humira</li> <li>Inadequate response to Humira (need for different anti-TNF or non-TNF)</li> <li>There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF</li> <li>Adverse reactions to Humira not expected with requested non step-preferred TIB</li> </ul> <p>AND</p> <p>Coverage approved for patients <math>\geq 18</math> years with:</p> <ul style="list-style-type: none"> <li>Active psoriatic arthritis</li> <li>Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy (patients between the ages of 6 and 17 may receive Stelara for plaque psoriasis without the requirement to try Humira first)</li> <li>Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids, or TNF blockers. (November 2016)</li> <li><b>Moderate to severe ulcerative colitis (UC); may use infliximab first in lieu of Humira</b></li> </ul> <p>Non-FDA approved uses are not approved. PA does not expire.</p> <p>Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), apremilast (Otezla), or rituximab (Rituxan)</p>
<ul style="list-style-type: none"> <li>testosterone cypionate and testosterone enanthate IM injections</li> </ul> <p><b>Androgens-Anabolic Steroids: Testosterone Replacement Therapies</b></p>	<p><b>Changes from the May 2022 meeting are in strikethrough.</b></p> <p>Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections.</p> <p><u>Manual PA Criteria:</u> testosterone cypionate and testosterone enanthate IM injections are approved if all criteria are met:</p> <ul style="list-style-type: none"> <li>Coverage approved for male patients if: <ul style="list-style-type: none"> <li>Patient is over the age of 17 years AND</li> <li>Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND</li> <li>Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND</li> <li>The patient does not have prostate cancer AND</li> <li>The patient is experiencing symptoms usually associated with hypogonadism</li> </ul> </li> </ul> <p>OR</p>

## Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"> <li>Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if: <ul style="list-style-type: none"> <li>Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM</li> <li>Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND</li> <li>Patient has no signs of breast cancer AND</li> <li>For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND</li> <li>Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND</li> <li><del>Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria</del></li> </ul> </li> </ul> <p>Non-FDA-approved uses are NOT approved. Not approved for concomitant use with other testosterone products. Prior Authorization does not expire</p>
<ul style="list-style-type: none"> <li>olaparib (Lynparza)</li> </ul> <p><b>Oncological Agents: Ovarian Cancer</b></p>	<p><b>Changes from the May 2022 meeting are in bold.</b></p> <p>Manual PA criteria applies to all new users of Lynparza.</p> <p><u>Manual PA Criteria:</u> Lynparza is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>Patient is 18 years of age or older</li> <li>Prescribed by or in consultation with a hematologist/oncologist or urologist</li> <li>Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test *see prostate diagnosis below for exception*</li> <li>Lynparza will be prescribed as treatment for one of the following diagnoses: <ul style="list-style-type: none"> <li>Recurrent or Stage IV Triple negative breast cancer</li> <li>Recurrent or Stage IV hormone receptor (+) (ER, PR, or both) HER2 (-) breast cancer AND was either: <ul style="list-style-type: none"> <li>Previously treated with prior endocrine therapy OR</li> <li>Was not an appropriate candidate for endocrine therapy</li> </ul> </li> <li>Recurrent advanced ovarian cancers (platinum-sensitive or platinum-resistant), fallopian tube or primary peritoneal cancers AND <ul style="list-style-type: none"> <li>Patient has received at least 3 prior lines of therapy AND</li> <li>Lynparza will not be used as a single agent</li> </ul> </li> <li>Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene (e.g. BRCA, ATM)-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior androgen receptor-directed therapy and taxane-based chemotherapy <ul style="list-style-type: none"> <li>Of note, a patient does not require both a BRCA mutation and another separate HRR mutation; any HRR mutation satisfies requirement – this is an exception to the initial requirement that a patient have a BRCA mutation specifically</li> </ul> </li> <li><b>Deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy</b></li> </ul> </li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>Lynparza will be prescribed as maintenance therapy for one of the following diagnoses: <ul style="list-style-type: none"> <li>Platinum-sensitive, relapsed, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND</li> </ul> </li> </ul>

# Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"> <li>• Patient has received 2 or more lines of platinum-based chemotherapy</li> <li>• Patient was in objective response (either complete or partial) to most recent treatment regimen</li> </ul> <p>Lynparza will not be combined with bevacizumab (Avastin)</p> <ul style="list-style-type: none"> <li>• Newly diagnosed, advanced, high-grade, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND <ul style="list-style-type: none"> <li>• Patient has had a complete or partial response to primary therapy with a platinum-based therapy</li> </ul> </li> <li>• Metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen OR</li> <li>• 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, the provider must list the diagnosis: _____.</li> <li>• Female patients are not pregnant or planning to become pregnant and will use highly effective contraception while taking Lynparza and for 6 months after the last dose</li> <li>• Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment</li> <li>• Male patients will use effective contraception while taking Lynparza and for at least 3 months after cessation of therapy</li> </ul> <p>Other non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> <li>• idelalisib (Zydelig)</li> </ul> <p><b>Oncological Agents</b></p>	<p><b>Changes from the May 2022 meeting are in strikethrough.</b></p> <p>Manual PA criteria applies to new users of Zydelig.</p> <p><u>Manual PA Criteria:</u> Coverage for Zydelig is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> <li>• Age ≥ 18 years</li> <li>• Drug is prescribed by or in consultation with a hematologist or oncologist</li> <li>• Zydelig will be used in one of the following indications: <ul style="list-style-type: none"> <li>○ Relapsed/refractory therapy for CLL/<del>SLL</del> without del(17p)/TP53 mutation <ul style="list-style-type: none"> <li>▪ Patient fits one of the following categories: <ul style="list-style-type: none"> <li>• Frail patient with significant comorbidity (not able to tolerate purine analogues)</li> <li>• Patient ≥ 65 years old with significant comorbidity</li> <li>• Patient &lt; 65 years old</li> </ul> </li> </ul> </li> <li>○ Relapsed/refractory therapy for CLL/<del>SLL</del> with del(17p)/TP53 mutation</li> <li>○ <del>Relapsed/refractory follicular lymphoma AND:</del> <ul style="list-style-type: none"> <li><del>• Patient has completed ≥ 2 prior therapies OR</del></li> <li><del>• Patient has completed 1 prior therapy and relapsed ≤ 2 years</del></li> </ul> </li> <li>○ Relapsed/refractory marginal zone lymphoma after 2 prior therapies</li> </ul> </li> <li>• Provider has reviewed the REMS program including the letter to healthcare providers and the fact sheet and has shared the medication guide and patient safety information card with the patient</li> <li>• Will monitor for hepatotoxicity, colitis, intestinal perforation, pneumonitis, infection, neutropenia, and Steven Johnson Syndrome/toxic epidermal necrolysis</li> <li>• Will monitor for cytomegalovirus reactivation</li> <li>• Will prophylax for <i>Pneumocystis jiroveci</i> pneumonia</li> <li>• If the patient is female, she is not pregnant or planning to become pregnant</li> </ul>

## Appendix C—Table of Prior Authorization (PA) Criteria

	<ul style="list-style-type: none"><li>• Female patients will not breastfeed</li><li>• Female patients of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation</li><li>• Male patients of reproductive potential will use effective contraception during treatment and for at least 3 months after discontinuation</li><li>• 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: _____</li></ul> <p>Non-FDA approved uses are NOT approved. Prior Authorization does not expire.</p>
--	---

## Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> <li>ubrogepant (Ubrelevy)</li> </ul> <p><b>Migraine Agents oral CGRPs</b></p>	<ul style="list-style-type: none"> <li>Retail: 10 tabs/30 days</li> <li>MTF/Mail: 30 tabs/90 days</li> </ul> <ul style="list-style-type: none"> <li>Note that Ubrelevy is currently available only as cartons containing 10 tablets per carton</li> </ul>
<ul style="list-style-type: none"> <li>rimegepant (Nurtec ODT)</li> </ul> <p><b>Migraine Agents oral CGRPs</b></p>	<p><b>For Acute Migraine Indication:</b></p> <ul style="list-style-type: none"> <li>Retail: 8 ODT/30 days</li> <li>MTF/Mail: 24 ODT/90 days</li> </ul> <p><b>For Migraine Prevention Indication, approved through PA process:</b></p> <ul style="list-style-type: none"> <li>Retail: 16 ODT/30 days</li> <li>MTF/Mail: 48 ODT/90 days</li> </ul> <ul style="list-style-type: none"> <li>Note that Nurtec ODT is only available as 8 ODT per pack</li> </ul>
<ul style="list-style-type: none"> <li>atogepant (Qulipta)</li> </ul> <p><b>Migraine Agents oral CGRPs</b></p>	<ul style="list-style-type: none"> <li>Retail: 30 tabs/30 days</li> <li>MTF/Mail: 90 tabs/90 days</li> </ul>
<ul style="list-style-type: none"> <li>abrocitinib (Cibinqo)</li> </ul> <p><b>Atopy</b></p>	<ul style="list-style-type: none"> <li>Retail: 30 day supply</li> <li>MTF/Mail: 60 day supply</li> </ul>
<ul style="list-style-type: none"> <li>naloxone 5 mg/0.5mL injection (Zimhi)</li> </ul> <p><b>Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists</b></p>	<ul style="list-style-type: none"> <li>All points of service: 4 cartridges (2 packs) per fill</li> </ul>
<ul style="list-style-type: none"> <li>pacritinib (Vonjo)</li> </ul> <p><b>Oncological Agents: Myelofibrosis</b></p>	<ul style="list-style-type: none"> <li>Retail: 30 day supply</li> <li>MTF/Mail: 60 day supply</li> </ul>
<ul style="list-style-type: none"> <li>tralokinumab-ldrm injection (Adbry)</li> </ul> <p><b>Atopy</b></p>	<ul style="list-style-type: none"> <li>Retail: 4 syringes/fill and a 30 day supply</li> <li>MTF/Mail: 8 syringes/fill and a 60 day supply</li> </ul>
<ul style="list-style-type: none"> <li>alectinib (Alecensa)</li> </ul> <p><b>Oncological Agents: Lung Cancer</b></p>	<p><b>Changes from the May 2022 meeting are in bold.</b></p> <ul style="list-style-type: none"> <li>Retail: <b>30 day supply</b></li> <li>MTF/Mail: <b>60 day supply</b></li> </ul>



## Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> <li>axitinib (Inlyta)</li> </ul> <p><b>Oncological Agents: Renal Cell Carcinoma</b></p>	<ul style="list-style-type: none"> <li>Retail: 30 day supply</li> <li>MTF/Mail 60day supply</li> </ul>
<ul style="list-style-type: none"> <li>Omnipod/Omnipod DASH</li> </ul> <p><b>Insulins: Miscellaneous Insulin Device</b></p>	<p><b>Changes from the May 2022 meeting are in bold.</b></p> <ul style="list-style-type: none"> <li>Retail: <b>#15 pods in 30 days</b></li> <li>Mail/MTF: <b>#45 pods in 90 days</b></li> </ul>

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
abrocitinib (Cibinqo)  Atopy	<ul style="list-style-type: none"> <li>Rinvoq</li> <li>Dupixent</li> <li>Adbry</li> </ul>	<ul style="list-style-type: none"> <li>50, 100, 200 mg tablets</li> <li>100 mg orally QD, may increase to 200 mg daily if no response</li> </ul>	Adults with refractory, moderate-severe atopic dermatitis	<ul style="list-style-type: none"> <li>Black Box warning-serious infection, mortality, malignancy, major CV events, thrombosis</li> </ul>	<ul style="list-style-type: none"> <li>2nd oral JAK-1 inhibitor for moderate-severe atopic dermatitis in adults</li> <li>More effective at improving IGA score and EASI-75 response by week 12 relative to placebo</li> <li>Indirect network meta-analysis demonstrates Cibinqo at higher dose more effective relative to comparators</li> <li>Carries notable black box safety warnings extrapolated from tofacitinib (Xeljanz) surveillance data with limited long-term data currently for atopic patients</li> <li>Provides little to no significant clinical advantage relative to other UF options</li> </ul>	<ul style="list-style-type: none"> <li>NF</li> </ul>
baclofen oral suspension (Fleqsuvy)  Skeletal Muscle Relaxants & Combinations	<ul style="list-style-type: none"> <li>baclofen tablets</li> <li>baclofen oral solution (Ozobax)</li> </ul>	<ul style="list-style-type: none"> <li>5 mg/mL oral suspension</li> <li>Increase dose slowly in divided doses until clinical response; max dose 80 mg daily (20 mg QID)</li> </ul>	<p>Spasticity from MS, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be used in patients with spinal cord injuries/disease</p> <p><u>Limitations of Use:</u> Not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders</p>	<p>AEs (≥15%)</p> <ul style="list-style-type: none"> <li>Drowsiness</li> <li>Dizziness</li> <li>Weakness</li> </ul>	<ul style="list-style-type: none"> <li>2<sup>nd</sup> oral liquid formulation of baclofen</li> <li>Available as a more concentrated suspension than Ozobax oral solution</li> <li>Approved based on bioequivalence to baclofen 20 mg tablets; no new clinical data</li> <li>Unlike baclofen oral solution (Ozobax), Fleqsuvy can be stored at room temperature, must be shaken, and must be discarded 2 months after opening</li> <li>Provides little to no compelling clinical advantage over existing agents</li> </ul>	<ul style="list-style-type: none"> <li>NF</li> </ul>

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
budesonide DR capsule (Tarpeyo)  Nephrology Agents Misc	<ul style="list-style-type: none"> <li>prednisone</li> <li>methylpred-nisolone</li> <li>budesonide DR capsules (Entocort EC)</li> <li>budesonide ER capsules (Ortikos)</li> <li>budesonide ER tablets (Uceris)</li> </ul>	<ul style="list-style-type: none"> <li>delayed release (DR) 4 mg capsules (Tarpeyo)</li> <li>Dose: 16 mg (4 caps) orally QAM ≥1 hour before a meal for 9 months</li> </ul>	Reduces proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression (generally a Urine protein to creatinine ratio [PCR] ≥ 1.5 g/g)	AEs (≥5%) <ul style="list-style-type: none"> <li>hypertension</li> <li>peripheral edema</li> <li>muscle spasms</li> <li>acne</li> <li>dermatitis</li> <li>weight increase</li> <li>dyspnea</li> <li>facial edema</li> <li>dyspepsia</li> <li>fatigue</li> <li>hirsutism</li> </ul>	<ul style="list-style-type: none"> <li>1st FDA-approved medication to reduce proteinuria in adults with primary immunoglobulin A nephropathy</li> <li>Approval based on reduction in proteinuria; it is not established if Tarpeyo can slow kidney function decline</li> <li>Clinical benefit of steroids in IgAN has not been established</li> <li>Limitations: continued approval contingent upon verification of clinical benefit in a confirmatory clinical trial, not established if the drug can slow kidney function decline, accelerated approval based on reduction in proteinuria</li> <li>Tarpeyo has not been studied against other steroids to determine if there are any efficacy or safety advantages in patients with IgAN</li> <li>Similar adverse event profiles to other budesonide formulations, but comparisons are difficult to make due to differences in populations and dosing</li> <li>Place in therapy is still yet to be determined</li> <li>Provides little to no compelling clinical advantage over existing agents</li> </ul>	<ul style="list-style-type: none"> <li>Tier 4/Not covered</li> </ul>
celecoxib/ tramadol (Seglentis) tablets  Narcotic Analgesics and Combinations	<ul style="list-style-type: none"> <li>tramadol</li> <li>celecoxib</li> </ul>	<ul style="list-style-type: none"> <li>Celecoxib 56 mg and tramadol 44 mg (Seglentis) in a coated tablet</li> <li>Dosed at 2 tablets every 12 hours as needed for pain</li> </ul>	Acute pain in adults severe enough to require opioid analgesics and for which alternative treatments are inadequate  <u>Limitations of Use:</u> Due to risks of addiction, abuse, & misuse with opioids, even at rec. doses, reserve for pts where alternative tx options aren't tolerated or haven't provided adequate analgesia	AEs (> 5% and > placebo) <ul style="list-style-type: none"> <li>nausea (30.1%)</li> <li>dizziness (16.9%)</li> <li>vomiting (15.8%)</li> <li>headache (11.5%)</li> <li>somnolence (8.2%)</li> </ul>	<ul style="list-style-type: none"> <li>Fixed-dose formulation of tramadol with celecoxib</li> <li>Studied in a phase 3 study comparing it to either tramadol or celecoxib as monotherapy</li> <li>Seglentis' dosage of two tablets twice a day (four total) does not offer a significant pill burden advantage</li> <li>Fixed-dose combination allows for less flexibility, for example, cannot choose to just take celecoxib when pain is less severe</li> <li>Provides no compelling clinical advantage over existing agents tramadol and celecoxib taken separately</li> </ul>	<ul style="list-style-type: none"> <li>Tier 4/Not covered</li> </ul>

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
<p>filgrastim-ayow injection (Releuko)</p> <p>WBC Stimulants: Filgrastims</p>	<ul style="list-style-type: none"> <li>tbo-filgrastim (Granix)</li> <li>filgrastim-aafi (Nivestym)</li> <li>filgrastim (Neupogen)</li> <li>filgrastim-sndz (Zarxio)</li> </ul>	<ul style="list-style-type: none"> <li>Available as a single-dose vial and as a prefilled syringe, both are available in two strengths:</li> <li>300 mcg/mL</li> <li>480 mcg/1.6 mL</li> <li>Dosing: 5 - 10 mcg/kg/day given once or twice a day</li> </ul>	<ul style="list-style-type: none"> <li>For treatment of the febrile neutropenia due to the following:</li> <li>acute myeloid leukemia</li> <li>bone marrow transplant</li> <li>non-malignant neutropenia's</li> </ul>	<p>AEs (<math>\geq</math> 5% difference vs. placebo)</p> <ul style="list-style-type: none"> <li>pyrexia, pain, rash, cough, dyspnea, epistaxis, anemia, diarrhea, hypoesthesia, alopecia</li> </ul>	<ul style="list-style-type: none"> <li>5th filgrastim, 10th drug in the White Blood Cell Stimulant class</li> <li>Another biosimilar to Neupogen</li> <li>No new clinical data</li> <li>Available as a single-dose vial and as a prefilled syringe</li> <li>Offers no compelling clinical advantages over existing formulary agents</li> </ul>	<ul style="list-style-type: none"> <li>UF and non-step-preferred</li> </ul>
<p>glycopyrrolate (Dartisla ODT)</p> <p>Anti-cholinergics-Antispasmodics</p>	<ul style="list-style-type: none"> <li>glycopyrrolate tablets (Robinul)</li> <li>glycopyrrolate solution (Cuvposa)</li> <li>omeprazole (Prilosec)</li> <li>pantoprazole (Protonix)</li> <li>famotidine (Pepcid)</li> </ul>	<ul style="list-style-type: none"> <li>1.7 mg ODT given BID or TID</li> <li>Dissolve on top of tongue and swallow w/o water</li> <li>Administer <math>\geq</math> 1 hour before or 2 hours after food</li> <li>Max daily dose is 6.8 mg</li> </ul>	<p>Reduce symptoms of peptic ulcer as an adjunct to treatment of peptic ulcer</p> <p><u>Limitations of Use:</u> Not indicated as monotherapy for treatment of peptic ulcer; effectiveness in peptic ulcer healing not established</p>	<ul style="list-style-type: none"> <li>blurred vision</li> <li>drowsiness</li> <li>decreased sweating</li> <li>flushing</li> <li>vomiting</li> <li>constipation</li> <li>dry mouth</li> <li>tachycardia</li> <li>urinary retention</li> </ul>	<ul style="list-style-type: none"> <li>Dartisla ODT was approved via the 505(b)2 pathway; no new clinical studies were conducted</li> <li>Not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established</li> <li>The most common AEs include blurred vision, drowsiness, decreased sweating, flushing, vomiting, constipation, dry mouth, tachycardia, and urinary retention</li> <li>Unlike H2 blockers and PPIs, only treats symptoms, does not heal peptic ulcer</li> <li>Provides little to no clinical benefit relative to existing formulary agents</li> </ul>	<ul style="list-style-type: none"> <li>Tier 4/Not covered</li> </ul>
<p>levoketoconazole (Recorlev)</p> <p>Endocrine Agents Miscellaneous</p>	<ul style="list-style-type: none"> <li>ketoconazole</li> <li>osilodrostat (Isturisa)</li> <li>metyrapone (Metopirone)</li> <li>mitotane tabs (Lysodren)</li> <li>pasireotide SQ (Signifor LAR) injection</li> <li>cabergoline</li> <li>mifepristone oral (Korlym)</li> </ul>	<ul style="list-style-type: none"> <li>150 mg tablets; 150 mg orally BID, with or without food</li> <li>Max: 600 mg BID (1200 mg daily)</li> </ul>	<p>Treatment of adults with Cushing's disease (CD) for whom pituitary surgery is not an option or has not been curative</p>	<p>Safety concerns include boxed warnings for hepatotoxicity, QT prolongation, and drug interactions</p>	<ul style="list-style-type: none"> <li>Enantiomer of ketoconazole approved for treatment of Cushing's disease (CD)</li> <li>Two pivotal trials (LOGICS and SONICS studies) evaluated reduction in urinary free cortisol</li> <li>Normalization of the mean urinary free cortisol concentration (mUFC) was seen in both studies compared to placebo</li> <li>Only one of the two studies is currently published and studies were small (&lt;200 pts total)</li> <li>No head to head studies were conducted with ketoconazole, osilodrostat, pasireotide, or other drugs used to treat CD</li> </ul>	<ul style="list-style-type: none"> <li>Tier 4/Not covered</li> </ul>

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					<ul style="list-style-type: none"> <li>• 27% of patients experienced at least one liver-related AE, with 20% of patients having liver enzyme elevations</li> <li>• Several retrospective studies with ketoconazole show results similar to Recorlev in normalization of mUFC (indirect comparison)</li> <li>• There is insufficient evidence to show Recorlev has any improvement in efficacy or safety compared with ketoconazole</li> <li>• Place in therapy remains unclear</li> <li>• Recorlev offers little to no compelling advantages over existing agents for the treatment of Cushing's syndrome</li> </ul>	
mitapivat (Pyrukynd)  Metabolic Agents- Miscellaneous: Replacement Enzymes	• None	<ul style="list-style-type: none"> <li>• Tablets: 5 mg, 50 mg</li> <li>• Supplied as a 28-day pack</li> <li>• Dosing: 5 mg BID with/without food, swallowed whole;</li> <li>• titrate and taper PRN</li> </ul>	Hemolytic anemia in adults with pyruvate kinase deficiency	<ul style="list-style-type: none"> <li>• Common AEs: decreases in estrone and estradiol in males, increases in urate, back pain, and arthralgia</li> </ul>	<ul style="list-style-type: none"> <li>• 1st approved treatment for hemolytic anemia in adults with pyruvate kinase deficiency</li> <li>• Has shown safety and effectiveness in a specific patient population with PK deficiency</li> <li>• Studied patients had at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant, and Hgb ≤ 10 g/dL</li> <li>• Not approved for children</li> <li>• Avoid in moderate or severe hepatic impairment</li> <li>• Labeling includes a warning for risk of acute hemolysis when therapy is abruptly discontinued</li> <li>• Provides the first drug-related treatment option for this rare disease</li> </ul>	• UF
naloxone 5 mg/0.5mL injection (Zimhi)  Alcohol Deterrents- Narcotic Antagonists	<ul style="list-style-type: none"> <li>• naloxone nasal 4mg/0.1mL (Narcan)</li> <li>• naloxone nasal 8mg/0.1mL (Kloxxado)</li> </ul>	<ul style="list-style-type: none"> <li>• 5 mg/0.5mL of naloxone in prefilled syringe</li> <li>• -IM/SQ to anterolateral thigh prn</li> <li>• May repeat every 2-3 minutes prn until EMS arrival</li> </ul>	Emergency treatment of known or suspected opioid overdose for adult and pediatric patients	<ul style="list-style-type: none"> <li>• Nausea, dizziness, lightheadedness, and elevated bilirubin</li> </ul>	<ul style="list-style-type: none"> <li>• Zimhi is an injectable formulation of naloxone approved via the 505(b)(2) pathway</li> <li>• No new clinical studies were completed</li> <li>• Quicker onset compared to intranasal agents</li> <li>• Provides another option for bystander treatment of opioid overdose</li> </ul>	• UF

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
<p>pacritinib (Vonjo)</p> <p>Oncological Agents: Myelofibrosis</p>	<ul style="list-style-type: none"> <li>• ruxolitinib (Jakafi)</li> <li>• fedratinib (Inrebic)</li> </ul>	<ul style="list-style-type: none"> <li>• 200 mg (2 x 100 mg oral capsules) BID</li> <li>• Specific dosage adjustments due to AEs listed in package insert</li> </ul>	<p>For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count &lt; 50 × 10<sup>9</sup>/L</p>	<p>AEs (≥ 20%)</p> <ul style="list-style-type: none"> <li>• diarrhea (48%)</li> <li>• thrombocytopenia (34%)</li> <li>• nausea (32%)</li> <li>• anemia (24%)</li> <li>• peripheral edema (20%)</li> </ul>	<ul style="list-style-type: none"> <li>• 1st approved drug for patients with cytopenic myelofibrosis</li> <li>• Demonstrated significant activity in reducing spleen volume</li> <li>• Substantial background data supporting this surrogate endpoint as a valid measure of reduction of disease burden and suggests correlation with survival</li> <li>• Current NCCN guidelines mention pacritinib as a possible treatment option for patients with low platelet counts, but make no recommendations on its use as guidelines were published before FDA approval</li> <li>• Safety: serious and fatal AEs did occur, but there is no black box warning on this medication</li> <li>• Offers a treatment option in a patient population with limited options and a poor prognosis</li> </ul>	<ul style="list-style-type: none"> <li>• UF</li> </ul>
<p>tenapanor (Ibsrela)</p> <p>GI-2: CIC and IBS-C</p>	<ul style="list-style-type: none"> <li>• linaclotide (Linzess)</li> <li>• plecanatide (Trulance)</li> <li>• lubiprostone (Am)</li> </ul>	<ul style="list-style-type: none"> <li>• 50 mg tablets</li> <li>• 50 mg BID;</li> <li>• Administer immediately prior to breakfast or the first meal of the day and immediately prior to dinner</li> </ul>	<p>Constipation-predominant irritable bowel syndrome (IBS-C) in adults</p>	<ul style="list-style-type: none"> <li>• Severe diarrhea, abdominal distension, flatulence, and dizziness</li> </ul>	<ul style="list-style-type: none"> <li>• New agent approved for adults with IBS-C</li> <li>• Novel mechanism of action as a sodium/hydrogen exchanger 3 (NHE3) inhibitor</li> <li>• Evaluated in 2 placebo controlled studies showing statistically significant results compared to placebo</li> <li>• Clinical significance is unclear and a significant placebo effect exists</li> <li>• No head-to-head studies with other IBS-C drugs</li> <li>• Under study for hyperphosphatemia; but does not yet have the indication</li> <li>• Other than a novel mechanism of action, Ibsrela offers no compelling advantages over existing agents given its limited indication, twice daily dosing, risk of severe diarrhea, and lack of clear clinical advantage in efficacy compared to placebo</li> </ul>	<ul style="list-style-type: none"> <li>• NF</li> </ul>

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
<p>torsemide 20 mg and 40 mg tablets (Soaanz)</p> <p>Diuretics</p>	<ul style="list-style-type: none"> <li>• bumetanide</li> <li>• ethacrynic acid</li> <li>• furosemide</li> <li>• torsemide</li> </ul>	<ul style="list-style-type: none"> <li>• 20 mg tablet daily</li> <li>• Titrate to desired response (max of 200 mg has been studied)</li> <li>• Available in 20 mg and 60 mg tablets</li> </ul>	<p>Intended for patients with heart failure or renal disease with edema that have concerns with excessive urination or hypokalemia</p>	<ul style="list-style-type: none"> <li>• Discontinuation of therapy due to adverse reactions occurred in 6% of patients</li> </ul>	<ul style="list-style-type: none"> <li>• Another tablet formulation of torsemide</li> <li>• No new phase 3 clinical trial data; approval based on torsemide data and 3 PK studies.</li> <li>• Max urine output occurs at ~3 hours with this formulation (extended duration of peak effect) vs. ~1 hour with IR formulation</li> <li>• Similar potassium excretion compared to torsemide</li> <li>• Available in fewer dose options than torsemide</li> <li>• Similar side effects to torsemide and other loop diuretics</li> <li>• Numerous alternative agents are available, place in therapy is unclear, and no benefits in terms of side effect profile</li> <li>• Provides little to no clinical benefit over torsemide formulation</li> </ul>	<ul style="list-style-type: none"> <li>• Tier 4/Not covered</li> </ul>
<p>tralokinumab-ldrm injection (Adbry)</p> <p>Atopy</p>	<ul style="list-style-type: none"> <li>• Dupixent</li> <li>• Rinvoq</li> <li>• Cibinqo</li> </ul>	<ul style="list-style-type: none"> <li>• 150 mg/mL solution in prefilled syringe</li> <li>• Initial dose 600mg SQ, then 300mg SQ every other week</li> <li>• May give 300mg every 4 weeks, if &lt;100kg and clear skin after 16wks</li> </ul>	<p>Adults with refractory, moderate-severe atopic dermatitis</p>	<ul style="list-style-type: none"> <li>• Upper respiratory tract infections, conjunctivitis, injection site reactions, eosinophilia</li> </ul>	<ul style="list-style-type: none"> <li>• 2<sup>nd</sup> monoclonal antibody (mAb) antagonist for moderate to severe AD treatment (after Dupixent)</li> <li>• Placebo-controlled studies demonstrated efficacy</li> <li>• Indirect NMA showed slightly less efficacy than Dupixent</li> <li>• Adbry offers an additional option for moderate to severe AD, however use is limited to a single indication</li> <li>• Provides no significant clinical advantage relative to existing formulary agents</li> </ul>	<ul style="list-style-type: none"> <li>• NF</li> </ul>
<p>tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twynéo)</p> <p>Acne Agents: Topical Acne &amp; Rosacea</p>	<ul style="list-style-type: none"> <li>• benzoyl peroxide</li> <li>• tretinoin</li> <li>• Epiduo Forte (nonformulary)</li> </ul>	<ul style="list-style-type: none"> <li>• Dosing: apply a thin layer to the affected areas once daily on clean and dry skin</li> </ul>	<p>For the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older</p>	<p>Application site AEs (≥ 1%):</p> <ul style="list-style-type: none"> <li>• pain (10.6%)</li> <li>• dryness (4.9%)</li> <li>• exfoliation (4.1%)</li> <li>• erythema (4%)</li> <li>• dermatitis (1.3%)</li> <li>• pruritus (1.3%)</li> <li>• irritation (1.1%)</li> </ul>	<ul style="list-style-type: none"> <li>• 1st fixed-dose combination of tretinoin and benzoyl peroxide (BP)</li> <li>• Tretinoin with BP is a guideline-recommended 1st line treatment option for acne</li> <li>• Contains the highest strength of tretinoin; doesn't allow for dose titration for tolerability</li> <li>• Several single-agent topical tretinoin products are available in creams, gels, and lotions</li> <li>• Single-agent BP is available both OTC and as a legend prescription product</li> <li>• Provides little to no compelling clinical advantage over existing agents tretinoin and benzoyl peroxide taken separately</li> </ul>	<ul style="list-style-type: none"> <li>• Tier 4/Not covered</li> </ul>

# Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
May 2022	<p><b>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated NF:</b></p> <p><i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:</i></p> <ul style="list-style-type: none"> <li>tenapanor (Ibsrela)</li> </ul> <p><b>Drug Class Review</b>  <b>Non-Insulin Diabetes Drugs: GLP1RAs</b>  <b>Designated UF:</b></p> <p><i>Note – all agents in the class are on the list:</i></p> <ul style="list-style-type: none"> <li>dulaglutide (Trulicity)</li> </ul> <p><b>Designated NF:</b></p> <p><i>Note – all agents in the class are on the list:</i></p> <ul style="list-style-type: none"> <li>semaglutide (Ozempic)</li> <li>exenatide once weekly (Bydureon BCise)</li> <li>exenatide twice daily (Byetta)</li> <li>lixisenatide (Adlyxin)</li> <li>liraglutide (Victoza)</li> </ul>	<p><b>Drug Class Reviews</b></p> <p><b>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF:</b></p> <p><i>Acute use exception applies</i></p> <ul style="list-style-type: none"> <li>naloxone 5 mg/0.5mL injection (Zimhi)</li> </ul> <p><i>Drugs in class not currently represented on EMMPI List:</i></p> <ul style="list-style-type: none"> <li>mitapivat (Pyrukynd)</li> <li>pacritinib (Vonjo)</li> <li>filgrastim-ayow injection (Releuko)</li> </ul> <p><b>Designated NF:</b></p> <p><i>Do not add due to TPharm5 changes:</i></p> <ul style="list-style-type: none"> <li>abrocitinib (Cibinqo)</li> <li>baclofen oral suspension (Fleqsuvy)</li> <li>tralokinumab-ldrm injection (Adbry)</li> </ul> <p><b>Drug Class Reviews</b>  <b>Oral CGRPs</b>  <b>Designated UF</b></p> <p><i>Acute use exception applies</i></p> <ul style="list-style-type: none"> <li>atogepant (Qulipta)</li> <li>rimegepant (Nurtec)</li> <li>ubrogepant (Ubrelevy)</li> </ul> <p><b>Line Extensions</b>  <b>Designated UF</b></p> <p><i>Similar/parent agent not on list:</i></p> <ul style="list-style-type: none"> <li>rivaroxaban 1 mg/1 mL oral suspension (Xarelto)</li> <li>lanadelumab-flyo (Takhzyro) 300 mg/ 2 mL syringe</li> </ul>



## **Appendix G—Implementation Dates\***

**Upon signing: July 27, 2022**

**Two weeks after signing: August 10, 2022**

**30 Days after Signing: August 31, 2022**

**60 days after signing: September 28, 2022**

**90 days after signing: October 26, 2022**

**120 Days after signing: November 30, 2022**

**\* Note that implementation occurs the first Wednesday following “X” days after signing of the minutes in all points of service.**

# Appendix H—Not Covered Drugs and Therapeutic Alternatives\*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2022	Nephrology Agents Miscellaneous	<ul style="list-style-type: none"> <li>budesonide (Tarpeyo)</li> </ul>	<ul style="list-style-type: none"> <li>prednisone</li> <li>methylprednisolone</li> <li>budesonide delayed release capsules (Entocort EC, generics)</li> </ul>	<ul style="list-style-type: none"> <li>120 days</li> </ul>
May 2022	Narcotic Analgesics and Combinations	<ul style="list-style-type: none"> <li>celecoxib/tramadol (Seglentis)</li> </ul>	<ul style="list-style-type: none"> <li>tramadol</li> <li>celecoxib</li> </ul>	<ul style="list-style-type: none"> <li>120 days</li> </ul>
May 2022	Anticholinergics-Antispasmodics	<ul style="list-style-type: none"> <li>glycopyrrolate (Dartisla ODT)</li> </ul>	<ul style="list-style-type: none"> <li>glycopyrrolate tablets</li> <li>glycopyrrolate oral solution (Cuvposa)</li> <li>omeprazole</li> <li>famotidine</li> </ul>	<ul style="list-style-type: none"> <li>120 days</li> </ul>
May 2022	Endocrine Agents Miscellaneous	<ul style="list-style-type: none"> <li>levoketoconazole (Recorlev)</li> </ul>	<ul style="list-style-type: none"> <li>ketoconazole</li> <li>metyrapone (Metopirone)</li> <li>osilodrostat (Isturisa)</li> <li>pasireotide (Signifor LAR -medical benefit)</li> </ul>	<ul style="list-style-type: none"> <li>120 days</li> </ul>
May 2022	Diuretics	<ul style="list-style-type: none"> <li>torsemide 20 mg and 60 mg tablets (Soaanz)</li> </ul>	<ul style="list-style-type: none"> <li>torsemide</li> <li>furosemide</li> <li>bumetanide</li> <li>ethacrynic acid</li> </ul>	<ul style="list-style-type: none"> <li>120 days</li> </ul>
May 2022	Acne Agents: Topical Acne & Rosacea	<ul style="list-style-type: none"> <li>tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twynéo)</li> </ul>	<ul style="list-style-type: none"> <li>tretinoin cream</li> <li>benzoyl peroxide cream</li> </ul>	<ul style="list-style-type: none"> <li>120 days</li> </ul>
February 2022	Pain Agents: NSAIDs	<ul style="list-style-type: none"> <li>celecoxib oral solution (Elyxyb)</li> </ul>	<ul style="list-style-type: none"> <li>celecoxib tablets</li> <li>ibuprofen</li> <li>naproxen</li> <li>diclofenac</li> <li>numerous other NSAIDs or combos</li> </ul>	<ul style="list-style-type: none"> <li>August 24, 2022 (120 days)</li> </ul>
Nov 2021	Antianxiety Agents: Benzodiazepines	<ul style="list-style-type: none"> <li>lorazepam ER capsule (Loreev XR)</li> </ul>	<ul style="list-style-type: none"> <li>lorazepam IR tablets</li> <li>alprazolam IR and XR tablets</li> </ul>	<ul style="list-style-type: none"> <li>June 15, 2022 (120 days)</li> </ul>
Nov 2021	Migraine Agents	<ul style="list-style-type: none"> <li>dihydroergotamine mesylate nasal spray (Trudhesa)</li> </ul>	<ul style="list-style-type: none"> <li>DHE nasal spray</li> <li>sumatriptan nasal and oral</li> <li>rizatriptan</li> </ul>	<ul style="list-style-type: none"> <li>June 15, 2022 (120 days)</li> </ul>

## Appendix H—Not Covered Drugs and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			<ul style="list-style-type: none"> <li>• zolmitriptan</li> <li>• eletriptan</li> </ul>	
Aug 2021	Antilipidemic-1s	<ul style="list-style-type: none"> <li>• rosuvastatin/ezetimibe (Roszet)</li> </ul>	<ul style="list-style-type: none"> <li>• rosuvastatin with ezetimibe</li> <li>• atorvastatin with ezetimibe</li> <li>• simvastatin/ezetimibe (Vytorin)</li> <li>• evolocumab (Repatha)</li> <li>• alirocumab (Praluent)</li> </ul>	<ul style="list-style-type: none"> <li>• June 15, 2022 (120 days)</li> </ul>
May 2021	Anticonvulsants-Antimania Agents	<ul style="list-style-type: none"> <li>• levetiracetam (Elepsia XR)</li> </ul>	<ul style="list-style-type: none"> <li>• levetiracetam ER</li> <li>• lamotrigine XR</li> <li>• topiramate ER</li> </ul>	<ul style="list-style-type: none"> <li>• June 15, 2022 (120 days)</li> </ul>
Feb 2021	Corticosteroids-Immune Modulators: High Potency	<ul style="list-style-type: none"> <li>• clobetasol propionate 0.05% lotion metered dose pump (Impeklo)</li> </ul>	<ul style="list-style-type: none"> <li>• betamethasone/propylene glycol 0.05% lotion</li> <li>• betamethasone dipropionate 0.05% gel</li> <li>• clobetasol propionate/emollient 0.05 % (emulsion) foam</li> <li>• clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo</li> <li>• fluocinonide 0.05% solution and gel</li> </ul>	<ul style="list-style-type: none"> <li>• June 15, 2022 (120 days)</li> </ul>
Feb 2021	Psoriasis Agents	<ul style="list-style-type: none"> <li>• calcipotriene/betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora)</li> </ul>	<ul style="list-style-type: none"> <li>• vitamin D analog (calcipotriene 0.005% cream, ointment or solution) with a high potency topical corticosteroid (clobetasol propionate 0.05% ointment, cream, solution and gel)</li> <li>• fluocinonide 0.05% cream, gel, and solution</li> <li>• calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary]</li> </ul>	<ul style="list-style-type: none"> <li>• June 15, 2022 (120 days)</li> </ul>

\*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. All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at <https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms>.

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.

The first Tier 4 products were designated at the February 2019 P&T Committee meeting, with implementation occurring on August 28, 2019. For a cumulative listing of all Tier 4 drugs to date, refer to previous versions of the DoD P&T Committee quarterly meeting minutes, found on the [health.mil](http://health.mil) website.

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

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
<b>Probiotics</b>		
May 2022	<b>RETAIN) these GCNs</b> <ul style="list-style-type: none"> <li>99616 <i>Bifidobacterium infantis</i> 4 mg cap (Align)</li> <li>97109 <i>Lactobacil 2/S.thermos/Bifido</i> 1 900B cell packet (VSL #3, Visbiome)</li> <li>36349 <i>L. rhamnosus</i> 5B cell powder pack (e.g., Culturelle)</li> <li>92016 <i>L. rhamnosus</i> 10B cell cap (e.g., Culturelle)</li> <li>34623 <i>L. rhamnosus</i> 15B cell cap sprinkle (e.g., Culturelle)</li> <li>05162 <i>Saccharomyces boulardii</i> 25 mg cap (e.g., Florastor)</li> </ul> <b>ADD these GCNs</b> <ul style="list-style-type: none"> <li>72179 <i>L. reuteri</i> 100mm cell tab chew (Biogaia, Gerber Good Start Grow Kids, Pedia-Lax Probiotic Yums)</li> <li>28678 <i>L. reuteri</i> 100 mm/5drop drops susp (Biogaia Protectis Baby, Gerber Soothe)</li> <li>37835 <i>L. reuteri</i>/vit D3 100mm-10 drops (Biogaia Protectis Baby-Vit D, Gerber Soothe Vit-D-Probiotic)</li> <li>24119 <i>L. acidophilus/Lactobac spor</i> 35mm-25mm tab (e.g., Acidophilus)</li> <li>08380 <i>L. acidophilus</i> cap (e.g., Acidophilus)</li> <li>24118 <i>L. acidophilus/pectin, citrus</i> 25mm-100mg tab (e.g., Acidophilus-Pectin)</li> </ul>	<b>REMOVE these GCNs</b> <ul style="list-style-type: none"> <li>06604 <i>Saccharomyces boulardii</i> 250 mg powder pack</li> </ul>
<b>Skin Preps: Rectal (Hemorrhoidal Agents)</b>		
May 2022	<b>RETAIN these GCNs</b> <ul style="list-style-type: none"> <li>28080 dibucaine 1% oint (Nupercainal)</li> <li>35585 phenylephrine HCl/cocoa butter 0.25-88.44 suppository (e.g., Preparation H)</li> </ul> <b>ADD this GCN</b> <ul style="list-style-type: none"> <li>97827 pramoxine 1% foam</li> </ul>	<b>REMOVE these GCNs</b> <ul style="list-style-type: none"> <li>35039 phenylephrine/mineral oil/petrolatum 0.25%-14% oint/applicator (e.g., Preparation H)</li> <li>97205 phenylephrine/pramoxine/glycerin/w.pet 0.25%-1% cream (e.g., Preparation H)</li> </ul>
<b>Ophthalmic Agents: Allergy</b>		
May 2022	<b>Confirm addition of this GCN</b> <ul style="list-style-type: none"> <li>68321 olopatadine 0.1% ophthalmic solution (Pataday Twice Daily Relief, generics)</li> </ul>	