DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2021

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on August 4 and 5, 2021. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Status of February and May 2021 Minutes—**Both the February 2021 and May 2021 meeting minutes have not been signed yet by the Director, DHA, due to the delay caused by the Secretary of Defense's zero based review of the TRICARE Beneficiary Advisory Panel (BAP).

2. **Clarification of Previous Minutes**

   a) **February 2021 Meeting—Utilization Management: Updated PAs for new FDA-approved indications or age ranges:** Due to the delay in the February P&T Committee minutes' signing, several PA updates that expand the criteria for patient access due to either new FDA-approved indications for oncology drugs or expanded age ranges were implemented in June, 2021. PAs where recommended updates to criteria that are not due to the above reasons are awaiting the BAP meeting and Director's signature.

   b) **February 2021 Meeting—Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors: empagliflozin (Jardiance) PA**: Updates to the PA criteria for the SGLT-2 inhibitors for non- diabetic indications were recommended at the February 2021 meeting. Due to the BAP delay, the empagliflozin PA was updated on June 4, 2021 to allow use for patients with heart failure and reduced ejection fraction or chronic kidney disease who do not have diabetes. Updates to the remaining SGLT-2 inhibitors await the BAP meeting and signing by the Director.

   c) **November 2020 Meeting—Attention Deficit Hyperactivity Drugs (ADHD)**: **lisdexamfetamine (Vyvanse) and Mandatory Mail requirements:** Vyvanse was added to the Expanded MTF/Mail Pharmacy Initiative (EMMPI) program at the November 2020 P&T Committee meeting, with an implementation date of March 3, 2021. Due to operational issues the EMMPI requirement for Vyvanse was removed on May 14, 2021. There are currently no schedule II ADHD drugs included on the EMMPI program.

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. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the three agents in the BTK inhibitor subclass, comprised of ibrutinib (Imbruvica), acalabrutinib (Calquence), and zanubrutinib (Brukinsa). The Committee comprehensively reviewed the evidence including what was reviewed when Imbruvica (tablet formulation), Calquence, and Brukinsa were presented as innovators in May 2018, February 2018, and February 2020, respectively.

The BTK inhibitors are indicated for use in chronic lymphocytic leukemia (CLL) and a variety of non-Hodgkin lymphoma subtypes including small lymphocytic lymphoma (SLL) and mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), non-germinal center B-Cell diffuse large B-Cell lymphoma (non-GCB-DLBCL), and Waldenström macroglobulinemia (WM).

The comprehensive evidence review included information from individual clinical trial data; guidelines from the National Cancer Comprehensive Network (NCCN), American Society of Clinical Oncology (ASCO), and European Society for Medical Oncology (ESMO); meta-analyses; FDA labeling; current Military Health System (MHS) patterns of use; and MHS provider comments.

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

- Ibrutinib (Imbruvica) has the greatest number of FDA-approved indications, guideline-recommended uses, and the most voluminous and validated evidence base. In the Military Health System, it is the most utilized and the de facto preferred agent by oncologists.
- Where data is available, by indirect comparison, via network meta-analysis, and in head-to-head trials, all three agents appear to be equally clinically effective.
- While their safety profiles largely overlap, each agent has unique features. Specialists will tailor their choice of agent based on patient comorbidities.
- Acalabrutinib (Calquence) and zanubrutinib (Brukinsa) have favorable safety profiles relative to ibrutinib (Imbruvica) among certain clinically significant adverse events. Some providers prefer acalabrutinib over ibrutinib, either for specific patient comorbidities or indications.
- Zanubrutinib (Brukinsa) is the newest of the three agents, and has an immature evidence base and generally lower rankings where guidelines recommend use, when compared to the other two drugs.
- The ibrutinib capsule formulation allows for more flexible dosage titration, either for increasing the dose or reducing the dose due to adverse events, compared to the ibrutinib tablets.
- Once a patient's disease becomes refractory to one BTK inhibitor, it tends to be refractory to all BTK inhibitors.

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

- CMA results showed that acalabrutinib (Calquence), ibrutinib (Imbruvica), and zanubrutinib (Brukinsa) were all cost effective, when compared to each other. For Imbruvica, the capsule formulations are more cost effective than the tablet formulations.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF, or Tier 4. BIA results showed that designating acalabrutinib (Calquence), ibrutinib (Imbruvica), and zanubrutinib (Brukinsa) as UF demonstrated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

    - UF
        - acalabrutinib (Calquence)
        - ibrutinib (Imbruvica)

        - zanubrutinib (Brukinsa)
    - NF – None
    - Tier 4/Not Covered – None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Existing PA criteria currently apply to all three drugs. For the ibrutinib tablets, further justification is required on the PA to state why the capsules cannot be used, due to more flexible dosage titration with the capsules. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) minor updates to the ibrutinib PA criteria to reflect the clinical and cost differences of the capsules and tablets, and recommended maintaining the current PA criteria for acalabrutinib and zanubrutinib. See Appendix C for the full criteria.

   Note that Brukinsa received new FDA indications following the August 2021 P&T Committee meeting, and prior to the BAP meeting and P&T Committee minutes' singing. The new indications are noted in Appendix C in bold.

3. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs. See Appendix D for the full QLs.

4. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—***Due to the complex dose adjustments and monitoring for the class, the P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current status - acalabrutinib, ibrutinib and zanubrutinib are not included on the EMMPI program.

5. ***COMMITTEE ACTION: UF, PA, QL EMMPI PROGRAM AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Based on the P&T Committee's recommendation, the effective date is March 2, 2022.

B. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass

*Background—*The P&T Committee evaluated the relative clinical effectiveness of the bowel preparations indicated for colon cleansing in preparation for colonoscopy. Drugs in the class include generic preparations comprised of polyethylene glycol (PEG) 3350 with and without additional electrolytes. Six branded products are marketed, Osmoprep, Plenvu, Clenpiq, Suprep, Sutab, and Moviprep. The class has not been previously reviewed for

formulary status, although Clenpiq, Plenvu and Sutab were evaluated as newly approved drugs at the February 2018, November 2018, and February 2021, respectively.

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

- Several different dosage formulations are available, including powders for reconstitution, oral solutions, and tablets. The bowel preparations vary in the amount of liquid that is required for consumption, ranging from 2 to 4 liters.
    - Full-volume (standard volume) preparations require consumption of 4 liters (L) of total volume and include Colyte, GoLYTELY, NuLYTELY, and TriLyte, and their generics.
    - Low-volume preparations range from 2 to 3.5 liters of total volume consumed and include Osmoprep (2 L), Plenvu (2 L), Clenpiq (2.2 L), Suprep (3 L), Sutab (3 L), and Moviprep (3 L). Although the tablet formulations (Osmoprep and Sutab) do not require mixing of solutions, significant additional water consumption is still required.
- There do not appear to be clinically relevant differences in efficacy, based on indirect evidence. Compared with standard-volume preparations, low volume products demonstrate superior bowel prep completion rate, improved adenoma detection rates, improved patient satisfaction for the prep and procedure, and increased likelihood that the patient will undergo future colonoscopy.
- Professional treatment guidelines recommend split-dose regimens over single dose traditional regimens (which are administered the day before the colonoscopy), due to improved cleansing. However, no one specific agent is recommended over another.
- Tolerability issues, including poor palatability and the requirement for large volumes of liquid may result in an inadequate bowel prep. Safety concerns vary by product and include gastrointestinal obstruction/perforation, gastric retention, and electrolyte disturbances, potentially exacerbating heart failure or renal dysfunction. PEG products are preferred in patients with heart failure, renal dysfunction or liver disease.
- Specific clinical considerations for the products are as follows:
    - **PEG 3350 with electrolytes powder for solution (Colyte, GoLYTELY, TriLyte, NULYTELY)** advantages include availability in generic formulations; approval for children as young as 6 months of age (TriLyte and NuLYTELY); additional indications for bowel cleansing prior to barium enema X-ray examinations (Colyte and GoLYTELY); and availability in sulfate-free formulations (TriLYTE

and NULYTELY). Disadvantages include the large volumes required (4 L), poor taste, and tolerability issues.

- **PEG 3350 with electrolytes powder for solution (MoviPrep**) is a low volume preparation (3 L) that has high MHS utilization, is well tolerated in elderly patients, and was frequently mentioned by providers as requiring inclusion on the formulary. MoviPrep should be used with caution in patients with phenylketonuria.
- **PEG 3350 with electrolytes powder for solution (Plenvu)** is a low volume (2 L) preparation that is similar to MoviPrep.
- **Sodium picosulfate, magnesium oxide, anhydrous citric acid oral solution (Clenpiq)** is a low volume formulation (2.2 L) indicated for patients 9 years of age and older that is already constituted and well-tolerated. Electrolyte disturbances can occur.
- **Sodium sulfate, potassium sulfate, magnesium sulfate, concentrated oral solution (Suprep)** is a low volume (3 L) product indicated for patients 12 years of age and older. Safety concerns include a higher risk of nausea, vomiting and abdominal distension compared to other products. Overall Suprep offers no compelling clinical advantages relative to the other bowel prep agents.
- **Sodium sulfate, potassium chloride, magnesium sulfate tablets (Sutab):** Although Sutab provides the convenience of a tablet, it requires consumption of 24 tablets and 3 L of extra volume. Overall Sutab offers no compelling clinical advantages relative to the other bowel prep agents.
- **Sodium phosphate tablets (Osmoprep)** requires 32 tabs and 2 L of extra volume and has existing low utilization in the MHS. Significant safety concerns include the boxed warning for acute phosphate nephropathy. Overall Osmoprep offers no compelling clinical advantages relative to the other bowel prep agents.
- **Sodium picosulfate, magnesium oxide, anhydrous citric acid power packets (Prepopik)** is an older formulation that was voluntarily discontinued from the market.

- In order to meet the needs of MHS beneficiaries, at least one product approved in young children, and at least one low volume product is required.

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

- CMA results showed that the generic standard volume PEG formulations (Colyte, GoLYTELY, NULYTELY, TriLYTE) were the most cost effective bowel preparations, followed by the branded products (ranked from most cost effective to least cost effective) MoviPrep, Plenvu, Clenpiq, Suprep, Sutab and Osmoprep.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, or NF, on the UF or Tier 4. BIA results showed that designating the generic PEG formulations, Moviprep, Plenvu, and Clenpiq as UF, and designating Suprep, Sutab, Osmoprep and Prepopik as NF, demonstrated significant cost avoidance for the MHS.

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

    - UF
        - PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics)
        - PEG 3350, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (NuLYTELY, TriLyte, generics)
        - PEG 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for oral solution (Moviprep)
        - PEG 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for solution (Plenvu)
        - sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution (Clenpiq) *(moves from NF to UF)*
    - NF
        - sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution (Suprep) *(moves from UF to NF)*
        - sodium sulfate, potassium chloride and magnesium sulfate tablets (Sutab)
        - sodium phosphate tablets (Osmoprep) *(moves from UF to NF)*
        - sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets (Prepopik) *(moves from UF to NF)*
    - Tier 4/Not Covered: None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (16 for, 1 opposed, 1 abstained, 0 absent) adding PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride

and potassium chloride powder for oral solution (generic GoLYTELY) to the BCF, based on cost effectiveness and existing high utilization in the MHS.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Suprep, Sutab, Osmoprep and Prepopik. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) AND NF TO MAIL REQUIREMENTS—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) exempting the non-formulary bowel preparations (Sutab, Suprep, Osmoprep, Prepopik) from the EMMPI program and nonformulary to mail requirement due to the acute use exception.

5. ***COMMITTEE ACTION: UF, BCF, MN, EMMPI PROGRAM AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Note that letters won't be sent to patients who have received Suprep, Sutab, Osmoprep or Prepopik, due to the acute use of these drugs, and since the majority of prescriptions are for one-time use. Based on the P&T Committee's recommendation, the effective date is March 2, 2022.

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed for group 1: (16 for, 0 opposed, 1 abstained, 1 absent); group 2: (14 for, 1 opposed, 1 abstained, 2 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 2021 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (for group 1: 16 for, 0 opposed, 1 abstained, 1 absent; group 2: 14 for, 0 opposed, 2 abstained, 2 absent; and for Accrufer 12 for, 4 opposed, 1 abstained, 1 absent) the following:

- UF:

- dasiglucagon injection (Zegalogue) – Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents for severe hypoglycemia
- infigratinib (Truseltiq) – Oncological agent for cholangiocarcinoma
- omalizumab syringe (Xolair) – Respiratory Interleukin for asthma, nasal polyps, and chronic idiopathic urticaria (CIU)
- pegcetacoplan injection (Empaveli) – Hematological agent for paroxysmal nocturnal hemoglobinuria (PNH)
- relugolix/estradiol/norethindrone (Myfembree) – Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
- riluzole oral film (Exservan) – Miscellaneous neurological agent for amyotrophic lateral sclerosis (ALS)
- semaglutide injection (Wegovy) – Weight loss agent and a GLP-1 receptor antagonist for the treatment of obesity
- sotorasib (Lumakras) – Oncological agent for non-small cell lung cancer (NSCLC)

- NF:
  - drospirenone/estetrol (Nextstellis) – Contraceptive Agents: Monophasics with 20 mcg estrogen
  - ferric maltol (Accrufer) – Electrolyte-Mineral-Trace Element Replacement for iron deficiency
  - viloxazine extended release (Qelbree) – Non-Stimulant for Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17 years of age
- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
  - rosuvastatin/ezetimibe (Roszet) – Antilipidemic 1
    - Roszet was recommended as Tier 4 as it has little to no additional clinical effectiveness relative to the statins that are combined with ezetimibe, and the needs of TRICARE beneficiaries are met by available alternative agents. Formulary alternatives include rosuvastatin taken with ezetimibe separately, atorvastatin with ezetimibe, simvastatin/ezetimibe (Vytorin), and the PCSK-9 inhibitors.

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended MN criteria for the following: 16 for, 0 opposed, 1 abstained, 1 absent for

Qelbree; 14 for, 0 opposed, 2 abstained, 2 absent for Nextstellis, and 12 for, 4 opposed, 1 abstained, 1 absent for Accrufer. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (group 1 16 for, 0 opposed, 1 abstained, 1 absent; group 2 14 for, 0 opposed, 2 abstained, 2 absent, and for Accrufer (12 for, 4 opposed, 1 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Weight loss drugs: Applying manual PA criteria to new users of Wegovy, consistent with the requirements for Saxenda and the other weight loss drugs. A trial of all the other weight loss drugs except Saxenda will be required before Wegovy.
- Oncologic drugs: Applying manual PA criteria to new users of Lumakras and Truseltiq, consistent with PA requirements in general for oncology drugs.
- Respiratory Interleukins: Applying manual PA criteria to new users of the Xolair syringe, consistent with the requirements for the other respiratory biologics intended for patient self-administration.
- LHRH Agonists-Antagonists: Applying manual PA criteria to new users of Myfembree, similar to the requirements for Oriahnn.
- ALS Drugs: Applying manual PA criteria to new users of Exservan oral film, consistent with the requirements for riluzole oral suspension (Tiglutik).
- Applying manual PA criteria to new users of Accrufer, Empaveli, Nextstellis, and Qelbree.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended group 1 (16 for, 0 opposed, 1 abstained, 1 absent); group 2 (14 for, 0 opposed, 2 abstained, 2 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, on March 2, 2022.
- **New Drugs Recommended for Tier 4/Not Covered 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, on June 15, 2022.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) Miscellaneous Insulin Devices—Omnipod and Omnipod DASH: PA and QLs: The Omnipod and Omnipod DASH cartridge pods are wearable, tubeless insulin management systems that are controlled using a personal diabetes manager (PDM). These FDA-approved medical devices must be filled with insulin by the patient, and supply up to 3 days (72 hours) of insulin. Omnipod systems are meant for those who require multi-day injections of insulin (defined as at least three times daily). The smartphone-like PDM allows for remote management of basal and bolus insulin dosing.

The Omnipod and Omnipod DASH are covered under the TRICARE pharmacy benefit, but the starter kit is packaged with the actual device and is not a pharmacy benefit. Prior authorization was recommended to reflect current TRICARE Policy Manual coverage requirements for external infusion pumps (EIPs).

In addition to PA, QLs were also recommended for Omnipod and Omnipod DASH, along with new QLs for similar external infusion pump, V-Go. (See Appendix D)

> ***COMMITTEE ACTION***: ***NEW MANUAL PA CRITERIA FOR OMNIPOD AND OMNIPOD DASH CARTRIDGES; NEW QLs for OMNIPOD, OMNIPOD DASH, and V-Go AND IMPLEMENTATION PLAN—***The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for new and current users of Omnipod and Omnipod DASH cartridge pods to ensure appropriate use in the expected patient population, as well as to ensure continued monitoring of blood glucose levels and proper patient education on the device. (See Appendix C for full criteria).
>
> The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the new PA criteria will become effective the first Wednesday 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA. (May 18, 2022)
>
> QLs were also recommended for Omnipod, Omnipod DASH, and V-Go, to ensure appropriate use. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the QLs for Omnipod, Omnipod DASHm and V-Go become effective the first Wednesday 2 weeks after signing of the minutes (prior to implementation of the PA). (See Appendix D)

b) Laxatives-Cathartics-Stool Softeners – Lactulose Packet (Kristalose, generics)—Lactulose formulated in packets (Kristalose brand and generic) are not

cost effective relative to other formulary lactulose products or other laxatives (i.e., glycerin, lactitol, polyethylene glycol 3350, sorbitol), which are all available in low-cost formulations. PA was recommended to require a trial of other cost effective lactulose solutions or laxatives prior to Kristalose packets.

COMMITTEE ACTION: NEW PA CRITERIA FOR KRISTALOSE, BRAND AND GENERICS AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for lactulose packets (Kristalose, generics) in new users, due to the significant cost differences compared with numerous available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2022). See Appendix C for the full criteria.

c) Vitamins: Prenatal – Prenatal Multivitamins (Neonatal-DHA, Neonatal FE)— Neonatal-DHA and Neonatal FE are prenatal dietary supplements manufactured by a single company and require a prescription prior to dispensing. The primary ingredients of Neonatal-DHA and Neonatal FE are similar to that found in Azesco, Zalvit, and Trinaz, which require manual PA. Several prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria. Manual PA criteria were recommended for all new and current users of Neonatal-DHA and Neonatal FE, to require a trial of cost-effective formulary prenatal vitamins first.

COMMITTEE ACTION: NEW PA CRITERIA FOR NEONATAL-DHA AND NEONATAL FE AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for Neonatal-DHA and Neonatal FE (regardless of the woman's age) in new users, due to the significant cost differences compared with numerous available alternative agents. The new PA will become effective the first Wednesday 90 days after the signing of the minutes. See Appendix C for the full criteria.

2. Updated PA Criteria and Step Therapy

Updates to the manual PA criteria and step therapy were recommended for the following products, due to availability of cost-effective alternative treatments, results from clinical trial data, clinical practice guideline updates, or provider recommendation. The updated PAs and step therapy outlined below will apply to new users. See Appendix C for full criteria.

a) Multiple Sclerosis Agents – ozanimod (Zeposia)—Zeposia is a sphingosine-1 phosphate receptor modulator originally approved for treating relapsing forms of multiple sclerosis. It recently gained approval for ulcerative colitis

(UC), another type of immune-mediated inflammatory disorder. At the time of review the trial supporting Zeposia for UC was not published. Other treatments, including non-biologics (e.g., azathioprine, sulfasalazine) and the targeted immunomodulatory biologic (TIBs) adalimumab (Humira) are well-established therapies for UC, and are more cost effective than Zeposia. The Zeposia PA was updated to allow for treatment of UC after a trial of non-biologic systemic therapy and trial of Humira.

COMMITTEE ACTION: ***UPDATED MANUAL PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updating the current PA criteria for Zeposia to require more clinically established and cost effective treatments first. See Appendix C for the full PA criteria.

b) Migraine Agents —rimegepant (Nurtec ODT): PA and QLs; and ubrogepant (Ubrelvy) and lasmiditan (Reyvow) – PA update: These three oral drugs were originally approved for acute treatment of migraine headache, and were reviewed at the May 2020 P&T Committee meeting. PA criteria currently apply. Rimegepant orally disintegrating tablets (Nurtec ODT) is now FDA-approved for preventive treatment of episodic migraine in adults. Other migraine preventive medications (e.g., antiepileptics, beta blockers, antidepressants, and the injectable calcitonin gene-related peptide [CGRP] antagonists) are available that have shown greater reductions in monthly migraine days than Nurtec ODT, based on indirect comparison, and are more cost-effective.

The PA criteria for Nurtec ODT was updated to require a trial of other preventive medications (oral agents, and injectable CGRPs) first. QLs were also updated for Nurtec ODT, as the new preventive indication allows for every other day dosing. The PAs for Nurtec ODT, Ubrelvy, and Reyvow were also updated to include renewal criteria, to assess for efficacy.

COMMITTEE ACTION: ***NURTEC ODT, UBRELVY, AND REYVOW, UPDATED MANUAL PA CRITERIA AND NURTEC ODT QL—***The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updating the current PA criteria for Nurtec ODT, Ubrelvy, and Reyvow and to also update the QLs on Nurtec ODT. See Appendix C for the full PA criteria and Appendix D for QLs.

3. Updated PA Criteria for New FDA-Approved Indications or Expanded Age Ranges

Updates to the PA criteria for several drugs were recommended due to new FDA-approved indications and expanded age ranges. The updated PA criteria summarized below will apply to new users. See Appendix C for full criteria.

- **Oncological Agents–avapritinib (Ayvakit)**—Includes the new indication for adult patients with advanced systemic mastocytosis (comprises patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia)
- **Targeted Immunomodulatory Biologic secukinumab (Cosentyx)**—Manual PA criteria now allow use in pediatric patients 6 years of age and older, as well as in adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- **Overactive Bladder Agents**
  - **mirabegron tablets and granules (Myrbetriq)**—The manual PA criteria were updated to allow for the new indication for treatment of neurogenic detrusor overactivity (NDO) in patients 3 years of age and older (for the granules) *(note that the granules were reviewed as an innovator at the November 2021 meeting)* and weighing 35 kg or more (for the tablets).
  - **fesoterodine (Toviaz)**—Manual PA criteria were updated to allow for the new indication for treatment of neurogenic detrusor overactivity (NDO) in patients 6 years of age and older and weighing more than 25 kg.
- **Hepatitis C Agents: Direct Acting Agents– sofosbuvir/velpatasvir (Epclusa) and authorized generic; glecaprevir/pibrentasvir (Mavyret)**—The manual PA criteria now allow use in pediatric patients 3 years of age and older as well as adults for treatment of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6**.**
- **ADHD Agents: Stimulants – amphetamine sulfate ODT (Evekeo ODT)**—The manual PA criteria now allow use in pediatric patients between the ages of 3 to 17 years for treatment of ADHD.
- **Gastrointestinal-2 Agents – obeticholic acid (Ocaliva)** —The manual PA criteria was revised and updated for safety information to narrow the indication for the patient population with primary biliary cholangitis (PBC), based on information from the manufacturer.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA— The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updates to the manual PA criteria for Ayvakit, Cosentyx, Myrbetriq, Toviaz, Epclusa and authorized generic, Mavyret, Evekeo ODT, and Ocaliva. See Appendix C for the full PA criteria.

B. Quantity Limits

1. ***General QLs:*** QLs were reviewed for the newly approved drugs where there are existing QLs for the class, (including hypoglycemia agents, electrolyte-mineral-trace element replacements, oncological agents, and respiratory interleukins), and a previously reviewed targeted immunomodulatory biologic (Stelara 90 mg syringe).

COMMITTEE ACTION: QLs—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Zegalogue, Lumakras, Truseltiq, Xolair syringe, Accrufer, and Stelara 90 mg strength only. See Appendix D for the QLs.

2. ***Antiinfectives: Anti-Helmintics: ivermectin (Stromectol)***: A review of MHS prescription data noted a large increase in the quantity of ivermectin dispensed at the Mail Order and Retail pharmacies, likely related to off-label use for COVID-19 infection. The recently updated 2021 updated National Institutes of Health (NIH) COVID-19 treatment guidelines state there is insufficient evidence to recommend either for or against the use of ivermectin for treatment of COVID-19. A quantity limit of 60 tablets per prescription fill at all 3 points of service (POS) were recommended to minimize potential off-label ivermectin use. The QLs will not impact the treatment regimens for FDA-approved uses (e.g., intestinal strongyloidiasis, scabies). The QLs noted here will not impact any DoD-conducted investigational trials. (See Appendix D)

   COMMITTEE ACTION: QLs—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for ivermectin. See Appendix D for the QLs.

C. Updated PAs and QLs Implementation Periods

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

- (16 for, 0 opposed, 1 abstained, 1 absent)
  - Updates to the current PA criteria in new users for Zeposia will become effective the first Wednesday 30 days after the signing of the minutes (Month day, 2021).
  - Updates to the current PA criteria in new users for Nurtec ODT, Ubrelvy, and Reyvow will become effective the first Wednesday 60 days after the signing of the minutes. (*Note that implementation occurred on October 5, 2021.)*
  - Updates to the current PA criteria in new users for the oncology drug Ayvakit; the TIB Cosentyx; the Overactive Bladder Agents Myrbetriq and Toviaz; the hepatitis C drugs Epclusa and authorized generic and Mavyret; the ADHD stimulant Evekeo ODT; the GI-2 agent Ocaliva will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2021)
- (17 for, 0 opposed, 0 abstained, 1 absent) the QLs listed in Appendix D will become effective the first Wednesday **2 weeks** after the signing of the minutes in all POS. Note that the QLs for Nurtec

ODT will be implemented before the PA is updated. (March 2, 2022).

VII. LINE EXTENSIONS

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

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION*—**The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMPI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (March 2, 2022).

- **Oncological Agents: Multiple Myeloma—**designating **selinexor (Xpovio) 40 mg twice weekly dosing, 40 mg, 60 mg, 80 mg, and 100 mg once weekly dosing** as UF, with the same manual PA criteria requirements, QL, and specialty status as Xpovio 20 mg.
- **TIBs:**
    - Designating **adalimumab (Humira CF) 80 mg/0.8 mL pen carton and starter package for pediatric UC** as UF, step-preferred, same manual PA criteria, QL, specialty status, and EMMPI List status similar to various other strengths and dosage forms of Humira CF.
    - Designating **risankizumab-rzaa (Skyrizi) 150 mg/mL pen injector and single syringe** as NF, non-step-preferred, same MN criteria, manual PA criteria, QL, specialty status, and EMMPI List status similar to Skyrizi 75 mg single-use prefilled syringe.
    - Designating **secukinumab (Cosentyx) 75 mg/0.5 mL syringe** as UF (step therapy required), same manual PA criteria, QL, specialty status, and EMMPI List status similar to Cosentyx 150 mg and 300 mg syringes and pens.
- **Pancreatic Enzyme Replacement Therapy (PERT)—**designating **lipase/protease/amylase (Pancreaze) 37k-97.3k capsule** as NF, same MN criteria, manual PA criteria, and EMMPI List status similar to various other strengths of Pancreaze.

- **Neurological Agents Miscellaneous: Movement Disorders—**designating **valbenazine (Ingrezza) 60 mg capsule** as UF, same manual PA criteria, and QL similar to Ingrezza 40 mg and 80 mg.
- **Anticonvulsants-Antimania Agents—**designating **cenobamate (Xcopri) 250 mg tablet** as UF and specialty status similar to other strengths of Xcopri.
- **Oncological Agents—**designating **avapritinib (Ayvakit) 25 mg and 50 mg tablets** as UF, same manual PA criteria, QL, and specialty status similar to Ayvakit 100 mg, 200 mg, and 300 mg.
- **Cystic Fibrosis Agents—**designating **elexacaftor/tezacaftor/ivacaftor (Trikafta) 50-25-37.5/75 mg tablet** as UF, same manual PA criteria, QL, and specialty status similar to Trikafta 100-50-75 mg/150 mg.
- **Calcium Channel Blocking Agents—**designating **nimodipine (Nymalize) 60 mg/10 mL oral syringe** as UF similar to Nymalize 30 mg/5 mL oral syringe.

VIII. PULMONARY 3 AGENTS: COMBINATIONS SUBCLASS— BUDESONIDE/GLYCOPYRROLATE/FORMOTEROL (BREZTRI INHALER) COPAYMENT CHANGE AND EMMPI PROGRAM INCLUSION

Background—The fixed-dose triple combination inhalers containing an inhaled corticosteroid, long-acting muscarinic antagonist, and long-acting beta agonist (ICS/LAMA/LABA) were reviewed for formulary status at the February 2021 Committee meeting. Both budesonide/glycopyrrolate/formoterol (Breztri) and fluticasone/umeclidinium/vilanterol (Trelegy) were recommended to remain on the UF. Following the meeting, more favorable pricing for Breztri became available, making it the most cost effective triple combination inhaler. (Note that Committee recommendations from February 2021 had not yet been implemented at the time of the August 2021 P&T Committee meeting, due to the BAP zero-based review.) As a result the Tier 1 copay was recommended for Breztri. In addition it was recommended to include Breztri on the EMMPI Program, as the Mail Order and MTF points of service are more cost effective than at retail network pharmacies. (*Note that this is an update from the February 2021 P&T Committee meeting minutes.)*

Applying the Tier 1 copay at both Retail and Mail will also encourage use of the most cost-effective triple fixed-dose combination inhaler. Additionally, lowering the copay for this agent is consistent with 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020, in that the P&T Committee "will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries."

COMMITTEE ACTION: BREZTRI COPAYMENT CHANGE, EMMPI PROGRAM ADDITION, AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent)

changing the copay for Breztri inhaler from Tier 2 (brand) to the Tier 1 (generic) copay at the purchased care points of service (Retail and Mail), and adding Breztri to the EMMPI program. Implementation will two weeks after signing of the minutes. *(Note addition to EMMPI is a change from the February 2021 P&T Committee meeting minutes.)*

IX. BRAND OVER GENERIC AUTHORIZATION FOR AMBRISENTAN (LETAIRIS) AND POST-IMPLEMENTATION REVIEW FOR PULMONARY ARTERIAL HYPERTENSION (PAH) DRUGS

Background—The PAH drugs including the endothelin receptor antagonist subclass were most recently reviewed for formulary placement in May 2019. The Committee originally recommended brand over generic authorization and Tier 1 status for branded ambrisentan (Letairis). However, multiple cost effective generic formulations were subsequently available prior to the implementation date of October 2019, so this requirement was removed at the August 2019 meeting.

At this meeting, the Committee reviewed overall trends in utilization and expenditures since implementation of the formulary recommendations in October 2019. The post-implementation review did reveal that supply of cost effective generic ambrisentan was unreliable. As a result, branded Letairis is currently more cost-effective than generic ambrisentan products. Due to these supply and cost issues, the Committee recommended implementing the brand over generic requirements for ambrisentan, requiring use of the branded Letairis formulation prior to a generic formulation, and applying the Tier 1 copay to the brand.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT FOR AMBRISENTAN (LETAIRIS), PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) requiring brand Letairis over generic ambrisentan in all new and current users, based on cost effectiveness. The prescriber will provide patient-specific justification as to why branded Letairis cannot be used. The Tier 1 (generic) copayment will apply to brand Letairis. The effective date will two weeks after signing of the minutes in all POS. 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 ambrisentan.

The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3):

> [W]hen 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.

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

Newly Approved Drugs per 32 CFR 199.21(g)(5)
See Appendix F for the mail order status of medications designated UF or NF during the August 2021 P&T Committee meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement. The implementation date for all of the recommendations from the August 2021 meeting listed in Appendices E and F, including those for newly approved drugs, will be effective upon the first Wednesday two weeks after the signing of the minutes.

COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—
The P&T Committee recommended (for group 1: 16 for, 0 opposed, 1 abstained, 1 absent; group 2: 14 for, 0 opposed, 2 abstained, 2 absent; and for Accrufer 12 for, 4 opposed, 1 abstained, 1 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. See Appendix F.

XI. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS

Management of the TRICARE pharmacy benefit requires a wide variety of actions, with various levels of involvement of the DoD P&T Committee, the Beneficiary Advisory Panel (BAP), and the Director, DHA. In May 2005 when the UF Rule was implemented, the P&T Committee developed a comprehensive list of the functions associated with formulary management and categorized each into one of three decision pathways, depending on the level of involvement required. Periodic updates have been made (May 2017 and May 2019 meeting minutes.)

The Committee reviewed an update to allow implementation of PAs and QLs for shortages/pandemic/other emergencies, after consultation with the P&T Committee Chair and others as needed (e.g., Deputy Assistant Director – Health Affairs). Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QLs implemented in these situations will be removed when the situation has resolved. (See Appendix I.)

XII. ITEMS FOR INFORMATION

A. Biosimilar and Specialty Generics: The Committee was briefed on the definition of and FDA approval pathway for biosimilars, and the current market place spend and utilization for biosimilars and specialty medications and biologics.

XIII. ADJOURNMENT

The meeting adjourned at 1500 hours on August 6, 2021. The next meeting will be in November 2021.

Appendix A—Attendance: August 2021 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 August 2021 DoD P&T Committee Meeting
Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives
Appendix I—DoD P&T Committee and the Updated Table of Processes and Recommendation/Approval Authorities
Appendix J—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

14 Feb 2022
Date

Appendix A—Attendance: August 2021 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Col Markus Gmehlin BSC	Chief, DHA Pharmacy Operations Division (POD)
CDR Scott Raisor	Interim Chief, Formulary Management Branch (Recorder)
MAJ Sebastian Welsh, MC	Army, Physician at Large
COL Jeffrey Neigh, MSC for COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, COL (Ret.) MC, USA for MAJ Wendra Galfand	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Lt Col Justin Lusk, BSC, for Col Corey Munro, BSC	Air Force, Pharmacy Officer
Maj Christin Destefano, MSC	Air Force, Oncologist
Lara Au, PharmD, BCOP	Oncology Pharmacist
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR William Agbo	DLA Troop Support
Bernadette Heron PharmD (Aug 4th) Francine Goodman, PharmD (Aug 5th)	Department of Veterans Affairs

Appendix A—Attendance: August 2021 P&T Committee Meeting

Guests	
CPT Hope Shen, MSC	DLA Troop Support
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Hilary Lewis	DHA Contracting Officer
Ms. Madison Northern	DHA Contracting
Mr. Hudson Tompkins	DHA Contracting
Ms. Grace Steier	DHA Contracting
Mr. Monroe Porter	DHA Contracting
Others Present	
MAJ Adam Davies, MSC	Chief, P&T Section, DHA Formulary Management Branch
Dr. Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Dr. Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Dr. Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
Dr. Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Dr. Julia Trang, PharmD	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
Mr. David Folmar	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Samantha Valliant	University of North Carolina at Chapel Hill PharmD student

Drug / Drug Class	Medical Necessity Criteria
Class Review MN Criteria	
• sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution (Suprep) • sodium sulfate, potassium chloride and magnesium sulfate tablets (Sutab) • sodium phosphate tablets (Osmoprep) • sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets (Prepopik) **Laxatives-Cathartics-Stool Softeners: Bowel Preparations**	• No alternative formulary agent: the patient is unable to comply with the mixing requirements for the formulary alternatives. **Formulary alternatives:** CoLyte, Galvilyte-A, Galvilyte-C, GalviLyte-G, NuLytely, GoLytely, TriLyte, MoviPrep, Clenpiq, Plenvu
Newly Approved Drugs MN Criteria	
• drospirenone /estetrol (Nextstellis) **Contraceptive Agents: Monophasics with 20 mcg estrogen**	• Patient has experienced significant adverse effects from formulary agents **Formulary alternatives:** ethinyl estradiol/drospirenone (Yaz, Yasmin), ethinyl estradiol/levonorgestrel (Sronyx, generics), or any other formulary contraceptive agents
• ferric maltol (Accrufer) **Electrolyte-Mineral-Trace Element Replacement**	• Patient has experienced significant adverse effects from two other oral iron products (must be different salts) **Formulary alternatives:** ferrous sulfate, ferrous gluconate, ferrous fumarate, and polysaccharide Fe complex
• viloxazine (Qelbree) **ADHD Agents: Non-Stimulants**	• Use of formulary ADHD non-stimulant agents are contraindicated • Formulary ADHD non-stimulant agents resulted in or are likely to result in therapeutic failure **Formulary ADHD non-stimulant alternatives:** atomoxetine (Strattera, generic), clonidine ER (Kapvay, generic), guanfacine ER (Intuniv, generic)

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	

• ibrutinib (Imbruvica)
 	
Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors
	Updates from the August 2021 meeting are in bold
	
	Manual PA is required for new users of Imbruvica capsules and tablets.
	
	<u>Manual PA Criteria</u>: Imbruvica is approved if all criteria are met:
	• The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for DoD
	• If the Rx is for Imbruvica tablets, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below.
	•
	• If the Rx is for the Imbruvica capsules, please continue with the PA criteria below.
	• If the Rx is for Imbruvica tablets, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below.
	
	• Patient is 18 years of age or older
	• Drug is prescribed by or in consultation with a hematologist/oncologist
	• Will be used in one of the following contexts:
	  • Pretreatment to limit the number of cycles of RhyperCVAD/rituximab maintenance therapy for Mantle Cell Lymphoma
	  • Second line (or subsequent therapy) for Mantle Cell Lymphoma
	  • Second line (or subsequent therapy) for Marginal Zone Lymphoma
	  • Second line (or subsequent therapy) for non-germinal center B cell-like Diffuse Large B Cell Lymphoma if unable to receive chemotherapy
	  • Frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation
	  • Patient fits one of the following categories:
	  • Frail patient with significant comorbidity (not able to tolerate purine analogues)
	  • Patient ≥ 65 years old with significant comorbidity
	  • Patients < 65 years old
	  • Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation
	  • Waldenström macroglobulinemia
	  • Chronic Graft versus Host Disease
	  • Monitor for bleeding, infection, hypertension, cardiac arrhythmias, cytopenias, and Tumor Lysis Syndrome
	  • If the patient is female, she is not pregnant or planning to become pregnant
	  • Breastfeeding female patients will be advised that the potential harm to the infant is unknown
	  • All patients (males and females) of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation
	  • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: **_____.**
	
	Other non-FDA-approved uses are not approved, except as noted above
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• acalabrutinib (Calquence)
 	
Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors
	(Note – no changes to the PA criteria made at the August 2021 meeting)
	
	Manual PA is required for all new users of Calquence
	
	<u>Manual PA Criteria</u>: Calquence is approved if all criteria are met:
	• Age 18 years of age or older
	• Must be prescribed by or in consultation with a hematologist/oncologist
	• Patient meets one of the following categories:
	  • Patient must have pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 that had a short response duration to prior therapy (< median progression-free survival).
	  • Patient will use acalabrutinib as **frontline or** relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation
	  • Patient fits one of following categories:
	  • Frail patient with significant comorbidity (not able to tolerate purine analogues)
	  • Patient ≥ 65 years old with significant comorbidity
	  • Patients < 65 years old
	  • Patient will use acalabrutinib as **frontline or** relapsed refractory therapy for CLL/SLL with del(17p)/TP53 mutation
	• If the patient has CLL, the patient's disease has no evidence of a BTK C481S mutation nor prior ibrutinib-refractory disease
	• Patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec
	• Monitor for bleeding, infection, cardiac arrhythmias, and cytopenias
	• If the patient is female and of childbearing potential, advise the patient of the risk of significant fetal harm
	• Female patients will not breastfeed during treatment and for at least 2 weeks following cessation of treatment
	• The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.
	
	Other non-FDA-approved uses are not approved, except as noted above
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• zanubrutinib (Brukinsa) **Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors**	**(Note – Changes made after the August 2021 meeting, and are in bold** Manual PA criteria apply to all new users of Brukinsa. Manual PA Criteria: Brukinsa is approved if all criteria are met: • Patient is 18 years if age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL). or • **Patient has Waldenström's macroglobulinemia (WM) or~~, a rare non-Hodgkin lymphoma~~** • **Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen** • • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment • The diagnosis Is NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.
Newly Approved Drug PAs	
• drospirenone /estetrol (Nextstellis) **Contraceptive Agents: Monophasics with 20 mcg estrogen**	Manual PA criteria apply to all new users of Nextstellis. Manual PA criteria: Nextstellis is approved if all criteria are met: • Provider acknowledges that ethinyl estradiol/drospirenone (Yaz, Yasmin) and numerous other contraceptives are available for TRICARE patients and do not require a PA. Providers are encouraged to consider changing the prescription to Yaz, Yasmin, or another formulary contraceptive • Patient has tried an ethinyl estradiol containing oral contraceptive and has had significant adverse effects attributed to the ethinyl estradiol component • Provider acknowledges that Nextstellis may be less effective in females with a body mass index (BMI) ≥ 30 kg/m^2 per the FDA label Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ferric maltol (Accrufer) **Electrolyte-Mineral-Trace Element Replacement**	Manual PA criteria apply to all new users of Accrufer. Manual PA criteria: Accrufer is approved if all criteria are met: • Patient has a documented diagnosis of iron deficiency • Patient is 18 years of age or older • Patient has tried and failed two oral iron products (must be different salts e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) for at least six weeks in duration for each product, unless contraindicated or clinically significant adverse effects are experienced. o The provider must provide the date of when the patient previously tried each medication, or the contraindication or clinically significant adverse effect that the patient experienced: o Oral iron product:_____ Date:_____ Contraindication or clinically significant adverse effect: _____ o Oral iron product:_____ Date:_____ Contraindication or clinically significant adverse effect: _____ • Provider acknowledges there is insufficient data on drug interactions at this time. Non-FDA-approved uses are not approved. Prior authorization expires in 6 months. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional 6 months for continuation of therapy if: • Patient is still iron deficient • Documentation of clinically significant improvement in patient's iron deficiency required.
• infigratinib (Truseltiq) **Oncological Agents**	Manual PA criteria apply to all new users of Truseltiq. Manual PA criteria: Truseltiq is approved if all criteria are met: • Patient is 18 years of age or older • Patient has previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. • The patient will be monitored for retinal pigment epithelial detachment, hyperphosphatemia, and soft-tissue mineralization • The drug is prescribed by or in consultation with a hematologist/oncologist • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 month after cessation of therapy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• pegcetacoplan injection (Empaveli) **Hematological Agents**	Manual PA criteria apply to all new users of Empaveli. Manual PA criteria: Empaveli is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • Patient has been counseled on the appropriate administration of the drug via infusion pump • Patient has been vaccinated against certain encapsulated bacteria (e.g., *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• riluzole oral film (Exservan) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Exservan. Manual PA criteria: Exservan is approved if all criteria are met: • Patient is diagnosed with amyotrophic lateral sclerosis (ALS) • Patient has dysphagia/swallowing dysfunction Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• relugolix/estradiol/ norethindrone (Myfembree) **Luteinizing Hormone-Releasing Hormone Agonists-Antagonists**	**Manual PA criteria apply to all new users of Myfembree. Note that the PA criteria are similar to Oriahnn, with differences bolded below.** Manual PA criteria: Myfembree is approved if all criteria are met: • Patient is 18 years of age or older • Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD) • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or a history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 • Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs or if the patient has a sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions • Patient does not have uncontrolled hypertension • Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly • Patient does not have osteoporosis • Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes • Patient does not have a history of breast cancer or other hormonally-sensitive malignancies • Patient does not have known liver impairment or disease • Provider agrees to counsel patients on the signs and symptoms of liver injury • Patient does not have undiagnosed abnormal uterine bleeding • Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors • **Patient is not using Myfembree with oral P-gp inhibitors (e.g., erythromycin) or combined P-gp and strong CYP3A inducers (e.g., rifampin)** Non-FDA-approved uses are not approved including **contraception** or pain associated with endometriosis. Prior authorization expires after 24 months (lifetime expiration). **Cumulative treatment with Oriahnn and Myfembree will not exceed 24 months during the patient's lifetime.**

Drug / Drug Class	Prior Authorization Criteria
• semaglutide injection (Wegovy) **Weight Loss Agents**	Manual PA criteria apply to all new users of Wegovy. Manual PA criteria: Wegovy is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a BMI ≥ to 30, or a BMI ≥ to 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried and failed or has a contraindication to all of the following agents (generic phentermine, Qsymia, Xenical, and Contrave). (Note: provider must include the date of use and duration of therapy or contraindication to the drug) o Phentermine: Date_____ Duration of therapy _____ o Qsymia: Date_____ Duration of therapy_____ o Xenical: Date _____ Duration of therapy _____ o Contrave: Date _____ Duration of therapy_____ • If the patient is diabetic, they must have tried and failed metformin and the DoD's preferred GLP1RAs (Trulicity and Bydureon BCise) • If the patient is an active duty service member, the individual is enrolled in a Service-specific Health/Wellness Program AND will adhere to Service policy, AND will remain engaged throughout course of therapy • Patient is not pregnant • Concomitant use of Wegovy with other GLP1RA drugs is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or does not have a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Non-FDA approved uses are NOT approved including diabetes mellitus and for those less than 18 years of age. • Initial prior authorization expires after 4 months and then annually. Non-FDA-approved uses are not approved, including for diabetes mellitus and for patients younger than 18 years of age. Initial prior authorization expires after 4 months, and then annually Renewal PA Criteria: Wegovy will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and remains on a reduced calorie diet • Wegovy will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.

Drug / Drug Class	Prior Authorization Criteria
• sotorasib (Lumakras) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of Lumakras. Manual PA criteria: Lumakras is approved if all criteria are met: • Patient is 18 years of age or older • Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test • The patient will be monitored for interstitial lung disease and hepatotoxicity • The drug is prescribed by or in consultation with a hematologist/oncologist • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• viloxazine (Qelbree) **ADHD Agents: Non-Stimulants**	Manual PA criteria apply to all new users of Qelbree. Manual PA criteria: Qelbree is approved if all criteria are met: • Patient is 6 to 17 years of age • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed, had an inadequate response, OR contraindication to amphetamine salts XR (Adderall XR, generic) or other long acting amphetamine or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to methylphenidate OROS and other (Concerta, generic) or other long acting methylphenidate or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to at least one non-stimulant ADHD medication (generic formulations of Strattera, Kapvay, or Intuniv) Non-FDA-approved uses are not approved (to include depression and anxiety). Prior authorization does not expire.

• omalizumab syringe (Xolair) **Respiratory Interleukins**	Manual PA criteria apply to all new users of Xolair syringe. <u>Manual PA criteria</u>: Xolair is approved for initial therapy for 12 months if <u>all</u> criteria are met: For all indications: • Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc. • Patient has received at least 3 doses of Xolair under the guidance of a healthcare provider without experiencing any hypersensitivity reactions • Provider agrees to ensure that the patient or caregiver is able to recognize symptoms of anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue. Provider agrees to counsel the patient that anaphylaxis has occurred up to 2 hours post administration and appropriate monitoring will occur. • Provider agrees to ensure that the patient or caregiver is able to treat anaphylaxis appropriately and consider co-prescribing epinephrine. • Provider agrees to ensure that the patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe with proper technique according to the prescribed dosing regimen • For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or dupilumab [Dupixent]) For Asthma: • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist, pulmonologist, or asthma specialist • The patient has moderate to severe asthma with baseline IgE levels that are greater than 30 IU/ml • The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi) ▪ Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse) ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) For chronic rhinosinusitis with nasal polyposis: • The patient is 18 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: ▪ Presence of nasal polyposis is confirmed by imaging or direct visualization AND ▪ At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Xolair will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND ▪ The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery

Drug / Drug Class	Prior Authorization Criteria
	For chronic idiopathic urticaria (CIU): • The patient is 12 years of age or older • The drug is prescribed by an allergist, immunologist, or dermatologist • Xolair is not indicated for any other form of urticaria • Patient has symptoms lasting for greater than 6 weeks • Patient remains symptomatic despite trial of at least 4 weeks with recommended urticarial dosing of a second generation H1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine) Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely. Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND • Asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations or improvements in forced expiratory volume in one second (FEV1) • Chronic rhinosinusitis with nasal polyposis: There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score • Chronic Idiopathic Urticaria: The patient has had a positive response to therapy and improvement in clinical symptoms to warrant maintenance of therapy
New PAs	
• Omnipod and Omnipod DASH **Insulins: Miscellaneous Insulin Device**	Manual PA applies to **new and current users** of Omnipod/Omnipod DASH Manual PA criteria—Omnipod/Omnipod DASH is approved if all criteria are met: • The patient has diabetes mellitus AND requires insulin therapy • 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 • The patient performs 4 or more blood glucose tests per day or is using a Continuous Glucose Monitoring (CGM) system • The patient has completed a comprehensive diabetes education program • The patient has demonstrated willingness and ability to play an active role in diabetes self-management Initial prior authorization expires after 1 year. Renewal criteria: 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: • Patient has been successful with therapy • 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)

Drug / Drug Class	Prior Authorization Criteria
• ambrisentan (generics) **Pulmonary Arterial Hypertension Agents (PAH) – Endothelin Receptor Antagonist (ERA) Subclass**	Manual PA criteria applies to new and current users of generic ambrisentan. Manual PA criteria—Ambrisentan generics are approved if all criteria are met: • The brand Letairis formulation is preferred product over generic Letairis (ambrisentan) 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 Letairis is a branded product, it will be covered at the generic formulary copayment or cost share.) • Please provide a patient-specific justification as to why the brand Letairis product cannot be used in this patient: _____(fill in the blank) • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of WHO group 1 • Patient and provider are enrolled in the Letairis REMS program • Patient is not pregnant • Women of childbearing potential must use adequate contraception • Patient has no history of LFT elevations on previous ERA therapy accompanied by signs or symptoms of liver toxicity or increases in bilirubin >2x ULN • Patient does not have moderate or severe liver impairment (e.g., Child-Pugh Class B or C) Non-FDA approved uses are not approved. Prior Authorization does not expire.
• lactulose packet (Kristalose, generics) **Laxatives-Cathartics-Stool Softeners**	Manual PA criteria applies to new users of lactulose packet (Kristalose, generics). Note: lactulose solution and other laxatives are available without a PA; providers are encouraged to consider changing the prescription to one of the drugs listed: lactulose solution or other laxatives (i.e., glycerin, lactitol, polyethylene glycol 3350, sorbitol) Manual PA criteria—Kristalose and generic packets are approved if all criteria are met: • Provider acknowledges that lactulose solution and other laxatives are available to DoD beneficiaries without the need of prior authorization • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives: (fill-in blank) Non-FDA approved uses are not approved. Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• prenatal MVI (Neonatal-DHA, Neonatal FE) **Vitamins: Prenatal**	Manual PA criteria applies to new users of prenatal MVI (Neonatal-DHA, Neonatal FE). Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, **Neonatal-DHA, and Neonatal FE** and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant Manual PA criteria—Azesco, Zalvit, Trinaz, Neonatal-DHA, or Neonatal FE is approved if all criteria are met: • Provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, Neonatal-DHA, and Neonatal FE and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant. Please consider changing the prescription to one of these agents • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives (fill-in the blank) Non-FDA approved uses are not approved. Prior Authorization does not expire.
Updated PAs	

Drug / Drug Class	Prior Authorization Criteria
• ozanimodd (Zeposia) **Multiple Sclerosis Agents**	**Updates from the August 2021 Meeting are in bold.** Manual PA criteria apply to all new users of Zeposia. Manual PA criteria: Zeposia is approved if all criteria are met: • All recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes CBC, LFT, varicella zoster virus (VZV) antibody serology, ECG, and macular edema screening as indicated. • **Patients of childbearing potential agree to use effective contraception during treatment and for 3 months after stopping therapy** • Do not use in patients with significant cardiac history, including: o Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization o Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker For relapsing Multiple Sclerosis • Zeposia is prescribed by a neurologist • Patient has a documented diagnosis of relapsing forms of MS • No concurrent use of other MS disease-modifying therapy • Patient has not failed a course of another S1p receptor modulator (e.g., Gilenya, Mazyzent) **For Ulcerative Colitis** **Coverage for Zeposia is approved if all criteria are met:** • **Patient has a diagnosis of moderate to severe active Ulcerative Colitis** • **The patient is 18 years of age or older** • **Humira is the Department of Defense's preferred targeted immunomodulatory biologic agent for ulcerative colitis.** • **The patient must have tried Humira AND:** o **Had an inadequate response to Humira OR** o **Experienced an adverse reaction to Humira that is not expected to occur with Zeposia OR** o **Has a contraindication to Humira** • • **The patient is not receiving oral immunomodulatory or biologic therapies concomitantly** • **The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)** Non-FDA-approved uses are not approved. Prior authorization does not expire.

• rimegepant (Nurtec ODT) **Migraine Agents**	**<u>Updates from the August 2021 Meeting are in bold</u>.** Manual PA criteria apply to all new users of rimegepant (Nurtec ODT). <u>Manual PA criteria</u>: Nurtec ODT is approved if <u>all</u> criteria are met: • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrelvy or another gepant) is not allowed • Not approved for patients who have clinically significant or unstable cardiovascular disease <u>For Acute Treatment</u> • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications o sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) **<u>For Prevention of Episodic Migraine</u>** • **The patient has episodic migraine as defined by one of the following:** o **Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR** o **Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months** • **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:** o **Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate** o **Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol** o **Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine** • **Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents** o **erenumab-aooe (Aimovig)** o **fremanezumab-vfrm (Ajovy)** o **galcanezumab-gnlm (Emgality)** Non-FDA-approved uses are NOT approved. **PA expires after 6 months** **Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if one of the following apply (Note that initial TRICARE PA approval is required for renewal):** **Acute Treatment** • **Patient has a documented positive clinical response to therapy** **Preventive Treatment** • **The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR** • **The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:** o **Migraine Disability Assessment (MIDAS)** • **Reduction of ≥ 5 points when baseline score is 11–20**

Drug / Drug Class	Prior Authorization Criteria
	• **Reduction of ≥ 30% when baseline score is > 20** o **Headache Impact Test (HIT-6)** • **Reduction of ≥ 5 points** o **Migraine Physical Functional Impact Diary (MPFID)** • **Reduction of ≥ 5 points**
• ubrogepant (Ubrelvy) **Migraine Agents**	**<u>Updates from the August 2021 Meeting are in bold</u>.** Manual PA criteria apply to all new users of ubrogepant (Ubrelvy). <u>Manual PA criteria</u>: Ubrelvy is approved if <u>all</u> criteria are met: • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or another gepant) is not allowed • Not approved for patients who have clinically significant or unstable cardiovascular disease • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications o sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • Patient has had a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT Non-FDA-approved uses are not approved. **PA expires after 6 months** **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):** **Acute Treatment** • **Patient has a documented positive clinical response to therapy**

Drug / Drug Class	Prior Authorization Criteria
• lasmiditan (Reyvow) **Migraine Agents**	**<u>Updates from the August 2021 Meeting are in bold</u>.** Manual PA criteria apply to all new users of lasmiditan (Reyvow). <u>Manual PA criteria</u>: Reyvow is approved if <u>all</u> criteria are met: • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Reyvow is not approved for patients who have history of hemorrhagic stroke • Reyvow is not approved for patients with a history of epilepsy or any other condition with increased risk of seizure • Not approved for patients who have clinically significant or unstable cardiovascular disease • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications o sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • The patient has a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT • If Reyvow is used with a triptan, provider acknowledges Reyvow and the triptan should not be used within 24 hours of each other • Reyvow will be used with caution in patients with low heart rate and/or those using beta blockers, such as propranolol Non-FDA-approved uses are not approved. **PA expires after 6 months** **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):** **Acute Treatment** • **Patient has a documented positive clinical response to therapy**

Drug / Drug Class	Prior Authorization Criteria
• avapritinib (Ayvakit) **Oncological Agents**	**<u>Updates from the August 2021 Meeting are in bold</u>.** Manual PA criteria apply to all new users of avapritinib (Ayvakit). <u>Manual PA criteria</u>: Ayvakit is approved if <u>all</u> criteria are met: • Patient is 18 years of age or older • Must be prescribed by or in consultation with a hematologist/oncologist • Patient has: o Pathologically confirmed unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation with or without the D842V mutation OR o **Advanced systemic mastocytosis (includes patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia)** OR • Provider agrees to monitor for intracranial bleeding and other central nervous system (CNS) adverse effects • 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: _____. • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy Other Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria

• secukinumab (Cosentyx)
 	
Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor Inhibitors
	Updates from the August 2021 meeting are in bold.
	
	Manual PA criteria apply to all new users of Cosentyx.
	
	Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.
	
	AND
	
	Manual PA Criteria: If automated criteria are not met, Cosentyx is approved if all criteria are met:
	• Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND:
	  • The patient had an inadequate response to Humira OR
	  • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
	  • The patient has a contraindication to Humira
	• Patient is 18 years of age or older AND has diagnosis/indication of one of the following:
	  • Active psoriatic arthritis (PsA)
	  • Active ankylosing spondylitis (AS)
	  • Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation AND patient has evidence of elevated CRP and/or MRI evidence of sacroiilitis and ASDAS ≥ 2.1
	OR
	• **Patient is 6 years of age or older** with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
	• Patient has had an inadequate response to non-biologic systemic therapy.
	• (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)?
	  • Does not apply to ankylosing spondylitis (AS) indication ONLY
	• Patient has had an inadequate response to at least two NSAIDs over a period of at least two months
	  • Applies to ankylosing spondylitis (AS) ONLY
	• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)
	• May not be used concomitantly with other TIBs agents
	
	Non-FDA-approved uses are NOT approved.
	Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• mirabegron tablets (Myrbetriq) **Overactive Bladder Agents**	**Updates from the August 2021 meeting are in bold.** Note that the previous automation has been removed. Manual PA criteria apply to all new users of mirabegron (Myrbetriq). Manual PA criteria: Myrbetriq is approved if all criteria are met: • The patient has a confirmed diagnosis of: o **Neurogenic detrusor overactivity (NDO)** o **Use granules unless patient weighs at least 35 kg, then use tablets unless documented swallowing difficulties** o **Provider acknowledges and knows that granules are not bioequivalent and cannot be substituted on a mg to mg basis to tablets and will not combine dosage forms to achieve a specific dose for pediatric patients** o **Patient does not have a CrCl less than 15 mL/min OR severe hepatic impairment (Child-Pugh Class C)** o **If the CrCl is between 15-29 mL/min OR patient has moderate hepatic impairment (Child-Pugh Class B) AND the patient weighs less than 35 kg, the dosage does not exceed 32 mg once a day for granules** o **If the CrCl is between 15-29 mL/min OR patient has moderate hepatic impairment (Child-Pugh Class B) AND the patient weighs at least 35 kg, the dosage does not exceed 48 mg once a day for tablets** **OR** o Overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency AND o The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training o The patient has: • Had a 12-week trial with 2 formulary step-preferred products (oxybutynin IR, oxybutynin ER, tolterodine ER) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such central nervous system effects due to comorbid conditions or other medications o Patient has tried and failed or has a contraindication to vibegron (Gemtesa) o The patient does not have: • A CrCl < 15 mL/min The patient's CrCl >15 mL/min OR • If the CrCl is between 15-29 mL/min, the dosage does not exceed 25 mg once a day Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• fesoterodine (Toviaz) **Overactive Bladder Agents**	**<u>Updates from the August 2021 meeting are in bold</u>.** Manual PA criteria apply to all new users of fesoterodine (Toviaz). <u>Manual PA criteria</u>: Detrol, Enablex, Gelnique, Oxytrol, Santura/Sanctura XR,Toviaz, or Vesicare is approved if <u>all</u> criteria are met: • *Note OTC Oxytrol for Women is the name of the over-the-counter (OTC) version of Oxytrol. This OTC medication is not covered under the TRICARE pharmacy benefit. Please enter your initials in the text box to acknowledge that OTC Oxytrol for Women is not covered under the TRICARE pharmacy benefit. • ***Toviaz only* Patient has confirmed and documented diagnosis of:** o **Neurogenic detrusor overactivity (NDO)** o **Patient is 6 years of age or older** o **Patient weighs more than 25 kg** o **Patient does not have a CrCl less than 30 mL/min OR severe hepatic impairment (Child-Pugh Class C)** **OR** • *All other medications listed to include Toviaz* The patient has a confirmed diagnosis of: o Overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency o Patient has had a trial tolterodine extended-release (Detrol LA), oxybutynin IR or ER, or trospium immediate-release (Sanctura immediate-release) and experienced an inadequate response OR experienced intolerable adverse effects OR have a contraindication to all of these medications which is not expected to occur with the requested medication Non-FDA-approved uses are not approved. Prior authorization does not expire.
• sofosbuvir/velpatasvir (Epclusa) • glecaprevir/pibrentasvir (Mavyret) **Hepatitis C Agents: Direct Acting Agents**	**<u>Updates from the August 2021 Meeting are in bold</u>.** Manual PA criteria apply to all new users of sofosbuvir/velpatasvir (Epclusa) and glecaprevir/pibrentasvir (Mavyret). <u>Manual PA criteria</u>: Epclusa, Harvoni, Mavyret, Sovaldi, Zepatier, or Viekira Pak is approved if <u>all</u> criteria are met: • *Note: The branded agents on the top of this form are the preferred agents for TRICARE. If the authorized generics of either Epclusa or Harvoni are required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. • ***Epclusa**, Harvoni, Mavyret, and **Sovaldi*** o Patient is 3 years of age or older • Zepatier and Viekira Pak o Patient is 18 years of age or older • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of chronic hepatitis C virus (HCV) infection • Patient has HCV genotype is 1a, 1b or other genotype 1, 2, 3, 4, 5, or 6 (check box) Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• sofosbuvir/velpatasvir (Authorized generic Epclusa) **Hepatitis C Agents: Direct Acting Agents**	**Updates from the August 2021 Meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of sofosbuvir/velpatasvir (Authorized generic Epclusa). Manual PA criteria: Authorized generic Epclusa is approved if all criteria are met: • *Note: The Brand Epclusa is preferred over the authorized generic product. Please provide a patient-specific justification as to why the brand Epclusa product cannot be used in this patient. (fill-in the blank) • Patient is ~~6~~ **3** years of age or older • ~~Patient weighs greater than or equal to 17 kg~~ • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of chronic hepatitis C virus (HCV) infection • Patient has HCV genotype is 1a, 1b or other genotype 1, 2, 3, 4, 5, or 6 (check box) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• amphetamine sulfate ODT (Evekeo ODT) **ADHD Agents: Stimulants**	**Updates from the August 2021 Meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of amphetamine sulfate ODT (Evekeo ODT). Manual PA criteria: Evekeo ODT is approved if all criteria are met: • Patient is ~~six~~ **three** to 17 years of age • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record • Must have tried, for at least two months, and failed OR has difficulty swallowing mixed amphetamine salts IR (Adderall, generic) • Must have tried, for at least two months, and failed OR has a contraindication to methylphenidate IR tablets or solution Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• obeticholic acid (Ocaliva) **Gastrointestinal-2 Agents**	**<u>Updates from the August 2021 Meeting are in bold</u>.** Manual PA criteria apply to all new users of obeticholic acid (Ocaliva). <u>Manual PA criteria</u>: Ocaliva is approved if <u>all</u> criteria are met: • The patient is 18 years of age or older • Patient has diagnosis of primary biliary cholangitis (PBC) • **Patient does not have decompensated cirrhosis, or have they had a prior decompensation event, or do they have compensated cirrhosis with evidence of portal hypertension (for example, ascites, gastroesophageal varices, or persistent thrombocytopenia)?** • Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician • Diagnosis of PBC has been confirmed by at least TWO of the following: o Alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values o Positive anti-mitochondrial antibodies (AMAs) o Histologic evidence of PBC from a liver biopsy • Patient has received ursodiol therapy (for example, ursodiol generics, Urso 250, Urso Forte, Actigall) for one year or greater and has had an inadequate response OR • Patient is unable to tolerate ursodiol therapy Non-FDA-approved uses are not approved. **PA expires after 1 year** **Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if all of the following criteria are met (Note that initial TRICARE PA approval is required for renewal):** **Acute Treatment** • Patient has responded to Ocaliva as determined by the prescribing physician (for example, improved biochemical markers of PBC [alkaline phosphatase (ALP), bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT) levels)

Drug / Drug Class	Quantity Limits
• ibrutinib (Imbruvica) **Leukemia and Lymphoma Agents: BTK Inhibitors**	Note: no change to current status ▪ MTF/Mail: maximum of 56 tablets for a 56 day supply ▪ Retail: maximum of 28 tablets for a 28 day supply ▪ MTF/Mail: maximum of 180 capsules for a 45 day supply ▪ Retail: maximum of 120 capsules for a 30 day supply
• acalabrutinib (Calquence) • zanubrutinib (Brukinsa) **Leukemia and Lymphoma Agents: BTK Inhibitors**	Note: no change to current status ▪ MTF/Mail: 60 day supply ▪ Retail: 30 day supply
• dasiglucagon injection (Zegalogue) **Antidotes-Overdose Agents: Hypoglycemia Agents**	▪ Retail/MTF/Mail: 2 syringes/pens per fill (one two-pack or two individual packs)
• ferric maltol (Accrufer) **Electrolyte-Mineral-Trace Element Replacement**	▪ Retail/MTF/Mail: 60 capsules/30 days and 30 day supply
• infigratinib (Truseltiq) **Oncological Agents**	▪ Retail/MTF/Mail: 28 day supply
• omalizumab syringe (Xolair) **Respiratory Interleukins**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• sotorasib (Lumakras) **Oncological Agents**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• semaglutide (Wegovy) **Weight Loss Agents**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• ivermectin (Stromectol) **Antiinfectives: Anti-Helmintics**	▪ Retail/MTF/Mail: 60 tablets per fill
• Omnipod, Omnipod DASH • V-Go **Insulins: Miscellaneous Insulin Device**	▪ Retail: Omnipod/Omnipod DASH: 10 pods/30 days V-Go: 1 system/30 days ▪ Mail/MTF: Omnipod/Omnipod DASH: 30 pods/90 days V-Go: 3 systems/90 days
• rimegepant (Nurtec ODT) **Migraine Agents**	▪ Retail: 16 ODTs/30 days ▪ MTF/Mail: 48 ODTs/90 days QLs increased for new QOD dosing for preventive treatment of migraine were implemented in October 2021
• ustekinumab (Stelara) 90 mg only **Targeted Immunomodulatory Biologics: Miscellaneous**	▪ Retail: 1 syringe per fill ▪ MTF/Mail: 3 syringes per fill Note: previous QL at MTF/Mail was 2 syringes per fill

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
dasiglucagon injection (Zegalogue) Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents for severe hypoglycemia	• glucagon nasal (Baqsimi) • glucagon autoinjector and pre-filled syringe (Gvoke)	• Autoinjector • PFS	Severe hypoglycemia in 6 year olds and older	• Injection site reaction • Diarrhea	• New glucagon formulation available as a prefilled syringe and auto-injector for rescue of hypoglycemia • Evaluated in three placebo-controlled clinical trials; established superiority in terms of efficacy • Common adverse effects are limited to nausea and vomiting, as well as injection site edema, headache and diarrhea • Faster time to plasma recovery compared to Gvoke (13.8 vs 10 mins), but shorter stability at room temperature vs Gvoke (12 vs 24 mos) • Zegalogue offers a significant advantage over the glucagon kit but offers no compelling clinical advantage over newer glucagon formulations and a disadvantage in shelf life	• UF • Do not add to EMMI list
drosperinone/ estetrol (Nextstellis) Contraceptive Agents	• ethinyl estradiol/ • drospirenone (Yaz) • other combined oral contraceptives	• Take one tablet by mouth at the same time every day in the order directed on the blister pack • Each pack consists of 28 tablets with 24 pink active tablets each containing drospirenone 3 mg and estetrol 14.2 mg and 4 white inert tablets	Contraception	Common ADRs (≥2%): • bleeding irregularities • mood disturbance • headache • breast symptoms • acne • dysmenorrhea • weight increase • libido decrease	• First contraceptive agent to contain the estrogen, estetrol • Overall Pearl Index (efficacy measure) met FDA guidance recommendations • Limitations of use: May be less effective in females with a BMI ≥ 30 kg/m2 • Indirectly compared to other combined oral contraceptives, Nextstellis has similar safety, discontinuation rates due to adverse events, and unscheduled bleeding profile • Post-marketing trials are required to assess venous thromboembolism risk • Further research is needed to confirm if there are any comparative efficacy or safety advantages with estetrol vs. ethinyl estradiol • Nextstellis is another oral contraceptive option in the crowded contraceptive class • No compelling clinical advantages over existing formulary options at this time	• NF • Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
ferric maltol (Accrufer) Electrolyte-Mineral-Trace Element Replacement	• ferrous sulfate • ferrous gluconate • ferrous fumarate • polysaccharide Fe complex	• One 30 mg capsule taken twice daily on an empty stomach • Treatment duration is variable, but typically is for at least 12 weeks	Iron deficiency	Most common ADRs (≥ 1%): • flatulence • diarrhea • constipation • feces discolored • abdominal pain • nausea • vomiting • abdominal discomfort • abdominal distension	• Ferric maltol is another option to treat iron deficiency in a crowded therapeutic space with many oral and IV iron formulations available • Effective at raising hemoglobin (Hgb) in inflammatory bowel disease, but only modestly effective in chronic kidney disease • Claims of better tolerability than other oral irons not substantiated due to lack of direct head-to-head trials • Lack of sufficient drug-drug interaction data is a clinical disadvantage • Offers little to no compelling clinical advantage over other available treatment options	• NF • Do not add to EMMI list
infigratinib (Truseltiq) Oncological Agent	• pemigatinib (Pemazyre)	• 25 and 100 mg oral capsules • 125 mg once daily x 21 days followed by 7 days off in a 28-day cycle • Swallow whole • Reduce dose for mild-moderate renal impairment and mild-moderate hepatic impairment	Adults with previously treated, unresectable locally advanced or metastatic cholangio-carcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test	• Common ADRs (≥20%): nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodyesthesia syndrome, arthralgia, dysgeusia, constipation, abd pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, vision blurred and vomiting • Common lab abnormalities (≥20%): ↑ creatinine, phosphate, alk phos, ALT, AST, lipase, calcium, urate, triglycerides, bilirubin, and ↓ phosphate, Hgb, lymphocytes,	• Accelerated approval with immature data in a low quality study without an active comparator; limited data currently available to review • Few clinically-effective treatment options for unresectable advanced refractory cholangiocarcinoma with 0% 5-year survival for inoperable disease • Median duration of response higher than 50% overall survival for disease state • Drug is poorly tolerated • Infigratinib is the second treatment option for cholangiocarcinoma with a FGFR2 fusion	• UF • Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
				sodium, platelets, leukocytes, albumin, and potassium		
omalizumab syringe (Xolair) Respiratory Interleukin	• benralizumab inj (Fasenra) • dupilumab inj (Dupixent) • mepolizumab inj (Nucala)	• prefilled syringe	• Moderate to severe allergic asthma, ≥ 6 years • Nasal Polyps, inadequate nasal corticosteroid response, ≥ 18 years • Chronic Idiopathic Urticaria (CIU), inadequate response to H1 antihistamines, ≥ 12 years	• BBW - Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair • ≥3% - headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness	• Omalizumab (Xolair) was the first biologic approved for moderate to severe asthma, but required physician office administration. • The new prefilled syringe makes it the 4th respiratory biologic approved for patient self-administration • Guidelines for asthma recommend Xolair for patients with elevated IgE • Guidelines for nasal polyps do not provide strong recommendations for using Xolair, although newer studies show a statistical improvement in symptom scores compared to placebo; MHS providers feel Dupixent is a better option • Xolair is in the treatment algorithm for chronic idiopathic urticaria • Xolair, by targeting IgE, provides another option in treating moderate to severe asthma and nasal polyps. It is the only respiratory biologic approved for CIU.	• UF • Do not add to EMMI list
pegcetacoplan injection (Empaveli) Hematological agent	<u>Medical benefit drugs</u> • eculizumab (Soliris) • ravulizumab-cwvz (Ultomiris)	• 1,080 mg/20 mL single-dose vials • Injected SQ via a pump twice each week • Dose: 1,080 mg infused over 20-40 min	• Paroxysmal nocturnal hemoglobinuria	• Common ADRs (incidence ≥10%): inj site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, viral infection, and fatigue	• Empaveli is a new targeted complement inhibitor approved for the rare disease of paroxysmal nocturnal hemoglobinuria (PNH) • Use of Empaveli increased Hgb and decreased the need for blood transfusions • Empaveli was superior to eculizumab for the change from baseline in hemoglobin level at Week 16 (P<0.0001) • Non-inferiority was demonstrated in the endpoints of transfusion avoidance and change from baseline in ARC • Contraindicated in patients not vaccinated against certain encapsulated bacteria • Empaveli provides another treatment option to treat rare PNH	• UF • Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
relugolix/ estradiol/ norethindrone (Myfembree) LHRH Agonist-Antagonists	• Elagolix 40mg, estradiol 1mg, norethindrone 0.5mg (Oriahnn) tablets	• Relugolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg tablets • One capsule once daily **for up to 24 months.** Start no later than 7 days after menses has started.	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	• Most common adverse events include hot flush, hyperhidrosis, or night sweats (10.6%), abnormal uterine bleeding (6.3%), alopecia (3.5%), and decreased libido (3.1%)	• Myfembree is the 2nd oral GnRH antagonist approved for the treatment of heavy menstrual bleeding associated with uterine fibroids (Oriahnn was the 1st) • Evaluated in two phase III studies; effective at decreasing heavy menstrual bleeding in more women than placebo • Treatment is limited to 24 months due to bone mineral density loss • Contraindicated in patients with a high risk of arterial, venous thrombotic, or thromboembolic disorders, pregnancy, osteoporosis, current or history of breast cancer or other hormonally-sensitive malignancies, known liver impairment or disease, undiagnosed abnormal uterine bleeding, or known hypersensitivity to ingredients of Myfembree. • In an indirect comparison, Myfembree appears to have similar efficacy and tolerability to Oriahnn. Oriahnn is dosed twice daily while Myfembree is dosed once daily. • Myfembree provides another option for the treatment of heavy menstrual bleeding associated with uterine fibroids for longer than three months.	• UF • Do not add to EMMI list
riluzole oral film (Exservan) Miscellaneous Neurological Agent	• riluzole 50 mg tablets • riluzole (Tiglutik) 50mg/10ml oral solution	• 50mg oral film • 50 mg BID taken at least 1 hour before or 2 hours after meals • Placed on top of the tongue and allowed to dissolve	ALS	• Most common ADRs (≥ 5% and greater than placebo): oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain	• Riluzole oral film is the first oral film for the treatment of ALS and the second option for patients with swallowing difficulties. • No new clinical trials were conducted on riluzole oral film; pharmacokinetics demonstrated equivalence with oral tablets. • Riluzole oral film provides little to no advantages over riluzole solution and is a second option other than crushing tablets for patients with dysphagia/swallowing difficulties.	• UF • Do not add to EMMI list

rosuvastatin calcium/ ezetimibe (Roszet) Antilipidemic-1	• rosuvastatin with ezetimibe • atorvastatin with ezetimibe • bempedoic acid/ezetimibe (Nexlizet) • evolocumab (Repatha)	Oral tablets • Strengths • 5 mg/10 mg • 10 mg/10 mg • 20mg /10 mg • 40 mg/10 mg	• Adjunct in patients with primary non-familial hyperlipidemia to reduce LDL-C • HoFH to reduce LDL-C	Similar to rosuvastatin and ezetimibe given separately	• 2nd fixed dose combination (FDC) of a statin/ezetimibe (Vytorin was 1st) • Approved using data from Crestor and Zetia (FDA 505b2 approval pathway) • No clinical trials conducted with this product other than LDL comparisons to statin monotherapy; but components well-studied • Limited indications, compared with Crestor label • LDL cholesterol reductions range from 64% to -72%, similar to giving rosuvastatin and ezetimibe together • DoD rosuvastatin available at $0 copay (Medication Adherence Program) • Other than offering a small convenience to patients with swallowing difficulties, Roszet offers no clinically compelling advantages compared to taking the individual components separately	• Tier 4/Not covered
semaglutide injection (Wegovy) Weight Loss Agent	• phentermine • phentermine/ topiramate (Qsymia) • naltrexone/ bupropion (Contrave) • liraglutide (Saxenda)	• Pre-filled, single-dose injection pen that delivers doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg • Dose: 2.4 mg subcutaneously once weekly	• Adjunct to diet and exercise for chronic weight management in adults with a body mass index (BMI) of: • ≥ 30 kg/m^2 or • ≥ 27 kg/m^2 with at least one weight-related comorbid condition (e.g. HTN, T2DM, Dyslipidemia)	<u>Contraindications:</u> Personal or family history of MTC or in patients with MEN 2 <u>Warnings</u> • Risk of thyroid C-cell tumors • Acute pancreatitis (fatal and non-fatal) (0.2% vs 0%) • Cholelithiasis and cholecystitis • Hypoglycemia • HR increases • Avoid in patients with a history of suicide attempts or ideation • Reduce dose of concomitant insulin or sulfonylureas • Acute kidney injury • <u>Most common ADRs</u>: nausea, diarrhea, vomiting	• Wegovy is another formulation of semaglutide approved for obesity as adjunctive treatment for patients with a BMI > 30kg/m2, or > 27kg/m2 with a comorbid condition • Wegovy is the second GLP-1 agonist approved for obesity, liraglutide (Saxenda) is the other • It is dosed once weekly, vs daily for Saxenda • Wegovy was evaluated in four studies, and consistently demonstrated statistical significance compared to placebo in weight-related outcomes • Most common ADRs include gastrointestinal effects that affect nearly half of patients • While Wegovy appears to have a much larger clinical effect than other obesity medications, the rate of adverse reactions remain high and there are no head-to-head comparisons with other agents. • Long-term cardiovascular, pancreas, and biliary effects are currently being investigated • Wegovy provides another GLP-1 treatment option for obesity however long-term duration of effect remains unclear	• UF • Do not add to EMMI list

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

sotorasib (Lumakras) Oncological Agent	none	960 mg orally once daily; swallow tablets whole with or without food; available in 120 mg tabs	NSCLC: adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test	• Most common ADRs (≥ 20%): diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough Common lab abnormalities ≥ 25%: decreased lymphocytes, Hgb, calcium and sodium; increased AST, ALT, alk phos and urine protein	• Sotorasib received an accelerated approval with immature data in a low quality study without an active comparator • Doubles progression-free survival relative to standard of care options (by indirect comparison) • Despite sotorasib's high serious adverse event rate, its discontinuation rate was < 10% • Sotorasib is the first and only FDA-approved KRAS inhibitor for NSCLC with unparalleledsurvival rates	• UF • Do not add to EMMI list
viloxazine extended-release (Qelbree) ADHD: Non-stimulant	• atomoxetine (Strattera) • clonidine ER (Kapvay) • guanfacine ER (Intuniv)	• extended-release oral capsules (100 mg, 150 mg, and 200 mg) • 6 to 11 years of age: start 100 mg once a day, may titrate in increments of 100 mg weekly to max of 400 mg once a day • 12 to 17 years of age: start 200 mg once a day, may titrate by an increment of 200 mg to max does of 400 mg once a day	Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age	Most common ADRs (≥ 5% and at least twice the rate of placebo): somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability	• Qelbree is the 4th non-stimulant for the treatment of ADHD • Only indicated for patients 6 to 17 years of age • Qelbree is a selective norepinephrine reuptake inhibitor with a similar mechanism of action to atomoxetine (Strattera), although there are no head-to-head trials comparing the agents • Approval was based on three short-term (6 or 8 week) placebo-controlled pivotal trials where Qelbree demonstrated moderate efficacy vs placebo • Non-stimulant agents are not recommended in most pediatrics and adolescents due to efficacy not being as robust • ADHD treatments should always be in combination with non-pharmacologic therapies • Provides an alternative treatment to atomoxetine and other formulary non-stimulant options, however provides no compelling advantage over existing agents	• NF • Do not add to EMMI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the August 2021 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
August 2021	**Pulmonary-3 Agents: Combinations UF** *Add to the EMMPI Program:* • budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere) *(Note this is updated from the February 2021 P&T Committee meeting minutes)* **Line Extensions** **Designated UF** *Similar/parent agent already on list (all new strengths or dosage forms):* • adalimumab pen carton (Humira CF) • adalimumab starter package for UC (Humira CF) • lipase/protease/amylase (Pancreaze) • secukinumab syringe (Cosentyx) **Line Extensions** **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar/parent agent already on list (new strength and dosage form):* risankizumab-rzaa (Skyrizi)	**Oncological Agents: Bruton Tyrosine Kinase Inhibitors UF (brand maintenance only)** *Maintain current status and do not add to EMMPI Program due complex dose-adjustment and some agents not being available at mail:* • acalabrutinib (Calquence) • ibrutinib (Imbruvica) • zanubrutinib (Brukinsa) **Laxatives, Cathartics, & Stool Softeners: Bowel Preparations NF** *Exempt from NF-2 Mail requirement due to acute use exception:* • sodium picosulfate, citric acid, mag oxide (Prepopik) • sodium phosphate tablets (OsmoPrep) • sodium SO4, K+ SO4, Mg SO4 (Suprep) • sodium SO4, KCl, Mg SO4 (Sutab) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Acute use or limited duration and drugs in class not currently represented on EMMPI List:* • dasiglucagon injection (Zegalogue) *Not yet clear if feasible to provide through mail order:* • infigratinib (Truseltiq) • omalizumab (Xolair) • pegcetacoplan injection (Empaveli) • riluzole oral film (Exservan) • sotorasib (Lumakras) *Similar agents not on list and comparable pricing at mail order vs MTFs or retail:* • relugolix/estradiol/norethindrone (Myfembree) • semaglutide (Wegovy) **Designated NF:** *Contraceptive exception/existing exclusion applies:* • drospirenone/estetrol (Nextstellis) *Exception due to a combination of factors:* • viloxazine (Qelbree) *Not yet clear if feasible to provide through mail order and similar pricing at mail order vs MTFs or retail:* • ferric maltol (Accrufer)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2021	**Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase inhibitors**	UF Class Review	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ None			Pending signing of the minutes: 2 weeks The effective date is March 2, 2022	▪ PAs and QLs for all three drugs	▪ Imbruvica tabs require a trial of caps first on the PA
			None	▪ acalabrutinib (Calquence) ▪ ibrutinib (Imbruvica) ▪ zanubrutinib (Brukinsa)	▪ None			

Appendix G—Table of Implemented Status of UF Recommendations/Decision Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2021	**Laxatives-Cathartics-Stool Softeners: Bowel Preparations**	UF Class Review	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ None			Pending signing of the minutes: 2 weeks The effective date is March 2, 2022	▪ No PAs or QLs	▪ Generic GoLYTELY added to the BfCF
			▪ PEG 3350, Standard volume (generic Golytely))	▪ PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution **(Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics**) ▪ PEG 3350 sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution **(NuLYTELY, TriLyte, generics)** ▪ PEG sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for oral solution **(Moviprep)** ▪ PEG sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for solution **(Plenvu)** ▪ sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution **(Clenpiq)**	▪ sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution **(Suprep)** ▪ sodium sulfate, potassium chloride and magnesium sulfate tablets **(Sutab)** ▪ sodium phosphate tablets **(Osmoprep)** ▪ sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets **(Prepopik)**			

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives (Last 12 months)*†

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
August 2021	Antilipidemic-1s	• rosuvastatin/ ezetimibe (Roszet)	• rosuvastatin with ezetimibe • atorvastatin with ezetimibe • simvastatin/ezetimibe (Vytorin) • evolocumab (Repatha) • alirocumab (Praluent)	• June 15, 2022 (120 days)
May 2021	Anticonvulsants-Antimania Agents	• levetiracetam (Elepsia XR)	• levetiracetam ER • lamotrigine XR • topiramate ER	• June 15, 2022 (120 days)
Feb 2021	Corticosteroids-Immune Modulators: High Potency	• clobetasol propionate 0.05% lotion metered dose pump (Impeklo)	• betamethasone/propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % (emulsion) foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• June 15,2 022 (120 days)
Feb 2021	Psoriasis Agents	• calcipotriene/ betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora)	• 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 • fluocinonide 0.05% cream, gel, and solution • calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary]	• June 15, 2022 (120 days)
Nov 2020	Attention-Deficit/ Hyperactivity Disorder (ADHD) Agents: Stimulants	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	• budesonide ER 9 mg capsules (Ortikos)	• budesonide ER tablets (Entocort EC, generics) • other corticosteroids	• June 2 2021
Nov 2020	Corticosteroids	• dexamethasone 20 mg tables (Hemady)	• dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	• fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler)	• fluticasone (Flovent Diskus) • fluticasone (Flovent HFA) • fluticasone furoate (Arnuity Ellipta) [non formulary] • beclomethasone (QVAR) [non formulary] • budesonide (Pulmicort Flexhaler) [non formulary] • ciclesonide (Alvesco) [non formulary] • flunisolide (Aerospan) [non formulary] • mometasone (Asmanex Twisthaler [non formulary]	• June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	• fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler)	• fluticasone/salmeterol (Advair Diskus) • fluticasone/salmeterol (Advair HFA) • fluticasone/vilanterol (Breo Ellipta) [non formulary] • mometasone/formoterol (Dulera) [non formulary] • budesonide/formoterol (Symbicort) [non formulary] • fluticasone/salmeterol (AirDuo Respiclick) [non formulary]	• June 2 2021
Nov 2020	Calcium Channel Blockers	• levamlodipine (Conjupri)	• amlodipine • felodipine • nifedipine • diltiazem • verapamil	• June 2 2021
Nov 2020	GI-2 Agents	• metoclopramide nasal spray (Gimoti)	• metoclopramide oral tablet (Reglan generics) • metoclopramide oral solution (Reglan, generics) • metoclopramide orally disintegrating tablet (Reglan ODT)	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	• calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic)	*Scalp Psoriasis:* • calcipotriene 0.005% solution • clobetasol 0.05% solution, shampoo • fluocinonide 0.05% solution • calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] *Psoriasis involving areas other than the scalp:* • calcipotriene 0.005% ointment, cream, solution • clobetasol 0.05% ointment, cream • fluocinonide 0.05% cream, ointment	• February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	• halcinonide 0.1% topical solution (Halog)	• betamethasone propylene glycol 0.05% cream • clobetasol propionate 0.05% cream and ointment • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream and ointment • fluocinonide 0.05% cream and ointment • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% ointment	• February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	• tazarotene 0.045% lotion (Arazlo)	• adapalene 0.1% lotion, gel, cream • adapalene 0.3% gel • clindamycin phosphate 1% gel, cream, lotion, and solution • clindamycin/ benzoyl peroxide 1.2% - 5% gel • tazarotene 0.1% cream • tretinoin 0.025%, 0.05%, and 0.1% cream • tretinoin 0.01% and 0.025% gel	• February 24, 2021

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

† For a cumulative list of previous Tier 4 recommendations, refer to the November 2020 DoD P&T Committee minutes, found at health.mil/pandt

Appendix I—DoD P&T Committee Processes and Recommendations/Approval Authorities
Updated August 6th 2020 (Updates are in Bold)

Process	Function
Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; **P&T Committee Chair and others as needed**	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non step preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to prior authorization forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator” drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting

	minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be "grandfathered" when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative. ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing "brand over generic" authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. The branded product will adjudicate at the Tier 1 co-pay at the Retail Pharmacy Network and Mail Order Pharmacy. The "brand over generic" authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating "line extension" products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug, and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., Handi-Haler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product.

	▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding forTPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA "health.mil" website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ **In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying manual PA criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QLs implemented in these situations will removed when the situation has resolved.**
Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments	▪ Classification of a medication as non-formulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication as Tier 4 (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and implementation plan (including effective date). ▪ Establishment of prior authorization requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing prior authorization (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of prior authorization requirements for a drug. ▪ Clarification of a medication as non-formulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as non-formulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as non-formulary (Tier 3 co-pay).

Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)	▪ Establishment of quantity limits for a medication or class of medications; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for non-formulary drugs. ▪ Addition or deletion of medications listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes on the Expanded MFT/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
ASCO	American Society of Clinical Oncology	LDL	Low density lipoprotein
ADHD	Attention Deficit Hyperactivity Disorder	LHRH	Leutinizing hormone releasing hormone
ADR	adverse drug reaction	L	liter
AE	Adverse event	LABA	Long acting beta agonists
ALS	Amyotrophic lateral sclerosis	LAMA	Long acting muscarinic antagonist
BCF	Basic Core Formulary	MCL	Mantle cell lymphoma
BIA	Budget impact analysis	MDI	Multiple daily injections
CFR	Code of Federal Regulations	MHS	Military Health System
CIU	Chronic idiopathic urticaria	MN	Medical Necessity
CLL	Chronic lymphocytic leukemia	MS	Multiple Sclerosis
CMA	Cost minimization analysis	MTF	Military Treatment Facility
CV	Cardiovascular	MZL	Marginal zone lymphoma
DHA	Defense Health Agency	NCCN	National Comprehensive Cancer Network
DHA	docosahexaenoic acid	NDAA	National Defense Authorization Act
DLBCL	diffuse large B-Cell lymphoma	NDC	National Drug Codes
DoD	Department of Defense	NDO	Neurogenic detrusor overactivity
DR	Delayed release	NSCLC	Non-small cell lung cancer
ECF	Extended Core Formulary	OAB	Overactive bladder
EIP	external insulin pump	ODT	Orally Disintegrating Tablet
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	OTC	Over the counter
ER	Extended release	PA	Prior authorization
FDC	Fixed drug combination	PAH	Pulmonary artery hypertension
FDA	U.S. Food and Drug Administration	PDM	personal diabetes manager
Fe	iron	PEG	polyethylene glycol
GCB	germinal center B-Cell	PNH	paroxysmal nocturnal hemoglobinuria
GLP-1 RA	Glucagon-like peptide-1 receptor antagonists	POD	Pharmacy Operations Division
Hgb	hemoglobin	POS	Point of service
ICS	Inhaled corticosteroid	PRN	As needed

Term	Definition	Term	Definition
QL	Quantity limits	SLL	small lymphocytic lymphoma
RCC	Renal cell carcinoma	TIB	Targeted Immunomodulatory Biologics
RRMS	Relapsing remitting multiple sclerosis	UC	Ulcerative colitis
SC	Subcutaneous	WM	Waldenström macroglobulinemia
SL	Sublingual		