DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS
February 2022

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on February 9 and 10, 2022. 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 - Status of February, May 2021, August 2021 and November 2021 P&T Committee meeting Minutes—The Beneficiary Advisory Panel (BAP) meeting for the four quarterly P&T Committee meetings were held on January 25-26, 2022. The February 2021, May 2021 August 2021and November 2021 Committee meeting minutes are set to be signed on February 14, 2022.

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. Oncological Agents: Subclasses for the following - Renal Cell Carcinoma (RCC); Epidermal Growth Factor Receptor (EGFR) + Non-Small Cell Lung Cancer (NSCLC); Non-Bruton Tyrosine Kinase Inhibitors (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL); Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors for BRCA+ Cancers (PARPIs); and Janus Kinase Inhibitors for Myelofibrosis (MF)

Background—The P&T Committee evaluated the relative clinical effectiveness for five oncology subclasses. The Committee reviewed a distillation of the evidence including attention to guideline recommended use, the strength of those recommendations, the levels of evidence supporting those recommendations, and, where applicable, comparative judgments about the qualitative differences in clinical effectiveness between agents. A safety evaluation of each subclass's agents included comparative quantitative as well as qualitative assessments. There are a total of 23 drugs in the subclasses, with only two products available in generic formulations (everolimus and erlotinib).

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

Renal Cell Carcinoma (RCC)

- Nine agents comprise the RCC subclass: axitinib (Inlyta), cabozantinib (Cabometyx), cabozantinib (Cometriq), everolimus (Afinitor, generic), lenvatinib (Lenvima), pazopanib (Votrient), sorafenib (Nexavar), sunitinib (Sutent), and tivozanib (Fotivda).
- Cumulatively, the 9 RCC agents are FDA-approved and/or guideline recommended to treat 14 different disease states including RCC, hepatocellular carcinoma, various forms of thyroid carcinoma, endometrial carcinoma, soft tissue sarcoma, gastrointestinal stromal tumors, pancreatic neuroendocrine tumors, melanoma, non-small cell lung cancer, acute myeloid leukemia, myelofibrosis, cutaneous T-cell lymphoma, bone cancers, and adenoid cystic carcinoma. With the exception of tivozanib (Fotivda) and everolimus (Afinitor) that are used exclusively in RCC, no two agents have perfectly overlapping usage in the exact same disease states.
- Where mutually indicated and/or guideline supported, comparisons can be drawn between agents for a particular disease context in a particular disease state, with some comparisons showing agents are largely qualitatively similar with similar overall clinical effectiveness, strengths of recommendation, and supporting levels of evidence. Meanwhile, other comparisons show a hierarchy of superiority. However, even where such comparisons are possible, it is difficult if not impossible to draw global conclusions about the relative clinical effectiveness of agents because a comparative conclusion among agents for one disease context of a specific disease state may differ from conclusions for another disease context or state.
- A review of safety shows that certain adverse events are class effects associated with mechanism of action, while others are unique to the specific agent. No two agents have identical safety profiles. However, overall the agents have similar tolerability.
- The RCC review concludes that the 9 subclass agents are significantly different from one another, and all the agents are necessary inclusions to the benefit.

Epidermal Growth Factor Receptor-Mutant Non-Small Cell Lung Cancer (EGFR+ NSCLC)

- Five agents comprise the EGFR+ NSCLC subclass: afatinib (Gilotrif), dacomitinib (Vizimpro), erlotinib (Tarceva, generic), gefitinib (Iressa) and osimertinib (Tagrisso).
- The 5 EGFR+ NSCLC agents are FDA-approved and/or guideline recommended to treat NSCLC, and erlotinib is also approved in pancreatic carcinoma. Osimertinib uniquely can be sequenced with the other EGFR+ NSCLC agents.
- The only disease context where all 5 agents are mutually comparable is frontline therapy for metastatic EGFR+ NSCLC. Osimertinib is the preferred frontline therapy. The remaining four agents have weaker strengths of recommendation supporting their use, with evidence showing qualitatively inferior outcomes relative to osimertinib but relatively equivalent between themselves. Only osimertinib and [axitinib are guideline-recommended in the relapsed/refractory setting, and axitinib only in combination with the medical benefit drug cetuximab (Erbitux)]. Osimertinib is the only subclass agent recommended in the adjuvant setting.
- A review of safety shows that rate of severe adverse events was similar between all EGFR+ NSCLC agents.
- The EGFR+ NSCLC review concludes that agents are only comparable in the treatment-naïve setting and that osimertinib and erlotinib are not true comparators to the remaining agents because of their alternative usages.

Non-Bruton Tyrosine Kinase Inhibitors for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (non-BTKIs for CLL/SLL)

- Three agents comprise the non-BTKIs for CLL/SLL subclass: duvelisib (Copiktra), idelalisib (Zydelig), and venetoclax (Venclexta).
- The three subclass agents mutually treat CLL/SLL with and without del7p/TP53 mutation. However, their other indications and guideline-supported use in Non-Hodgkin Lymphomas and Acute Myeloid Leukemia (for venetoclax) do not overlap.
- Venetoclax is guideline recommended for CLL/SLL in both the treatment-naïve and relapse-refractory settings. Duvelisib and idelalisib are only used in the relapsed/refractory setting. In the relapsed/refractory setting, venetoclax is the preferred regimen over duvelisib and idelalisib regardless of del17p/TP53 status and patient risk category. While duvelisib and idelalisib have the same strength of recommendation and levels of evidence supporting their use, idelalisib has qualitatively superior overall clinical effectiveness across the disease contexts in which both agents are used.

- A review of safety shows qualitatively and quantitatively unique safety profiles for each agent. Venetoclax has the least number of severe events that resulted in warnings/precautions on the label and has no black box warnings. Duvelisib and idelalisib have a greater number of warnings relative to venetoclax. Duvelisib and idelalisib also have overlapping but non-identical black box warnings.
- The non-BTKIs for CLL/SLL review concludes that mechanism of action categorizes the agents by usage, guideline support, and safety profiles. Agents are only comparable in the relapsed/refractory context of CLL/SLL and such a comparison shows a clear hierarchy of overall clinical effectiveness with venetoclax superior to idelalisib and both venetoclax and idelalisib superior to duvelisib.

Poly (Adenosine Diphosphate-Ribose) Polymerase Inhibitors for BRCA+ Cancers (PARPI)

- Four agents comprise the PARPI subclass: niraparib (Zejula), olaparib (Lynparza), rucaparib (Rubraca), and talazoparib (Talzenna).
- The four PARPI agents have overlapping but non-identical FDA-approved indications: olaparib is approved for ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer. Niraparib is only indicated for ovarian cancer. Rucaparib is indicated for ovarian cancer and prostate cancer. Talazoparib is indicated only for breast cancer.
- Where mutually indicated and/or guideline supported, comparisons can be drawn between agents, showing that the PARPI products are largely qualitatively similar with similar overall clinical effectiveness, strengths of recommendation, and supporting levels of evidence. However, the absence of evidence supporting the use of certain agents in particular disease states limits the ability to draw comparative conclusions of global efficacy across the various disease states. Rather only indirect comparisons can be drawn using olaparib as a reference point.
- The PARPI products show statistically significant differences in rates of severe adverse events, with olaparib and talazoparib showing lower rates than niraparib and rucaparib. No statistically significant difference is observed between olaparib and talazoparib, nor between niraparib and rucaparib.
- The PARPI review concludes that the products are not broadly comparable because of the difference in approved indications, but where mutually used, the agents have qualitatively similar overall clinical effectiveness. However, olaparib and talazoparib demonstrate quantitative superior safety in terms of reduced rates of severe adverse events.

Janus Kinase Inhibitors for Myelofibrosis (MF)

- Only two agents comprise the MF subclass: fedratinib (Inrebic) and ruxolitinib (Jakafi).
- Ruxolitinib is used in a variety of hematopoietic disorders including myelofibrosis, polycythemia vera, essential thrombocythemia, and graft vs. host disease. Fedratinib is only indicated and guideline supported for treating myelofibrosis.
- Ruxolitinib and fedratinib have overlapping but non-identical guideline supported use in myelofibrosis; only ruxolitinib is recommended in low-risk patients. The comparative conclusion between the two agents depends on the disease context. For example, in high-risk non-transplant candidates with treatment-naïve disease, ruxolitinib has superior overall qualitative clinical effectiveness. However, in the relapsed/refractory setting, fedratinib shows qualitatively superior efficacy. Another difference is that in the relapsed/refractory setting, fedratinib can be used in ruxolitinib refractory disease (but not vice-a-versa; ruxolitinib was not tested in fedratinib-refractory disease).
- Ruxolitinib and fedratinib have significantly different rates of adverse events with fedratinib showing greater rates of hematologic and gastrointestinal adverse events. Fedratinib also uniquely increases the risk of Wernicke's encephalopathy due to an indirect thiamine deficiency from malnutrition related to its poor gastrointestinal tolerability.
- The MF review concludes that fedratinib and ruxolitinib are not true comparators given the difference in usage, context of use within the same disease state, and clinically significant difference in adverse event profiles.

Overall Conclusions

- Comparative clinical statements between members within all five subclasses are confounded by differences between agents based on usage, guidelines, and safety profiles.
- Where agents are comparable, comparisons are often limited to either a subset of agents, a subset of disease states and/or disease contexts, or a combination of the two.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids and also conducted a budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- BIA was performed to evaluate the projected spend and cost avoidance after considering the solicited bids. BIA results showed that designating all of the

24 drugs in the 5 subclasses as UF demonstrated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

   - UF
     - Renal Cell Carcinoma (RCC)
       - axitinib (Inlyta)
       - cabozantinib (Cabometyx)
       - cabozantinib (Cometriq)
       - everolimus (Afinitor tab and disperz tab; generic)
       - lenvatinib (Lenvima)
       - pazopanib (Votrient)
       - sorafenib (Nexavar)
       - sunitinib (Sutent)
       - tivozanib (Fotivda)
     - Epidermal Growth Factor Receptor (EGFR) plus Non-Small Cell Lung Cancer (NSCLC)
       - afatinib (Gilotrif)
       - dacomitinib (Vizimpro)
       - erlotinib (Tarceva; generic)
       - gefitinib (Iressa)
       - osimertinib (Tagrisso)
     - Non-Bruton Tyrosine Kinase Inhibitor (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
       - duvelisib (Copiktra)
       - idelalisib (Zydelig)
       - venetoclax (Venclexta)
     - Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors
       - olaparib (Lynparza)
       - niraparib (Zejula)
       - rucaparib (Rubraca)
       - talazoparib (Talzenna)

    - Myelofibrosis
        - ruxolitinib (Jakafi)
        - fedratinib (Inrebic)
- NF - None
- Tier 4 (Not covered) - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***PA criteria currently apply to 10 drugs. Newer products that have been reviewed as innovators generally have PA criteria. PAs are in place based on NCCN guideline recommendations suggesting step therapy (e.g., RCC – Fotivda) or for safety issues or poor tolerability (e.g., Myelofibrosis: Inrebic; EGFR+NCSLC: Vizimpro). PAs are in place for all the drugs in the class for the PARPIs and the non-BTKIs for CLL/SL subclass.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) to maintain the current PAs for the drugs listed below. The most current PA criteria is found on the TRICARE Formulary Search Tool at: https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/.

- RCC: Fotivda
- EGFR+NCLC: Vizimpro
- Non-BTKIs for CLL/SL: Copiktra, Zydelig, Venclexta
    - For Copiktra, refer to the Utilization Management section on pp15-16 for the removal of the indication for relapsed or refractory follicular zone lymphoma
- PARPIs: Lynparza, Zejula, Rubraca, Talzenna
- Myelofibrosis: Inrebic

3. ***COMMITTEE ACTION: QUANTITY LIMITS—***Quantity limits currently apply to all the drugs in the subclasses. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) maintaining the current QLs, which are found on the TRICARE Formulary Search Tool.

4. ***COMMITTEE ACTION: UF and IMPLEMENTATION PERIOD—*** The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) an effective date upon signing of the minutes in all points of service. (See Appendix G for the actual implementation dates.)

B. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products

Background—The P&T Committee evaluated the relative clinical effectiveness of the agents used for treating severe hypoglycemia in diabetic patients. The drugs in the class all contain glucagon as the active ingredient. There are three new branded products marketed, glucagon nasal (Baqsimi), glucagon subcutaneous (SC) injection (Gvoke), and dasiglucagon SC injection (Zegalogue). The drugs were individually reviewed as innovators. Baqsimi and Gvoke were reviewed and made UF in November 2019 and Zegalogue was reviewed and made UF in August 2021.

Note that the older injectable glucagon products are more difficult to administer than the newer products and will not be discussed in detail.

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

- Professional treatment guidelines from the American Diabetes Association and Diabetes Canada recommend using glucagon to treat severe hypoglycemia events. Diabetic patients at increased risk for hypoglycemia should have access to a glucagon product. However, the guidelines do not give a preference for any one agent over another.
- Older formulations of glucagon (e.g., Glucagon emergency kit, GlucaGen Hypokit) have been available for several years in intramuscular (IM) formulations that require reconstitution prior to administration.
- The three ready-to-use formulations offer significant advantages over existing agents in emergency situations due to their ease of use. Gvoke and Zegalogue are available as SC injections that don't require reconstitution, while Baqsimi is administered nasally.
- Specific clinical considerations for the products are as follows:
  - *Zegalogue* is available in a prefilled syringe and autoinjector, and is approved in patients as young as 6 years of age. It has an approximately 3 minute slower onset of action compared to glucagon IM. Common adverse events include injection site reactions. Disadvantages include that Zegalogue should not be used in patients with latex allergy, as the grey cap contains latex. Once removed from the refrigerator, Zegalogue has a shelf life of 12 months at room temperature, compared to 2 years at room temperature with Baqsimi and Gvoke.
  - *Baqsim*i nasal spray advantages include it is the only non-injectable glucagon formulation, and is easy for both patient and caregiver administration. Its onset of action is approximately 3 minutes slower compared to glucagon IM. It is approved for patients as young as 4 years of age. Unique adverse events with Baqsimi include localized upper respiratory tract irritation due to the nasal administration route.

- *Gvoke* advantages include FDA-approval in children as young as 2 years of age. The available formulations include a prefilled syringe and autoinjector for SC use. The onset of action is approximately 4 minutes slower compared to glucagon IM. The adverse event profile is similar to Zegalogue.

- Overall, there is a high degree of therapeutic interchangeability between the newer products, with treatment success approaching 100%.
- The P&T Committee recognizes that the newer glucagon preparations (nasal and autoinjectors) offer a significant advantages in terms of ease of administration.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Baqsimi, Gvoke and Zegalogue were all cost effective agents.
- BIA was performed to evaluate the potential impact of designating the three newer glucagon agent as UF, NF, or Tier 4 on the formulary. BIA results showed that designating all the products as UF demonstrated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:
   - UF
     - glucagon nasal (Baqsimi)
     - glucagon prefilled syringe, autoinjector, and kit (Gvoke, Gvoke Hypopen, Gvoke PFS)
     - dasiglucagon prefilled syringe and autoinjector (Zegalogue)
   - NF - None
   - Tier 4 (Not covered) – None
   - Note that the older IM products (Glucagon emergency kit, GlucaGen Hypokit, GluGen Diagnostic) will remain on the formulary

2. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) maintaining the current quantity limits for the hypoglycemia agents (Baqsimi, Gvoke, and Zegalogue). See Appendix D for the full QLs.
3. ***COMMITTEE ACTION: TIER 1 COST SHARE—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) lowering the

current Tier 2 cost-share for glucagon nasal (Baqsimi) to the generic Tier 1 cost-share.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the 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. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes." Lowering the cost-share for Baqsimi will provide a greater incentive for beneficiaries to use the most cost-effective glucagon product in the purchased care points of service.

4. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) exempting glucagon nasal (Baqsimi), glucagon injection (Gvoke), and dasiglucagon injection (Zegalogue) from the EMMPI requirement due to acute use exception. (*See the November 2021 and previous quarterly meeting minutes for a description of the EMMPI program and how it applies to NF drugs and maintenance drugs).*

5. ***COMMITTEE ACTION: UF, QUANTITY LIMITS, Tier1 COST SHARE, EMMPI IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service (POS). (See Appendix G for the actual implementation date.)

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (Group 1 and Group 2: 17 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2022 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—*** The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 0 abstained, 0 absent); and for celecoxib oral solution (Elyxyb): (15 for, 1 opposed, 0 abstained, 1 absent) the following:

- UF
  - asciminib (Scemblix) – Oncological Agent for chronic myelogenous leukemia (CML)
  - avacopan (Tavneos) – Hematological Agent for microscopic polyangiitis and granulomatosis with polyangiitis
  - marabavir (Livtencity) – Antiviral for CMV infection/disease
  - topiramate oral solution (Eprontia) – Anticonvulsant-Antimania Agent for Epilepsy, migraine headache, and Lennox-Gastaut syndrome
  - vosoritide injection (Voxzogo) – Miscellaneous Growth Stimulating Agent for pediatric achondroplasia
- NF
  - atogepant (Qulipta) – Migraine agent for acute treatment of migraines
  - carbidopa/levodopa IR scored tab (Dhivy) – a scored immediate-release tablet formulation of carbidopa and levodopa for Parkinson's disease
  - lonapegsomatropin-tcgd injection (Skytrofa) – Growth stimulating Agent
  - maralixibat (Livmarli) – Miscellaneous Metabolic Agent for treatment of cholestatic pruritus in Alagille syndrome
  - ropeginterferon alfa-2b-njft injection (Besremi) – Hematological Agent for polycythemia vera
  - varenicline nasal solution (Tyrvaya) –Dry Eye Disease agent
- Tier 4 (Not covered): See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
  - celecoxib oral solution (Elyxyb) – NSAIDs: another formulation of celecoxib as an oral solution approved for acute treatment of migraines
    - Elyxyb was recommended as Tier 4/Not Covered status as it has little to no additional clinical benefit relative to other NSAIDs, and the needs of TRICARE beneficiaries are met by available alternative agents. Formulary alternatives include ibuprofen, naproxen, diclofenac, and numerous other NSAIDs or combo products.

2. ***COMMITTEE ACTION: MN CRITERIA—*** The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); and for group 2: (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Besremi, Dhivy, Livmarli, Qulipta, Skytrofa, and Tyrvaya. See Appendix B the full criteria.

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

   - Oncologic drugs: Applying manual PA criteria to new users of Scemblix.
   - Growth Stimulating Agents: Applying manual PA criteria to new users of Skytrofa, similar to the other products in the class. A trial of Norditropin, the step-preferred product is required first.
   - Migraine Agents: Applying manual PA criteria to new users of Qulipta, similar to the other oral migraine agents.
   - Applying manual PA criteria to new users of Besremi, Dhivy, Eprontia, Livmarli, Tavneos, Tyrvaya, and Voxzogo.

4. ***COMMITTEE ACTION: EMMPI—*** The P&T Committee recommended (for group 1: 16 for, 0 opposed, 0 abstained, 1 absent; and for group 2: 17 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

5. ***COMMITTEE ACTION: UF, TIER 4, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); and for group 2: (17 for, 0 opposed, 0 abstained, 0 absent); and for celecoxib oral solution (Elyxyb): (15 for, 1 opposed, 0 abstained, 1 absent) an effective date of the following

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

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. **New Manual PA Criteria**

   a) **Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)**

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

   1) **Antilipidemics-2: Fenofibrates – fenofibrate 120 mg (Fenoglide)—**Fenoglide is a new fenofibrate formulation available in a 120 mg strength. There are several formulations of fibric acid derivatives currently available, including gemfibrozil (Lopid, generics), generic fenofibrate micronized/nonmicronized formulations (including Lofibra), and fenofibrate nanocrystallized (Tricor). Fenoglide is made by a sole manufacturer and is not cost-effective relative to other fibric acid derivatives.

   2) **Pain Agents: NSAIDs – indomethacin 50 mg suppositories (Indocin)—**The indomethacin suppositories are markedly not cost-effective. All other formulations of indomethacin (suspension and capsules) and various other NSAIDs (generic meloxicam, ibuprofen suspension, diclofenac potassium, and naproxen) are included on the TRICARE pharmacy benefit and do not require prior authorization criteria. OTC NSAIDs are also widely available.

   3) **Vitamins: Prenatal – Prenatal Multivitamin (Neonatal Plus)—**Neonatal Plus is a prenatal dietary supplement manufactured by a single company which requires a prescription prior to dispensing. The primary ingredients of Neonatal Plus are similar to that found in Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, and Neonatal Complete which require manual PA and are very expensive. Several cost-effective 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.

      COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Neonatal Plus (regardless of the woman's age), Fenoglide, and Indocin suppositories in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 90 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

   b) **Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy - testosterone cypionate and testosterone enanthate—**The Testosterone

Replacement Therapy (TRT) class was reviewed for formulary placement in August 2012, with PA criteria required for the gel and topical formulations. Other formulations reviewed as innovators accordingly have PA criteria (e.g., oral Jatenzo [February 2020] and SC Xyosted [February 2019]). The IM injectable products were not included in the 2012 review, due to low utilization and cost at that time. They remain Uniform Formulary "by default" (since not previously reviewed) with no Prior Authorization requirements. A DHA provider workgroup requested that the DoD P&T Committee evaluate the need for a PA for the injectable testosterone formulations.

There has been a notable increase in utilization of the injectable products, while use of the topicals has declined across all age groups. Several commercial health plans have PAs in place for the injectable TRT formulations.

COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing PA criteria for testosterone cypionate and testosterone enanthate IM in new users, to ensure appropriate clinical use.

The Committee also recommended updating the existing PA criteria for the topicals and all other brand and generic TRT formulations (e.g., Fortesta, Androgel, Testim, Jatenzo, Xyosted etc.), to ensure that the provider has investigated the etiology of low testosterone levels, as several clinical conditions (e.g., untreated DM) can lower testosterone levels. This criteria will not apply when the TRTs are used for the indication of gender dysphoria. The new PA will become effective the first Wednesday 90 days after the signing of the minutes. See Appendix C for full criteria.

2. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. The most current PA criteria is found on the TRICARE Formulary Search Tool at: https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/.

a) **Respiratory Interleukins–dupilumab (Dupixent)—**The manual PA criteria were updated to expand use in children as young as 6 years of age for add-on maintenance therapy for moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

b) **Hepatitis C Agents: Direct Acting Agents–elbasvir/grazoprevir (Zepatier)**—The manual PA criteria were updated for Zepatier, allowing use in children as young as 12 years of age or weighing 30 kg or more for chronic hepatitis C virus (HCV) genotype 1 or 4 infection.

c) **Atypical Antipsychotic Agents**

- **brexpiprazole (Rexulti)—**The manual PA criteria were updated to allow use in children as young as 13 years of age for schizophrenia (Rexulti was previously only approved for adults)
- **lumateperone (Caplyta)**—Includes the new indication for depressive episodes associated with bipolar disorder I or II in adults, as monotherapy or as adjunct to lithium or valproate.

d) Targeted Immunomodulatory Biologics

- **risankizumab-rzaa (Skyrizi)**—Includes the new indication for active PsA in adults.
- **secukinumab (Cosentyx)**—Includes the new indication for active enthesitis-related arthritis (ERA) in patients 4 years of age and older. The manual PA criteria were also updated allowing use in children as young as 2 years of age for PsA. Note that for the ERA indication a trial of a non-biologic (e.g., methotrexate, sulfasalazine, mesalamine steroids or azathioprine) is not required.
- **tofacitinib (Xeljanz/Xeljanz XR)**—Includes the new indication for active ankylosing spondylitis in adults who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) blockers. Note that for the ankylosing spondylitis indication, a trial of a non-biologic (e.g., methotrexate, sulfasalazine, mesalamine steroids or azathioprine) is not required. The PA update also includes the new safety warnings for the drug class *(See the November 2021 meeting minutes for the safety updates made for Rinvoq and Olumiant)***.**
- **upadacitinib (Rinvoq ER)**—Includes the new indication for active psoriatic arthritis (PsA) in adults who have had an inadequate response or intolerance to one or more TNF blockers. *Note that the Atopic Dermatitis indication will be discussed at the May 2022 P&T meeting in more detail, and thus is not included in this PA update.*

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Dupixent, Zepatier, Rexulti, Caplyta, Skyrizi, Cosentyx, Xeljanz/Xeljanz XR and Rinvoq ER in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

3. Updated PA Criteria for Removal of Indication

Oncological Agents: Non-Bruton Tyrosine Kinase Inhibitor (Non-BTKI) for Chronic Lymphocytic Leukemia–duvelisib (Copiktra)—Copiktra was

reviewed as a newly approved drug in November 2018, and PA criteria for follicular lymphoma was implemented at that time. In December 2021, the manufacturer of Copiktra voluntarily withdrew the indication for Copiktra in patients with relapsed or refractory follicular lymphoma following at least 2 previous systemic therapies. The manufacturer determined this indication was no longer merited, based on the current treatment landscape for follicular lymphoma in the U.S. and the logistics, cost, and timing of the post-marketing requirements for the drug. This indication was originally approved by the FDA in September 2018 via accelerated pathway and was contingent upon the manufacturer completing confirmatory trials to receive full approval.

COMMITTEE ACTION: COPIKTRA UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to remove the follicular lymphoma indication for new users but will allow current users to consult their provider as to whether continued treatment is clinically appropriate. The other FDA-approved indications for Copiktra are not affected and will remain on the PA (e.g., relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL), and for other indications when supported in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.)

Implementation will be effective the first Wednesday 60 days after signing of the minutes.

B. Quantity Limits

QLs were reviewed for the newly approved drugs where there are existing QLs for the class, including the Myelogenous Leukemia, Miscellaneous Metabolic Agents, Miscellaneous Growth Stimulating Agents, Hematological Agents, Migraine Agents, and Ophthalmic Dry Eye products.

COMMITTEE ACTION: QLs AND IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) QLs for Scemblix, Livmarli, Voxzogo, Tavneos, Qulipta, and Tyrvaya, with implementation occurring the first Wednesday two weeks after signing of the minutes. See Appendix D for the QLs.

C. Line Extensions

The P&T Committee clarified the formulary status for 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) **Hepatitis C Agents: Direct Acting Agents—**designating **glecaprevir/pibrentasvir (Mavyret) 50 mg-20 mg oral pellet** as UF, with the same manual PA criteria requirements, QL, EMMPI List status, and specialty status as Mavyret 100 mg-40 mg tablet.

b) **Hepatitis C Agents: Direct Acting Agents—**designating **sofosbuvir/velpatasvir (Epclusa) 150 mg-37.5 mg and 200 mg-50 mg oral pellets** as UF, with the same manual PA criteria requirements, QL, EMMPI List status, and specialty status as Epclusa 400 mg-100 mg and 200 mg-50 mg tablets.

c) **Respiratory Interleukins—**designating **dupilumab (Dupixent) 100 mg and 150 mg syringes** as UF, with the same manual PA criteria requirements, QL, EMMPI List status, and specialty status as Dupixent 200 mg and 300 mg pens and syringes.

d) **Antiretrovirals: Combinations—**designating **bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy) 30 mg-120 mg-15 mg tablet** as UF and specialty status as Biktarvy 50 mg-200 mg-25 mg tablet.

e) **Hematological Agents: Sickle Cell Anemia Agents—**designating **voxelotor (Oxbryta) 300 mg tablet for oral suspension** as UF, with the same manual PA criteria requirements, and specialty status as Oxbryta 500 mg tablet.

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the formulary status for the line extension products as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. REMOVAL OF BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE/SALMETEROL DRY POWDER INHALER (ADVAIR DISKUS) Pulmonary Is: Inhaled Corticosteroid/Long Acting Beta Agonist Inhalers:

Brand over generic PA requirements and a Tier 1 (generic) co-payment have applied to fluticasone/salmeterol dry powder inhaler (Advair Diskus DPI) since May 2019, due to cost effectiveness compared to AB-rated generics (e.g. Wixela). The branded agent, Advair Diskus is no longer the most cost effective inhaled corticosteroid/long-acting beta agonist (LABA/ICS) dry powder inhaler at the MTF and Mail Order points of service. Generic prices of fluticasone/salmeterol DPI will continually be monitored.

COMMITTEE ACTION: REMOVAL OF BRAND OVER GENERIC FOR ADVAIR DISKUS—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing the Advair Diskus brand over generic PA requirement. As a result, the current PA criteria for the generic fluticasone/salmeterol DPI will be removed. The branded Advair Diskus will remain available at the Tier 1 (generic) co-payment at the Mail Order and the Retail network pharmacies, until further direction from the P&T Committee.

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

Background—The DoD P&T Committee continued reviewing the OTC drugs on the MHS GENESIS OTC list, with the goal of conducting a broad review of the remaining classes on the list. The primary consideration for this broad review was MTF utilization, with products accounting for more than 5,000 MTF prescriptions in the most recent quarter considered for addition, and products with fewer than 50 prescriptions considered for deletion from the list.

The MHS GENESIS OTC list is a list of NDCs for OTC products that will successfully adjudicate through the outpatient pharmacy system at MHS GENESIS sites (not including OTCs that are already covered under the TRICARE pharmacy benefit, including diabetic supplies [e.g., test strips and syringes], tobacco cessation agents, and OTCs specifically added to the benefit by the DoD P&T Committee). While the list does not affect MTFs still on the CHCS system, non-GENESIS MTFs are encouraged to implement the list locally.

The MHS GENESIS OTC list does not affect inpatient, clinic, or emergency use within MTFs and does not hinder purchases of OTC medications through the prime vendor for either inpatient or outpatient use. The list also does not establish policies as to which of the items on the list may be included in Self-Care programs, although it does have a tangential impact on such programs, since Service policies require OTC products dispensed through self-care programs to be added to patient profiles, and OTC products need to be on the MHS GENESIS list to adjudicate through PDTS and show up on patient profiles.

The MHS GENESIS OTC list is generally controlled at drug/strength/dosage form level, with the pharmacy contractor (Express-Scripts) periodically refreshing the list to account for the introduction of new NDCs. MTFs may request changes to the MHS GENESIS OTC (addition or deletion of products not already on the list (at drug/strength/dosage form level)) by completing the MTF Drug Review Request form (including obtaining concurrence from their local P&T and supplying rationale) and forwarding the completed form to the Formulary Management Branch. Details on how to submit changes to the list will be provided to the MTFs.

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—The P&T Committee tabled two groups of drugs, the GI-2 Agents: Probiotics subclass, and the rectal Skin Prep agents to allow for a more in-depth review at the May 2022 quarterly P&T Committee meeting. With respect to the remaining classes/subclasses, the P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent):

- Retaining, removing, and adding OTC products to the MHS GENESIS OTC List as specified in Appendix I
- Implementation dates of 180 days following signing of the minutes for products removed from the list, and two weeks for products added to the list.

- Sending letters to patients with prescriptions for OTC products being removed from the list that are typically used chronically.

Appendix I outlines specific products retained or added to the MHS GENESIS OTC List. For the sake of completeness, Appendix I includes previously reviewed classes and products tabled for review in May 2022, as well as those addressed during the broad review at this meeting.

IX. ITEMS FOR INFORMATION

A. Annual Review of Newly Approved Drugs

The Committee was briefed on the cost implications for the newly approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. Since the start of the program, 401 drugs have been reviewed, including 52 reviewed in calendar year 2021 alone, with an additional 19 drugs reviewed as line extensions. For the 52 innovators reviewed in 2021, almost half (46%) were existing drugs in new formulations. Only 8 products were truly novel agents, including 6 for orphan diseases (Bylvay, Empaveli, Imcivree, Lupkynis, Welireg, Zokinvy). Updates on the metrics for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

B. Post-Implementation Review: Rapid Acting Insulins

The Committee reviewed utilization and cost trends for the Rapid Acting Insulins (RAI), which were evaluated at the November 2019 Committee meeting, and implemented in July 2020. Novolog was maintained as BCF, with Humalog as UF; there was one Tier 4 selection, Fiasp. The RAI formulary action resulted in in significant and sustained cost avoidance for the MHS, without affecting the numbers of patients receiving an RAI.

C. Tier 4/Not Covered Re-Review: Migraine Agents: Triptans – sumatriptan 10 mg nasal spray (Tosymra)

The Committee evaluated clinical and cost information for Tosymra, which was evaluated at the November 2019 meeting and designed as Tier 4 on June 3, 2020. Tosymra is a sumatriptan 10 mg/spray nasal device which uses a new excipient and is indicated for acute treatment of migraine with or without aura

Clinical trial data show Tosymra is at least as efficacious as sumatriptan 20 mg/spray in achieving headache freedom at 2 hours post dose. There is no new evidence to suggest that Tosymra confers any significant advantages in efficacy or safety compared to the other sumatriptan nasal formulations. A CMA failed to detect any significant changes in cost effectiveness from the November 2019 P&T Committee review. Tosymra will remain designated as Tier 4.

D. Pilocarpine 1.25% ophthalmic solution (Vuity) is not a TRICARE covered benefit. Vuity is a new prescription eye drop that treats age-related blurred vision (presbyopia). The drug requires long-term administration due to the short duration of action (6 hours), and it does not reverse the underlying problem. Vuity is not medically necessary, and thus will not be part of the TRICARE pharmacy benefit.

X. ADJOURNMENT

The meeting adjourned at 1645 hours on February 10, 2022. The next meeting will be in May 2022.

Appendix A—Attendance: February 9-10, 2022 DoD P&T Committee Meeting:
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the February 2022 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives
Appendix I—MHS GENESIS OTC Text List

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

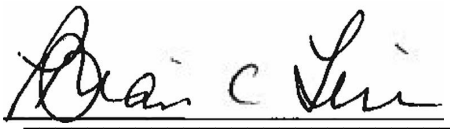
John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:



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

25 April 2022
Date

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, USPHS	Acting Chief, Formulary Management Branch (Recorder)
MAJ Sebastian Welsh, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, COL (Ret.) MC, USA	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Officer
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Lt Col 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
Col Corey Munro, BSC	Air Force, Pharmacy Officer
Lara Au, PharmD, BCOP	Oncology Pharmacist
Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR William Agbo	DLA Troop Support

Guests	
Lt Col Matt Cowan	DLA Troop Support
Lt Col Francisco Boral	DLA Troop Support
LCDR Samuel Mendoza	DLA Troop Support
Sooyun Kim, Pharm.D.	DLA Troop Support
Mr. Dwight Bonham	DHA Contracting Officer
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Patricia Legra	DHA Contracting Officer
Ms. Tracy Banks	DHA Contracting Officer
Ms. Madison Northern	DHA Contracting Officer
Mr. Hudson Tompkins	DHA Contracting Officer
Others Present	
MAJ Adam Davies, MSC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
David Folmar, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, RPh	DHA Formulary Management Branch Contractor
Michael Lee, RPh	DHA Formulary Management Branch Contractor
Capt Ana Chavis, MSC	BAMC pharmacy resident
Sarah Bandy, Pharm D	University of Texas at Austin/UTHSCSA pharmacy resident

Drug / Drug Class	Medical Necessity Criteria
Newly Approved Drugs MN Criteria	
• maralixibat (Livmarli) **Metabolic Agents-Miscellaneous**	• All five formulary agents (ursodiol, cholestyramine, rifampin, naltrexone, and at least 1 antihistamine) have resulted in therapeutic failure **Formulary alternatives:** ursodiol, cholestyramine, diphenhydramine, rifampin, naltrexone
• ropeginterferon alfa-2b-njft injection (Besremi) **Hematological Agents**	• Patient has experienced significant adverse effects from at least 1 formulary agent • At least 1 formulary agent has resulted in therapeutic failure **Formulary alternatives:** hydroxyurea, Pegasys
• carbidopa/levodopa IR scored tab (Dhivy) **Parkinson's Agents**	• Formulary agents have resulted in therapeutic failure • No alternative formulary agent: Patient cannot achieve the dose with generic IR carbidopa/levodopa **Formulary alternatives:** generic IR carbidopa/levodopa
• atogepant (Qulipta) **Migraine Agents**	• Formulary agents resulted in therapeutic failure **Formulary alternatives:** Nurtec ODT, Aimovig, Emgality, Ajovy
• lonapegsomatropin-tcgd injection (Skytrofa) **Growth stimulating agents**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from <u>all</u> formulary agents **Formulary alternatives:** Norditropin (step-preferred), Omnitrope, Zomacton
• varenicline nasal solution (Tyrvaya) **Ophthalmic: Dry Eye**	• Formulary agents have resulted in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis/Multidose), lifitegrast 5% (Xiidra)

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug Pas	
• asciminib (Scemblix) **Oncological Agents**	Manual PA criteria apply to all new users of Scemblix Manual PA criteria: Scemblix is approved if all criteria are met: • Patient is 18 years of age or older • Scemblix is prescribed by or in consultation with a hematologist/oncologist • The patient has Philadelphia chromosome-positive CML (Ph+ CML) in chronic phase (CP) and was previously treated with two or more tyrosine kinase inhibitors • The provider will monitor for myelosuppression, pancreatitis, hypertension, hypersensitivity, and cardiovascular toxicity • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment. • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week 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: _____. Non-FDA-approved uses are not approved. Prior authorization does not expire.
• avacopan (Tavneos) **Hematological Agents**	Manual PA criteria apply to new users of Tavneos. Manual PA criteria: Tavneos is approved initially for 6 months if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a rheumatologist • Patient has a documented diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's) and microscopic polyangiitis (MPA) • Patient meets one of the following criteria (either a or b): a. Positive ELISA test for anti-proteinase-3 (PR-3) b. Positive ELISA test for anti-myeloperoxidase (MPO) • Patient has documentation of baseline Birmingham vasculitis activity score (BVAS), with at least one of the following criteria (at least a, b, or c): a. At least 1 major item (i.e. gangrene, scleritis/episcleritis, hearing loss, massive hemoptysis/alveolar hemorrhage, respiratory failure, ischemic abdominal pain, rise/fall in serum creatinine, meningitis, CVA); b. At least 3 non-major items; c. At least 2 renal items of proteinuria and hematuria • Patient has experienced or has a high probability to experience significant adverse effect from prednisone • Tavneos is prescribed in combination with cyclophosphamide or rituximab, unless clinically significant adverse effects are experienced or both cyclophosphamide or rituximab are contraindicated Non-FDA-approved used are not approved including Immunoglobulin A nephropathy, Hidradenitis suppurativa, acne inversa, and C3 Glomerulopathy (C3G). Prior Authorization expires after 6 months Renewal criteria (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply: • Patient has responded positively to therapy as evidenced by at least a 50% reduction in BVAS from baseline or remission (BVAS of zero) AND • If request is for a dose increase, new dose does not exceed 60 mg (2 tabs) per day

• atogepant (Qulipta) **Migraine Agents**	**Changes from February 2022 meeting are in strikethrough.** Manual PA criteria apply to all new users of Qulipta. Manual PA criteria: Qulipta is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed • ~~Not approved for patients who have clinically significant or unstable cardiovascular disease~~ • Patient has Episodic Migraine as defined by the following: o 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 8 to 14 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. Prior Authorization expires after 6 months. Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply • 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 • 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

• lonapegsomatropin-tcgd injection (Skytrofa) **Growth Stimulating Agents**	Manual PA criteria apply to all new users of Skytrofa The provider acknowledges that Norditropin is the Department of Defense's preferred somatropin agent. Manual PA criteria: Skytrofa is approved if all criteria are met: • Patient is a pediatric patient at least one year of age and older who weights at least 11.5 kg • Skytrofa is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients • Skytrofa is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment • Patient has one or more of the following: o Patient has a contraindication to Norditropin OR o Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Skytrofa *Note, all possible preservative formulations are available between Norditropin, Omnitrope and Zomacton. *Note that patient preference for a particular device is insufficient grounds for approval of an NF agent. AND • Patient requires a less than daily dosing regimen due to needle intolerance or aversion Non-FDA-approved uses are not approved, including Idiopathic Short Stature, normal aging process, obesity, and depression Coverage not approved for concomitant use of multiple somatropin agents. Prior authorization expires in 1 year; provider must fill out a new PA.
• maralixibat (Livmarli) **Metabolic Agents-Miscellaneous**	Manual PA criteria apply to all new users of Livmarli. Manual PA criteria: Livmarli is approved if all criteria are met: • Patient is 1 year of age or older • The patient has diagnosed Alagille syndrome with severe refractory pruritus • The prescription is written by a pediatric gastroenterologist, or pediatric hepatology transplant specialist • The patient has been evaluated for possible orthotopic liver transplant (OLT) • The patient has previously tried and failed all of the following: o ursodiol o cholestyramine o rifampin o naltrexone o At least one antihistamine (e.g. Atarax, Benadryl, etc.) Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD), progressive familial intrahepatic cholestasis (PFIC), biliary atresia, and other cholestatic diseases are not approved. Prior Authorization expires after 6 months. Renewal criteria (Initial TRICARE PA approval is required for renewal) Coverage will be approved for an additional six months if the following apply: • Patient must demonstrate significant improvement in pruritus symptoms.

• ropeginterferon alfa-2b-njft injection (Besremi) **Hematological Agents**	Manual PA criteria apply to all new users of Besremi. Manual PA criteria: Besremi is approved for 1 year if all criteria are met: • Provider acknowledges that another pegylated interferon (Pegasys) is available at the formulary copay and without requiring prior authorization • Patient is 18 years of age or older • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient has a confirmed diagnosis of polycythemia vera (PV) • Patient is high-risk (age >60 years and/or prior history of thrombosis) • Patient is currently taking aspirin 81-100mg daily and is undergoing regular phlebotomy (to maintain hematocrit < 45%) • Patient must try and fail or be intolerant or resistant to (showing phlebotomy-dependence and/or progressive splenomegaly) hydroxyurea OR • The patient has a contraindication to hydroxyurea (e.g., pregnancy) Non-FDA-approved uses are NOT approved including myeloproliferative neoplasms, essential thrombocythemia (ET), or adult T-cell leukemia (ATL). Prior Authorization expires after 1 year. Renewal criteria**:** (Initial TRICARE PA approval is required for renewal) Coverage is approved for an additional year if the following criteria are met: • Patient has a documented improvement in symptoms

• topiramate oral solution (Eprontia)
 	
Anticonvulsants-Antimania Agents
	Manual PA criteria apply to all new users of Eprontia.
	
	Manual PA criteria: Eprontia is approved if all criteria are met:
	• PA does not apply to patients less than 12 years of age (age edit)
	• Eprontia is prescribed by or in consultation with an adult or pediatric neurologist
	• Patient has a diagnosis of one of the following:
	  ○ For epilepsy monotherapy: Partial onset seizure or primary generalized tonic-clonic seizures in patients 2 years or age or older
	  ○ For epilepsy adjunctive therapy: Partial onset seizure or primary generalized tonic-clonic seizures or seizures associated with Lennox Gastaut syndrome in patients 2 years of age or older
	  ○ For Migraine: preventive treatment in patients 12 years of age or older
	• Patient requires a liquid formulation due to swallowing difficulty or has a feeding tube and cannot use topiramate (sprinkles)
	
	Non-FDA-approved uses are not approved
	Prior Authorization does not expire.

• carbidopa/levodopa IR scored tab (Dhivy) **Parkinson's Agents**	Manual PA criteria apply to all new users of Dhivy Manual PA criteria: Dhivy is approved if all criteria are met: • Provider acknowledges that generic immediate-release carbidopa/levodopa is available without a PA (e.g. generic Sinemet) • The patient has tried and failed a generic immediate-release formulation of carbidopa/levodopa OR • The patient cannot achieve the required dose with generic immediate-release carbidopa/levodopa (e.g. generic Sinemet) Non-FDA-approved uses are not approved. Prior Authorization does not expire. .
• varenicline nasal solution (Tyrvaya) **Ophthalmic: Dry Eye**	Manual PA criteria apply to all new users of Tyrvaya. Manual PA criteria: Tyrvaya is approved if all criteria are met: • The patient is 18 years of age or older • Tyrvaya is prescribed by an ophthalmologist or optometrist • Patient has a diagnosis of dry eye disease as supported by both of the criteria below: o Positive symptomology screening for dry eye disease from an appropriate measure o At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: o At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) o Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • If the patient has moderate to severe Dry Eye Disease: o Patient has tried and failed an adequate course (at least 6 weeks) of treatment of lifitegrast or cyclosporine treatment Non-FDA-approved uses are not approved. Prior Authorization expires after 1 year Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely if all criteria are met: o The drug is prescribed by an ophthalmologist or optometrist. o The patient must have documented improvement in ocular discomfort. o The patient must have documented improvement in signs of dry eye disease.

• vosoritide (Voxzogo) **Growth Stimulating Agents: Miscellaneous**	Manual PA criteria apply to all new users of Voxzogo. Manual PA criteria: Voxzogo is approved if all criteria are met: • Patient is 5 years of age or older • Drug is prescribed by or in consultation with a pediatric endocrinologist • Patient has a documented diagnosis of achondroplasia with open epiphyses • Patient/Caregiver and provider acknowledge that Voxzogo was FDA approved in an accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials • Patient/Caregiver and provider acknowledge that a clinical benefit with Voxzogo has not been proven • Patient/Caregiver have been instructed on how to properly use, store, and administer Voxzogo • Provider agrees to monitor growth and adjust dose according to body weight • Provider agrees to permanently discontinue Voxzogo upon closure of epiphyses Non-FDA-approved uses are not approved. Prior Authorization expires after 1 year; provider must fill out a new PA..
• fenofibrate 120 mg tablets (Fenoglide) **Antilipidemics-2: Fenofibrates**	Manual PA criteria applies to new and current users of fenofibrate 120 mg tablets (Fenoglide). Manual PA Criteria: Fenoglide 120 mg tablets are approved if all criteria are met: • The provider acknowledges that other formulations of fenofibrate, including Tricor, Trilipix, and Lofibra, are available to DoD beneficiaries without the need of prior authorization. Providers are encouraged to consider changing the prescription to another fenofibrate formulation. • The provider must explain why the patient cannot take one generic fenofibrate 134 mg capsule or two fenofibrate 54 mg tablets or another formulation of fenofibrate *(fill-in blank)* Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

• indomethacin suppository (Indocin) **Pain Agents: NSAID**	Manual PA criteria applies to new and current users of indomethacin suppositories (Indocin). Manual PA Criteria: diclofenac 25 mg tablet is approved if all criteria are met: • The provider acknowledges that several other indomethacin formulations, including generic indomethacin suspension and capsules are available to TRICARE beneficiaries without requiring prior authorization. Providers are encouraged to consider changing the prescription to another indomethacin formulation • The provider acknowledges that several other NSAIDs are available to TRICARE beneficiaries without requiring prior authorization including generic meloxicam, ibuprofen suspension, diclofenac potassium, and naproxen • The provider must explain why the patient requires Indocin suppositories and cannot take generic indomethacin suspension, indomethacin capsules, or other formulary NSAIDs *(fill-in blank)* Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• prenatal MVI (Neonatal Plus) **Vitamins: Prenatal**	Manual PA criteria applies to new and current users of prenatal MVI (Neonatal Plus). Manual PA Criteria: Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, or **Neonatal Plus** is approved if all criteria are met: • The 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, Neonatal FE, and Neonatal Complete and **Neonatal Plus**. The preferred vitamins listed above 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 • The provider must explain why the patient requires Neonatal Plus and cannot take one of the cost effective formulary alternatives *(fill-in blank)* Non-FDA-approved uses are NOT approved. Prior Authorization does not expire.

• testosterone cypionate and testosterone enanthate IM injections
 	
Androgens-Anabolic Steroids: Testosterone Replacement Therapies
	<u>The bolded questions will be also added to all other brand and generic formulations of TRT that currently require PA (Fortesta, Androgel, Testim, Jatenzo, Xyosted, etc)</u>
	
	Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections.
	
	<u>Manual PA Criteria</u>: testosterone cypionate and testosterone enanthate IM injections are approved if all criteria are met:
	• Coverage approved for male patients if:
	  • Patient is over the age of 17 years AND
	  • Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND
	  • **Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND**
	  • The patient does not have prostate cancer AND
	  • The patient is experiencing symptoms usually associated with hypogonadism
	OR
	• Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:
	  • Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM
	  • Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND
	  • Patient has no signs of breast cancer AND
	  • For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND
	  • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND
	  • Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria
	
	Non-FDA-approved uses are NOT approved.
	Not approved for concomitant use with other testosterone products.
	Prior Authorization does not expire.

Drug / Drug Class	Quantity Limits
• dasiglucagon SC injection (Zegalogue) • glucagon injection (Gvoke Hypopen and Pre-Filled Syringe) **Antidotes-Overdose Agents: Hypoglycemia Agents**	▪ Zegalogue and Gvoke: Retail/MTF/Mail: 2 syringes/pens per fill (one two-pack or two individual packs) ▪ Baqsimi: Retail/MTF/Mail: 2 nasal spray units per fill (one two-pack or two individual)
• glucagon kit (Glucagon Emergency) • glucagon powder for injection (GlucaGen Hypokit and GlucGen Diagnostic) **Antidotes-Overdose Agents: Hypoglycemia Agents**	▪ Retail/MTF/Mail: 2 kits per fill
• asciminib (Scemblix) **Oncological Agents**	▪ Retail/MTF/Mail: 30 day supply
• atogepant (Qulipta) **Migraine Agents**	▪ Retail: 30 tabs/30 days ▪ MTF/Mail: 90 tabs/90 days
• avacopan (Tavneos) **Hematological Agents**	▪ Retail/MTF/Mail: 30 day supply
• maralixibat (Livmarli) **Metabolic Agents-Miscellaneous**	▪ Retail/MTF/Mail: 30 day supply
• varenicline nasal solution (Tyrvaya) **Ophthalmic: Dry Eye**	▪ Retail: 1 package (2 bottles in each package) in 30 days ▪ MTF/Mail: 3 packages (2 bottles in each package) in 90 days
• vosoritide (Voxzogo) **Growth Stimulating Agents: Miscellaneous**	▪ Retail/MTF/Mail: 30 day supply

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
asciminib (Scemblix) Oncological Agents: Chronic Myelogenous Leukemia	• bosutinib (Bosulif) • ponatinib (Iclusig)	• Tablet-20/40 mg • Ph+ CML in CP: 80 mg PO qday or 40 mg PO bid • Ph+ CML in CP with T3151 Mutation: 200 mg PO bid • Avoid food at least 2 hrs before and 1 hr after taking Scemblix; swallow tabs whole (do not break, crush, nor chew)	CML in chronic phase (CP)	• Most common ADRs: (≥ 20%) URTI, musculoskeletal pain, fatigue, nausea, rash, and diarrhea • Common lab abnormalities (≥ 20%): decreased PLT, neutrophils, Hgb; and increased triglycerides, CPK, ALT, lipase, and amylase	• Scemblix is one of the few agents indicated as a third line or later treatment option for Ph+ CML-CP • Robust objective response (major molecular response) but immature survival data • Unique safety profile relative to bosutinib; better tolerated • Scemblix is an important addition to treatment options for later-line treatment of Ph+ CML-CP	• UF
atogepant (Qulipta) Migraine Agents	• Emgality • Ajovy • Aimovig • Nurtec ODT	• Tablet-10/30/60mg • Dosing- 10, 30, or 60 mg by mouth once daily w/wo food	Preventive treatment of episodic migraine in adults	• >5%: constipation, nausea, fatigue	• The 5th CGRP agent and 2nd oral CGRP antagonist for migraine prevention • Well tolerated with minimal side effect profile • Indirect comparison shows similar efficacy to the injectable agents used for prevention of migraine • No significant clinical advantage over other CGRP treatments for episodic migraine prevention	• NF
avacopan (Tavneos) Hematological Agents	• prednisone • cyclophos-phamide • azathioprine • mycophen-olate • rituximab	• 10 mg capsules • 30 mg (three caps) by mouth BID with food	Microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)	• >5%: HA, HTN, N/V/D, rash, fatigue, upper abdominal pain, dizziness, increased creatinine, and paresthesia	• First oral complement 5a receptor antagonist used adjunctively with glucocorticoids • Avacopan use resulted in decreased prednisone use and was noninferior to tapered prednisone for remission at week 26 • Showed reduced risk of glucocorticoid toxic events due to its sparing effects • Possibly useful as an alternative to prednisone use in patients suffering from GPA/MPA • Most common adverse events include nausea, headache, vomiting and rash • Avacopan is an additional option for therapy but does not change guideline directed therapy	• UF

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
carbidopa/ levodopa (Dhivy) Parkinson's Agents	• Carbidopa/ levodopa IR tab 25 mg/ 100 mg • Carbidopa/ levodopa ODT tab 25 mg /100 mg	• 25 mg carbidopa/100 mg levodopa scored oral tablet	Parkinson's disease (PD)	• Same as other carbidopa/levodopa formulations	• Dhivy is another formulation of carbidopa/levodopa approved via 505(b)2 pathway for PD • Dhivy has additional scorings for smaller dosing • No new studies were conducted • Dhivy provides no compelling advantage over existing agents other than scored tablets	• NF
celecoxib oral solution (Elyxyb) Pain Agents: NSAIDs	• celecoxib capsules • diclofenac powder packet (Cambia) • ibuprofen • naproxen • APAP/aspirin/ caffeine	• 120 mg (4.8 mL) with or without food; max of one dose/day • 60 mg (2.4 mL) dose for moderate hepatic impairment or poor metabolizers of CYP2C9 substrates	Acute treatment of migraines in adults with or without aura	ADR > 2% and greater than placebo: • Dysgeusia (3%)	• Elyxyb is a new oral solution formulation of celecoxib approved for adult migraine treatment with or without aura • Approved through a 505(b)(2) application • Only one of the two pivotal trials demonstrated a statistically significant improvement in freedom from pain at 2 hours vs. placebo • Elyxyb's time to peak concentrations is faster than celecoxib capsules, but slower than other NSAIDs for migraine • Patients with swallowing difficulties already have an easy to swallow celecoxib option (capsules can be opened up and mixed with applesauce) • There are many other effective, formulary and OTC migraine medications available • Elyxyb provides little to no clinical advantage over existing agents	• Tier 4/Not covered
lonapegsoma-tropin-tcgd injection (Skytrofa) Growth Stimulating Agents	• Genotropin • Norditropin	• Single dose, prefilled cartridges • SC dosing at 0.24 mg/kg body weight once-weekly • Doses: 3/3.6/4.3/5.2/6.3/7.6 /9.1/11/13.3 mg	Growth hormone	• Most common ADRs (≥5%) in peds: viral infection, pyrexia, cough, N/V/D, hemorrhage, abdominal pain, and arthralgia and arthritis	• Skytrofa is a long-acting somatropin prodrug whose primary advantage is weekly dosing instead of daily dosing required with the other growth hormone stimulating agents • Skytrofa is non-inferior to Genotropin • Somatropin products are clinically interchangeable • Skytrofa is another treatment option in an already crowded class for growth hormone deficiency	• NF and non-step-preferred

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
marabavir (Livtencity) Antivirals	• ganciclovir • valganciclovir • foscarnet • cidofovir	• 400 mg (two 200 mg tablets) PO BID with or without food (given for 8 weeks duration in pivotal study) • Dose adjustments for drug interactions with carbamazepine, phenytoin, or phenobarbital	Adults and children (12 years of age and older and weighing ≥35 kg) with post-transplant CMV infection / disease refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet	ADRs > 10%: • Taste disturbance (46%) • Nausea (21%) • Diarrhea (19%) • Vomiting (14%) • Fatigue (12%)	• Livtencity is a treatment option for patients with post-transplant CMV infections who are refractory to other medications • Available as a well-tolerated oral medication that offers a new mechanism of action • Superior to investigator-assigned treatment for viremia clearance and clearance plus symptom control maintained after therapy • Associated with less nephrotoxicity than foscarnet, less myelotoxicity than valganciclovir and ganciclovir, and fewer discontinuations than investigator-assigned treatment • One disadvantage is that it can lead to increased concentrations of immunosuppressants like tacrolimus, requiring increased monitoring • Likely to be reserved as last-line therapy • Adds to the armamentarium for a disease with serious consequences in post-transplant patients	• UF
maralixibat (Livmarli) Metabolic Agents-Miscellaneous	• chole-styramine • rifampin • hydroxyzine • naltrexone • odevixibat (Bylvay)	• Oral solution • 9.5 mg/mL in 30 mL bottles • Starting dose week 1: 190 mcg/kg daily for 1 week • Week 2: 380 mcg/kg if tolerated	Cholestatic pruritus in Alagille syndrome	• ≥ 5%: V/D, abdominal pain, fat soluble vitamin deficiency (FSVD), liver enzyme abnormalities, GI bleeding, bone fractures	• Livmarli is a new ileal bile acid transporter (IBAT) inhibitor • Only indicated for the treatment of cholestatic pruritus in patients 12 months of age and older • According to guidelines, use of ursodeoxycholic acid or cholestyramine should be first line, rifampin is second line followed by naltrexone and antihistamines for adjunctive therapy • The data for the primary and secondary endpoints were statistically significant • Adverse effects ≥ 5% diarrhea, abdominal pain, vomiting, fat soluble vitamin deficiency (FSVD), liver enzyme abnormalities, GI bleeding, bone fractures • Despite offering symptomatic control, studies on mortality and morbidity are not known • No effect on disease progression	• NF

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
ropeginterferon alfa-2b-njft injection (Besremi) Hematological Agents	• hydroxyurea • peginterferon alfa-2a injection (Pegasys) • ruxolitinib (Jakafi) • busulfan (Myleran)	• SubQ Injection: 500 mcg/mL single-dose PFS • 100 mcg SQ every 2 weeks • Increase by 50 mcg every 2 weeks until parameters stabilize (Hct < 45%, Plt < 400 x 109/L, and leukocytes < 10 x 109/L) • Max 500 mcg • Start at 50 mcg if currently receiving hydroxyurea	Polycythemia vera	Common ADRs (>40%) reported: • influenza-like illness • arthralgia • fatigue • pruritus • nasopharyngitis • musculoskeletal pain	• Besremi is another pegylated interferon and the only FDA-approved treatment for polycythemia vera (PV) without symptomatic splenomegaly • NCCN guidelines recommend hydroxyurea or Pegasys as first-line options in patients with high-risk PV • There are no head to head studies with similar agents, making statements about comparative effectiveness difficult • Besremi is pharmacologically similar to Pegasys (both are pegylated interferons) and would be expected to have a similar place in therapy • Clinically meaningful differences in efficacy and safety between Besremi and Pegasys or Pegintron cannot be established	• NF
topiramate oral solution (Eprontia) Anticonvulsants-Antimania Agents	• topiramate IR 200 mg tablet • topiramate ER capsule • topiramate ER 200 mg capsule (Qudexy XR)	• 25 mg/ml in 473 ml bottle • Varies depending on age and indication	Epilepsy, migraine, Lennox-Gastaut	• Epilepsy >10%: paresthesia, anorexia, speech, fatigue, dizziness, nervous, slowing, vision, fever • Migraine >5%: paresthesia, hypoesthesia, anorexia, memory, taste, N/D, abd pain, URI	• Eprontia is another formulation of topiramate in an oral solution approved via the 505(b)2 pathway • No new clinical studies were completed; has only shown bioequivalence to topiramate sprinkles • Other than being the only topiramate oral solution, Eprontia offers no major clinical benefit relative to other topiramate formulations	• UF
varenicline nasal solution (Tyrvaya) Ophthalmic: Dry Eye	• Restasis • Restasis multi-dose • Cequa • Xiidra	• 1 spray (0.05 mL [0.03 mg of Tyrvaya]) in each nostril BID • Available as a nasal spray bottle containing 60 sprays	To increase tear production in patients with kerato-conjunctivitis sicca (dry eye) ≥ 18 years of age	Most common AEs (incidence > 5% of patients): sneezing (82%), cough (16%), throat irritation (13%), and instillation-site (nose) irritation (8%)	• Tyrvaya is a new formulation of varenicline approved as a nasal spray for dry eye disease • Cholinergic agonist that activates the parasympathetic pathway to increase tear production • Does not address any underlying issues • Evaluated in two unpublished studies compared to varenicline 0.06 mg spray and vehicle. • Statistically superior to placebo based on the Schirmer Tear Test and met the MCID of 5 mm	• NF

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					• No statistically significant difference vs. placebo for symptomatic dry eye • Duration of therapy was limited to 4 weeks • Overall, well tolerated with but different ADRs compared to ophthalmic treatment options • No head to head studies have been conducted with other DED agents (e.g. Xiidra, Restasis) • Guidelines have not addressed Tyrvaya;, place in therapy remains unclear, and long-term benefit has not been determined • Providers agree with recommending trials of OTC products and trials of Restasis or Xiidra • The spray acts in as little as 14 days, rather than the 3–6 months required for existing prescription drugs, and it doesn't irritate the eyes. • Tyrvaya offers a novel mechanism for treating DED however there are no compelling advantages over existing agents	
vosoritide injection (Voxzogo) Growth Stimulating Agents: Miscellaneous	• Growth hormone therapy (off-label)	• Once daily subcutaneous injection based on patient weight • Available as 0.4 mg, 0.56 mg, or 1.2 mg lyophilized powder in a single-dose vial for reconstitution	Increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses	Most common adverse reactions (>10%) are injection site erythema, injection site swelling, vomiting, injection site urticaria, arthralgia, decreased blood pressure, and gastroenteritis	• First C type natriuretic peptide (CNP) analog approved for this condition (achondroplasia) • Approved via accelerated approval; continued approval may be contingent upon verification of clinical benefit in confirmatory trials • Compared to placebo in one phase 3 study • Vosoritide provided a statistically significant change from baseline in annualized growth velocity (AGV) at Week 52 compared to placebo (-0.17 vs 1.4) • Most common ADRs (> 10%) include injection site erythema, swelling, and urticaria, vomiting, arthralgia, decreased blood pressure, and gastroenteritis • Voxzogo offers a once daily injectable treatment option for pediatric patients with achondroplasia	• UF

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)
February 2022	**Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • varenicline nasal solution (Tyrvaya) *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, pending availability at mail, and pending final cost:* • lonapegsomatropin-tcgd injection (Skytrofa) • ropeginterferon alfa-2b-njft injection (Besremi) **Line Extensions** **Designated UF** *Similar/parent agent already on list (all new strengths or dosage forms):* • dupilumab syringe (Dupixent)	**Drug Class Reviews** *Acute use exception applies* • glucagon (Baqsimi, Gvoke, Zegalogue) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Drugs in class not currently represented on EMMPI List and comparable pricing at mail order vs MTFs or retail:* • asciminib (Scemblix) • topiramate oral solution (Eprontia) *Not yet clear if feasible to provide through mail:* • avacopan (Tavneos) • marabavir (Livtencity) *Not yet clear if feasible to provide through mail and final cost pending:* • vosoritide injection (Voxzogo) **Designated NF:** *Not yet clear if feasible to provide through mail order:* • maralixibat (Livmarli) • carbidopa/levodopa IR scored tab (Dhivy) *Exception due to comparable pricing at mail order vs MTFs or retail and similar agents not on list:* • atogepant (Qulipta) **Line Extensions** **Designated UF** *Similar/parent agent not on list:* • glecaprevir/pibrentasvir (Mavyret) • sofosbuvir/velpatasvir (Epclusa) • bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy) • voxelotor (Oxbryta)

Appendix G—Implementation Dates*

Upon signing: April 27, 2022 (for signing date of April 26, 2022)

Two weeks after signing: May 11, 2022

30 Days after Signing: June 1, 2022

60 days after signing: June 29, 2022

90 days after signing: July 27, 2022

120 Days after signing: August 24, 2022

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

Appendix H—Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
February 2022	Pain Agents: NSAIDs	• celecoxib oral solution (Elyxyb)	• celecoxib tablets • ibuprofen • naproxen • diclofenac • numerous other NSAIDs or combo products	• Month day, (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	• lorazepam ER capsule (Loreev XR)	• lorazepam IR tablets • alprazolam IR and XR tablets	• June 15, 2022 (120 days)
Nov 2021	Migraine Agents	• dihydroergotamine mesylate nasal spray (Trudhesa)	• DHE nasal spray • sumatriptan nasal and oral • rizatriptan • zolmitriptan • eletriptan	• June 15, 2022 (120 days)
Aug 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, 2022 (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	• June 15, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			• fluocinonide 0.05% cream, gel, and solution • calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary]	
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
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]	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			• budesonide/formoterol (Symbicort) [non formulary] • fluticasone/salmeterol (AirDuo Respiclick) [non formulary]	
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
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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
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. All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms.

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

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

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

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Analgesics and Combinations (reviewed May 2019, acetaminophen 325 mg tablet updated May 2021)		
Feb 2022	**Already reviewed (RETAIN)** • 16903 - acetaminophen 120 MG SUPP.RECT • 16905 - acetaminophen 325 MG SUPP.RECT • 16907 - acetaminophen 650 MG SUPP.RECT • 16908 - acetaminophen 80 MG SUPP.RECT • 16932 - acetaminophen 160 MG/5ML LIQUID • 16964 - acetaminophen 325 MG TABLET • 16965 - acetaminophen 500 MG TABLET • 16971 - acetaminophen 80 MG TAB CHEW • 26911 - acetaminophen 160 MG/5ML ORAL SUSP • 27794 - acetaminophen 160 MG/5ML ORAL SUSP	
Anesthetic Agents : Local (topical anesthetic agents reviewed May 2019)		
Feb 2022	**RETAIN these GCNs** • 48591 - phenol 1.4 % SPRAY (Mucous Membrane) (e.g., Chloroseptic) • 30354 - benzocaine/menthol 15MG-3.6MG LOZENGE (e.g., Cepacol) • 30355 - benzocaine/menthol 15MG-2.6MG LOZENGE (e.g., Cepacol) **Already reviewed (RETAIN)** • 30671 - benzocaine/menthol 20 %-0.5 % AEROSOL (Topical) (Dermoplast) • 30730 - dibucaine 1 % OINT. (G) (Topical)	**REMOVE these GCNs** • 00740 - benzocaine 20 % SPRAY (e.g., Hurricaine Spray) • 12200 - benzocaine 20 % GEL (GRAM) (e.g., Orajel) • 29244 - benzocaine 20 % SPRAY (Hurricaine One Spray)
Antibacterials		
Feb 2022	**RETAIN these GCNs** • 30011 - chlorhexidine gluconate 4 % LIQUID (e.g., Hibiclens) • 45334 - povidone-iodine 10 % SOLUTION (e.g., Betadine)	**REMOVE these GCNs** • 29723 - povidone-iodine 10 % MED. SWAB (e.g., Betadine) • 29731 - povidone-iodine 7.5 % SOLUTION (e.g., Betadine) • 29761 - povidone-iodine 10 % OINT. (G) (e.g., Betadine)

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Antibiotics : Combinations		
Feb 2022	**RETAIN these GCNs** • 31811 - bacitracin 500 UNIT/G PACKET • 31812 - bacitracin 500 UNIT/G OINT. (G) • 31810 - bacitracin zinc 500 UNIT/G OINT. (G) • 31813 - bacitracin zinc 500 UNIT/G OINT PACK • 85459 - neomycin/bacitracin/polymyxin B 3.5-400-5K OINT. (G)	**REMOVE these GCNs** • 21311 - bacitracin/polymyxin B sulfate 500-10K/G OINT. (G)
Antiemetic-Antivertigo Agents		
Feb 2022	**RETAIN these GCNs** • 18301 - meclizine HCl 12.5 MG TABLET • 18312 - meclizine HCl 25 MG TAB CHEW	**REMOVE these GCNs** • 18302 - meclizine HCl 25 MG TABLET
Antifungals (Topical antifungals reviewed Aug 19; vaginal antifungals reviewed Nov 20)		
Feb 2022	**Already reviewed (RETAIN)** **Topical antifungals** • 30370 - clotrimazole 1 % CREAM (G) • 62498 - terbinafine HCl 1 % CREAM (G) • 30310 - tolnaftate 1 % POWDER **Vaginal antifungals** • 28360 - clotrimazole 1 % CREAM/APPL • 28380 - miconazole nitrate 2 % CREAM/APPL • 69380 - miconazole nitrate 200 MG-2 % KIT	
Antihistamine-1 : First Generation and Combinations		
Feb 2022	**RETAIN these GCNs** • 46512 - chlorpheniramine maleate 4 MG TABLET • 45971 - diphenhydramine HCl 25 MG CAPSULE • 46071 - diphenhydramine HCl 25 MG TABLET • 45972 - diphenhydramine HCl 50 MG CAPSULE • 48831 - diphenhydramine HCl 12.5MG/5ML LIQUID	**REMOVE these GCNs** • 46503 - chlorpheniramine maleate 2 MG/5 ML SYRUP • 46541 - chlorpheniramine maleate 12 MG TABLET ER • 31607 - diphenhydramine HCl 25 MG CAPSULE • 27481 - diphenhydramine HCl 25 MG TABLET • 27482 - diphenhydramine HCl 50 MG CAPSULE • 46032 - diphenhydramine HCl 12.5MG/5ML ELIXIR • 46062 - diphenhydramine HCl 12.5MG/5ML SYRUP

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Antihistamine-1 : Second Generation and Combinations		
Feb 2022	**RETAIN these GCNs** • 13866 - cetirizine HCl/pseudoephedrine 5 MG-120MG TAB ER 12H • 24394 - fexofenadine/pseudoephedrine 180-240MG TAB ER 24H • 63565 - fexofenadine/pseudoephedrine 60MG-120MG TAB ER 12H • 63570 - loratadine/pseudoephedrine 5 MG-120MG TAB ER 12H • 63577 - loratadine/pseudoephedrine 10MG-240MG TAB ER 24H • 49290 - cetirizine HCl 1 MG/ML SOLUTION • 60521 - loratadine 10 MG TAB RAPDIS • 60562 - loratadine 5 MG/5 ML SOLUTION NOTE: OTC versions of cetirizine, loratadine, and fexofenadine tablets are available at all points of service on the DoD pharmacy benefit	**REMOVE these GCNs** • 21771 - cetirizine HCl 10 MG TAB CHEW • 27714 - cetirizine HCl 5 MG/5 ML SOLUTION • 28661 - loratadine 5 MG TAB RAPDIS
Antihistamine-2 Blockers		
Feb 2022	**ADD these GCNs** • 46432 – famotidine 10 MG TABLET	
Antiinfectives : Anti-Helmintics (pyrantel pamoate reviewed Aug 20)		
Feb 2022	**Already reviewed (RETAIN):** • 43170 - pyrantel pamoate 50 MG/ML ORAL SUSP	
Antiinfectives : Miscellaneous		
Feb 2022	**RETAIN these GCNs** • 44520 -permethrin 1 % LIQUID (e.g., Nix) • 91071 -piperonyl butoxide/pyrethrins 4%-0.33% SHAMPOO (e.g., Rid)	
Antilipidemics-2 : Dietary Supplements		
Feb 2022	**RETAIN these GCNs** • 26059 - omega-3 fatty acids/fish oil 300-1000MG CAPSULE • 97298 - omega-3 fatty acids/fish oil 340-1000MG CAPSULE • 21465 - omega-3/dha/epa/fish oil 500-1000MG CAPSULE • 23414 - omega-3/dha/epa/fish oil 300-1000MG CAPSULE • 28126 - omega-3/dha/epa/fish oil 1000 MG CAPSULE	**REMOVE these GCNs** • 98676 - omega-3 fatty acids/fish oil 360-1200MG CAPSULE • 34819 - omega-3s/dha/epa/fish oil 300-1000MG CAPSULE DR • 46508 - omega-3/dha/epa/fish oil 300-1000MG CAPSULE

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Antiplatelet-Hemorrhelogic Agents : Pain Miscellaneous (reviewed Aug 2020)		
Feb 2022	**Already reviewed (RETAIN)** • 00161 - aspirin 81 MG TABLET DR • 16701 - aspirin 325 MG TABLET • 16713 - aspirin 81 MG TAB CHEW • 16720 - aspirin 325 MG TABLET DR	
Bandages and Dressings (designated by NDC)		
Feb 2022		**REMOVE these NDCs** • 08137116144 - adhesive bandage 2.875" X4" BANDAGE • 08137116286 - adhesive bandage BANDAGE • 08137116152 - adhesive tape 1" X 10 YD TAPE • 08137116124 - gauze bandage 2" X 2" BANDAGE • 08137116128 - gauze bandage 4" X 4" BANDAGE • 08137116147 - gauze bandage 4" X 4" SPONGE • 42167001801 - transparent dressing 4"X4 3/4" BANDAGE
Binders-Chelators-Antidotes-Overdose Agents		
Feb 2022	**RETAIN these GCNs** • 34577 -dextrose/dextrin/maltose 24 G/31 G GEL (GRAM) (e.g., Insta-glucose)	
Compounding Supplies		
Feb 2022		**REMOVE these GCNs** • 40099 - compound vehicle susp SF no.20 ORAL SUSP • 45550 - sorbitol solution 70 % SOLUTION
Corticosteroids-Immune Modulators : Low Potency (reviewed Aug 19)		
Feb 2022	**Already reviewed (RETAIN)** • 30942 - hydrocortisone 1 % CREAM (G) • 30951 - hydrocortisone 1 % OINT. (G) • 30942 - hydrocortisone/aloe vera 1 % CREAM (G)	

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Cough-Cold Agents		
Feb 2022	**ADD these GCNS** • 17802 - dextromethorphan polistirex 30 MG/5 ML SUS ER 12H (e.g., Delsym) **RETAIN these GCNs** • 96445 - triprolidine/pseudoephedrine 2.5MG-60MG TABLET (e.g., Aprodine) • 99512 -dextromethorphan/benzocaine 5MG-7.5MG LOZENGE (e.g., Cepacol Sore Throat) • 53491 - guaifenesin/dextromethorphan 100-10MG/5 LIQUID • 53495 - guaifenesin/dextromethorphan 100-10MG/5 SYRUP • 53550 - guaifenesin/dextromethorphan 600MG-30MG TAB ER 12H • 02482 - guaifenesin 200 MG TABLET • 02512 - guaifenesin 100 MG/5ML LIQUID • 18906 - guaifenesin 400 MG TABLET • 35905 - guaifenesin 600 MG TAB ER 12H • 98863 - guaifenesin 1200 MG TAB ER 12H • 54980 - guaifenesin/pseudoephedrne HCl 600MG-60MG TAB ER 12H (e.g., Mucinex-D) • 89731 - guaifenesin/pseudoephedrne HCl 1200-120MG TAB ER 12H (e.g., Mucinex-D) • 23944 - phenylephrine HCl 10 MG TABLET (e.g., Contac D Cold) • 20462 - pseudoephedrine HCl 15 MG/5 ML LIQUID • 20481 - pseudoephedrine HCl 30 MG TABLET • 20482 - pseudoephedrine HCl 60 MG TABLET • 26901 - pseudoephedrine HCl 120 MG TABLET ER	**REMOVE these GCNs** • 12933 - brompheniramine/pseudoephedrine 1-15MG/5ML LIQUID • 44021 - chlorpheniramine/pseudoephedrine 2-30MG/5ML LIQUID • 44023 - chlorpheniramine/pseudoephedrine 4 MG-60 MG TABLET • 34672 - codeine phosphate/guaifenesin 10-100MG/5 LIQUID • 34673 - codeine phosphate/guaifenesin 20-200/10 LIQUID • 91713 - codeine phosphate/guaifenesin 10-100MG/5 LIQUID • 17803 - dextromethorphan HBr 5 MG/5 ML SYRUP (e.g., Vicks Dayquil)) • 23807 - guaifenesin/dextromethorphan 400MG-20MG TABLET • 53497 - guaifenesin/dextromethorphan 100-5 MG/5 LIQUID • 13645 - pseudoephedrine HCl 30 MG/5 ML LIQUID (e.g., Sudafed) • 33788 - pseudoephedrine HCl 30 MG TABLET
Diagnostic Agents (designated by NDC)		
Feb 2022		**REMOVE these NDCs** • 65702012810 - prothrombin time test strips STRIP
Dietary Supplements		
Feb 2022	**RETAIN these GCNs** • 24536 - ubidecarenone 200 MG CAPSULE (e.g., Coenzyme Q10) • 95128 - ubidecarenone 100 MG CAPSULE (e.g., Coenzyme Q10)	**REMOVE these GCNs** • 49232 - ubidecarenone 30 MG CAPSULE (e.g., Coenzyme Q10)

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Devices (designated by NDC)		
Feb 2022	**RETAIN these NDCs** Sharps containers: • 08080143699 - container,empty EACH • 08290305487 - container,empty EACH • 08290305488 - container,empty EACH • 08290305490 - container,empty EACH • 08290323487 - container,empty EACH	**REMOVE these NDCs** • 38779879503 - adapter cap for bottle EACH • 08290305489 - container,empty EACH • 00283118520 - medical supply, miscellaneous EACH • 63323000130 - vial,empty VIAL • 49502020801 - inhaler,assist device,accesory EACH • 49502020802 - inhaler,assist device,accesory EACH • 49502020803 - inhaler,assist device,accesory EACH Note: inhaler spacers are covered under the pharmacy benefit at all points of service
Durable Medical Equipment		
Feb 2022		**REMOVE these NDCs** • 00573304001 - cold-hot pack EACH
Electrolyte-Mineral-Trace Element Replacement (Calcium products reviewed Feb 20): Iron Replacement		
Feb 2022	**RETAIN these GCNs** • 04515 - ferrous fumarate 324(106)MG TABLET (e.g., Hemocyte) • 30287 - ferrous gluconate 324(37.5) TABLET • 97503 - ferrous gluconate 324(38)MG TABLET • 04695 - ferrous sulfate 325(65) MG TABLET • 41529 - ferrous sulfate 220 (44)/5 ELIXIR • 97721 - ferrous sulfate 15 MG/ML DROPS • 98527 - ferrous sulfate 324(65)MG TABLET DR • 99233 - ferrous sulfate 220 (44)/5 SOLUTION • 04580 - iron polysaccharide complex 150 MG CAPSULE (e.g., Niferex 150)	**REMOVE these GCNs** • 10510 - ferrous gluconate 240(27)MG TABLET • 04663 - ferrous sulfate 300 MG/5ML LIQUID • 34358 - ferrous sulfate 220 (44)/5 ELIXIR • 33224 - iron polysaccharide complex 15 MG/ML DROPS (Novaferrum drops)
Electrolyte-Mineral-Trace Element Replacement (Calcium products reviewed Feb 20): Calcium, Magnesium, Potassium, Zinc		
Feb 2022	**RETAIN these GCNs** • 28999 - magnesium chloride 71.5 MG TABLET DR (e.g., Slow-Mag) • 92902 - magnesium chloride 64 MG TABLET DR (e.g., Slow-Mag) • 04091 - magnesium oxide 400 MG TABLET (e.g., Magox-400) • 04093 - magnesium oxide 420 MG TABLET • 04095 - magnesium oxide 500 MG TABLET • 45064 - magnesium oxide 400 MG TABLET • 05030 - potassium iodide 130 MG TABLET • 99087 - sodium,potassium phosphates 280-250MG POWD PACK (e.g., Phos-Nak) • 04911 - zinc sulfate 50(220)MG TABLET	• 33797 - magnesium carbonate 54 MG/5 ML LIQUID (Magonate) • 42769 - magnesium chloride 70 MG TABLET DR (e.g., Slow-Mag) • 45085 - magnesium oxide 400 MG TABLET • 04912 - zinc sulfate 25(110) MG TABLET

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
	• 97145 - zinc sulfate 50(220)MG CAPSULE **Already reviewed (RETAIN)** • 03721 - calcium carbonate 500(1250) TABLET • 07872 - calcium carbonate 500 MG/5ML ORAL SUSP • 23323 - calcium carbonate/vitamin D3 600 MG-10 TABLET • 09821 - calcium citrate 200(950)MG TABLET	
Emollients		
Feb 2022	**RETAIN these GCNs** • 23043 - ammonium lactate 12 % CREAM (G) • 20941 - ammonium lactate 12 % LOTION • 44160 - emollient base CREAM (G) (e.g., Vanicream) • 21329 - lanolin CREAM (G) • 46446 - lanolin 72 % OINT. (G) • 13738 - lanolin alcohol/mo/w.pet/ceres CREAM (G) (e.g., Eucerin) • 77729 - mineral oil/petrolatum, white CREAM (G) (e.g., Dermacerin) • 21689 - mineral oil/hydrophil petrolat OINT. (G) (e.g., Aquaphor) • 88340 - mineral oil/petrolatum, white OINT. (G) (Absorbase) • 36830 - petrolatum, white OINT. (G) • 69950 - petrolatum, white 41 % OINT. (G)	**REMOVE these GCNs** • 20942 - ammonium lactate 12 % LOTION • 26555 - glycerin 99.5 % SOLUTION • 22542 - lanolin 50 % OINT. (G) • 30705 - lanolin 100 % OINT. (G) • 77709 - mineral oil/w.pet/alcohols/sls CREAM (G) (Velvachol) • 32160 - vits A and D/white pet/lanolin OINT PACK
Gastrointestinal-2 Agents : Antacids		
Feb 2022	**RETAIN these GCNs** • 07893 - calcium carbonate 200(500)MG TAB CHEW • 63910 - mag hydrox/aluminum hyd/simeth 200-200-20 ORAL SUSP (e.g., Alamag) • 63915 - mag hydrox/aluminum hyd/simeth 400-400-40 ORAL SUSP • 63951 - mag hydrox/aluminum hyd/simeth 200-200-25 TAB CHEW • 64114 - magnesium carb/aluminum hydrox 105-160MG TAB CHEW (e.g., Gaviscon) • 07855 - sodium bicarbonate 650 MG TABLET	**REMOVE these GCNs** • 07894 - calcium carbonate 300MG(750) TAB CHEW • 14196 - mag carb/aluminum hydrox/algin 358-95/15 ORAL SUSP (e.g., Gaviscon) • 07852 - sodium bicarbonate 325 MG TABLET
Gastrointestinal-2 Agents : Antidiarrheals		
Feb 2022	**RETAIN these GCNs** • 08420 - bismuth subsalicylate 262 MG TAB CHEW • 26970 - bismuth subsalicylate 262MG/15ML ORAL SUSP (e.g., Kaopectate) • 08550 - loperamide HCl 2 MG TABLET	**REMOVE these GCNs** • 08421 - bismuth subsalicylate 262 MG TABLET (e.g., Kaopectate) • 26971 - bismuth subsalicylate 525MG/15ML ORAL SUSP (e.g., Kaopectate) • 08370 - loperamide HCl 2 MG CAPSULE • 23400 - loperamide HCl 1 MG/5 ML LIQUID • 25065 - loperamide HCl 1MG/7.5ML LIQUID

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Gastrointestinal-2 Agents : Probiotics		
Feb 2022	**Currently on list (to be reviewed in May 22)** • 99616 - Bifidobacterium infantis 4 MG CAPSULE (Align) • 97109 - Lactobacil 2/S.thermo/Bifido 1 900B CELL PACKET (e.g., Visbiome) • 34623 - Lactobacillus rhamnosus GG 15B CELL CAP SPRINK (e.g., Culturelle) • 36349 - Lactobacillus rhamnosus GG 5B CELL POWD PACK (e.g., Culturelle) • 92016 - Lactobacillus rhamnosus GG 10B CELL CAPSULE (e.g., Culturelle) • 05162 - Saccharomyces boulardii 250 MG CAPSULE (e.g., Florastor) • 06604 - Saccharomyces boulardii 250 MG POWD PACK (e.g., Florastor)	
Gastrointestinal-2 Agents (no subclass)		
Feb 2022	**RETAIN these GCNs** • 08260 - simethicone 40MG/0.6ML DROPS SUSP • 08281 - simethicone 80 MG TAB CHEW • 08282 - simethicone 125 MG TAB CHEW	**REMOVE these GCNs** • 94652 - simethicone 180 MG CAPSULE
Keratolytics		
Feb 2022	**RETAIN these GCNs** • 22930 - benzoyl peroxide 10 % GEL (GRAM) • 22931 - benzoyl peroxide 5 % GEL (GRAM) • 22932 - benzoyl peroxide 2.5 % GEL (GRAM) • 24673 - benzoyl peroxide 10 % CLEANSER • 99676 - benzoyl peroxide 5 % CLEANSER • 22711 - salicylic acid 17 % GEL (GRAM) (Compound W) • 22811 - salicylic acid 17 % LIQUID (e.g., Compound W) • 47162 - salicylic acid 40 % ADH. PATCH (e.g., Corn Remover) • 79591 - salicylic acid/sulfur 2 %-2 % SHAMPOO (e.g., Sebulex Shampoo) • 24772 - urea 20 % CREAM (G) (e.g., Ureacin-20, Carmol 20) • 24791 - urea 10 % LOTION (e.g., Carmol 10)	**REMOVE these GCNs** • 28610 - benzoyl peroxide 10 % LOTION • 28611 - benzoyl peroxide 5 % LOTION • 29303 - benzoyl peroxide 9.8 % FOAM (e.g., BP Foam, Enzoclear) • 22981 - benzoyl peroxide 4 % CLEANSER • 22982 - benzoyl peroxide 5 % CLEANSER • 22984 - benzoyl peroxide 10 % CLEANSER • 22818 - salicylic acid 2 % CLEANSER (e.g., Clearasil Daily Cleanser) • 22462 - salicylic acid 17 % KIT (e.g., Corn-Callus Remover) • 24770 - urea 10 % CREAM (G) (e.g., Atrac-tain)

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Laxatives-Cathartics-Stool Softeners (reviewed Feb 20)		
Feb 2022	**RETAIN these GCNs** • 07950 - magnesium hydroxide 400 MG/5ML ORAL SUSP (e.g., Milk of Magnesia) **Already reviewed (RETAIN)** • 08731 - bisacodyl 10 MG SUPP.RECT • 08762 - bisacodyl 5 MG TABLET DR • 09101 - docusate sodium 100 MG CAPSULE • 09131 - docusate sodium 50 MG/5 ML LIQUID • 08860 - glycerin ADULT SUPP.RECT • 08861 - glycerin PEDIATRIC SUPP.RECT • 09240 - magnesium citrate SOLUTION • 86212 - polyethylene glycol 3350 17 G/DOSE POWDER • 45889 - psyllium husk (with sugar) 3 G/7 G POWDER • 46303 - psyllium husk (with sugar) 3 G/12 G POWDER • 43199 - psyllium husk/aspartame 3 G/5.8 G POWDER • 00701 - sennosides 8.6 MG TABLET • 08660 - sennosides 8.8MG/5ML SYRUP • 13483 - sennosides/docusate sodium 8.6MG-50MG TABLET • 66559 - sodium phosphate,mono-dibasic 19G-7G/118 ENEMA • 98276 - sodium phosphate,mono-dibasic 9.5-3.5/59 ENEMA	
Medical Supplies (designated by NDC)		
Feb 2022		**Remove these NDCs** • 38779737402 - topical cream metered-dose dev EACH
Nasal Allergy Agents: Corticosteroids (reviewed Feb 21)		
Feb 2022	**Already reviewed (RETAIN)** • 34062 - oxymetazoline 0.05% spray (e.g., Afrin)	**REMOVE these GCNs** **None at this meeting; however, the following will be removed as a result of the Feb 21 review:** • 40708 - budesonide 32 mcg spray (e.g., Rhinocort) • 37683 - fluticasone propionate 50 mcg spray susp (e.g., Flonase Allergy) • 46790 - cromolyn sodium 5.2 mg spray (Nasalcrom) • 34182 - phenylephrine 0.125% drops (e.g., Little Noses) • 34122 - phenylephrine 0.25% spray (e.g., Neosynephrine) • 34123 - phenylephrine 0.5% spray (e.g., Neosynephrine)

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Ophthalmic Miscellaneous : Artificial Tears (reviewed Nov 19)		
Feb 2022	**Already reviewed (RETAIN)** • 34571 - carboxymethyl/gly/poly80/PF 0.5-1-0.5% DROPERETTE • 37381 - carboxymethylcellulose sodium 0.5 % DROPS • 37384 - carboxymethylcellulose sodium 0.5 % DROPERETTE • 98569 - carboxymethylcellulose sodium 1 % DROPER GEL • 28068 - mineral oil/petrolatum,white 42.5-57.3% OINT. (G) • 98935 - mineral oil/petrolatum,white 15 %-83 % OINT. (G) • 99222 - mineral oil/petrolatum,white 42.5-56.8% OINT. (G) • 99250 - mineral oil/petrolatum,white 20%-80% OINT. (G) • 99952 - mineral oil/petrolatum,white 3 %-94 % OINT. (G)	
Ophthalmic Miscellaneous (reviewed Nov 19, hypromellose 0.3% gel reviewed Aug 20)		
Feb 2022	**Already reviewed (RETAIN)** • 27956 - hypromellose 0.3 % GEL (GRAM) • 31880 - sodium chloride 5 % OINT. (G) • 31923 - sodium chloride 5 % DROPS	
Oral Care Agents : Oxidizing Agents		
Feb 2022		**REMOVE these GCNs** • 17035 - sodium hypochlorite 0.25 % SOLUTION (e.g., Dakin's) • 17036 - sodium hypochlorite 0.5 % SOLUTION (e.g., Dakin's) • 97216 - sodium hypochlorite 0.125 % SOLUTION (e.g., Dakin's)
Otic Agents		
Feb 2022	**RETAIN these GCNs** • 34401 - carbamide peroxide 6.5 % DROPS (e.g., Debrox)	
Pain Agents : Pain Miscellaneous (reviewed May 19)		
Feb 2022	**Already reviewed (RETAIN)** • 35743 - ibuprofen 200 MG TABLET • 35749 - ibuprofen 100 MG TAB CHEW • 35930 - ibuprofen 100 MG/5ML ORAL SUSP	

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Psoriasis Agents		
Feb 2022		**REMOVE these GCNs** • 99006 - coal tar 2 % OINT. (G) (e.g., Elta Tar)
Respiratory Agents Miscellaneous (reviewed Feb 21)		
Feb 2022	**Already reviewed (RETAIN)** • 36878 - sod chlor,bicarb/squeez bottle PACK W/DEV • 34291 - sodium chloride 0.65 % SPRAY • 34300 - sodium chloride 0.65 % DROPS • 24904 - sodium chloride/sodium bicarb PACKET	
Saline		
Feb 2022	**RETAIN these GCNs** • 03121 - sodium chloride 1 G TABLET	**REMOVE these GCNs** • 26657 - sodium chloride 1000 MG TABLETSOL
Sedative-Hypnotic Agents : Ethanolamines		
Feb 2022	**RETAIN these GCNs** • 11730 - doxylamine succinate 25 MG TABLET Note: Doxylamine is on the DOD pharmacy benefit and available at all three points of service	
Skin Preps : Antiseptics		
Feb 2022	**ADD these GCNs** • 28780 - alcohol antiseptic pads MED. PAD	**REMOVE these GCNs** • 27828 - phenol 1.5 % LIQUID (Castellani Paint Modified)
Skin Preps : Irritants/Counter-Irritants (muscle rubs and capsaicin reviewed May 19)		
Feb 2022	**RETAIN these GCNs** • 23611 - coal tar 0.5 % SHAMPOO (e.g., Denorex for Dry Scalp) • 23612 - coal tar 2 % SHAMPOO (e.g., X-Seb T Plus) **Already reviewed (RETAIN)** • 23373 - capsaicin 0.1 % CREAM (G) • 33560 - capsaicin 0.025 % CREAM (G)	**REMOVE these GCNs** • 23615 - coal tar 1 % SHAMPOO (e.g, T-Gel) **REMOVE these NDCs** • 41167008046 - tens unit electrodes EACH (Icy Hot Smart Relief) • 41167008045 - TENS units and TENS electrodes COMBO. PKG (Icy Hot Smart Relief)
Skin Preps : Protectives		
Feb 2022	**RETAIN these GCNs** • 97587 - calamine/zinc oxide 8 %-8 % LOTION • 46612 - modified lanolin 100 % CREAM (G) • 27937 - menthol/zinc oxide 0.44-20.6% OINT. (G) (e.g., Calmoseptine) • 35565 - petrolatum,white 42 % OINT. (G) • 22080 - zinc oxide 20 % OINT. (G) • 22083 - zinc oxide 40 % OINT. (G) (e.g., Boudreauxs)	**REMOVE these GCNs** • 36519 - lanolin,anhydrous OINT. (G) • 32838 - petrolatum,white OINT PACK • 98544 - zinc oxide 12.8% OINT. (G) (e.g, Triple Paste)

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
	• 23565 - zinc oxide 16 % OINT. (G) (e.g., Boudreauxs)	
Skin Preps (no subclass)		
Feb 2022	**RETAIN these GCNs** • 31828 - calcium acetate/aluminum sulf 952-1347MG POWD PACK (e.g., Domeboro) • 25328 - glycerin/witch hazel 12.5%-50% MED. PAD • 28286 - witch hazel 50 % MED. PAD • 78090 - parab/cet alc/stryl alc/pg/sls CLEANSER (Ceta-Klenz) **Currently on list (rectal products, to be reviewed in May 22)** • 28080 - dibucaine 1 % OINT. (G) (e.g., Nupercainal) • 35039 - phenyleph/mineral oil/petrolat 0.25 %-14% OINT/APPL (e.g., Preparation H) • 97205 - phenyleph/pramoxin/glycr/w.pet 0.25%-1% CREAM (G) (e.g., Preparation H) • 35585 - phenylephrine HCl/cocoa butter 0.25-88.44 SUPP.RECT (e.g., Preparation H)	
Sleep Disorders : Insomnia Agents (reviewed May 21)		
Feb 2022	**Already reviewed (RETAIN)** • 68738 - melatonin 3 MG TABLET • 99671 - melatonin 5 MG TABLET	**REMOVE these GCNs** **None at this meeting; however, the following will be removed as a result of the May 21 review:** • 94035 – melatonin 1 mcg tablet spray • 13448 – melatonin 5 mg SL tablet • 31649 – melatonin 10 mg MPHASE
Urinary Agents Miscellaneous		
Feb 2022	**RETAIN these GCNs** • 12000 - sod phos di, mono/K phos mono 250 MG TABLET (e.g., K-Phos Neutral)	**REMOVE these GCNs** • 14065 - potassium citrate/citric acid 1100-334/5 SOLUTION (e.g., Polycitra-K)
Vitamins : Fat Soluble (vitamin D products reviewed Feb 20)		
Feb 2022	**RETAIN these GCNs** • 94161 - vitamin A 10000 UNIT CAPSULE • 15257 - vitamin E (dl,tocopheryl acet) 90 MG CAPSULE • 14683 - vitamin E (dl,tocopheryl acet) 180 MG CAPSULE **Already reviewed (RETAIN)** • 00223 - cholecalciferol (vitamin D3) 25 MCG TABLET • 26416 - cholecalciferol (vitamin D3) 10(400)/ML DROPS • 53740 - cholecalciferol (vitamin D3) 10 MCG TABLET	**REMOVE these GCNs** • 94501 - vitamin E 50 UNIT/ML DROPS • 94531 - vitamin E 100 UNIT CAPSULE • 94532 - vitamin E 200 UNIT CAPSULE • 27554 - vitamin E 400 UNIT CAPSULE • 24957 - vitamin E (dl,tocopheryl acet) 45 MG CAPSULE • 26036 - vitamin E (dl,tocopheryl acet) 22.5MG(50) DROPS

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
	• 93242 - cholecalciferol (vitamin D3) 125 MCG CAPSULE • 94411 - ergocalciferol (vitamin D2) 200 MCG/ML DROPS	
Vitamins : Multivitamins (Renal & Ocular)		
Feb 2022	**ADD these GCNs** 35396 - vit C/E/Zn/coppr/lutein/zeaxan 250MG-90MG CAPSULE (Preservision AREDS 2) **RETAIN these GCNs** • 04332 - B complex w-C no.20/folic acid 1 MG CAPSULE (e.g., Renal Caps) • 12987 - folic acid/vit B complex and C 0.8 MG TABLET (e.g., Nephro-Vite)	
Vitamins : Multivitamins		
Feb 2022	**RETAIN these GCNs** • 95500 - multivitamin TABLET • 95501 - multivitamin,therapeutic TABLET (Thera-tabs) • 32287 - multivitamin with folic acid 400 MCG TABLET (e.g., Therems) • 42475 - multivit-mins 56/folic/K/coQ10 200-1000 TAB CHEW (e.g., Dekas Plus) • 29262 - mv-min 51/folic acid/vit K/ubi 100-350MCG TAB CHEW (e.g, Aquadeks) • 44518 - mv-mn/iron/FA/vit K/chol/coQ10 22.5MG-400 TAB CHEW (e.g., Dekas Bariatric)	**REMOVE these GCNs** • 40257 - multivit-mins 53/folic/K/coQ10 200-1000 CAPSULE ((Dekas Plus) • 28413 - multivit-min/ferrous gluconate 9 MG/15 ML LIQUID (e.g., Multi-Vite) • 33555 - multivit-min/ferrous gluconate 9 MG/15 ML LIQUID (e.g., Centrum) • 43605 - mv-mn/iron/FA/vit K/chol/coQ10 22.5MG-400 TAB CHEW
Vitamins : Pediatric		
Feb 2022	**RETAIN these GCNs** • 97775 - pedi multivit 40/phytonadione 400 MCG/ML DROPS (Aquadeks) • 48106 - pedi mv no.189/ferrous sulfate 11 MG/ML DROPS (Poly-Vi-Sol with Iron) • 48289 - pediatric multivitamin no.192 250-50/ML DROPS (Poly-Vi-Sol)	**REMOVE these GCNs** • 40267 - pedi multivit no.128/vitamin K 500 MCG/ML LIQUID (Dekas Plus) • 36166 - vit A palmitate/vit C/vit D3 750-35/ML DROPS (e.g, Pedia Tri-Vite) • 48267 - vit A palmitate/vit C/vit D3 250-50/ML DROPS (Tri-Vi-Sol)
Vitamins : Prenatal (reviewed Nov 17)		
Feb 2022	**ADD these GCNs** • 46129 - PNV151/Fe/FA/o3/dha/epa/fish 27-800-260 CAPSULE (Prenatal Multi-DHA) **RETAIN these GCNs** • 30909 - PNV no.95/ferrous fum/folic ac 28MG-0.8MG TABLET • 44966 - prenatal no.137/iron/folic acd 27MG-0.8MG TABLET • 30958 - prenatal vits96/iron fum/folic 27MG-0.8MG TABLET Note: numerous legend prenatal vitamins are dispensed at all three points of service	

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Vitamins : Water Soluble (Vitamins B1, B2, B6, B7)		
Feb 2022	**RETAIN these GCNs** • 95032 - thiamine HCl 50 MG TABLET (vit B1) • 95033 - thiamine HCl 100 MG TABLET (vit B1) • 65061 - thiamine mononitrate 100 MG TABLET (vit B1) • 95014 - riboflavin 100 MG TABLET (vit B2) • 94971 - pyridoxine HCl 100 MG TABLET (vit B6) • 94976 - pyridoxine HCl 50 MG TABLET (vit B6) • 94977 - pyridoxine HCl 25 MG TABLET (vit B6)	**REMOVE these GCNs** • 16993 - biotin 5 MG CAPSULE (vit B7) • 16994 - biotin 5 MG TABLET (vit B7)
Vitamins : Water Soluble (Vitamin B12, Folic Acid, Vitamin C)		
Feb 2022	**RETAIN these GCNs** • 94565 - cyanocobalamin 500 MCG TABLET (vitamin B12) • 94566 - cyanocobalamin 1000 MCG TABLET (vitamin B13) • 94783 - folic acid 0.4 MG TABLET • 27629 - levomefolate calcium 15 MG TABLET (e.g., Elfolate) • 28219 - mecobal/levomefolat Ca/B6 phos 2-3-35 MG TABLET (e.g., Foltanx) • 94327 - ascorbic acid 500 MG TABLET (vit C)	• 94563 - cyanocobalamin 100 MCG TABLET (vitamin B12) • 94700 - cyanocobalamin 1000 MCG TAB SUBL (vitamin B14) • 94784 - folic acid 0.8 MG TABLET • 26718 - levomefolate calcium 7.5 MG TABLET (e.g., Elfolate) • 34346 - levomefolate/algal oil 7.5-90.314 CAPSULE (e.g., Deplin-Algal Oil) • 34347 - levomefolate/algal oil 15-90.314 CAPSULE (e.g., Deplin-Algal Oil) • 20602 - ascorbic acid 500 MG/5ML LIQUID • 94333 - ascorbic acid 500 MG TAB CHEW • 94363 - ascorbic acid 500 MG/5ML SYRUP

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

I. CONVENING

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

II. ATTENDANCE

The attendance roster is listed in Appendix A.

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

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

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

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

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

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

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

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

Overall Conclusions

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

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

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

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

   - UF
     - dulaglutide (Trulicity)
   - NF
     - semaglutide (Ozempic)
     - exenatide once weekly (Bydureon BCise) *moves from UF/BCF to NF*
     - exenatide twice daily (Byetta)
     - liraglutide (Victoza)
     - lixisenatide (Adlyxin)
     - Note that for Bydureon BCise, Byetta, Victoza and Adlyxin, a trial of both Trulicity and Ozempic are required
   - Tier 4 (Not covered) - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***PA criteria have applied to the GLP1RAs for several years, requiring a trial of metformin first, unless the patient has had an adverse event, inadequate response or a contraindication. Currently a trial of dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise) are required, prior to use of one of the non-step-preferred products.

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

   All new and current users of Bydureon BCise (which is now moving to NF status), Byetta, Victoza and Adlyxin will now require a trial of both Trulicity and Ozempic. Children as young as 10 years can receive Victoza or Bydureon BCise without a trial of Trulicity and Ozempic, as these two products are the only GLP1RAs approved for children. *(Note that after the May 2022 meeting a clinical trial evaluating use of Trulicity in adolescents was published; even though Trulicity is not currently approved for use in adolescents, the PA will allow use of Trulicity for children.)* See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: BCF RECOMMENATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) adding dulaglutide (Trulicity) to the Basic Core Formulary (BCF) and removing exenatide once weekly (Bydureon BCise) from the BCF.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) medical necessity criteria for Adlyxin, Byetta, Bydureon BCise, Ozempic, and Victoza. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS —***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the GLP1RAs on the EMMPI list.

6. ***COMMITTEE ACTION: UF, BCF, MN, PA, EMMPI and IMPLEMENTATION PERIOD—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service.; and 2) DHA send letters to beneficiaries who are affected by the formulary decision. (See Appendix G for the actual implementation dates.)

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

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

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

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

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

Professional Treatment Guidelines

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

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

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

Efficacy

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

Safety

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

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

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

Distinguishing Characteristics

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

Overall Conclusions

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

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

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

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

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

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

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

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

3. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the quantity limits for Ubrelvy and Qulipta, and updating the QLs for Nurtec ODT, to allow for the migraine prevention indication (which will be approved in the PA criteria). See Appendix D for the full QLs.

4. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining excluding the three oral CGRP antagonists from the EMMPI program.

5. ***COMMITTEE ACTION: UF, PA, QUANTITY LIMITS, EMMPI IMPLEMENTATION PERIOD—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. (See Appendix G for the actual implementation date.)

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent; and Group 2: 16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 2022 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—*** The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following:

   - UF
     - filgrastim-ayow injection (Releuko) – White Blood Cell Stimulants - filgrastims. Note that as part of this recommendation Releuko will be designated as non-step-preferred.
     - mitapivat (Pyrukynd) – Miscellaneous metabolic agent for pyruvate kinase deficiency
     - naloxone 5 mg/0.5mL injection (Zimhi) – Narcotic Antagonist
     - pacritinib (Vonjo) – Oncologic agent for myelofibrosis
   - NF

- abrocitinib (Cibinqo) – Atopy drug class; oral Janus kinase (JAK) inhibitor for atopic dermatitis
- baclofen oral suspension (Fleqsuvy) – Skeletal Muscle Relaxant spasticity associated with multiple sclerosis
- tenapanor (Ibsrela) – Gastrointestinal-2 Agent for Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
- tralokinumab-ldrm injection (Adbry) – Atopy drug class; injectable agent for atopic dermatitis

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

- Alternatives include torsemide tablets, bumetanide, furosemide, and ethacrynic acid.

- tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twyneo) – Acne Agent; combination of tretinoin and benzoyl peroxide approved for acne vulgaris in 9 years of age and older
  - Alternatives include the individual components of tretinoin and benzoyl peroxide, Epiduo, Epiduo Forte

2. ***COMMITTEE ACTION: MN CRITERIA—*** The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for criteria for Adbry, Cibinqo, Fleqsuvy, and Ibsrela (see Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: PA CRITERIA—*** The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Releuko will be non-step-preferred, requiring a trial of both Granix and Nivestym prior to use. The same manual PA criteria that currently applies to the non-step-preferred filgrastims Neupogen and Zarxio will apply to new users of Releuko.
- Applying manual PA criteria to new users of Adbry and Cibinqo, requiring a trial of topical corticosteroids and topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus), similar to the requirements for other products approved for atopic dermatitis, including Dupixent, Opzelura cream and Rinvoq (*see Utilization Management section*).
- Applying manual PA criteria to new users of Fleqsuvy, similar to the current PA for baclofen oral solution (Ozobax).
- Applying manual PA criteria to new users of Ibsrela, similar to the current PA for prucalopride (Motegrity).
- Applying manual PA criteria to new users of Pyrukynd, consistent with the FDA indications and monitoring requirements.

4. ***COMMITTEE ACTION: EMMPI—*** The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

5. ***COMMITTEE ACTION: UF, TIER 4, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following

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

VI. UTILIZATION MANAGEMENT

A. PA Criteria

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

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

a) **Antiemetic/Antivertigo Agents—meclizine 25 mg chewable tablet (Antivert)—**Meclizine is an older antiemetic widely available in 12.5 mg and 25 mg tablets in prescription and over-the-counter (OTC) formulations. A new 25 mg chewable tablet has come to market manufactured by a single company which requires a prescription prior to dispensing.

b) **Endocrine Agents Miscellaneous—lanreotide 120 mg injection—**Lanreotide 120 mg injection is a new Somatuline Depot formulation only available in this one dosage strength. Somatuline Depot is more cost-effective than the lanreotide 120 mg injection made by a sole manufacturer.

c) **Selective Serotonin Reuptake Inhibitors (SSRIs)—citalopram 30 mg capsule—**Citalopram 30 mg capsules are manufactured by a single company and are markedly not cost-effective relative to other generic SSRIs. All other formulations of citalopram and various other SSRIs are included on the TRICARE pharmacy benefit and do not require prior authorization criteria.

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

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

2. Updated PA Criteria for New FDA-Approved Indications

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

a) **Anticonvulsants-Antimania Agents—fenfluramine oral solution (Fintepla)**—The manual PA criteria were updated to expand use for Lennox-Gastaut syndrome.

b) **Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)**—The manual PA criteria were updated to expand use for adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy**.**

c) **Targeted Immunomodulatory Biologics (TIBs)**

- **ustekinumab (Stelara)**—The manual PA criteria were updated to expand use for moderate to severe ulcerative colitis (UC). Patients must first try adalimumab (Humira) before use of Stelara for UC. Alternatively, the medical benefit drug infliximab (Remicade) may be used first in lieu of Humira.
- **upadacitinib (Rinvoq)—**The manual PA criteria were updated for Rinvoq to expand use for atopic dermatitis (AD) and moderately to severely active ulcerative colitis (UC). For AD, patients must first try a high potency topical corticosteroid and a topical calcineurin inhibitor similar to other agents approved for AD. For UC, patients must first try adalimumab (Humira) before use of Rinvoq. Additionally, other non-

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

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

3. Updated PA Criteria for Removal of Indication

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

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

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

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

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

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

c) **Anti-Inflammatory Immunomodulatory Ophthalmic Agents: cenegermin-bkbj ophthalmic solution (Oxervate)**—Oxervate was reviewed as a new drug in February 2019 and is FDA-approved to treat neurotrophic keratitis. Manual PA criteria currently allow for an indefinite duration of use. PA Criteria were updated to expire after 6 months to ensure an appropriate duration of therapy, consistent with the product labeling for Oxervate.

d) **Miscellaneous Insulin Devices: Omnipod, Omnipod DASH**—Manual PA criteria and quantity limits were recommended for Omnipod and Omnipod DASH in November 2021. These devices may be used for up to 72 hours but could be changed every 48 hours. The renewal PA criteria were updated to remove the previously listed limit for duration of use. QLs were updated to reflect the change as well (See section below on QLs and Appendix C).

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

B. Quantity Limits

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

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

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

C. Line Extensions

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

a) **Anticoagulants—**designating **rivaroxaban 1 mg/mL oral solution (Xarelto)** as UF, with the same formulary status and EMMPI List status as Xarelto tablets

b) **Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis—**designating **lanadelumab-flyo (Takhzyro) 300 mg/2 mL syringe** as UF, with the same manual PA criteria requirements, QL, and specialty status as Takhzyro vials

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

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

X. ITEMS FOR INFORMATION

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

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

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

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

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

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

XI. ADJOURNMENT

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

Appendix A—Attendance: May 4-5, 2022 DoD P&T Committee Meeting:
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 2022 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives
Appendix I—MHS GENESIS OTC Text List

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

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

27 Jul 2022
Date

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

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

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• semaglutide (Ozempic) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Patient has experienced significant adverse effects from dulaglutide (Trulicity) which is not expected to occur with semaglutide (Ozempic) **Formulary alternatives:** dulaglutide (Trulicity)
• exenatide once weekly (Bydureon BCise) • exenatide twice daily (Byetta) • liraglutide (Victoza) • lixisenatide (Adlyxin) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Patient has experienced significant adverse effects from dulaglutide (Trulicity) and semaglutide (Ozempic) which is not expected with the non-preferred products. • No alternative formulary agent - for Victoza and Bydureon BCise only: patient is between the ages of 10 to less than 18 years **Formulary and non-formulary alternatives:** dulaglutide (Trulicity) and semaglutide (Ozempic)
Newly Approved Drugs MN Criteria	
• abrocitinib (Cibinqo) **Atopy**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** dupilumab (Dupixent), topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus), high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
• baclofen oral suspension (Fleqsuvy) **Skeletal Muscle Relaxants & Combinations**	• No alternative formulary agent. Patient cannot swallow and crushed tablets are not an option. **Formulary alternatives:** baclofen tablets
• tenapanor (Ibsrela) **Gastrointestinal-2: CIC & IBS-C**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** Linzess, Trulance, Amitiza
• tralokinumab injection (Adbry) **Atopy**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** dupilumab (Dupixent), topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus), high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	

• dulaglutide (Trulicity)
• semaglutide (Ozempic)
 	
Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)
	The only change from the May 2022 meeting is new patients receiving Ozempic do not require a trial of Trulicity first.
	
	All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.
	
	Manual PA criteria—Trulicity or Ozempic are approved (i.e., a trial of metformin is NOT required) if:
	
	• The patient has a confirmed diagnosis of Type 2 diabetes mellitus.
	• The patient has experienced any of the following issues on metformin:
	  • impaired renal function precluding treatment with metformin
	  • history of lactic acidosis
	• The patient has had inadequate response to metformin
	• The patient has a contraindication to metformin
	
	Non-FDA-approved uses are not approved.
	Prior Authorization does not expire.

• exenatide once weekly (Bydureon BCise)
• exenatide twice daily (Byetta)
• liraglutide (Victoza)
• lixisenatide (Adlyxin)
 	
Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)
	Changes from the May 2022 meeting are in bold and strikethrough.
	
	All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.
	
	New and current users of Bydureon BCise, Byetta, Victoza, or Adlyxin, must try ~~Bydureon/Bydureon BCise~~ Trulicity and Ozempic first.
	
	Manual PA criteria—Bydureon BCise, Byetta, Victoza, or Adlyxin is approved (i.e., a trial of metformin is NOT required) if:
	
	• The patient has a confirmed diagnosis of Type 2 diabetes mellitus.
	• The patient has experienced any of the following issues on metformin:
	  • impaired renal function precluding treatment with metformin
	  • history of lactic acidosis
	• The patient has had inadequate response to metformin
	• The patient has a contraindication to metformin
	
	AND
	
	In addition to the above criteria regarding metformin the following PA criteria would apply specifically to new and current users of Bydureon BCise, Byetta, Victoza, and Adlyxin:
	
	• The patient has had an inadequate response to Trulicity and **~~Bydureon BCise~~ Ozempic OR**
	• **For Victoza and Bydureon BCise, patient is age 10 years to < 18 years.**
	
	Non-FDA-approved uses are not approved.
	Prior Authorization does not expire

• atogepant (Qulipta) **Migraine Agents oral CGRP**	**There were no changes made at the May 2022 meeting** Manual PA criteria apply to all new users of Qulipta. Manual PA criteria: Qulipta is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed • Patient has Episodic Migraine as defined by the following: o 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 8 to 14 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. Prior Authorization expires after 6 months. Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply: • 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: • Migraine Disability Assessment (MIDAS) - Reduction of ≥ 5 points when baseline score is 11–20 - Reduction of ≥ 30% when baseline score is > 20 • Headache Impact Test (HIT-6) - Reduction of ≥ 5 points • Migraine Physical Functional Impact Diary (MPFID) - Reduction of ≥ 5 points

• rimegepant (Nurtec ODT) **Migraine Agents oral CGRP**	**Updates from the May 2022 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of rimegepant (Nurtec ODT). Manual PA criteria: Nurtec ODT is approved if all 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**~~ For Acute Treatment • 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) For Prevention of Episodic Migraine • 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) • **If approved for prevention: authorized quantity limit is 16 ODT for 30 days or 48 ODT for 90 days** Non-FDA-approved uses are NOT approved. PA expires after 6 months. Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply: 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: • Migraine Disability Assessment (MIDAS) - Reduction of ≥ 5 points when baseline score is 11–20 - Reduction of ≥ 30% when baseline score is > 20 • Headache Impact Test (HIT-6): Reduction of ≥ 5 points • Migraine Physical Functional Impact Diary (MPFID): Reduction of ≥ 5 points

• ubrogepant (Ubrelvy) **Migraine Agents oral CGRP**	**Updates from the May 2022 Meeting are in strikethrough.** Manual PA criteria apply to all new users of ubrogepant (Ubrelvy). Manual PA criteria: Ubrelvy is approved if all 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 • 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
Newly Approved Drug PAs	

• abrocitinib (Cibinqo)
 	
Atopy
	Manual PA criteria apply to all new users of abrocitinib (Cibinqo).
	
	Manual PA criteria: abrocitinib (Cibinqo) is approved if all criteria are met:
	• Patient is 18 years of age or older
	• Medication is prescribed by an allergist, dermatologist, or immunologist
	• Drug is used to treat moderate to severe atopic dermatitis
	• Patient failed, has a contraindication, or intolerability to one medication in EACH of the following two categories:
	  • Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND
	  • Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
	• Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy
	• Patient has had a negative TB test in the last 12 months (or is adequately managed)
	• Patient has no history of venous thromboembolism (VTE)
	• Provider is aware of the boxed FDA warnings
	• Patient does not have neutropenia (ANC < 1000)
	• Patient does not have lymphocytopenia (ALC < 500)
	• Patient does not have anemia (Hgb < 8)
	• Patient is not taking a concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulatorys
	Non-FDA-approved uses are not approved.
	PA expires in 1 year. Renewal PA criteria will be approved indefinitely.
	Renewal criteria: The patient's disease severity has improved and stabilized to warrant continued therapy

• baclofen oral suspension (Fleqsuvy) **Skeletal Muscle Relaxants & Combinations**	Manual PA criteria apply to all new users of baclofen oral solution (Ozobax) and **baclofen oral suspension (Fleqsuvy)**. Manual PA criteria: baclofen oral solution (Ozobax) or **baclofen oral suspension (Fleqsuvy)** is approved if all criteria are met: • Baclofen will be used for spasticity • Patient requires baclofen and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience Non-FDA-approved uses are not approved. Prior authorization does not expire.
• filgrastim-ayow injection (Releuko) **WBC Stimulants: Filgrastims**	Manual PA criteria apply to all new users of filgrastim (Neupogen), **filgrastim-ayow (Releuko)**, and filgrastim-sndz (Zarxio). Manual PA criteria: filgrastim (Neupogen), **filgrastim-ayow (Releuko)**, or filgrastim-sndz (Zarxio) is approved if all criteria are met: • Provider acknowledges that tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) are the preferred filgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen), filgrastim-sndz (Zarxio), or filgrastim-ayow (Releuko) • Patient has experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen), filgrastim-sndz (Zarxio), or filgrastim-ayow (Releuko) Non-FDA-approved uses are not approved. Prior authorization does not expire.

• tenapanor (Ibsrela)
 	
Gastrointestinal-2: CIC & IBS-C
	Manual PA criteria apply to all new users of Ibsrela.
	Manual PA criteria: Ibsrela is approved if all criteria are met:
	• Patient is 18 years of age or older
	• Patient has had documented symptoms for ≥ 3 months
	• Patient has diagnosis of IBS-C
	• Patient has tried and failed all formulary agents including Linzess, Amitiza, and Trulance
	• Patient does not have GI obstruction
	• Patient has documentation of failure of an increase in dietary fiber/dietary modification
	• Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes defined as:
	  ◦ osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)
	  ◦ bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids;
	  ◦ stool softener (e.g., docusate)
	  ◦ stimulant laxative (e.g., bisacodyl, sennosides)
	• Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Trulance, Zelnorm, Motegrity, Symproic, Relistor, or Movantik)
	Non-FDA-approved uses are not approved including opioid-induced constipation (OIC), chronic idiopathic constipation (CIC), and hyperphosphatemia.
	Prior authorization expires in 1 year.
	Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved for an additional year if both of the following applies:
	• Patient has had improvement in constipation symptoms
	• Patient is not taking any of these agents concomitantly Amitiza, Linzess, Trulance, Motegrity, Zelnorm, Symproic, Relistor, Movantik

• tralokinumab-ldrm injection (Adbry)
 	
Atopy
	Manual PA criteria apply to all new users of Adbry.
	
	Manual PA criteria: Adbry is approved if all criteria are met:
	• Patient is 18 years of age or older
	• The drug is prescribed by a dermatologist, allergist, or immunologist
	• The patient has moderate to severe atopic dermatitis
	• The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
	  • Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND
	  • Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
	• The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
	
	Non-FDA-approved uses are not approved.
	PA expires in 1 year
	
	Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:
	• The patient's disease severity has improved and stabilized to warrant continued therapy.

• mitapivat (Pyrukynd) **Metabolic Agents-Miscellaneous: Replacement Enzymes**	Manual PA criteria apply to all new users of Pyrukynd. Manual PA criteria: Pyrukynd is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a documented diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency • Patient has a documented presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, at least one of which is a missense variant • Patient has a hemoglobin less than or equal to 10 g/dL • Patient and provider are aware that abrupt discontinuation may lead to acute hemolysis Non-FDA-approved uses are not approved including patients who were homozygous for the c.1436G>A (p.R479H) variant or had 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Prior authorization expires in 6 months. Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies: • Patient has experienced a ≥ 1.5 g/dL sustained increase in Hgb from baseline after 24 weeks of therapy.

Utilization Management New PAs	
• citalopram 30 mg capsule **Antidepressants and Non-Opioid Pain Syndromes: SSRIs**	Manual PA criteria apply to all new and current users of citalopram 30 mg capsules. Manual PA criteria: Citalopram 30 mg capsule is approved if all criteria are met: • Provider acknowledges other strengths of citalopram and other formulary SSRIs are available without prior authorization. • Provider must explain why the patient cannot take a combination of lower strengths to achieve the desired dose. Non-FDA-approved uses are not approved. Prior authorization does not expire.
• ketoprofen 25 mg capsule • **Pain Agents: NSAIDs**	Manual PA criteria apply to new and current users of ketoprofen 25 mg capsule. Manual PA criteria: Ketoprofen 25 mg capsule is approved if all criteria are met: • Provider acknowledges that other strengths of ketoprofen and other formulary NSAIDs are available without the need of prior authorization. • The provider must explain why the patient requires ketoprofen 25 mg capsule and cannot take the cost-effective generic ketoprofen or other formulary NSAIDs Non-FDA-approved uses are not approved. Prior authorization does not expire.
• lanreotide acetate 120 mg injection **Endocrine Agents Misc**	Manual PA criteria apply to all new and current users of lanreotide acetate 120 mg injection. Manual PA criteria: Lanreotide acetate 120 mg injection is approved if all criteria are met: • Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization. • Provider must explain why the patient cannot use the 120 mg Somatuline Depot brand. Non-FDA-approved uses are not approved. Prior authorization does not expire.
• meclizine 25 mg chewable tab (Antivert) **Anti-Emetic/ Antivertigo Agents**	Manual PA criteria apply to new and current users of meclizine 25 mg chewable tablet (Antivert). Manual PA criteria: Meclizine 25 mg chewable tablet (Antivert) is approved if all criteria are met: • Provider is aware and acknowledges that meclizine 25 mg tablet is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred meclizine 25 mg tablet • The provider must explain why the patient requires meclizine 25 mg chewable tablet (Antivert) and cannot take the cost-effective meclizine 25 mg tablet (fill-in blank) Non-FDA-approved uses are not approved. Prior authorization does not expire.

• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	**Updates from the May 2022 meeting are in strikethrough.** Manual PA applies to all new users of Firdapse. Manual PA Criteria: Firdapse is approved if: • ~~Provider acknowledges that amifampridine (Ruzurgi) is a cost-effective alternative to Firdapse and is the preferred amifampridine agent. The provider should consider writing a new prescription for Ruzurgi.~~ • Patient is 18 years of age or older • Firdapse is prescribed by an oncologist or neurologist • The patient has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS) • ~~The patient must try amifampridine (Ruzurgi) first~~ Non-FDA-approved uses are not approved. PA does not expire.
• cenegermin-bkbj ophthalmic solution (Oxervate) **Anti-inflammatory Immunomodulatory Ophthalmic Agents**	**Updates from the May 2022 meeting are in bold and strikethrough**. Manual PA criteria apply to all new users of Oxervate. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 2 years • Patient has a documented diagnosis of neurotrophic keratitis • Drug is prescribed by a cornea specialist or ophthalmologist • Patient does not wear contact lenses during treatment course Non-FDA-approved uses are NOT approved. PA ~~does not expire~~ **expires after 6 months**.
• cyclosporine 0.05% ophthalmic emulsion single-dose **Anti-Inflammatory Immunomodulatory Ophthalmics: Ophthalmic Immunomodulatory Agents Subclass**	Manual PA criteria applies to new and current users (at MTF and Mail) of generic cyclosporine 0.05% ophthalmic emulsion. Manual PA criteria – Cyclosporine 0.05% ophthalmic emulsion generics are approved if all criteria are met: • The brand Restasis single-dose formulation is DoD's preferred product over generic single-dose cyclosporine 0.05% ophthalmic emulsion and is covered at the lowest copayment, which is the generic formulary copayment for non-Active Duty patients, and at no cost share for Active Duty patients. (Although Restasis is a branded product, it will be covered at the generic formulary copayment or cost share.) • Please provide a patient-specific justification as to why the generic single-dose cyclosporine 0.05% ophthalmic emulsion product must be used in this patient: _____(fill in the blank) Non-FDA approved uses are not approved. Prior Authorization does not expire.

• fenfluramine oral solution (Fintepla) **Anticonvulsants-Antimania Agents**	**Changes from the May 2022 meeting are in bold.** Manual PA is required for all new users of Fintepla. Manual PA Criteria: Fintepla is approved if all criteria are met. • Must be prescribed by a neurologist • Patient has a diagnosis of Dravet Syndrome **or Lennox-Gastaut syndrome** • Must be used as adjunct therapy with other anticonvulsant medications • Prescriber must abide by and the patient has been informed of the REMS program including safety risks and requirements of regular echocardiogram (ECHO) monitoring for valvular heart disease and pulmonary hypertension Non-FDA-approved uses are not approved including for weight loss. Prior authorization does not expire.
• Omnipod and Omnipod DASH **Insulins: Miscellaneous Insulin Device**	**Updates from the May 2022 meeting are in bold and strikethrough**. 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)**~~

• upadacitinib (Rinvoq) **Targeted Immunomodulatory Biologics (TIBs): Miscellaneous**	**Updates from the May 2022 meeting are in bold.** Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq ER). Manual PA Criteria: Rinvoq is approved if all criteria are met: *For Rheumatoid Arthritis* • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis • The provider also acknowledges that for rheumatoid arthritis a trial of Xeljanz or Olumiant is required before Rinvoq. • The patient is 18 years of age or older • The patient has a diagnosis of active rheumatoid arthritis (RA) • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz or Olumiant OR • Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with Rinvoq OR • Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq *For Psoriatic Arthritis* • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for psoriatic arthritis. • The provider also acknowledges that for psoriatic arthritis a trial of Xeljanz is required before Rinvoq. • The patient has a diagnosis of active psoriatic arthritis (PsA) • The patient is 18 years of age or older • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz OR • Patient has experienced an adverse reaction to Xeljanz or OR Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq ***For Atopic Dermatitis*** • **The patient is 12 years of age or older** • **The drug is prescribed by a dermatologist, allergist, or immunologist** • **The patient has moderate to severe atopic dermatitis** • **The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent)** • **The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:** ▪ **Topical Corticosteroids:**

	○ **For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)** ○ **For patients 12 to 17 year of age: any topical corticosteroid AND** ▪ **Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)** • **The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy** ***For Ulcerative Colitis*** • **Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis** • **The patient is 18 years of age or older** • **The patient has moderately to severely active ulcerative colitis** • **Patient has had an inadequate response to Humira OR** • **Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR** • **Patient has a contraindication to Humira** • **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.)** *For all indications* • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not receiving other targeted immunobiologics with Rinvoq ER except for Otezla, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Talz, Xeljanz or Xeljanz XR or Tremfya? Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, or ulcerative colitis **For atopic dermatitis, PA expires in 1 year** **<u>Renewal criteria</u>: initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if the following apply:** • **Atopic Dermatitis - The patient's disease severity has improved and stabilized to warrant continued therapy**

• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs): Non-TNF Inhibitors**	**Updates from the May 2022 meeting are in bold.** Note that Humira is the Department of Defense's preferred targeted biologic agent. 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, coverage is approved for Stelara if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Adverse reactions to Humira not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy (patients between the ages of 6 and 17 may receive Stelara for plaque psoriasis without the requirement to try Humira first) • Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids, or TNF blockers. (November 2016) • **Moderate to severe ulcerative colitis (UC); may use infliximab first in lieu of Humira** Non-FDA approved uses are not approved. PA does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), apremilast (Otezla), or rituximab (Rituxan

• testosterone cypionate and testosterone enanthate IM injections
 	
Androgens-Anabolic Steroids: Testosterone Replacement Therapies
	Changes from the May 2022 meeting are in strikethrough.
	
	Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections.
	
	Manual PA Criteria: testosterone cypionate and testosterone enanthate IM injections are approved if all criteria are met:
	• Coverage approved for male patients if:
	  • Patient is over the age of 17 years AND
	  • Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND
	  • Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND
	  • The patient does not have prostate cancer AND
	  • The patient is experiencing symptoms usually associated with hypogonadism
	OR

	• Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:
	  • Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM
	  • Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND
	  • Patient has no signs of breast cancer AND
	  • For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND
	  • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND
	  • ~~**Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria**~~
	
	Non-FDA-approved uses are NOT approved.
	Not approved for concomitant use with other testosterone products.
	Prior Authorization does not expire

• olaparib (Lynparza)
 	
Oncological Agents: Ovarian Cancer
	Changes from the May 2022 meeting are in bold.
	
	Manual PA criteria applies to all new users of Lynparza.
	
	<u>Manual PA Criteria:</u> Lynparza is approved if <u>all</u> criteria are met:
	• Patient is 18 years of age or older
	• Prescribed by or in consultation with a hematologist/oncologist or urologist
	• Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test *see prostate diagnosis below for exception*
	• Lynparza will be prescribed as treatment for one of the following diagnoses:
	  • Recurrent or Stage IV Triple negative breast cancer
	  • Recurrent or Stage IV hormone receptor (+) (ER, PR, or both) HER2 (-) breast cancer AND was either:
	  • Previously treated with prior endocrine therapy OR
	  • Was not an appropriate candidate for endocrine therapy
	  • Recurrent advanced ovarian cancers (platinum-sensitive or platinum-resistant), fallopian tube or primary peritoneal cancers AND
	  • Patient has received at least 3 prior lines of therapy AND
	  • Lynparza will not be used as a single agent
	
	  • Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene (e.g. BRCA, ATM)-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior androgen receptor-directed therapy and taxane-based chemotherapy
	  • Of note, a patient does not require both a BRCA mutation and another separate HRR mutation; any HRR mutation satisfies requirement – this is an exception to the initial requirement that a patient have a BRCA mutation specifically
	
	  • **Deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy**
	OR
	• Lynparza will be prescribed as maintenance therapy for one of the following diagnoses:
	  • Platinum-sensitive, relapsed, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND

	• Patient has received 2 or more lines of platinum-based chemotherapy • Patient was in objective response (either complete or partial) to most recent treatment regimen Lynparza will not be combined with bevacizumab (Avastin) • Newly diagnosed, advanced, high-grade, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND • Patient has had a complete or partial response to primary therapy with a platinum-based therapy • Metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis: _____. • Female patients are not pregnant or planning to become pregnant and will use highly effective contraception while taking Lynparza and for 6 months after the last dose • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Male patients will use effective contraception while taking Lynparza and for at least 3 months after cessation of therapy Other non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• idelalisib (Zydelig) **Oncological Agents**	**Changes from the May 2022 meeting are in strikethrough.** Manual PA criteria applies to new users of Zydelig. <u>Manual PA Criteria:</u> Coverage for Zydelig is approved if <u>all</u> criteria are met: • Age ≥ 18 years • Drug is prescribed by or in consultation with a hematologist or oncologist • Zydelig will be used in one of the following indications: o Relapsed/refractory therapy for CLL/~~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 • Patient < 65 years old o Relapsed/refractory therapy for CLL/~~SLL~~ with del(17p)/TP53 mutation ~~o Relapsed/refractory follicular lymphoma AND:~~ ~~▪ Patient has completed ≥ 2 prior therapies **OR**~~ ~~▪ Patient has completed 1 prior therapy and relapsed ≤ 2 years~~ o Relapsed/refractory marginal zone lymphoma after 2 prior therapies • Provider has reviewed the REMS program including the letter to healthcare providers and the fact sheet and has shared the medication guide and patient safety information card with the patient • Will monitor for hepatotoxicity, colitis, intestinal perforation, pneumonitis, infection, neutropenia, and Steven Johnson Syndrome/toxic epidermal necrolysis • Will monitor for cytomegalovirus reactivation • Will prophylax for *Pneumocystis jiroveci* pneumonia • If the patient is female, she is not pregnant or planning to become pregnant

	• Female patients will not breastfeed • Female patients of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation • Male patients of reproductive potential will use effective contraception during treatment and for at least 3 months 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: _____ Non-FDA approved uses are NOT approved. Prior Authorization does not expire.

Drug / Drug Class	Quantity Limits
• ubrogepant (Ubrelvy) **Migraine Agents oral CGRPs**	▪ Retail: 10 tabs/30 days ▪ MTF/Mail: 30 tabs/90 days ▪ Note that Ubrelvy is currently available only as cartons containing 10 tablets per carton
• rimegepant (Nurtec ODT) **Migraine Agents oral CGRPs**	**For Acute Migraine Indication:** ▪ Retail: 8 ODT/30 days ▪ MTF/Mail: 24 ODT/90 days **For Migraine Prevention Indication, approved through PA process:** ▪ Retail: 16 ODT/30 days ▪ MTF/Mail: 48 ODT/90 days ▪ Note that Nurtec ODT is only available as 8 ODT per pack
• atogepant (Qulipta) **Migraine Agents oral CGRPs**	▪ Retail: 30 tabs/30 days ▪ MTF/Mail: 90 tabs/90 days
• abrocitinib (Cibinqo) **Atopy**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• naloxone 5 mg/0.5mL injection (Zimhi) **Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists**	▪ All points of service: 4 cartridges (2 packs) per fill
• pacritinib (Vonjo) **Oncological Agents: Myelofibrosis**	▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
• tralokinumab-ldrm injection (Adbry) **Atopy**	▪ Retail: 4 syringes/fill and a 30 day supply ▪ MTF/Mail: 8 syringes/fill and a 60 day supply
• alectinib (Alecensa) **Oncological Agents: Lung Cancer**	**Changes from the May 2022 meeting are in bold.** ▪ Retail: **30 day supply** ▪ MTF/Mail: **60 day supply**

Drug / Drug Class	Quantity Limits
• axitinib (Inlyta) **Oncological Agents: Renal Cell Carcinoma**	▪ Retail: 30 day supply ▪ MTF/Mail 60day supply
• Omnipod/Omnipod DASH **Insulins: Miscellaneous Insulin Device**	**Changes from the May 2022 meeting are in bold.** ▪ Retail: **#15 pods in 30 days** ▪ Mail/MTF: **#45 pods in 90 days**

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
abrocitinib (Cibinqo) Atopy	• Rinvoq • Dupixent • Adbry	• 50, 100, 200 mg tablets • 100 mg orally QD, may increase to 200 mg daily if no response	Adults with refractory, moderate-severe atopic dermatitis	• Black Box warning-serious infection, mortality, malignancy, major CV events, thrombosis	• 2nd oral JAK-1 inhibitor for moderate-severe atopic dermatitis in adults • More effective at improving IGA score and EASI-75 response by week 12 relative to placebo • Indirect network meta-analysis demonstrates Cibinqo at higher dose more effective relative to comparators • Carries notable black box safety warnings extrapolated from tofacitinib (Xeljanz) surveillance data with limited long-term data currently for atopic patients • Provides little to no significant clinical advantage relative to other UF options	• NF
baclofen oral suspension (Fleqsuvy) Skeletal Muscle Relaxants & Combinations	• baclofen tablets • baclofen oral solution (Ozobax)	• 5 mg/mL oral suspension • Increase dose slowly in divided doses until clinical response; max dose 80 mg daily (20 mg QID)	Spasticity from MS, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be used in patients with spinal cord injuries/disease <u>Limitations of Use</u>: Not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders	AEs (≥15%) • Drowsiness • Dizziness • Weakness	• 2nd oral liquid formulation of baclofen • Available as a more concentrated suspension then Ozobax oral solution • Approved based on bioequivalence to baclofen 20 mg tablets; no new clinical data • Unlike baclofen oral solution (Ozobax), Fleqsuvy can be stored at room temperature, must be shaken, and must be discarded 2 months after opening • Provides little to no compelling clinical advantage over existing agents	• NF

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
budesonide DR capsule (Tarpeyo) Nephrology Agents Misc	• prednisone • methylpred-nisolone • budesonide DR capsules (Entocort EC) • budesonide ER capsules (Ortikos) • budesonide ER tablets (Uceris)	• delayed release (DR) 4 mg capsules (Tarpeyo) • Dose: 16 mg (4 caps) orally QAM ≥1 hour before a meal for 9 months	Reduces proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression (generally a Urine protein to creatinine ration [PCR] ≥ 1.5 g/g)	AEs (≥5%) • hypertension • peripheral edema • muscle spasms • acne • dermatitis • weight increase • dyspnea • facial edema • dyspepsia • fatigue • hirsutism	• 1st FDA-approved medication to reduce proteinuria in adults with primary immunoglobulin A nephropathy • Approval based on reduction in proteinuria; it is not established if Tarpeyo can slow kidney function decline • Clinical benefit of steroids in IgAN has not been established • Limitations: continued approval contingent upon verification of clinical benefit in a confirmatory clinical trial, not established if the drug can slow kidney function decline, accelerated approval based on reduction in proteinuria • Tarpeyo has not been studied against other steroids to determine if there are any efficacy or safety advantages in patients with IgAN • Similar adverse event profiles to other budesonide formulations, but comparisons are difficult to make due to differences in populations and dosing • Place in therapy is still yet to be determined • Provides little to no compelling clinical advantage over existing agents	• Tier 4/Not covered
celecoxib/ tramadol (Seglentis) tablets Narcotic Analgesics and Combinations	• tramadol • celecoxib	• Celecoxib 56 mg and tramadol 44 mg (Seglentis) in a coated tablet • Dosed at 2 tablets every 12 hours as needed for pain	Acute pain in adults severe enough to require opioid analgesics and for which alternative treatments are inadequate <u>Limitations of Use</u>: Due to risks of addiction, abuse, & misuse with opioids, even at rec. doses, reserve for pts where alternative tx options aren't tolerated or haven't provided adequate analgesia	AEs (> 5% and > placebo) • nausea (30.1%) • dizziness (16.9%) • vomiting (15.8%) • headache (11.5%) • somnolence (8.2%)	• Fixed-dose formulation of tramadol with celecoxib • Studied in a phase 3 study comparing it to either tramadol or celecoxib as monotherapy • Seglentis' dosage of two tablets twice a day (four total) does not offer a significant pill burden advantage • Fixed-dose combination allows for less flexibility, for example, cannot choose to just take celecoxib when pain is less severe • Provides no compelling clinical advantage over existing agents tramadol and celecoxib taken separately	• Tier 4/Not covered

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
filgrastim-ayow injection (Releuko) WBC Stimulants: Filgrastims	• tbo-filgrastim (Granix) • filgrastim-aafi (Nivestym) • filgrastim (Neupogen) • filgrastim-sndz (Zarxio)	• Available as a single-dose vial and as a prefilled syringe, both are available in two strengths: • 300 mcg/mL • 480 mcg/1.6 mL • Dosing: 5 - 10 mcg/kg/day given once or twice a day	• For treatment of the febrile neutropenia due to the following: • acute myeloid leukemia • bone marrow transplant • non-malignant neutropenia's	AEs (≥ 5% difference vs. placebo) • pyrexia, pain, rash, cough, dyspnea, epistaxis, anemia, diarrhea, hypoesthesia, alopecia	• 5th filgrastim, 10th drug in the White Blood Cell Stimulant class • Another biosimilar to Neupogen • No new clinical data • Available as a single-dose vial and as a prefilled syringe • Offers no compelling clinical advantages over existing formulary agents	• UF and non-step-preferred
glycopyrrolate (Dartisla ODT) Anti-cholinergics-Antispasmodics	• glycopyrrolate tablets (Robinul) • glycopyrrolate solution (Cuvposa) • omeprazole (Prilosec) • pantoprazole (Protonix) • famotidine (Pepcid)	• 1.7 mg ODT given BID or TID • Dissolve on top of tongue and swallow w/o water • Administer ≥ 1 hour before or 2 hours after food • Max daily dose is 6.8 mg	Reduce symptoms of peptic ulcer as an adjunct to treatment of peptic ulcer <u>Limitations of Use:</u> Not indicated as monotherapy for treatment of peptic ulcer; effectiveness in peptic ulcer healing not established	• blurred vision • drowsiness • decreased sweating • flushing • vomiting • constipation • dry mouth • tachycardia • urinary retention	• Dartisla ODT was approved via the 505(b)2 pathway; no new clinical studies were conducted • Not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established • The most common AEs include blurred vision, drowsiness, decreased sweating, flushing, vomiting, constipation, dry mouth, tachycardia, and urinary retention • Unlike H2 blockers and PPIs, only treats symptoms, does not heal peptic ulcer • Provides little to no clinical benefit relative to existing formulary agents	• Tier 4/Not covered
levoketoconazole (Recorlev) Endocrine Agents Miscellaneous	• ketoconazole • osilodrostat (Isturisa) • metyrapone (Metopirone) • mitotane tabs (Lysodren) • pasireotide SQ (Signifor LAR) injection • cabergoline • mifepristone oral (Korlym)	• 150 mg tablets; 150 mg orally BID, with or without food • Max: 600 mg BID (1200 mg daily)	Treatment of adults with Cushing's disease (CD) for whom pituitary surgery is not an option or has not been curative	Safety concerns include boxed warnings for hepatotoxicity, QT prolongation, and drug interactions	• Enantiomer of ketoconazole approved for treatment of Cushing's disease (CD) • Two pivotal trials (LOGICS and SONICS studies) evaluated reduction in urinary free cortisol • Normalization of the mean urinary free cortisol concentration (mUFC) was seen in both studies compared to placebo • Only one of the two studies is currently published and studies were small (<200 pts total) • No head to head studies were conducted with ketoconazole, osilodrostat, pasireotide, or other drugs used to treat CD	• Tier 4/Not covered

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					• 27% of patients experienced at least one liver-related AE, with 20% of patients having liver enzyme elevations • Several retrospective studies with ketoconazole show results similar to Recorlev in normalization of mUFC (indirect comparison) • There is insufficient evidence to show Recorlev has any improvement in efficacy or safety compared with ketoconazole • Place in therapy remains unclear • Recorlev offers little to no compelling advantages over existing agents for the treatment of Cushing's syndrome	
mitapivat (Pyrukynd) Metabolic Agents-Miscellaneous: Replacement Enzymes	• None	• Tablets: 5 mg, • mg, 50 mg • Supplied as a 28-day pack • Dosing: 5 mg BID with/without food, swallowed whole; • titrate and taper PRN	Hemolytic anemia in adults with pyruvate kinase deficiency	• Common AEs: decreases in estrone and estradiol in males, increases in urate, back pain, and arthralgia	• 1st approved treatment for hemolytic anemia in adults with pyruvate kinase deficiency • Has shown safety and effectiveness in a specific patient population with PK deficiency • Studied patients had at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant, and Hgb ≤ 10 g/dL • Not approved for children • Avoid in moderate or severe hepatic impairment • Labeling includes a warning for risk of acute hemolysis when therapy is abruptly discontinued • Provides the first drug-related treatment option for this rare disease	• UF
naloxone5 mg/0.5mL injection (Zimhi) Alcohol Deterrents-Narcotic Antagonists	• naloxone nasal 4mg/0.1mL (Narcan) • naloxone nasal 8mg/0.1mL (Kloxxado)	• 5 mg/0.5mL of naloxone in prefilled syringe • -IM/SQ to anterolateral thigh prn • May repeat every 2-3 minutes prn until EMS arrival	Emergency treatment of known or suspected opioid overdose for adult and pediatric patients	• Nausea, dizziness, lightheadedness, and elevated bilirubin	• Zimhi is an injectable formulation of naloxone approved via the 505(b)(2) pathway • No new clinical studies were completed • Quicker onset compared to intranasal agents • Provides another option for bystander treatment of opioid overdose	• UF

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
pacritinib (Vonjo) Oncological Agents: Myelofibrosis	• ruxolitinib (Jakafi) • fedratinib (Inrebic)	• 200 mg (2 x 100 mg oral capsules) BID • Specific dosage adjustments due to AEs listed in package insert	For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count < 50 × 10^9/L	AEs (≥ 20%) • diarrhea (48%) • thrombocytopenia (34%) • nausea (32%) • anemia (24%) • peripheral edema (20%)	• 1st approved drug for patients with cytopenic myelofibrosis • Demonstrated significant activity in reducing spleen volume • Substantial background data supporting this surrogate endpoint as a valid measure of reduction of disease burden and suggests correlation with survival • Current NCCN guidelines mention pacritinib as a possible treatment option for patients with low platelet counts, but make no recommendations on its use as guidelines were published before FDA approval • Safety: serious and fatal AEs did occur, but there is no black box warning on this medication • Offers a treatment option in a patient population with limited options and a poor prognosis	• UF
tenapanor (Ibsrela) GI-2: CIC and IBS-C	• linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Am	• 50 mg tablets • 50 mg BID; • Administer immediately prior to breakfast or the first meal of the day and immediately prior to dinner	Constipation-predominant irritable bowel syndrome (IBS-C) in adults	• Severe diarrhea, abdominal distension, flatulence, and dizziness	• New agent approved for adults with IBS-C • Novel mechanism of action as a sodium/hydrogen exchanger 3 (NHE3) inhibitor • Evaluated in 2 placebo controlled studies showing statistically significant results compared to placebo • Clinical significance is unclear and a significant placebo effect exists • No head-to-head studies with other IBS-C drugs • Under study for hyperphosphatemia; but does not yet have the indication • Other than a novel mechanism of action, Ibsrela offers no compelling advantages over existing agents given its limited indication, twice daily dosing, risk of severe diarrhea, and lack of clear clinical advantage in efficacy compared to placebo	• NF

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
torsemide 20 mg and 40 mg tablets (Soaanz) Diuretics	• bumetanide • ethacrynic acid • furosemide • torsemide	• 20 mg tablet daily • Titrate to desired response (max of 200 mg has been studied) • Available in 20 mg and 60 mg tablets	Intended for patients with heart failure or renal disease with edema that have concerns with excessive urination or hypokalemia	• Discontinuation of therapy due to adverse reactions occurred in 6% of patients	• Another tablet formulation of torsemide • No new phase 3 clinical trial data; approval based on torsemide data and 3 PK studies. • Max urine output occurs at ~3 hours with this formulation (extended duration of peak effect) vs. ~1 hour with IR formulation • Similar potassium excretion compared to torsemide • Available in fewer dose options than torsemide • Similar side effects to torsemide and other loop diuretics • Numerous alternative agents are available, place in therapy is unclear, and no benefits in terms of side effect profile • Provides little to no clinical benefit over torsemide formulation	• Tier 4/Not covered
tralokinumab-ldrm injection (Adbry) Atopy	• Dupixent • Rinvoq • Cibinqo	• 150 mg/mL solution in prefilled syringe • Initial dose 600mg SQ, then 300mg SQ every other week • May give 300mg every 4 weeks, if <100kg and clear skin after 16wks	Adults with refractory, moderate-severe atopic dermatitis	• Upper respiratory tract infections, conjunctivitis, injection site reactions, eosinophilia	• 2nd monoclonal antibody (mAb) antagonist for moderate to severe AD treatment (after Dupixent) • Placebo-controlled studies demonstrated efficacy • Indirect NMA showed slightly less efficacy than Dupixent • Adbry offers an additional option for moderate to severe AD, however use is limited to a single indication • Provides no significant clinical advantage relative to existing formulary agents	• NF
tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twyneo) Acne Agents: Topical Acne & Rosacea	• benzoyl peroxide • tretinoin • Epiduo Forte (nonformulary)	• Dosing: apply a thin layer to the affected areas once daily on clean and dry skin	For the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older	Application site AEs (≥ 1%): • pain (10.6%) • dryness (4.9%) • exfoliation (4.1%) • erythema (4%) • dermatitis (1.3%) • pruritus (1.3%) • irritation (1.1%)	• 1st fixed-dose combination of tretinoin and benzoyl peroxide (BP) • Tretinoin with BP is a guideline-recommended 1st line treatment option for acne • Contains the highest strength of tretinoin; doesn't allow for dose titration for tolerability • Several single-agent topical tretinoin products are available in creams, gels, and lotions • Single-agent BP is available both OTC and as a legend prescription product • Provides little to no compelling clinical advantage over existing agents tretinoin and benzoyl peroxide taken separately	• Tier 4/Not covered

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
May 2022	**Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • tenapanor (Ibsrela) **Drug Class Review** **Non-Insulin Diabetes Drugs: GLP1RAs** **Designated UF:** *Note – all agents in the class are on the list:* • dulaglutide (Trulicity) **Designated NF:** *Note – all agents in the class are on the list:* • semaglutide (Ozempic) • exenatide once weekly (Bydureon BCise) • exenatide twice daily (Byetta) • lixisenatide (Adlyxin) • liraglutide (Victoza	**Drug Class Reviews** **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Acute use exception applies* • naloxone 5 mg/0.5mL injection (Zimhi) *Drugs in class not currently represented on EMMPI List:* • mitapivat (Pyrukynd) • pacritinib (Vonjo) • filgrastim-ayow injection (Releuko) **Designated NF:** *Do not add due to TPharm5 changes:* • abrocitinib (Cibinqo) • baclofen oral suspension (Fleqsuvy) • tralokinumab-ldrm injection (Adbry) **Drug Class Reviews** **Oral CGRPs** **Designated UF** *Acute use exception applies* • atogepant (Qulipta) • rimegepant (Nurtec) • ubrogepant (Ubrelvy) **Line Extensions** **Designated UF** *Similar/parent agent not on list:* • rivaroxaban 1 mg/1 mL oral suspension (Xarelto) • lanadelumab-flyo (Takhzyro) 300 mg/ 2 mL syringe

Appendix G—Implementation Dates*

Upon signing: July 27, 2022

Two weeks after signing: August 10, 2022

30 Days after Signing: August 31, 2022

60 days after signing: September 28, 2022

90 days after signing: October 26, 2022

120 Days after signing: November 30, 2022

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2022	Nephrology Agents Miscellaneous	• budesonide (Tarpeyo)	• prednisone • methylprednisolone • budesonide delayed release capsules (Entocort EC, generics)	• 120 days
May 2022	Narcotic Analgesics and Combinations	• celecoxib/ tramadol (Seglentis)	• tramadol • celecoxib	• 120 days
May 2022	Anticholinergics-Antispasmodics	• glycopyrrolate (Dartisla ODT)	• glycopyrrolate tablets • glycopyrrolate oral solution (Cuvposa) • omeprazole • famotidine	• 120 days
May 2022	Endocrine Agents Miscellaneous	• levoketoconazole (Recorlev)	• ketoconazole • metyrapone (Metopirone) • osilodrostat (Isturisa) • pasireotide (Signifor LAR -medical benefit)	• 120 days
May 2022	Diuretics	• torsemide 20 mg and 60 mg tablets (Soaanz)	• torsemide • furosemide • bumetanide • ethacrynic acid	• 120 days
May 2022	Acne Agents: Topical Acne & Rosacea	• tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twyneo)	• tretinoin cream • benzoyl peroxide cream	• 120 days
February 2022	Pain Agents: NSAIDs	• celecoxib oral solution (Elyxyb)	• celecoxib tablets • ibuprofen • naproxen • diclofenac • numerous other NSAIDs or combos	• August 24, 2022 (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	• lorazepam ER capsule (Loreev XR)	• lorazepam IR tablets • alprazolam IR and XR tablets	• June 15, 2022 (120 days)
Nov 2021	Migraine Agents	• dihydroergotamine mesylate nasal spray (Trudhesa)	• DHE nasal spray • sumatriptan nasal and oral • rizatriptan	• June 15, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			• zolmitriptan • eletriptan	
Aug 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, 2022 (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)

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms.

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

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

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

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Probiotics		
May 2022	**RETAIN) these GCNs** • 99616 *Bifidobacterium infantis* 4 mg cap (Align) • 97109 *Lactobacil 2/S.thermos/Bifido* 1 900B cell packet (VSL #3, Visbiome) • 36349 *L. rhamnosus* 5B cell powder pack (e.g., Culturelle) • 92016 *L. rhamnosus* 10B cell cap (e.g., Culturelle) • 34623 *L. rhamnosus* 15B cell cap sprinkle (e.g., Culturelle) • 05162 *Saccharomyces boulardii* 25 mg cap (e.g., Florastor) **ADD these GCNs** • 72179 *L. reuteri* 100mm cell tab chew (Biogaia, Gerber Good Start Grow Kids, Pedia-Lax Probiotic Yums) • 28678 *L. reuteri* 100 mm/5drop drops susp (Biogaia Protectis Baby, Gerber Soothe) • 37835 *L. reuteri*/vit D3 100mm-10 drops (Biogaia Protectis Baby-Vit D, Gerber Soothe Vit-D-Probiotic) • 24119 *L. acidophilus/Lactobac spor* 35mm-25mm tab (e.g., Acidophilus) • 08380 *L. acidophilus* cap (e.g., Acidophilus) • 24118 L. acidophilus/pectin, citrus 25mm-100mg tab (e.g., Acidophilus-Pectin)	**REMOVE these GCNs** • 06604 *Saccharomyces boulardii* 250 mg powder pack
Skin Preps: Rectal (Hemorrhoidal Agents)		
May 2022	**RETAIN these GCNs** • 28080 dibucaine 1% oint (Nupercainal) • 35585 phenylephrine HCl/cocoa butter 0.25-88.44 suppository (e.g., Preparation H) **ADD this GCN** • 97827 pramoxine 1% foam	**REMOVE these GCNs** • 35039 phenylephrine/mineral oil/petrolatum 0.25%-14% oint/applicator (e.g., Preparation H) • 97205 phenylephrine/pramoxine/ glycerin/w.pet 0.25%-1% cream (e.g., Preparation H)
Ophthalmic Agents: Allergy		
May 2022	**Confirm addition of this GCN** • 68321 olopatadine 0.1% ophthalmic solution (Pataday Twice Daily Relief, generics)	

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS
August 2022

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on August 3rd and 4th, 2022.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of May 2022 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the May 2022 DoD P&T Committee meeting on July 27, 2022.

B. Clarification of Previous Minutes:

1. **February 2022 Meeting—MHS GENESIS OTC Test List—products removed from the list:** The implementation date is 180 days after signing on Oct 26, 2022, not 120 days, due to the need to send 17 different letters to patients notifying them of the changes.

2. **May 2022-Restasis Brand Over Generic authorization—**The brand over generic requirement for cyclosporine 0.05% ophthalmic emulsion single-dose (brand Restasis) at the Mail Order and Military Treatment Facilities (MTFs) points of service will be removed, due to inability to operationalize. However, the Tier 1 copay for brand Restasis at Mail Order and Retail Network pharmacies will remain in place. Implementation will now occur 30 days after signing.

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. Antidepressants and Non-Opioid Pain: Subclasses for the following – Selective Serotonin Reuptake Inhibitors (SSRIs); Selective Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs); Norepinephrine/Dopamine Reuptake Inhibitors (NDRIs); and Gamma-Aminobutyric Acid Analogs (GABAs)

Background—The P&T Committee evaluated the relative clinical effectiveness of 4 subclasses in the Antidepressants and Non-Opioid Pain Drug Class. The full drug class was first reviewed for formulary placement in November 2011, with several new entrants to the class individually reviewed as new drugs. There are currently 30 products from 8 different subclasses on the uniform formulary. The drugs in the class are now largely available as generic formulations, however, 9 branded products remain. The clinical and cost effectiveness review focused on these 9 branded products.

The drugs in the class are approved for a variety of indications, including major depressive disorder (MDD), generalized anxiety disorder, (GAD), obsessive compulsive disorder (OCD), panic disorder (PD), seasonal affective disorder (SAD), diabetic peripheral neuropathic pain (DPNP), fibromyalgia (FM), and restless leg syndrome (RLS).

The clinical review focused on an extensive review of professional treatment guidelines for the various indications, provider feedback from the pertinent subspecialties, meta-analyses evaluating efficacy and safety, and other factors, including dosing frequency, dosage titration and tapering, and issues in special populations, including pregnancy and adolescents. The major clinical attributes of the drugs are discussed below.

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

Selective Serotonin Reuptake Inhibitors (SSRIs)

- *vortioxetine (Trintellix) (note that the previous brand name was Brintellix)*
  - Trintellix has been designated NF since it was first reviewed in February 2014. Trintellix carries a single indication for MDD, in contrast to the other generic SSRIs (including citalopram, fluoxetine, paroxetine and sertraline) that are indicated for multiple conditions.
  - The 2022 Department of Defense/Veterans Affairs (DoD/VA) Clinical Practice Guideline for MDD lists Trintellix as an initial pharmacotherapy option, along with other SSRIs, SNRIs, bupropion, mirtazapine, trazadone, and vilazodone, although this is based on an overall weak recommendation.
  - A 2018 Lancet network meta-analysis concluded Trintellix did not demonstrate significantly improved efficacy or tolerability when compared to other SSRIs for MDD.

- Limited data suggests Trintellix carries less risk for sexual dysfunction and cognitive impairment compared to other antidepressants. Trintellix also has the unique advantage among SSRIs for allowing abrupt discontinuation of treatment, if needed.

- *vilazodone (Viibryd)*
  - Viibryd has been designated as NF since the original review in November 2011. Viibryd carries a single indication for MDD. It is also listed in the 2022 VA/DoD Clinical Practice Guideline for MDD as an initial pharmacotherapy option along with numerous other options, as previously stated with Trintellix.
  - A 2018 Lancet network meta-analysis concluded Viibryd did not demonstrate significantly improved efficacy or tolerability compared to other SSRIs for MDD. When compared to other SSRIs, Viibryd has a higher incidence of gastrointestinal adverse effects including diarrhea and nausea.
- *paroxetine mesylate (Pexeva)*
  - Pexeva is indicated for major depressive disorder (MDD), generalized anxiety disorder, obsessive compulsive disorder (OCD), and panic disorder. Unlike its competitor, paroxetine hydrochloride (Paxil), Pexeva lacks additional approval for post-traumatic stress disorder and seasonal affective disorder. Several clinical practice guidelines for each of Pexeva's indications recommends SSRIs overall for first-line treatment, with no recommendation for a superiority of a specific formulation or brand product.
  - There is limited clinical data available with Pexeva, as FDA-approval was based on the information using data from paroxetine hydrochloride (Paxil). There is no data to show that Pexeva confers any clinically relevant advantages over Paxil.

Selective Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs)

- *levomilnacipran (Fetzima)*
  - Fetzima is an enantiomer of milnacipran (Savella). It is only indicated to treat MDD. Among the wide array of other treatment options for MDD, several generic SNRIs are available on the formulary, including duloxetine, venlafaxine, and desvenlafaxine.
  - A 2018 Lancet network meta-analysis concluded Fetzima did not confer significantly improved efficacy or tolerability compared to other SNRIs for MDD. Among the SNRIs, Fetzima carries a lower risk for gastrointestinal adverse effects.

- *milnacipran (Savella)*
    - Savella is only approved for treating fibromyalgia. The 2016 European Alliance of Associations for Rheumatology guideline supports treatment of fibromyalgia with Savella, however, this is in addition to a variety of other treatment options, including duloxetine, amitriptyline, and pregabalin.
    - A 2016 Rheumatology International network meta-analysis concluded that Savella did not demonstrate greater efficacy or tolerability when compared to duloxetine or pregabalin.
- *duloxetine delayed release (Drizalma Sprinkle)*
    - Duloxetine delayed-release capsules are a sprinkle formulation of duloxetine that was originally designated NF in November 2019. No clinical trials were used to gain FDA approval, as the efficacy and safety relied on the data from duloxetine (Cymbalta). Drizalma has the same FDA indications as duloxetine.
    - Although Drizalma Sprinkle provides a formulation for patients with swallowing difficulties, it provides no compelling advantages compared to existing formulary agents, including generic duloxetine.
    - DoD specialists (child and adult psychiatrists, and neurologists) also supported that Drizalma Sprinkle is not needed on the formulary.

Norepinephrine/Dopamine Reuptake Inhibitors (NDRIs)

- *bupropion hydrobromide (Aplenzin)*
    - Aplenzin is an extended release hydrobromide formulation of bupropion; its generic counterpart is bupropion hydrochloride extended release (Wellbutrin XL). Both agents are bioequivalent and approved for the same indications (MDD and SAD).
    - Guidelines from the 2010 American Psychiatric Association and 2019 National Institute for Health Care and Excellence recommend the same array of medication options for MDD and SAD. As previously stated, the most recent clinical guideline for MDD (2022 DoD/VA CPG) lists bupropion, but does not endorse a specific formulation (e.g., hydrochloride vs. hydrobromide). Several other subclasses are also listed as initial pharmacotherapy options for MDD.
    - There are no compelling benefits of Aplenzin compared to generic bupropion formulations.

Gamma-Aminobutyric Acid Analogs (GABAs)

- *gabapentin ER 24 hour tablets (Gralise)*

- Gralise is an extended release formulation of gabapentin indicated for Post Herpetic Neuralgia (PHN). The 2004 American Academy of Neurology PHN guidelines recommend multiple first line treatment options, including gabapentin, pregabalin, tricyclic antidepressants, opioid, and the lidocaine patch.
- A 2015 Lancet Neurology network meta-analysis concluded Gralise did not result in significantly greater efficacy for pain relief for PHN when compared to gabapentin and gabapentin enacarbil.
- Notably, Gralise carries a possible lower risk for dizziness and somnolence when compared to other gabapentin formulations. However it also requires a large tablet burden to reach recommended dosing.

- *gabapentin enacarbil (Horizant)*
  - Horizant is another extended release gabapentin formulation due to its prodrug characteristics. Horizant is indicated for PHN and Restless Leg Syndrome. The 2016 American Academy of Neurology guideline lists Horizant as a first-line treatment option, along with multiple other drugs from other classes, as mentioned previously.
  - Network meta-analyses evaluating fibromyalgia (2015 Lancet Neurology) and RLS (2013 JAMA Internal Medicine) both concluded that Horizant did not confer additional efficacy when compared to other gabapentin formulations and pregabalin, respectively.
  - Although Horizant is unique among the GABAs for allowing abrupt discontinuation if administered at doses lower than 600 mg per day, it carries a possible high risk of dizziness and somnolence when compared to other agents in the subclass.

Overall Conclusions

- The 2011 P&T efficacy conclusions remain largely unchanged; the brand-only agents reviewed do not offer significantly improved efficacy when compared to other generic agents across similar indications and subclass.
  - A comprehensive clinical efficacy evaluation for mood disorders is not possible at this time, as some agents were approved based on bioequivalence to a generic competitor, and did not have new clinical data for review.
- The 2011 P&T safety conclusions remain largely unchanged; the brand only agents do not offer significantly improved tolerability when compared to other generic competitors across like indications.

- Of note, Trintellix offers limited data supporting a lower risk of sexual dysfunction and cognitive impairment compared to other antidepressants.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and also conducted a budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- Cost minimization analysis (CMA) results showed the following: All 9 branded products, Trintellix, Viibryd, Pexeva, Fetzima, Savella, Drizalma Sprinkles, Gralise, Horizant, and most notably, Aplenzin, were not cost effective relative to the generic formulations in the 4 respective subclasses.
- Budget Impact Analysis (BIA) and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating vortioxetine (Trintellix), vilazodone (Viibryd), and all generically-available agents as UF, with bupropion hydrobromide (Aplenzin), duloxetine delayed release (Drizalma Sprinkle), gabapentin (Gralise), gabapentin enacarbil (Horizant), levomilnacipran (Fetzima), milnacipran (Savella), and paroxetine mesylate (Pexeva) as NF demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:
   - UF
     - vortioxetine (Trintellix) *moves from NF to UF*
     - vilazodone (Viibryd) *moves from NF to UF*
     - Note that the antidepressants in the class that are currently available in generic formulations will remain UF.
   - NF
     - paroxetine mesylate (Pexeva) mov*es from UF to NF*
     - duloxetine DR (Drizalma sprinkle)
     - levomilnacipran (Fetzima)
     - milnacipran (Savella)
     - bupropion hydrobromide XR (Aplenzin)
     - gabapentin ER 24 hr tablets (Gralise)
     - gabapentin enacarbil (Horizant)
   - Tier 4 (Not covered) – None

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained) the following with regard to PA criteria for all 9 branded agents. There was no change to the current PA criteria for Drizalma Sprinkles, which requires the provider to justify why this formulation is needed (write-in). New manual PA criteria were recommended for paroxetine mesylate (Pexeva) and vilazodone (Viibryd), in new users.

   For the remaining products where PA criteria are already in place (Trintellix, Fetzima, Savella, Gralise, Horizant, and Aplenzin), updates were recommended in new users. Automation that is currently in place for Trintellix, Fetzima, Savella, Gralise, and Horizant was removed. For all the PAs, the provider should consider non-pharmacologic options along with drug therapy. Additionally, a trial of two to three alternate formulary agents is recommended first for all the branded drugs. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained) new MN criteria for Pexeva and Aplenzin, and maintaining the current MN criteria for Drizalma Sprinkle, Fetzima, Savella, Gralise, and Horizant that is currently in place. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS*** —The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the current exclusion for the 9 NF agents from the EMMPI program.

5. ***COMMITTEE ACTION: UF, MN, PA, EMMPI and IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the NF recommendation for Pexeva. (See Appendix G for the actual implementation dates.)

B. Overactive Bladder Agents (OAB) – Beta3 (β-3) Adrenergic Agonists Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the OAB β-3 adrenergic agonists. The subclass is comprised of mirabegron (Myrbetriq), vibegron (Gemtesa) and mirabegron extended-release (ER) granules for oral suspension (Myrbetriq Granules); the products were previously reviewed as new drugs in May 2014, May 2021, and November 2021, respectively. PA currently applies to all three drugs.

The previous OAB formulary review in November 2012 included the older antimuscarinic drugs [e.g. oxybutynin (Ditropan), tolterodine (Detrol), and solifenacin (Vesicare), etc.], however, they were not part of this current review.

Mirabegron (Myrbetriq) and vibegron (Gemtesa) are both approved for the treatment of OAB, while Myrbetriq Granules are only approved for neurogenic detrusor overactivity (NDO).

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

Professional Treatment Guidelines

- The 2019 OAB guidelines from the American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (AUA/SUFU) state the following:
    - Clinicians should offer behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, and fluid management) as first-line therapy to all patients with OAB. *(Standard, Evidence strength: Grade B)*
    - Clinicians should offer oral anti-muscarinics or oral β-3-adrenoceptor agonists as second-line therapy *(Standard, Evidence Strength Grade B)*
    - If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with one antimuscarinic medication, then a dose modification or a different anti-muscarinic medication or a β-3-adrenoceptor agonist may be tried. *(Clinical Principle)*

Antimuscarinics vs. β-3-adrenergic agonists

- The antimuscarinics and β-3-agonists show similar efficacy for treating OAB, however the β-3-agonists have fewer side effects, such as dry mouth. One retrospective, matched cohort study found a higher risk of dementia with the antimuscarinics compared to the β-3 agonists. Limitations to this analysis include the observational study design, and that overall the difference in dementia rates between the groups was relatively small. *(BJU Intl 2020)*

Mirabegron vs. Vibegron

- For mirabegron, there was no new data that would support changes to the previous clinical conclusions from 2014; compared to placebo, mirabegron produced statistically significant reductions in incontinence episodes, but the clinical effect is small and there is a high placebo response rate.
- Vibegron has not been directly compared against mirabegron in a head-to-head trial, but indirect comparisons suggest similar efficacy.

Mirabegron

- Advantages of mirabegron include its long marketing history (it was FDA-approved in 2012), and existing high utilization in the Military Health System

(MHS). It is also indicated for use in combination with the antimuscarinic solifenacin (Vesicare). Disadvantages include that mirabegron is formulated as an ER tablet that cannot be crushed.

- The Myrbetriq granules are solely indicated for NDO, and currently have very low MHS utilization.

Vibegron

- Benefits of vibegron compared to mirabegron include fewer drug interactions, lack of clinically significant effects on blood pressure, and that the tablets can be crushed.

Overall Conclusions

- Overall, there is a high degree of therapeutic interchangeability between mirabegron and vibegron based on efficacy data. For safety, although there are subtle differences that favor vibegron over mirabegron, most patients could use either drug.
- In order to meet the needs of MHS beneficiaries, at least one β-3 agonist is required on the formulary.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- (CMA) results showed that mirabegron (Myrbetriq) was more cost effective than vibegron (Gemtesa).
- BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating mirabegron (Myrbetriq) and vibegron (Gemtesa) both as UF demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
  - mirabegron tablets (Myrbetriq)
  - mirabegron ER granules for oral suspension (Myrbetriq granules) *moves from NF to UF*
  - vibegron (Gemtesa)
- NF – None
- Tier 4 (Not covered) – None

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***— PA criteria have been in place for Myrbetriq, Gemtesa and the Myrbetriq Granules since they were originally reviewed as new drugs. The PA criteria requires a trial of an antimuscarinic first. Additionally, at the May 2021 review of Gemtesa, the Myrbetriq PA was revised to require a trial of Gemtesa

in new users, based on cost-effectiveness. However due to the delay of the Beneficiary Advisory Panel meeting (due to the zero-based review), implementation did not occur until March 2022.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) minor updates to the current manual PA criteria for Myrbetriq and Gemtesa in new users. The current requirements for a trial of an antimuscarinic first before use of a β-3 agonist will be maintained, as the AUA/SUFU guidelines place the antimuscarinics and β-3 agonists on equal footing, and do not prefer the β-3 agonists over the antimuscarinics. Practices from commercial healthcare plans also require an antimuscarinic before a β-3 agonist. A trial of only one antimuscarinic will be required, instead of the current requirement for two prior drugs.

Minor updates were made to the dosage modifications based on renal function. Additionally, the current requirement for a trial of Gemtesa prior to Myrbetriq will be removed. There were no changes made to the existing Myrbetriq Granules PA criteria. (See Appendix C)

3. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) removing mirabegron tabs (Myrbetriq) and mirabegron ER granules for oral suspension (Myrbetriq Granules) from the program. Vibegron (Gemtesa) is not on the program.

4. ***COMMITTEE ACTION: UF, PA, EMMPI IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. (See Appendix G for the actual implementation date.)

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 2022 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:
   - UF

- alpelisib (Vijoice) – Oncological agent for PIK3CA-related overgrowth spectrum (PROS)
- daridorexant (Quviviq) – Sleep Disorders: dual orexin receptor antagonist (DORA) for treating insomnia
- edaravone oral suspension (Radicava ORS) – Miscellaneous Neurological Agent for amyotrophic lateral sclerosis (ALS) and a new oral version of an IV medication
- ganaxolone oral suspension (Ztalmy) – Anticonvulsant for treating seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency
- insulin glargine solostar unbranded authorized biologic (from Winthrop labs) – Basal insulin; note that as part of this recommendation, this product will be designated as non-step-preferred.
- mavacamten (Camzyos) – Miscellaneous Cardiovascular Agent for symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM)

- NF:
  - amlodipine oral solution (Norliqva) – Dihydropyridine Calcium Channel Blocker (CCB) alternate dosage form for hypertension
  - cyclosporine 0.1% ophthalmic emulsion (Verkazia) – Ophthalmic for vernal keratoconjunctivitis
  - donepezil patch (Adlarity) – Alzheimer's agent for mild, moderate, to severe dementia and a patch version of an available oral agent
  - leuprolide SC injection (Camcevi Kit) – Leuprolide-hormone-release hormone (LHRH) agent for treatment of advanced prostate cancer
  - tapinarof 1% cream (Vtama) – Psoriasis Agent
  - tirzepatide SC injection (Mounjaro) – Glucagon-like peptide-1 (GLP-1) receptor agonist for type 2 diabetes
  - testosterone undecanoate 112.5 mg capsule (Tlando) – Oral Testosterone Replacement Therapy; note that as part of this recommendation, this product will be designated as non-step-preferred.
  - vonoprazan/amoxicillin (Voquezna Dual Pak) – Miscellaneous Anti-infective for *Helicobacter pylori* (*H. pylori*) infection
  - vonoprazan/amoxicillin/clarithromycin; (Voquezna Triple Pak) – Miscellaneous Anti-infective for *Helicobacter pylori* (*H. pylori*) infection

- Tier 4 (Not covered): The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents. See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
    - baclofen oral granules (Lyvispah) – Skeletal Muscle Relaxant; another alternative formulation of baclofen for multiple sclerosis spasticity
        - Alternatives include baclofen tablets, baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy)
    - benzoyl peroxide 5% cream (Epsolay) – keratolytic for rosacea
        - Alternatives include other legend and OTC benzoyl peroxide formulations; metronidazole 1% gel (MetroGel, generics), azelaic acid 15% gel (Finacea) and NF products, including minocycline 1.5% topical foam (Zilxi) minocycline 50 mg capsule; minocycline 4% foam (Amzeeq); brimonidine tartrate 0.33% gel (Mirvaso); and ivermectin 1% cream (Soolantra)

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for criteria for Adlarity, Camcevi Kit, Mounjaro, Norliqva, Tlando, Verkazia, Voquezna Double Pak, Voquezna Triple Pak, and Vtama (see Appendix B for the full criteria.)

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

- Applying manual PA criteria to new users of tirzepatide (Mounjaro) consistent with the other NF GLP1-RA, Ozempic. A trial of metformin will be required before Mounjaro.
- Applying manual PA criteria to new users of Quviviq, similar to the criteria in place for the other DORAs, Belsomra and Dayvigo. A trial of zolpidem extended-release or eszopiclone is required first before a DORA.
- Applying manual PA criteria to new users of the insulin glargine solostar unbranded authorized biologic, consistent with the criteria for the other non-preferred basal insulins. A trial of Lantus is required first.
- Applying manual PA criteria to new users of Tlando, consistent with the criteria already in place for the oral testosterone products (Jatenzo) and the other topical testosterone replacement products. A trial of the step-preferred product Fortesta is required first.

- Applying manual PA criteria to new users of Verkazia, consistent with the existing PA criteria for other ophthalmic cyclosporine products. Patients who are younger than age 21 years and who have a history of cyclosporine 0.05% ophthalmic emulsion (Restasis) in the past 180 days do not require a manual PA for Verkazia (age edit and auto-look back). The Restasis PA was also updated to allow use in patients younger than 18 years. *(See the Utilization Management section on page 18 for updates to the Restasis PA criteria).*
- Applying PA criteria to new users of Vtama, consistent with what is already in place for other topical Psoriasis Drugs.
- Applying PA criteria to new users of Vijoice, Radicava ORS, Ztalmy, Camzyos, Voquezna Double Pak, Voquezna Triple Pak, Adlarity, and Camcevi Kit

4. ***COMMITTEE ACTION: EMMPI***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

5. ***COMMITTEE ACTION: UF, TIER 4, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended for (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

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

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)—tiotropium dry powder inhaler (Spiriva HandiHaler)—Spiriva HandiHaler was reviewed in February 2013 and added to the BCF. In November 2016, a follow-on product, tiotropium soft mist inhaler (Spiriva Respimat), was reviewed as a new drug and also added to the BCF. Both formulations are indicated for maintenance treatment of chronic obstructive pulmonary disease (COPD), and to reduce the risk of COPD exacerbations. They produce similar improvements in forced expiratory

volume in one second (FEV1), and have safety profiles that reflect the other LAMAs.

The Spiriva HandiHaler requires insertion of the dry powder capsules into the device, and also requires a minimum inspiratory flow rate of 30 mL/min to activate the inhaler. Generics are not expected for at least two years. For Spiriva Respimat, patients with dexterity issue may have difficulty assembling and priming the device. However, advantages of the Respimat device include that more drug is deposited in the lungs, rather than the oral cavity; it is a passive inhalation device which does not rely on the patient's inspiratory effort; and it has an additional indication for maintenance treatment of asthma in patients 6 years of age and older. Spiriva Respimat is more cost-effective than Spiriva HandiHaler.

COMMITTEE ACTION: SPIRIVA HANDIHALER NEW PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria in new and current users of Spiriva HandiHaler, in order to encourage use of Spiriva Respimat, due to compelling advantages of the delivery mechanism. The new PA will become effective the first Wednesday 120 days after the signing of the minutes, and DHA will send letters to affected patients prior to and following implementation. Additionally, Spiriva HandiHaler will be added to the rapid response ("safety net") program, which is included in the new TPharm5 contract. See Appendix C for the full criteria.

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

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

a) **Renin-Angiotensin Anti-hypertensives (RAAs)—valsartan 20 mg/5 mL oral solution—**Valsartan is an angiotensin receptor blocker (ARB) that is available in cost-effective generic formulations, along with several other ARBs (e.g., losartan, candesartan, telmisartan, etc). Valsartan oral solution is not cost effective compared to the other ARBs.
b) **Non-Insulin Diabetes Drugs: Biguanides Subclass—metformin immediate release (IR) 625 mg tablets—**Numerous other metformin IR (500 mg and 850 mg) and ER (750 mg and 1000 mg) formulations are more cost-effective than this 625 mg IR formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN— The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for valsartan 20 mg/5 mL oral solution and metformin 625 mg IR tablets in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA criteria for several drugs, due to new FDA-approved indications. The updated PA criteria outlined below will apply to new users. See Appendix C for the full criteria.

a) Atopy Agents (now incorporates the previously titled Respiratory Interleukins)—dupilumab injection (Dupixent)

i. Eosinophilic Esophagitis (EoE): Dupixent recently gained a new indication for treating EoE. A trial of both a proton pump inhibitor (PPI) and topical glucocorticoid is required prior to using Dupixent in new users, based on the current EoE clinical practice guidelines from the American Academy of Allergy, Asthma and Immunology (AAAI) and MHS provider feedback. Note that topical glucocorticoids in this case refers to spraying a high potency inhaled corticosteroid in the mouth and then swallowing the dose (due to extensive first pass metabolism), or making a slurry out of budesonide respules.

ii. Atopic Dermatitis in young children: The Dupixent manual PA criteria were also updated to allow for expanded use as add-on maintenance treatment of atopic dermatitis in children aged 6 months to 5 years whose disease is not adequately controlled with topical prescription treatments.

b) Targeted Immunomodulatory Biologics (TIBs): oral Janus Kinase (JAK) inhibitors—upadacitinib (Rinvoq)—The manual PA criteria were updated for Rinvoq to expand use for treating ankylosing spondylitis (AS) in new users. There are currently no head-to-head trials comparing the efficacy of one biologic over another for AS. Based on current clinical practice guidelines for AS, availability of other TIBs with indications for AS [including the TNF-inhibitor adalimumab (Humira) and the anti-IL-17 product secukinumab (Cosentyx)], and due to safety issues with the oral JAK inhibitors as a class, a trial of two non-steroidal anti-inflammatory drugs (NSAIDs), Humira and Cosentyx is required prior to using Rinvoq.

c) TIBs: apremilast (Otezla)—PA criteria for Otezla have applied since August 2014 for the original indications of psoriatic arthritis and moderate-to-severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy. Step-therapy applies to the TIBs, requiring a trial of Humira first for

these indications. Otezla's package labeling has recently been expanded to include adults with mild cases of plaque psoriasis.
Based on clinical practice guidelines for treating psoriasis and feedback from MHS dermatologists, a trial of Humira will not be required for patients with mild plaque psoriasis. However, other standard therapies, including phototherapy and a moderate-to-high potency topical corticosteroid, steroid sparing agent and other topical agents, will be required first.

d) **Attention Deficit Hyperactivity Disorder (ADHD): Non-Stimulants—viloxazine extended release (Qelbree)—**PA criteria have been in place for Qelbree since it was reviewed as a new drug at the August 2021 DoD P&T Committee meeting. At the time Qelbree was approved for treating ADHD only in children between the ages of 6 and 17 years. Qelbree has recently received an indication for treating adults.
For adults with ADHD, the PA criteria will be more stringent than in children, as a trial of methylphenidate (e.g., Concerta), mixed amphetamine salts (e.g., Adderall XR), atomoxetine (Strattera), and another non-stimulant [guanfacine ER (Intuniv) or clonidine ER (Kapvay)] will be required before Qelbree in new users. This requirement is due to the limited number of patients included in the trials used to gain FDA-approval (only 175 adults were studied for six weeks); the safety concerns with Qelbree in adults (including increases in heart rate and blood pressure); and the availability of numerous other cost-effective stimulants and non-stimulants for treating ADHD.

   For children, updates were made to allow pediatric patients with swallowing difficulties to bypass the requirement for a trial of a different non-stimulant first, since Qelbree capsules can be opened up and mixed with applesauce. The other non-stimulants cannot be crushed or chewed.

e) **Miscellaneous Metabolic Agents—setmelanotide injection (Imcivree)**—The PA was updated for the new indication of chronic weight management in adults and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to Bardet-Beidl syndrome was added to the PA.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Dupixent, Rinvoq, Otezla, Qelbree and Imcivree in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

4. Removal of PA

a) **Topical Acne and Rosacea Agents: azelaic acid 15% (Finacea, generics)**—The P&T Committee evaluated an MTF request to remove the PA criteria for Finacea and add it to the Basic Core Formulary (BCF). Azelaic acid 15% gel is approved for treating rosacea, but is commonly used for acne. Step therapy

requires a trial of topical metronidazole first for rosacea. Finacea is now available in cost-effective generic formulations.

There is high quality evidence that topical azelaic acid decreases inflammatory lesions and erythema in rosacea. Additionally, for acne the 2016 American Academy of Dermatology guidelines give azelaic acid a class A recommendation with level 1 evidence. Azelaic acid is also rated as pregnancy category B.

The P&T Committee recommended removing the PA criteria for azelaic acid 15% gel; it remains on the UF, but will not be added to the BCF. Note that the current PA criteria for azelaic acid 20% cream (Azelex), which is approved for acne, will remain in place.

b) Respiratory Agents Miscellaneous: epinephrine Auto-Injector (Auvi-Q)—PA criteria for the Auvi-Q talking epinephrine auto-injector device were re-instated in February 2020, due to the resolution of the national shortage of EpiPen. Since 2020, the price of Auvi-Q has dropped significantly, and the nationwide supply of epinephrine autoinjectors appears stable. The P&T Committee recommended removing the Auvi-Q PA.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) removing the PA criteria for azelaic acid 15% gel and Auvi-Q auto-injector. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

5. Updated PA Criteria for Reasons other than new Indications

a) Ophthalmic Dry Eye Class: cyclosporine 0.05% ophthalmic emulsion single dose (Restasis)—PA criteria for Restasis currently allow use in patients older than 18 years of age. The PA criteria will now have an age edit to allow patients younger than 18 to bypass the PA criteria. The change in age will enable Restasis to be used in patients with vernal keratoconjunctivitis, rather than Verkazia, if the provider chooses. There were no other changes made; adults who do not have a claim for Restasis in the past 120 days are required to go through the PA. See Appendix C.

b) Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs) —The GLP-1RAs were reviewed for formulary placement in May 2022, with implementation set to occur on September 28, 2022. Trulicity was designated BCF, with a trial of metformin required. For Trulicity an automated look back was added; if a patient has received any diabetic drug in the past 720 days coverage will be allowed.

6. Updated PA Criteria for Removal of Indication

Over the past several months, the FDA has removed certain indications from some oncology drugs due to safety issues. The P&T Committee recommended updates to the PAs below, based on recent FDA action.

Oncologic Agents - Poly Adenosine Diphosphate Ribose Polymerase- (PARP) Inhibitor: rucaparib (Rubraca)—The indication for BRCA-mutated ovarian cancer after at least two prior chemotherapies has been removed, due to increased risk of death compared to chemotherapy in the third-line ovarian cancer treatment setting. The indications remain for ovarian cancer as second-line maintenance treatment in chemotherapy responders and also for previously treated BRCA-mutant metastatic castration-resistant prostate cancer.

Oncologic Agents - Non-Bruton Tyrosine Kinase Inhibitors for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (non-BTKIs for CLL/SLL): duvelisib (Copiktra)—A recent clinical trial reported a possible increased risk of death with Copiktra compared to another medication for leukemia and lymphoma. Additionally there was a higher risk of serious side effects with Copiktra, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and elevated liver enzyme levels. Although the FDA has not yet formally removed the indications for CLL/SLL, the P&T Committee will continue to monitor FDA actions and respond accordingly with updating the PA if needed.

COMMITTEE ACTION: RUBRACA UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) to remove the Rubraca indication for BRCA-mutated ovarian cancer after at least two prior chemotherapies. If any updates are made to the Copiktra label, the corresponding PA criteria will be updated accordingly. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

B. Quantity Limits

1. **Newly approved drugs:** QLs were reviewed for the newly approved drugs where there are existing QLs for the class, or due to recommended treatment course durations.

   COMMITTEE ACTION: NEW DRUGS QLs AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for Vijoice, Voquezna Dual PAK, and Voquezna Triple PAK. See Appendix D for the QLs.

2. **Specialty Drugs QLs:** An extensive review of quantity limits for specialty medications was presented. Quantity limits for Specialty medications were systematized based on the principles listed below. Additionally administrative authority for the Formulary Management Branch to establish and make changes to days

supply and quantity limits for specialty medications as needed was also presented (see Appendix J for the Table of Administrative Authorities).

- Starting with current Mail Order days supply limits (e.g., up to 56 days supply per fill) or "quantity per days supply" (e.g., up to 120 tablets per 60 day supply), simplify requirements by changing to a days supply limit wherever possible
- Keep limits consistent across points of service
- Whenever possible, maintain consistency among similar drugs
- In general, do not set limits lower than the current limits at Mail Order, unless the product is not available at or not currently dispensed from the Mail Order pharmacy
- For products with a current Mail Order days supply limit between 31 and 60 days (e.g., 45 days supply), allow up to a 60 day supply (depending on product packaging)
- Allow the current benefit limits for non-specialty drugs (typically 30 days supply at Retail pharmacies, but up to 90 days supply with multiple copays; up to 90 days supply at MTFs and Mail) to apply to Specialty medications in selected classes (e.g., leuprolides, octreotide, growth hormone, and multiple sclerosis agents)
- In general, limit to no more than 30 days supply for products with current limits of 21-30 days supply and limited distribution medications not currently filled at Mail Order
- In general, limit starter packs to one pack per fill, with no refills
- While days supply limits are preferable logistically, keep current quantity per days supply limits in special cases where days supply limits may allow overuse
- Do not exceed REMS requirements
- Consider recommendations from providers and specialty pharmacists

COMMITTEE ACTION: SPECIALTY DRUGS QLs AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the QLs for the specialty drugs as discussed above, with implementation occurring 30 days after signing of the minutes.

C. Line Extensions

The P&T Committee clarified the formulary status for three 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) Antiretrovirals: Combinations—designating abacavir /dolutegravir/lamivudine tablets for oral suspension (Triumeq PD) as UF, with the same formulary status as the parent Triumeq

b) Pulmonary Arterial Hypertension (PAH)—designating treprostinil dry powder inhaler (Tyvaso DPI) as UF with the same PA as Tyvaso solution for inhalation

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) the formulary status for the line extension products as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE PROPIONATE HYDROFLUOROALKANE (FLOVENT HFA) AND TIER 1 COPAY

The Inhaled Corticosteroids (ICS) subclass was reviewed in May 2014, and Flovent dry powder inhaler (DPI) and hydrofluoroalkane (HFA) inhalers were designated as BCF and step-preferred. A generic fluticasone propionate HFA formulation has entered the market, however this product is less cost-effective compared to brand Flovent HFA. Therefore, the branded Flovent HFA/Flovent DPI product will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy).

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT FOR FLUTICASONE PROPIONATE HFA INHALER, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) requiring brand Flovent HFA or Flovent DPI in all new and current users at all three points of service, based on cost effectiveness. The prescriber will provide patient-specific justification as to why brand Flovent HFA or Flovent DPI cannot be used. The Tier 1 (generic) copayment will apply to both brand Flovent HFA and DPI. The effective date will be 2 weeks after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

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

VIII. BRAND OVER GENERIC AUTHORIZATION FOR MESALAMINE 1.2 gm (LIALDA)

Brand over generic PA requirements originally applied to mesalamine 1.2 gram tablets (Lialda) in September 2017, due to cost effectiveness. In April 2020, cost-effective generic mesalamine formulations were available at the Mail Order and MTFs, however, generic prices at Retail pharmacies were not cost effective. On May 20, 2020, the brand over generic requirements were administratively removed at the Mail Order and MTF points of service, but remained at Retail pharmacies. The cost of generic mesalamine 1.2 gram tablets has now fallen at the Retail POS.

COMMITTEE ACTION: REMOVAL OF LIALDA BRAND OVER GENERIC REQUIREMENT TIER 2 COPAYMENT AND IMPLEMENTATION PERIOD— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent), to remove the brand Lialda over generic PA requirement at the Retail Network. The co-pay for brand Lialda at Retail pharmacies will increase back to the Tier 2 copay. The effective date will be 2 weeks after signing of the minutes.

IX. RE-EVALUATION OF NF GENERICS/EMMPI REQUIREMENTS: BETA BLOCKERS—NEBIVOLOL (BYSTOLIC)

The P&T Committee reviewed the current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per unit, for generic nebivolol (Bystolic). The P&T Committee agreed that, while the unit cost of generic nebivolol has dropped significantly from the previous generic and brand cost, it is still substantially higher than generic beta blocker formulations of metoprolol tartrate, metoprolol succinate, and atenolol, which are on the Uniform Formulary. The P&T Committee also noted that generic nebivolol is most competitively priced at retail compared to mail and MTF. There are 4 generic manufacturers available, suggesting stable generic prices and likely a continued decrease in the cost of nebivolol.

COMMITTEE ACTION: NEBIVOLOL FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) that nebivolol (Bystolic, generics) remain NF but be exempted from the mail order requirement on the basis of comparable decreasing and competitive pricing at retail, effective the first Wednesday two weeks after the signing of the minutes. See Appendix F.

X. NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) 2017 PILOT PROGRAM: INCORPORATION OF VALUE-BASED HEALTH CARE IN PURCHASED CARE COMPONENT OF TRICARE AND MEDICATION ADHERENCE

*Background—*A pilot program outlined in the NDAA 2017 required identification of high-value medications where copayments or cost shares would be reduced for targeted populations of covered beneficiaries. The DoD P&T Committee identified rosuvastatin (Crestor generics) and insulin glargine pens (Lantus pens) as candidates for inclusion in the pilot, which was intended to assess the effects of copayment reduction or elimination on medication adherence

rates. Additionally, the amount of any reduced or eliminated copay would be credited towards the patient's deductible/catastrophic cap. Implementation occurred on January 1, 2018, to align with recommended regulatory language. (*See the November 2017 and August 2017 DoD P&T Committee minutes)*

Pilot results showed there was no meaningful change in adherence, positive or negative, for patients receiving Lantus pens or rosuvastatin following a reduction in copay.

As required by NDAA 2017 termination of the pilot will occur on December 31, 2022, therefore the following changes will occur:

- Because Rosuvastatin is a generic, the copay will increase from the current $0 co-pay back to the Tier 1 copay at the Mail Order and Retail network pharmacies, as generic co-pays are statutorily required and absent statutory authority to exclude a specific item or service from otherwise required co-pays, they cannot be waived. Patients will be notified of the copay change via letter.
- The catastrophic cap credit for the reduced/eliminated copays will end.
- These changes will occur on January 1, 2023.

The Committee also discussed the copays for Lantus, a branded drug. At the August 2017 Basal Insulin drug class review, the Lantus pens and vials were both designated as BCF, based on provider opinion, clinical and cost effectiveness, and MHS utilization patterns. The conclusion at the time was that the majority of MHS patients could be treated with Lantus, as there was a lack of compelling advantages of the newer basal insulin analogs.

> ***COMMITTEE ACTION: LANTUS PENS AND VIALS TIER 1 COPAY AND IMPLEMENTATION PLAN—***The P&T Committee recommended (15 for, 0 against, 0 abstained, 1 absent) the following:
>
> - Insulin glargine pens (Lantus pens): Maintaining the Tier 1 copay at the Mail Order and Retail Network
> - Insulin glargine vials (Lantus vials): Applying the Tier 1 copay at the Mail Order and Retail Network
> - Implementation will occur on January 1, 2023.
>
> The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the 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. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes." Lowering the cost-share for Lantus pens and vials will provide a greater incentive for beneficiaries to use the most cost-effective basal insulin product in the purchased care points of service.

XI. OVER-THE-COUNTER MEDICATIONS—MHS GENESIS OTC TEST LIST

A. Purpose of the MHS GENESIS OTC List

Background—At retail pharmacies and the Mail Order pharmacy, OTC medications are limited to those explicitly included in the TRICARE pharmacy benefit (e.g., diabetic supplies, tobacco cessation agents), as well as medications added to the Uniform Formulary and covered by TRICARE under provisions of 32 CFR 199.21(h)(5) as being cost-effective and clinically effective compared with other drugs in the same therapeutic class (e.g., loratadine, cetirizine, fexofenadine, levonorgestrel 1.5 mg [Plan B One-Step and its generics], and doxylamine 25 mg).

Historically, MTFs have dispensed a wide variety of OTC medications, as determined by the local MTF. A transition to a more uniform list of OTC products available across MTFs was recommended. Additionally, standardization was necessary due to the implementation of MHS GENESIS, the new electronic health record system. The MHS GENESIS OTC list was implemented on March 29, 2018; it is a list of NDCs for OTC products that will successfully adjudicate through the outpatient pharmacy system at MHS GENESIS sites. The P&T Committee has been systematically reviewing OTCs on the MHS GENESIS list since 2018 in order to finalize the list, with the last two categories reviewed in May 2022. (*Please refer to P&T Committee meeting minutes for May 2019, August 2019 and February 2022 for more background information*.)

Clarification—Although the goal of the MHS GENESIS OTC list is to provide a streamlined, standardized list of drugs that will adjudicate through the Pharmacy Data Transaction Service (PDTS), MTFs are <u>not</u> required to include every item on the list locally. Inclusion of an OTC product on the MHS GENESIS OTC list only allows for adjudication of a product at a MHS GENESIS site, and does not mandate inclusion on MTF formularies (i.e.; "may' have, not "must" have locally).

In addition, the MHS GENESIS OTC list does not affect purchasing of OTC medications through the prime vendor for either inpatient or out-patient use. It is also not intended to provide guidance for MTF self-care programs. However, since Service policies require products dispensed through such programs to be added to patient profiles, OTC products dispensed as part of MTF self-care programs do need to be on the MHS GENESIS OTC list in order to adjudicate through PDTS and show up on patient profiles.

B. Changes to the List: Vitamin D products update

*Background—*The DoD P&T Committee reviewed a request from the TRICARE nutritional community for addition of two additional vitamin D products to the MHS GENESIS OTC list to support an MTF standard: vitamin D3 (cholecalciferol) 2000 unit caps/tabs and 50,000 caps. Currently the list contains the following products: vitamin D3 (cholecalciferol) 400 u/mL drops and 400-, 1000-, and 5000-unit tablets, and vitamin D2 (ergocalciferol) 8000 u/mL drops. In addition, vitamin D2 (ergocalciferol) 50,000 unit caps are legend products and widely dispensed at all three points of service.

The request for vitamin D3 50,000 was based on evidence of slightly higher vitamin D concentrations compared to vitamin D2; however the clinical significance of this is unclear.

With respect to the 2000 unit strength, CHCS MTFs currently dispense similar quantities of the capsule and tablet products.

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding vitamin D3 2000 unit tabs and caps and 50,000 unit caps to the MHS GENESIS OTC list. See Appendix I which outlines specific products retained or added to the MHS GENESIS OTC List.

C. Maintenance of the MHS GENESIS OTC Test List—General Process and MTF Requests

The MHS GENESIS OTC list is generally controlled at drug/strength/dosage form level, with the pharmacy contractor, Express-Scripts (ESI) periodically refreshing the list to account for the introduction of new NDCs. MTFs proposing additions or deletions from the list (at drug/strength/dosage form level) may fill out the MTF Drug Review Request Form (DHA Form 111), which may be found on the Formulary Management Branch (FMB) Sharepoint page: https://info.health.mil/hco/pharmacy/FMB/SitePages/Home.aspx).

This form requires the rationale for the proposed change, as well as sign-off by a local MTF P&T Committee before it will be presented to the DoD P&T Committee. If MTFs are encountering difficulties due to the lack of a specific NDC for products already represented on the list, or shortages arise for products already on the list, they may contact the FMB without going through the MTF Request Form process.

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—In order to facilitate ongoing maintenance of the list, the P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) on the following:

- Changes to be managed administratively by FMB:
  - Requests for addition of products to the list where a similar agent is on the list
  - Changes requested as a result of a shortage or other availability issue (e.g., OTC status changes), where similar agents are already on the list
  - Changes for administrative reasons that don't affect adjudication through PDTS (e.g., management of formulary lists)
- Changes to be handled administratively, but brought to the P&T Committee afterward for review
  - Changes requested as a result of a shortage or other availability issue, where similar agents aren't already on the list
- Changes requiring P&T Committee review

- Addition of products where similar agents are not already on the list (e.g., adding new category of products)
- Deletion of products that result in no agents on the list in a given category

XII. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS—NEW MEDICAL DEVICES

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 (*Refer to the May 2017, May 2019, August 2020, and August 2021 meeting minutes*.)

Medical devices are not part of the TRICARE Pharmacy benefit, with limited exceptions (e.g., certain diabetic supplies [continuous glucose monitoring systems, self-monitoring blood glucose test strips] and spacers for inhalers, [Aerochamber]). Medical devices are primarily covered by the TRICARE Health Plan and any additions to the pharmacy benefit are not meant to replace this pathway for procuring medical devices. A process for identifying how and when to review new versions of medical devices currently covered under the TRICARE pharmacy benefit is needed. There is currently no statutory or regulatory requirement mandating that the DoD P&T Committee review new FDA-approved medical devices or that the TRICARE Pharmacy benefit cover such devices.

The Committee discussed and approved a process of reviewing medical devices for inclusion on the DoD Uniform Formulary. Any new version/model of a currently covered device is not automatically included on the UF; new versions/models must first be reviewed by the DoD P&T Committee for clinical and cost effectiveness before being added to the TRICARE pharmacy benefit. Issues such as Trade Agreement Act noncompliance or other regulatory factors may preclude addition to the UF. See Appendix J for details on the device review pathway in the updated Administrative Authorities document.

> ***COMMITTEE ACTION: MEDICAL DEVICE REVIEW PROCESS—***The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the process for considering and reviewing new versions/models of medical devices currently covered under the TRICARE pharmacy benefit for UF status.

VIII. SPECIALTY MEDICATION DEFINITION

The P&T Committee revised the definition of Specialty medications established by the P&T Committee in Aug 2014 to the following: Specialty medications will be based on one or more of the following characteristics:

1. One or more of the following clinical factors:
   - Difficult to administer
   - Special handling or storage
   - Intense monitoring
   - High risk of adverse drug events
   - Frequent dose adjustments
   - REMS programs in place
   - Benefits of ongoing training for patients
   - Not widely used in practice
   - Other drugs in the class are designated as specialty
2. The cost of the medication to DoD exceeds a cost factor based on that used by CMS to identify Specialty medications (top 1% of spend within DoD per 30 day-supply)
3. Upon future evaluation, the Specialty Pharmacy Program continues to provide value to the patient and/or DoD

COMMITTEE ACTION: SPECIALTY MEDICATION DEFINITION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the factors mentioned above as defining a specialty medication for the MHS.

VIV. ITEMS FOR INFORMATION

A. **Post-Implementation Review: Pancreatic Enzyme Replacement Products:** The Committee reviewed utilization and cost trends for the Pancreatic Enzyme Replacement (PERT) Products, which were reviewed for formulary placement in November 2018. The formulary actions of using Tier 1 and implementing step preference for the class resulted in significant and sustained cost avoidance for the MHS.

XV. ADJOURNMENT

The meeting adjourned at 1715 hours on August 4, 2022. The next meeting will be in November, 2022.

Appendix A—Attendance: August 4-5, 2022 DoD P&T Committee Meeting:
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

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

26 OCT 2022
Date

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
MAJ Megan Donahue, MC	Army, Physician at Large
LTC Joseph Taylor, MSC	Army, Pharmacy Consultant
LTC Rosco Gore, MC	Army, Internal Medicine Physician
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Capt Jamie Geringer, MC for Lt Col Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
LTC Jason Burris, MC	Army, Oncology Physician
Walter Downs, MD	Physician at Large, DHA
Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR Samuel Mendoza	Defense Logistics Agency

Guests	
CDR Daniel True, USPHS	Bureau of Prisons
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Mr. Ralph Bowie	DHA Contracting
Others Present	
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
David Folmar, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, RPh	DHA Formulary Management Branch Contractor
Michael Lee, RPh	DHA Formulary Management Branch Contractor
Dean Valibhai, PharmD	DHA Purchased Care Branch
LT Vivian Le, MSC	Navy Pharmacy Resident, San Diego

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• paroxetine mesylate (Pexeva) **Anti-Depressants & Non-Opioid Pain**	• Formulary agents have resulted in therapeutic failure **Formulary alternatives:** SSRI: citalopram, escitalopram, fluoxetine, sertraline, fluvoxamine, paroxetine hydrochloride IR; SNRI: venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER
• bupropion hydrobromide XR (Aplenzin) **Anti-Depressants & Non-Opioid Pain**	• Formulary agents have resulted in therapeutic failure **Formulary alternatives:** bupropion HCl (IR, SR, ER)
• duloxetine DR sprinkle (Drizalma Sprinkle) **Anti-Depressants & Non-Opioid Pain**	• No alternative formulary agent: Patient requires duloxetine but cannot swallow duloxetine capsules **Formulary alternatives:** duloxetine capsules, fluoxetine oral syrup/oral solution, citalopram solution, sertraline solution, venlafaxine sprinkle
• levomilnacipran XR (Fetzima) **Anti-Depressants & Non-Opioid Pain**	• Use of formulary alternatives is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents that are not expected to occur with Fetzima • Formulary alternatives have resulted in therapeutic failure • Patient previously responded to nonformulary agent and changing would incur unacceptable risk • No alternative formulary agent **Formulary alternatives:** selective serotonin reuptake inhibitors, serotonin/norepinephrine reuptake inhibitor (except milnacipran), tricyclic antidepressants, mirtazapine, bupropion, serotonin antagonist reuptake inhibitors, mononamine oxidase inhibitors
• milnacipran (Savella) **Anti-Depressants & Non-Opioid Pain**	• Use of formulary alternatives is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary alternatives that are not expected to occur • Formulary alternatives have resulted in therapeutic failure • Patient previously responded to nonformulary agent and changing would incur unacceptable risk **Formulary alternatives:** reuptake inhibitor (except levomilnacipran), tricyclic antidepressants, mirtazapine, bupropion, serotonin antagonist reuptake inhibitors, mononamine oxidase inhibitors

• gabapentin ER 24 hr tablets (Gralise) • gabapentin enacarbil (Horizant) **Anti-Depressants & Non-Opioid Pain**	• Use of formulary alternatives is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary alternatives **Formulary alternatives:** gabapentin or the formulary non-opioid pain syndrome agents.
Newly Approved Drugs MN Criteria	
• amlodipine oral solution (Norliqva) **Calcium Channel Blockers**	• No alternative formulary agent – patient has swallowing difficulties and can't take amlodipine tabs **Formulary alternatives:** amlodipine (generic), or other DHP CCBs (felodipine, isradipine)
• cyclosporine 0.1% ophthalmic emulsion (Verkazia) **Ophthalmic Dry Eye**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis) or cyclosporine 0.09% (Cequa)
• donepezil patch (Adlarity) **Alzheimer's Agents**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** donepezil tablets, rivastigmine patch (Exelon), galantamine
• leuprolide SC injection (Camcevi Kit) **LHRH Agonists – Antagonists**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents **Formulary alternatives:** Lupron-Depot; Eligard
• tapinarof 1% cream (Vtama) **Psoriasis Agents**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** moderate to high potency topical corticosteroids (e.g., betamethasone, clobetasol, fluocinonide), topical calcineurin inhibitors (i.e., pimecrolimus, tacrolimus)

• testosterone undecanoate 112.5 mg capsule (Tlando) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	• Patient has experienced significant adverse effects from ALL listed formulary agents • ALL listed formulary agents resulted in therapeutic failure **Formulary alternatives:** Androderm patch, testosterone 2% gel (Fortesta), testosterone 1% gel (generic to Androgel), and Testim 1% gel
• tirzepatide SC injection (Mounjaro) **Diabetes Non Insulin: Glucagon-Like Peptide-1 (GLP1_ Receptor Agonists**	• Patient has experienced significant adverse effects from Trulicity which is not expected to occur with Mounjaro **Formulary alternatives:** Trulicity
• amoxicillin; vonoprazan (Voquezna Dual Pak) • amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) **Anti-Infectives: Miscellaneous**	• A trial of two formulary treatment courses/combinations resulted in therapeutic failure **Formulary alternatives:** omeprazole, lansoprazole, amoxicillin, rifabutin, clarithromycin, bismuth subsalicylate, metronidazole, tetracycline, other PPIs or H2 blockers

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• paroxetine mesylate (Pexeva) **Anti-Depressants & Non-Opioid Pain - SSRI**	**PA criteria apply to all new users of Pexeva. (New PA criteria)** Manual PA criteria: Pexeva is approved if all criteria are met: • Patient is 18 years of age or older. • Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. • Patient has a diagnosis of depression, anxiety, obsessive compulsive disorder, or panic disorder • Patient has tried and failed generic paroxetine at maximally tolerated dose AND • The patient has a contraindication to, intolerability to, or has failed a trial of TWO other formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• vilazodone (Viibryd) **Anti-Depressants & Non-Opioid Pain - SSRI**	**PA criteria apply to all new users of Viibryd. (New PA criteria)** Manual PA criteria: Viibryd is approved if all criteria are met: • Patient is 18 years of age or older. • Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication. • Patient is being treated for depression • The patient has a contraindication to, intolerability to, or has failed a trial of THREE formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose). Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• vortioxetine (Trintellix) **Anti-Depressants & Non-Opioid Pain - SSRI**	**Updates to the Feb 2014 meeting are in bold ~~and strikethrough~~** **Note that previous automation has been removed** PA criteria apply to all new users of Trintellix. Manual PA criteria: Trintellix is approved if all criteria are met: • Patient is 18 years of age or older. • **Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication.** • **Patient is being treated for depression** • **The patient has a contraindication to, intolerability to, or has failed a trial of TWO formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose).** • ~~**Patients are required to try a generic SSRI, duloxetine, SNRI (except milnacipran), tricyclic antidepressant, mirtazapine> bupropion, serotonin antagonist reuptake inhibitor (trazodone, ornefazodone), or mononamine oxidase inhibitor first**~~ Non-FDA-approved uses are not approved. Prior Authorization does not expire.

• duloxetine DR (Drizalma Sprinkle) **Anti-Depressants & Non-Opioid Pain - SNRI**	**Note – There were no changes made at the August 2022 meeting.** PA does not apply to patients 12 years of age and younger (age edit). PA criteria apply to all new users of Drizalma Sprinkle older than 12 years of age. Manual PA Criteria: Drizalma Sprinkle is approved if all criteria are met: • Provider must explain why the patient requires Drizalma sprinkle capsules and cannot take alternatives. Non-FDA-approved uses are not approved. PA expires in one year. Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.
• levomilnacipran XR (Fetzima) **Anti-Depressants & Non-Opioid Pain - SNRI**	**Updates to the Feb 2014 meeting are in bold ~~and strikethrough~~** **Note that previous automation has been removed** PA criteria apply to all new users of Fetzima Manual PA criteria: Fetzima is approved if all criteria are met: • Patient is 18 years of age or older. • **Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication.** • ~~**Patients are required to try a generic SSRI, duloxetine, SNRI (except milnacipran), tricyclic antidepressant, mirtazapine> bupropion, serotonin antagonist reuptake inhibitor (trazodone, ornefazodone), or mononamine oxidase inhibitor first**~~ • **Patient is being treated for depression** • **The patient has a contraindication to, intolerability to, or has failed a trial of THREE formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose).** Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• milnacipran (Savella) **Anti-Depressants & Non-Opioid Pain - SNRI**	**Updates to the Nov 2011 meeting are in bold ~~and strikethrough~~** **Note that previous automation has been removed** PA criteria apply to all new users of Savella Manual PA criteria: Savella is approved if all criteria are met: • Patient is 18 years of age or older. • ~~**All new users of Savella are required to try a non-opioid pain syndrome agent including SNRI including milnacipran, TCA, cyclobenzaprine, gabapentin or pregabalin**~~ • **Patient is being treated for fibromyalgia** • **Patient has tried and failed duloxetine at maximally tolerated dose AND** • **The patient has a contraindication to, intolerability to, or has failed a trial of ONE other formulary medication at maximally tolerated dose (examples of formulary agents include pregabalin, amitriptyline, cyclobenzaprine).** Non-FDA-approved uses are not approved. Prior Authorization does not expire.

• bupropion hydrobromide XR (Aplenzin) **Anti-Depressants & Non-Opioid Pain - NDRI**	**Updates to the Nov 2017 meeting are in bold ~~and strikethrough~~** **Note that previous automation has been removed** PA criteria apply to all new users of Aplenzin Manual PA criteria: Aplenzin is approved if all criteria are met: • The patient is 18 years or older. • **The patient does not have a history of seizure disorder or conditions that increase the risk of seizure (e.g. bulimia, anorexia nervosa, severe head injury).** • **Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e. CBT, sleep hygiene) are encouraged to be used in conjunction with this medication.** • **~~New and current users of Aplenzin are required to try generic bupropion ER and a second antidepressant first.~~** • **The patient has being treated for depression or seasonal affective disorder** • **Patient has tried and failed bupropion extended release at maximally tolerated dose AND** • **The patient has a contraindication to, intolerability to, or has failed a trial of TWO other formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose).** Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• gabapentin ER 24 hr tablets (Gralise) **Anti-Depressants & Non-Opioid Pain - GABA**	**Updates to the May 2012 meeting are in bold ~~and strikethrough~~** **Note that previous automation has been removed** PA criteria apply to all new users of Gralise Manual PA criteria: Gralise is approved if all criteria are met: • Patient is 18 years of age or older. • **~~The patient has a contraindication to or experienced adverse events with gabapentin or the formulary non-opioid pain syndrome agents which is not expected to occur with Horizant or Gralise.~~** • **Patient is being treated for post herpetic neuralgia and:** • **Patient has tried and failed gabapentin or pregabalin at maximally tolerated dose AND** • **Patient has a contraindication to, intolerability to or has tried and failed a TCA at maximally tolerated dose.** Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• gabapentin enacarbil (Horizant) **Anti-Depressants & Non-Opioid Pain - GABA**	**Updates to the May 2012 meeting are in bold ~~and strikethrough~~** **Note that previous automation has been removed** PA criteria apply to all new users of Horizant Manual PA criteria: Horizant is approved if all criteria are met: • **~~The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.~~** • **~~The patient has experienced adverse events (AEs) with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.~~** **For post herpetic neuralgia:** • **Patient is 18 years of age or older**

	• **Patient has tried and failed gabapentin or pregabalin at maximally tolerated dose AND** • **Patient has a contraindication to, intolerability to or has tried and failed a TCA at maximally tolerated dose.** **For restless leg syndrome:** • **Patient is 18 years of age or older.** • **Patient has tried and failed gabapentin or pregabalin at maximally tolerated dose AND** • **Patient has contraindication to, intolerability to or has tried and failed pramipexole or rotigotine at maximally tolerated dose.** Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• mirabegron tablets (Myrbetriq) **Overactive Bladder Agents – β-3 Agonists**	**Updates from the August 2022 meeting are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of mirabegron (Myrbetriq). Manual PA criteria: Myrbetriq is approved if all criteria are met: • Overactive Bladder ◦ The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency AND ◦ The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training ◦ The patient has had a 12-week trial with **one ~~two formulary step-preferred products~~ generic antimuscarinic medication** (oxybutynin IR, oxybutynin ER, tolterodine ER, **trospium, solifenacin, darifenacin or fesoterodine**) 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, **advanced age** or other medications ◦ ~~**Patient has tried and failed or has a contraindication to vibegron (Gemtesa)**~~ ◦ The patient's **~~does not have a Cr Cl <15 mL/min~~ estimated creatinine clearance (CrCl)/glomerular filtration rate (eGFR) is ≥15 mL/min/1.73m^2 and the provider is aware that the dose should not exceed 25 mg a day in patients with a CrCl/eGFR between 15 – 29 mL/min/1.73m^2** ◦ ~~**If the CrCl is between 15-29 mL/min, the dosage does not exceed 25 mg QD**~~ **OR** • Neurogenic Detrusor Overactivity (NDO) ◦ The patient has a confirmed diagnosis of neurogenic detrusor overactivity (NDO) secondary to detrusor overactivity and/or myelomeningocele ◦ The drug is prescribed by or in consultation with a urologist or nephrologist ◦ The provider acknowledges that the granules are not bioequivalent and cannot be substituted on a mg to mg basis with the tablets and will not combine dosage forms to achieve a specific dose ◦ Provider acknowledge that there are detailed renal and hepatic dose adjustments in the package labeling and agrees to consult this before prescribing in this special population ◦ Provider acknowledge that oxybutynin is available for patients with neurogenic detrusor overactivity and does not require prior authorization ◦ Patient has tried and failed or has a contraindication to oxybutynin ◦ The patient weighs greater than or equal to 35 kg Non-FDA-approved uses are not approved. Prior authorization does not expire.

• mirabegron extended release granules for oral suspension (Myrbetriq Granules)
 	
Overactive Bladder Agents – β-3 Agonists
	No changes made at the August 2022 meeting
	
	Note that the previous automation for Myrbetriq granules and tablets has been removed
	
	Manual PA criteria: Myrbetriq Granules are approved if all criteria are met:
	• Myrbetriq granules for oral suspension are prescribed by or in consultation with a urologist or nephrologist
	• The prescription is written for neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele, and not for overactive bladder
	• Provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization
	• Patient has tried and failed or has a contraindication to oxybutynin
	• Patient requires Myrbetriq granules for oral suspension for one of the following reasons:
	  • The patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, etc) and not convenience. OR
	  • The patient weighs less than 35 kg
	• Provider acknowledges that Myrbetriq granules for suspension are not bioequivalent to and cannot be substituted on a mg to mg basis to the Myrbetriq tablets
	• Provider acknowledges that Myrbetriq granules for suspension and the Myrbetriq tablets will not be combined to achieve a specific dose
	• Provider acknowledges the detailed renal and hepatic dosing adjustments in the package labeling and agrees to consult this before prescribing the granules in these special populations
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.

• vibegron (Gemtesa) **Overactive Bladder Agents – β-3 Agonists**	**Updates from the August 2022 meeting are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of Gemtesa. <u>Manual PA criteria</u>: Gemtesa is approved if <u>all</u> criteria are met: • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with **one ~~two formulary step preferred products~~ generic antimuscarinic** (oxybutynin IR, oxybutynin ER, tolterodine ER, **trospium, solifenacin, darifenacin or fesoterodine)** and had therapeutic failure OR • The patient has experienced central nervous system adverse events with at least one oral OAB medication OR is at increased risk for such central nervous system effects due to comorbid conditions, **advanced age** or other medications, • The patient's creatinine clearance (CrCl) **)/glomerular filtration rate (eGFR) is ≥15 mL/min/1.73m^2 ~~is greater than 15 mL/min~~** Non-FDA-approved uses are not approved. Prior authorization does not expire.

Newly Approved Drug PAs	
• alpelisib (Vijoice) **Oncological Agents**	PA criteria apply to all new users of alpelisib (Vijoice). Manual PA criteria: Vijoice is approved if all criteria are met: • Prescription is written by or in consultation with a medical geneticist or vascular surgeon • Patient has a documented diagnosis of PIK3CA Related Overgrowth Spectrum (PROS) which the provider determines to be severe and requiring systemic therapy • Patient has documented evidence of a mutation in the PIK3CA gene Non-FDA-approved uses are not approved PA expires in one year Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if • The patient has a documented positive clinical response to therapy
• amlodipine oral solution (Norliqva) **Calcium Channel Blockers**	PA does not apply to patients less than 12 years of age (age edit). PA criteria apply to all new users of Norliqva. Manual PA criteria: Norliqva is approved if all criteria are met • Provider must explain why the patient requires amlodipine oral solution and cannot take amlodipine tablets or amlodipine suspension Non-FDA-approved uses are not approved PA does not expire
• cyclosporine 0.1% ophthalmic emulsion (Verkazia) **Ophthalmic Dry Eye**	Note that an age edit and automated look back apply. • Patients who are younger than age 21 years who have a history of Restasis do not require a PA; Verkazia is approved • Patients younger than age 21 who **do not** have a history of Restasis require manual PA • Manual PA is required in all new patients 21 years of age and older Automated PA criteria: The patient is younger than age 21 years AND has filled a prescription for cyclosporine 0.05% ophthalmic solution (Restasis) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. Manual PA Criteria: If automated criteria are not met, coverage is approved for Verkazia if all criteria are met: • Verkazia is prescribed by or in consultation with an optometrist or ophthalmologist • Patient has moderate to severe vernal keratoconjunctivitis (VKC) • Patient has tried and failed an adequate course of at least one mast cell stabilizer/antihistamine (i.e., olopatadine, azelastine, epinastine, lodoxamide, cromolyn) • Patient has tried and failed, or has a contraindication to an adequate course of cyclosporine 0.05% ophthalmic emulsion (Restasis) Non-FDA-approved uses are NOT approved including dry eye disease, graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) and LASIK associated dry eye PA does not expire

• daridorexant (Quviviq) **Sleep Disorders: Insomnia Agents**	Manual PA criteria apply to all new users of **Quviviq**, Belsomra, and Dayvigo. Manual PA Criteria: **Quviviq,** Belsomra, Dayvigo is approved if all criteria are met: • Provider acknowledges the following agents are available without prior authorization: zolpidem IR and ER, zaleplon, eszopiclone • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), sleep hygiene, and the patient will continue with non-pharmacologic therapies throughout treatment • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release OR eszopiclone • Patient has no current or previous history of narcolepsy • Patient has no current or previous history of drug abuse Non FDA-approved uses are not approved Prior authorization expires in 1 year Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be renewed for an additional 1 year if the renewal criteria are met: • Patient has not adequately responded to non-pharmacologic therapies • Patient agrees to continue with non-pharmacologic therapies including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), and/or sleep hygiene • Patient continues to respond to the drug

• donepezil patch (Adlarity)
 	
Alzheimer's Agents
	Manual PA criteria apply to all new users of donepezil transdermal system (Adlarity).
	
	Manual PA criteria: Coverage is approved if all criteria are met:
	• The patient is 18 years of age or older
	• The medication is being prescribed in consultation with a neurologist, psychiatrist, or specialist in geriatric medicine.
	• The patient is being treated for mild, moderate, or severe dementia of the Alzheimer's type.
	• The patient must have tried and failed, have a contraindication to, or have had an adverse reaction to both of the following::
	  • One oral donepezil formulation (e.g., donepezil 5 mg or, 10 mg tab or orally dissolving tablets [ODT]) AND
	  • One topical agent: rivastigmine transdermal system (Exelon patch).
	
	Non-FDA approved uses are NOT approved.
	PA does not expire.

• edaravone oral suspension (Radicava ORS) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Radicava ORS. Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by a neurologist. • The patient has a diagnosis of amyotrophic lateral sclerosis (ALS). • The disease duration is two years or less • The patient has a score of ≥ 2 points for each item of ALS Functional Rating Scale–Revised (ALSFRS-R). • The patient has preserved respiratory function (forced vital capacity ≥ 80%) Non-FDA approved uses are NOT approved. PA does not expire.

• ganaxolone oral suspension (Ztalmy) **Anticonvulsants-Antimania Agents**	Manual PA criteria apply to all new users of ganaxolone (Ztalmy) Manual PA criteria: Coverage is approved if all criteria are met: • Drug is prescribed by or in consultation with pediatric neurologist • Patient has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed with a genetic test Non-FDA approved uses are NOT approved. PA does not expire.
• insulin glargine solostar authorized biologic **Basal Insulins**	Manual PA criteria apply to all new users of insulin glargine solostar Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Lantus is the DoD's preferred basal insulin and preferred insulin glargine. Prescriptions written for Lantus do not require prior authorization and are available at the lowest Tier 1 copay. • Patient must have tried and failed insulin glargine (Lantus) Non-FDA approved uses are NOT approved. PA does not expire.
• leuprolide SC injection (Camcevi Kit) **LHRH Agonists-Antagonists**	Manual PA criteria apply to all new users of Camcevi. Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by or in consultation with an oncologist or urologist • Patient has a diagnosis of advanced prostate cancer • Patient has intolerability to, or has failed alternative formulary leuprolide injections (i.e. Lupron Depot, Eligard) Non-FDA approved uses are NOT approved. PA does not expire.

• mavacamten (Camzyos)
 	
Cardiovascular Agents Miscellaneous
	Manual PA criteria apply to all new users of Camzyos.
	
	Manual PA criteria: Camzyos is approved if all criteria are met:
	• The patient is 18 years of age and older
	• Drug is prescribed by a cardiologist
	• The patient has documented evidence of obstructive hypertrophic cardiomyopathy (HCM)
	• Left ventricular outflow tract (LVOT) pressure gradient is greater than or equal to 50 mmHg
	• The patient has NYHA Class II to III obstructive HCM that is symptomatic (e.g., dyspnea, chest pain, light headedness, syncope, fatigue, reduced exercise capacity)
	• The patient's left ventricular ejection fraction (LVEF) is greater than or equal to 55%
	• Patient has failed therapy with at least **one** agent from **both** of the following classes:
	  ◦ Beta blocker (non-vasodilating) – propranolol, metoprolol AND
	  ◦ Calcium channel blockers (non-dihydropyridine) – verapamil, diltiazem
	• Patient must not be on dual calcium channel blocker and beta blocker therapy concurrently
	• Patient must not be receiving ranolazine or disopyramide concurrently
	• Patient and provider must be aware of the risks of systolic dysfunction as outlined by REMS

	• Provider and patient must agree to comply to all requirements of the REMS program, including echocardiogram at 0, 4, 8, 12 weeks follow by every 12 weeks and drug interaction monitoring requirements • If the patient is of child-bearing age, the patient must not be pregnant and will receive counseling for effective contraception during therapy and for 4 months after the last dose Non-FDA-approved uses are not approved PA expires in 1 year, • Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be renewed indefinitely if the patient has responded to therapy, as evidenced by improvement in obstructive hypertrophic cardiomyopathy symptoms

• tapinarof 1% cream (Vtama)
 	
Psoriasis Agents
	Manual PA criteria apply to all new users of tapinarof (Vtama).
	
	Manual PA criteria: Vtama is approved if all criteria are met:
	• Patient is 18 years of age of older.
	• The patient has a diagnosis of plaque psoriasis.
	• The medication is being prescribed in consultation with a dermatologist.
	• The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following:
	  • at least one moderate to high potency topical corticosteroid (e.g., clobetasol propionate 0.05% ointment, cream, solution and gel; fluocinonide 0.05% ointment, cream, solution) AND
	  • at least one topical calcineurin inhibitor (e.g. tacrolimus, pimecrolimus)
	Non-FDA approved uses are not approved.
	PA does not expire.

• testosterone undecanoate 112.5 mg capsules (TLando) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	Manual PA criteria applies to new users of users of Jatenzo and **TLando** Manual PA Criteria: Jatenzo or **TLando** is approved if all criteria are met: • Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions • Patient is a male age 18 years of age or older • The patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL. • Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed (From Feb 2022 meeting PA update for the testosterone replacement therapy drug class) • Patient is experiencing signs and symptoms usually associated with hypogonadism • Patient has tried testosterone 2% gel (Fortesta) OR testosterone 1% gel (Androgel generic) for a minimum of 90 days AND failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after use of the agent) AND without improvement in symptoms OR • Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta OR generic testosterone 1% gel, that is not expected to occur with Jatenzo or **TLando** • The patient requires a testosterone replacement therapy (TRT) that has a low risk of skin-to-skin transfer between family members OR • Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:

	• Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM
	• Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND
	• Patient has no signs of breast cancer AND
	• For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND
	• Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND
	• ~~**Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria**~~ **(deleted May 2022)**
	• Patient does not have any of the following:
	  • Hypogonadism conditions not associated with structural or genetic etiologies (e.g. "age-related" hypogonadism), carcinoma of the breast or suspected carcinoma of the prostate
	  • Uncontrolled hypertension or is at risk for cardiovascular events (e.g., myocardial infarction or stroke) prior to start of Jatenzo or **Tlando** therapy or during treatment (based on the product's boxed warning of increased risk of major adverse cardiovascular events and hypertension)
	
	Non-FDA-approved uses are NOT approved.
	Not approved for concomitant use with other testosterone products.
	Prior Authorization does not expire

• tirzepatide (Mounjaro)
 	
Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)
	Manual PA criteria apply to all new users of Mounjaro.
	
	All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.
	
	<u>Manual PA criteria</u>: Coverage is approved if all criteria are met:
	• Provider acknowledges that Trulicity is available on the UF and has an indication to reduce the risk of major adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors, Mounjaro does not have this indication
	• The patient has a confirmed diagnosis of Type 2 diabetes mellitus
	• The patient has experienced any of the following issues on metformin:
	  • impaired renal function precluding treatment with metformin OR
	  • history of lactic acidosis
	• The patient has had inadequate response to metformin OR
	• The patient has a contraindication to metformin
	
	Non-FDA approved uses are NOT approved, including for weight loss in patients who do not have diabetes
	PA does not expire

• vonoprazan, amoxicillin (Voquezna Dual Pak) • vonoprazan, amoxicillin, clarithromycin (Voquezna Triple Pak) **Anti-Infectives Miscellaneous**	Manual PA criteria apply to all new users of Voquezna Dual & Triple Pak Manual PA criteria: Coverage is approved if all criteria are met: • The provider acknowledges that other medications to treat *H. pylori* including lansoprazole, amoxicillin, and clarithromycin are on the TRICARE formulary and are available without a PA • Patient is 18 years of age or older • Prescription is written by or in consultation with a gastroenterologist or infectious disease specialist • Patient has tried and failed two 14-day trials of therapy with guideline-recommended first-line therapies (Appropriate treatment combinations of: omeprazole, lansoprazole, amoxicillin, rifabutin, clarithromycin, bismuth subsalicylate, metronidazole, tetracycline, and PPI or H2 blockers) for *H. pylori* • Note: Failure is defined as failure to eradicate *H. pylori* infection after a 14-day course of therapy Non-FDA approved uses are NOT approved PA renewal is not allowed; A new PA is required for each course of therapy
Utilization Management New PAs	
• tiotropium dry powder inhaler (Spiriva HandiHaler) **Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)**	Manual PA criteria apply to all **new and current** users of Spiriva HandiHaler. Manual PA criteria: Spiriva HandiHaler is approved if all the following criteria are met: • The provider acknowledges that Spiriva Respimat is the Department of Defense's preferred long-acting muscarinic antagonist and does not require prior authorization. • The provider must document a patient-specific reason as to why the patient requires Spiriva Handihaler and cannot use the Spiriva Respimat device. (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• metformin 625 mg IR tablets **Non-Insulin Diabetes Drugs: Bigaunides**	Manual PA criteria apply to all **new and current** users of metformin IR 625 mg tablets. Manual PA criteria: Metformin IR 625 mg tablets are approved if all criteria are met: • Provider acknowledges other metformin formulations, including the 500 mg and 850 mg immediate release tablets, and 750 mg and 1000 mg extended release tablets are available without requiring prior authorization. • The provider must explain why the patient can't take a different metformin formulation. (blank write-in) Non-FDA-approved uses are not approved. Prior authorization does not expire.

• valsartan 20 mg/5mL oral solution **Renin Angiotensin Antihypertensives (RAAs): Angiotensin Receptor Blockers (ARBs)**	Manual PA criteria apply to all **new and current** users of valsartan 20 mg/5mL oral solution. Manual PA criteria: Valsartan 20 mg/5mL oral solution is approved if all criteria are met: • Provider acknowledges other angiotensin receptor blockers (ARBs) including valsartan, telmisartan and losartan are available without requiring prior authorization. • The provider must explain why the patient can't take a tablet formulation of an (ARB) (blank write-in) Non-FDA-approved uses are not approved. Prior authorization does not expire.
Utilization Management Updated PAs	
• dupilumab (Dupixent) **Atopy Agents (Formerly Respiratory Interleukins)**	**Updates from the August 2022 meeting for EoE and atopic dermatitis are in bold and strikethrough. Note that no changes were made for the asthma or nasal polyps indications.** Manual PA is required for all new users of dupilumab (Dupixent). Manual PA Criteria: Dupixent coverage will be approved for initial therapy for 12 months if all criteria are met: ***For Eosinophilic Esophagitis:*** • **The patient is 12 years of age or older and weighs at least 40 kilograms (~88 lbs)** • **The drug is prescribed by or in consultation with a gastroenterologist or allergy/immunology specialist** • **Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy** • **For EoE, the patient has tried and failed an adequate course of both the following:** ▪ **Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND** ▪ **Topical glucocorticoids [e.g. fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, clinically significant adverse effects are experienced, or in children maximal doses can not be reached due to concerns for growth suppression or adrenal insufficiency** **Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND** • **Eosinophilic Esophagitis (EoE):** ▪ **For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e):** **a) Reduced intraepithelial eosinophil count; OR** **b) Decreased dysphagia/pain upon swallowing; OR** **c) Reduced frequency/severity of food impaction; OR** **d) Reduced vomiting/regurgitation; OR** **e) Improvement in oral aversion/failure to thrive** ▪ **For relapse: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval**

	For Atopic Dermatitis: • The patient is at least **6 months** ~~**years**~~ of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe or uncontrolled atopic dermatitis • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: o For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) o For patients 6 to 17 year of age: any topical corticosteroid AND ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy *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 one of the following ▪ Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/mcL OR ▪ Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months • For eosinophilic asthma, the patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following; ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR ▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • For eosinophilic asthma, the patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi), ▪ Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, 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

	• Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments ▪ 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 • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength AND • For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) 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 • Eosinophilic Esophagitis (EoE): ▪ For <u>maintenance:</u> patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e): f) Reduced intraepithelial eosinophil count; OR g) Decreased dysphagia/pain upon swallowing; OR h) Reduced frequency/severity of food impaction; OR i) Reduced vomiting/regurgitation; OR j) Improvement in oral aversion/failure to thrive ▪ For <u>relapse:</u> prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval • Asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use • Atopic Dermatitis: The patient's disease severity has improved and stabilized to warrant continued therapy • Chronic rhinosinusitis with nasal polyposis : There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score.

• upadacitinib (Rinvoq) **Targeted Immunomodulatory Biologics (TIBs): Miscellaneous**	**Updates from the Aug 2022 meeting are in bold. Note that there were not changes to the criteria for the other indications (RA, PsA, AD, Ulcerative Colitis)** Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq ER). Manual PA Criteria: Rinvoq is approved if all criteria are met: ***For Ankylosing Spondylitis*** • **Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ankylosing spondylitis** • **The patient is 18 years of age or older** • **The patient has ankylosing spondylitis** • **Patient has had an inadequate response to Humira and Cosentyx OR** • **Patient has experienced an adverse reaction to Humira and Cosentyx that is not expected to occur with the requested agent OR** • **Patient has a contraindication to Humira and Cosentyx AND** • **Patient has had an inadequate response to at least two NSAIDs over a period of at least two months** *For all indications* • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, **or ankylosing spondylitis** *For Rheumatoid Arthritis* • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis • The provider also acknowledges that for rheumatoid arthritis a trial of Xeljanz or Olumiant is required before Rinvoq. • The patient is 18 years of age or older • The patient has a diagnosis of active rheumatoid arthritis (RA) • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz or Olumiant OR • Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with Rinvoq OR • Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq *For Psoriatic Arthritis*

	• Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for psoriatic arthritis. • The provider also acknowledges that for psoriatic arthritis a trial of Xeljanz is required before Rinvoq. • The patient has a diagnosis of active psoriatic arthritis (PsA) • The patient is 18 years of age or older • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz OR • Patient has experienced an adverse reaction to Xeljanz or OR Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq *For Atopic Dermatitis* • The patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent) • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: o For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) o For patients 12 to 17 year of age: any topical corticosteroid AND ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy *For Ulcerative Colitis* • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis • The patient is 18 years of age or older • The patient has moderately to severely active ulcerative colitis • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira • 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.) *For all indications* • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease

	• Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, **or ankylosing spondylitis;** For atopic dermatitis, PA expires in 1 year Renewal criteria: initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if the following apply: Atopic Dermatitis - The patient's disease severity has improved and stabilized to warrant continued therapy

• apremilast (Otezla) **TIBs**	**Updates from the August 2022 meeting are in bold and strikethrough. Note that there were no changes made to the existing criteria for treating oral ulcers associated with Behçet's disease or active psoriatic arthritis (PsA).** Manual PA criteria applies to new users of Otezla *For Mild Plaque Psoriasis* Manual PA Criteria: **Coverage approved for patients ≥ 18 years with mild plaque psoriasis who are candidates for systemic therapy or phototherapy if the following criteria are met:** • **The patient has a contraindication to, intolerability to, or has failed treatment with medications from at least TWO of these THREE categories:** ▪ **Moderate to High Potency Topical Corticosteroids (class 1 – class 5) e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream, betamethasone dipropionate 0.05% cream/lotion/ointment, etc.** ▪ **Steroid Sparing Agents: Vitamin D analogs (e.g. calcipotriene and calcitriol), tazarotene, or topical calcineurin inhibitors (e.g. tacrolimus and pimecrolimus)** ▪ **Other Topicals: emollients, salicylic acid, anthralin, or coal tar AND** • **The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy** *For Psoriatic Arthritis and Moderate to Severe Plaque Psoriasis* Step therapy and manual PA criteria apply to all new users of Otezla. 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, coverage is approved for Otezla if: • Contraindications exist to Humira. • Inadequate response to Humira. • Adverse reactions to Humira not expected with requested non-step-preferred TIB. AND Coverage approved for patients ≥ 18 years with: • Oral ulcers associated with Behçet's disease (Please note: A trial of Humira first is not required for Behçet's disease.) • Active psoriatic arthritis (PsA). • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR? • If yes: Fill in the blank write-in referencing literature to support combination, and patient will be monitored closely for adverse effects. Has the patient had an inadequate response to non-biologic systemic therapy? (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? ~~**Patient has negative TB test result in past 12 months (or TB is adequately managed).**~~ Non-FDA-approved uses are not approved. PA does not expire.

• viloxazine (Qelbree) **ADHD Agents: Non-Stimulants**	**Updates from the August 2022 meeting are in bold** Manual PA criteria apply to all new users of Qelbree. Manual PA criteria: Qelbree is approved if all criteria are met: **For Adults:** • **Patient is 18 years of age or older** • **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 atomoxetine (generic Strattera)** • **Patient has tried and failed, had an inadequate response, OR contraindication to at least one other non-stimulant ADHD medication (generic formulations of Kapvay or Intuniv)** ▪ **For children and adolescents:** • 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) • **OR if patient is under the age of 18 and cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, autism spectrum disorder, etc.) and not convenience, then a trial of one non-stimulant ADHD medication (generic formulations of Strattera, Kapvay, or Intuniv) is not required** Non-FDA-approved uses are not approved (to include depression and anxiety). Prior authorization does not expire.
• setmelanotide (Imcivree) **Miscellaneous Metabolic Agents**	**Updates from the August 2022 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Imcivree. Manual PA criteria: Imcivree is approved if all criteria are met: • Patient is 6 years of age or older • Patient has a confirmed diagnosis (via genetic testing) of POMC-, PCSK1-, or LEPR-deficiency that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) **OR** • **The patient has monogenic or syndromic obesity due to Bardet-Beidl syndrome (BBS)** • Patient and provider agree to evaluate weight loss after 12-16 weeks of treatment. Imcivree should be discontinued if a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential

	Initial prior authorization expires in 4 months. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Imcivree is approved for 1 year for continuation of therapy for **POMC-, PCSK1-, or LEPR-deficiency or BBS** if all criteria are met: • The patient has a documented improvement (a decrease from baseline) in at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential. Non-FDA approved uses are NOT approved including Alström Syndrome, ~~**Bardet-Biedl Syndrome (BBS),**~~ POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity
• cyclosporine 0.05% ophthalmic emulsion single dose (Restasis) **Ophthalmic Dry Eye**	**Updates from the August 2022 meeting are in Bold** **Patients younger than 18 years of age do not require a PA** Automated PA: If there is no Restasis, Cequa, or Xiidra prescription in the past 120 days, a manual PA is required. Manual PA criteria: Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • The patient is 18 years of age or older • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: • Positive symptomology screening for moderate to severe dry eye disease from an appropriate measure • At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) ▪ Patient must try and fail the following: o At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systame, Lacrilube]) o Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. • Restasis is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) Non-FDA-approved uses are not approved. PA expires in one year. Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all criteria are met: • The drug is prescribed by an ophthalmologist or optometrist. • The patient must have documented improvement in ocular discomfort. • The patient must have documented improvement in signs of dry eye disease.

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• alpelisib (Vijoice) **Oncological Agents**	▪ Retail/MTF/Mail: 28-days supply
• amoxicillin; vonoprazan (Voquezna Dual Pak) **Anti-Infective Miscellaneous**	▪ Retail/MTF/Mail: 1 pack/14 days
• amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) **Anti-Infective Miscellaneous**	▪ Retail/MTF/Mail: 1 pack/14 days

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
alpelisib (Vijoice) ONCOLOGICAL AGENTS	• alpelisib (Piqray)	• 50, 125, & 200 mg film-coated tablets in blister packs for 28 day supply • Dosing: Pediatrics (age 2 -1yr8): 50 mg QD with food; consider titrating to 125 mg after 24 weeks if patient ≥ 6 years old; Adults: 250 mg QD with food	treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA Related Overgrowth Spectrum (PROS) who require systemic therapy	• ≥ 5%: Diarrhea, stomatitis, hyperglycemia, eczema, dry skin, alopecia, headache, cellulitis	• 1st approved drug for PIK3CA-related overgrowth spectrum (PROS) • Alpelisib (Piqray) previously approved for breast cancer • Accelerated approval based on a small, single-arm study • Response observed in 27% of patients • Diarrhea, stomatitis, and hyperglycemia were the most common ADRs • Offers a new treatment option in a serious, rare disease with limited treatment options	• UF
amlodipine oral solution (Norliqva) CALCIUM CHANNEL BLOCKING AGENT	• amlodipine (Norvasc) • amlodipine susp (Katerzia) • isradipine (Dynacirc) • lisinopril solution (Qbrelis)	• Solution; Oral • adults: 5 mg QD; max of 10 mg QD • pediatrics: 2.5 mg QD; max of 5 mg QD	HTN down to age 6	• peripheral edema 10%	• 2nd DHP calcium channel blocker (CCB) available in a liquid formulation and the 1st oral solution • amlodipine oral suspension Katerzia is NF from Nov 2019 – no PA required • Approved via 5050b2 application using data from Norvasc tablets • No clinical data available • Provides no compelling clinical advantage over existing CCBs or other antihypertensives	• NF • Add to EMMI List

amoxicillin; vonoprazan (Voquezna Dual Pak) amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) ANTIINFECTIVES: MISCELANEOUS	• omeprazole, amox, clarith • omeprazole, amox, rifabutin (Talicia)	**Dual** • Capsule, Tablet • vonoprazan 20 mg BID + amoxicillin 1000 mg TID ± food x 14 days **Triple:** • Capsule, Tablet, Tablet • vonoprazan 20 mg + amoxicillin 1000 mg + clarithromycin 500 mg BID (12 hours apart) ± food x 14 days	Treatment of *Helicobacter pylori* (*H. pylori*) infection in adults	• ADRs (≥ 2%): diarrhea, abdominal pain, vulvovaginal candidiasis (VVC) and nasopharyngitis	• Voquezna is a new combination of acid suppression and antibacterials approved for treatment of *H. pylori* infection in adults, co-packaged for a 14-day treatment course • Vonoprazan is a new molecular entity that suppresses gastric acid secretion by inhibiting the H+, K+-ATPase enzyme system in a potassium competitive manner • Available as a dual product (Voquezna Dual Pak) containing vonoprazan and amoxicillin or Available as a triple combination product (Voquezna Triple Pak) containing vonoprazan, amoxicillin, and clarithromycin • Evaluated in 1 trial compared to traditional *H. pylori* treatment including lansoprazole, amoxicillin, and clarithromycin (LAC) • Among all randomized patients with *H. pylori,* Voquezna Dual Pak had a cure rate of 77.2% compared to a cure rate of 68.5% with LAC • Voquezna Dual Pak and Triple Pak's place in therapy is yet to be determined, but it is likely to be used as a later-line agent for refractory cases	• NF • Do not add to EMMI list
baclofen oral granules (Lyvispah) SKELETAL MUSCLE RELAXANTS & COMBINATIONS	• baclofen tablets • baclofen soln (Ozobax) • baclofen susp (Fleqsuvy)	• Granules; Oral in 5 mg, 10 mg, and 20 mg packets • Increase dose slowly in divided doses until clinical response; max dose 80 mg daily (20 mg QID); can be emptied into the mouth, mixed with liquids or soft foods, or be given via feeding tube	For the treatment of spasticity from MS, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be used in patients with spinal cord injuries/disease Limitations of Use: Not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders	• ADRs≥ 15%: drowsiness, dizziness, and weakness	• Lyvispah is the third oral alternate dosage formulation of baclofen, available as an oral granule • Approved based on bioequivalence to baclofen oral tablets • Lyvispah does not require refrigeration and can be emptied into the mouth, mixed with liquids or soft foods, or be given via feeding tube • Received provider feedback that states there is not a need for this drug • Provides little compelling clinical advantage over existing agents	• Tier 4/Not Covered

benzoyl peroxide 5% cream (Epsolay) ACNE AGENTS: TOPICAL ACNE & ROSACEA	• benzoyl peroxide gel • azaleic acid (Finacea gel) • metronidazole gel	• Cream; Topical • Available as a 30 g pump • Apply to the affected areas once daily	For the treatment of inflammatory lesions of rosacea in adults	• ADRs ≥1%: application site reactions: pain, erythema, pruritis and edema	• Epsolay is a new benzoyl peroxide cream for the treatment of inflammatory lesions of rosacea • Differs from other benzoyl peroxides in its microencapsulation technology and controlled-release formulation, but no head-to-head clinical trials compare Epsolay to other benzoyl peroxides or rosacea drugs to determine if there is any added benefit • A little less than half of Epsolay treated patients achieved IGA success and the drug was well tolerated • Inflammatory lesions of rosacea are typically treated with: metronidazole, azelaic acid, ivermectin, doxycycline or isotretinoin; benzoyl peroxide is not a 1st-line treatment option for rosacea • Provides little compelling clinical advantage over existing agents in the treatment of rosacea	• Tier 4/Not Covered
cyclosporine 0.1% ophthalmic emulsion (Verkazia) OPHTHALMIC: DRY EYE	• cyclosporine 0.09% (Cequa) • cyclosporine 0.05% (Restasis) • Cromolyn 4% • Lodoxamide 0.1% (Alomide)	• Ophthalmic emulsion 0.1% (0.3 mL vial) • 5 vials are packaged in an aluminum pouch; 6, 12, or 24 pouches are packaged in a box • Each box contains either 30, 60 or 120 vials • 1 gtt QID	treatment of Helicobacter pylori (H. pylori) infection in adults	• ≥ 1%: pain, erythema, pruritis, edema/swelling	• Mast cell stabilizer/antihistamine are recommended for first line treatment of VKC • Verkazia is the first cyclosporine ophthalmic emulsion FDA approved for VKC – however other forms of cyclosporine ophthalmic are recommended for treatment • Providers would like to have the higher concentration available • Verkazia provides little to no compelling clinical advantage over existing agents to treat VKC	• NF • Add to EMMI list

daridorexant (Quviviq) SLEEP DISORDERS: INSOMNIA AGENTS	• zolpidem 12.5mg (Ambien CR) • eszopiclone (Lunesta) • suvorexant (Belsomra) • lemborexant (Dayvigo)	• Tablet; Oral • Tablets: 25 mg, 50 mg; each comes in a 30 count bottle	Multiple Sclerosis associated spasticity	• Eye pain (12%)	• Quviviq is the third DORA approved for insomnia (sleep onset and maintenance) • Quviviq has the same contraindications, drug interactions, and warnings compared to the other DORAs (Dayvigo and Belsomra) • All the DORAs carry a risk of somnolence; Quiviq has the additional slightly higher incidence of headache compared to the other DORAs • Quviviq does not have Alzheimer's insomnia and driving performance data, unlike its competitors • Quviviq has not been studied in any head to head trials with any other insomnia agents • In its clinical trial results, a dose dependent response was observed, with the higher 50 mg strength reaching improved efficacy for all primary endpoints relative to the 25 mg strength and placebo • Quviviq provides no significant clinical advantages compared to other existing insomnia agents	• UF Before Branded Agents Step • Add to EMMI list
donepezil patch (Adlarity) ALZHEIMER'S AGENTS	• donepezil (Aricept, Aricept ODT) • rivastigmine patch (Exelon patch) • galantamine	• System; Transdermal • Transdermal System, • 5 mg/day and 10 mg/day	• Rosacea	• Eye pruritus (8%)	• Adlarity is a topical formulation of donepezil indicated for mild, moderate, and severe Alzheimer's dementia • It is the second topical AChEI for treatment of AD dementia • No new clinical studies were completed, only demonstrated bioequivalence to donepezil tablets • Offers once weekly treatment frequency, the longest of comparative agents for AD dementia • Provides another option for treatment of Alzheimer's associated dementia	• NF • Do not add to EMMI list

edaravone oral suspension (Radicava ORS) NEUROLOGICAL AGENTS MISCELLANEOUS	• riluzole (Rilutek) • riluzole film (Exservan) • edaravone IV (Radicava IV)	• Suspension; Oral • 105 mg (5 mL) orally or feeding tube (NG, PEG) in the morning after overnight fasting. Food should not be consumed for 1 hour after administration except water. • Initial course: daily dosing for 14 days followed by 14 days drug-free • Subsequent: daily dosing for 10 days out of 14-day period, followed by 14 days drug-free	• vernal keratoconjunctivitis	• ≥ 5%: headache, somnolence	• Radicava ORS is another formulation of edaravone • No new clinical studies were published for FDA approval, the oral solution demonstrated bioequivalence to IV edavarone • ICER Review 2022, for a narrow subset of ALS patients, IV edaravone demonstrated a clinically meaningful change in ALSFRS-R scores; and as a result deems oral edaravone to be comparable or incremental compared to riluzole • JAMA Neurology 2022, long term cohort study concludes that addition of IV edarovone to standard treatment (riluzole) did not cause a significant change to disease progression rates, time to noninvasive ventilation, and survival probability • Provides another treatment option for ALS patients	• UF • Do not add to EMMI list
ganaxolone oral suspension (Ztalmy) ANTICONVULSANTS-ANTIMANIA AGENTS	• levetiracetam oral soln • valproic acid oral soln • vigabatrin powder packet	• Suspension; Oral • Oral suspension (50mg/mL) • 110 mL per bottle	• treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	• 505(b)(2) to oral donepezil	• Ztalmy is indicated for seizures associated with CDD • CDD is a rare pediatric neurodevelopmental disorder with early onset and severe, refractory, multiple, evolving seizure types • Ztalmy's clinical trial demonstrated a 27% median reduction of motor seizure frequency in CDD patients relative to placebo • No head to head trials with other AEDs are available at this time • Ztalmy is another anti-epileptic option for refractory seizures in CDD	• UF • Do not add to EMMI list

insulin glargine solostar authorized biologic INSULINS: BASAL	• insulin glargine (Lantus, Semglee, -yfgn, Basaglar)	• Injectable; Injection • 100 units/mL • 10 mL MDV • 3 mL single-patient-use prefilled pen	mild, moderate, and severe dementia of the Alzheimer's type	• Headache, pruritus, insomnia, cramps, abd pain, const/diar	• Current condition set is only one product step preferred (Lantus) and all others NF and non-step preferred • Insulin glargine by Winthrop is another insulin glargine formulation approved for Type 1 and Type 2 diabetes mellitus in adults and pediatrics • 7th long acting basal insulin analog • Utilize clinical trials from the original Lantus NDA application • No differences in efficacy or safety compared to another insulin glargine • Provides no compelling clinical advantage over existing formulary agents	• UF and Non-Step Preferred • Add to EMMI list
leuprolide SC injection (Camcevi Kit) LHRH AGONISTS-ANTAGONISTS	• leuprolide (Eligard) • leuprolide (Lupron Depot) • leuprolide (Fensolvi)	• Emulsion; Subcutaneous • 42 mg administered subcutaneously once every 6 months • Injectable emulsion: 48 mg leuprolide mesylate = 42 mg leuprolide	treatment of amyotrophic lateral sclerosis	(≥10%) contusion, gait disturbance, headache	• Camcevi is the 3rd leuprolide formulation approved for the treatment of advanced prostate cancer • Approval was based on the results from an open-label, single-arm study, where 98% of eligible patients achieved castrate levels (serum testosterone suppression to ≤ 50 ng/dL) at 28 days, and 97% maintained this endpoint through 336 days • No head-to-head studies have been completed with other leuprolide formulations • Camcevi provides no compelling clinical advantage compared to existing formulary agents	• NF

mavacamten (Camzyos) CARDIOVASCULAR AGENTS MISCELLANEOUS	• diltiazem (Cardizem) • metoprolol (Toprol XL) • propranolol (Inderal LA) • verapamil (Calan SR) • disopyramide (Norpace)	• Capsule; Oral • 2.5, 5, 7.5 or 10 mg caps • Complicated dosage titration/adjustment based on LV outflow track gradient ad	Seizures associated with CDKL5 deficiency (CDD); DEA schedule pending	somnolence	• 1st cardiac myosin inhibitor for treatment of NYHA class II-III obstructive hypertrophic cardiomyopathy (oHCM) • Guidelines recommend non-vasodilating beta blockers, non-DHB CCB, and disopyramide or surgery for severe cases • Limited evidence suggests potential benefit in cardiac remodeling, rather than just treating symptoms (BB, CCB, disopyramide treat symptoms) • REMS program implemented for risk of heart failure with treatment • ICER rated as promising but inconclusive compared to disopyramide or usual care due to lack of mortality data, lack of active comparator data and risk of heart failure	• UF • Do not add to EMMI list
tapinarof 1% cream (Vtama) PSORIASIS AGENTS	• calcipotriene/ betamethasone (Taclonex) • calcipotriene 0.005% (Dovonex) • pimecrolimus 1% (Elidel) • ruxolitinib 1.5% (Opzelura)	• Cream; Topical • Cream (1%); 1 gram= 10 mg of tapinarof • 60 g tube	T1DM and T2DM	pyrexia	• Aryl hydrocarbon receptor agonist for treatment of psoriasis in adults • Vtama 1% cream was evaluated in two clinical trials and achieved significant reduction in PGA scores relative to placebo • No head-to-head studies with other topical agents • Most common adverse events include folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza • Vtama offers an additional option for treating psoriasis, however numerous alternative formulary agents are available, its use is limited to a single indication, there is no direct comparative efficacy data available at this time, and its place in therapy is unclear	• NF • Add to EMMI list

testosterone undecanoate 112.5 mg capsule (Tlando) ANDROGENS-ANABOLIC STEROIDS: TESTOSTERONE REPLACEMENT THERAPIES	• Fortesta Gel • Testim Gel • Androgel • Jatenzo Cap • Androderm Patch	• Capsule; Oral • Dose: 225 mg PO BID w/ food • Available as 112.5 mg capsules • Bottles of #120	For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone; Limitations of Use: safety and efficacy in males < 18 years old have not been established	ADRs ≥ 2%: increased blood prolactin, hypertension, increased hematocrit, upper respiratory tract infection, weight increased, headache, and musculoskeletal pain	• Tlando is the 2nd oral capsule testosterone undecanoate and the 14th available testosterone • Unlike Jatenzo, Tlando does not require dose titration • In an open-label, single-arm study, 80% of patients taking Tlando met the primary outcome specified testosterone concentration • Tlando was well tolerated • There are numerous alternative testosterone formulations available; Tlando's place in therapy remains unclear, and there is no compelling clinical advantage over existing formulary agents	• NF and Non-Step Preferred • Add to EMMI list

tirzepatide SC injection (Mounjaro) DIABETES NON-INSULIN; GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONISTS INJECTABLE	• dulaglutide (Tuclicity) • semaglutide (Ozempic) • exenatide (Bydureon BCise)	• Injectable; Injection • 2.5mg, 5mg, 7.5mg, 10mg, 12.5mg, or 15mg SQ once weekly in pre-filled single dose auto-injector pens	treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.	seasonal allergy	• Mounjaro is the first dual acting GLP-1 and GIP agonist approved for use in adults with T2DM as an adjunct to diet and exercise administered SubQ once weekly • Tirzepatide was studied for T2DM in the SURPASS clinical trial program and was evaluated against other GLP1RAs (semaglutide and dulaglutide), rapid-acting and basal insulins, oral agents, and as monotherapy in treatment naïve patients • The primary end point (HbA1c reduction) was statistically significant in comparison to baseline, with average A1c reductions between 1.8-2.1% for 5 mg and between 1.7-2.4% for both 10 mg and 15 mg strengths • Patients lost between 12 lb. (5 mg strength) and 25 lb. (15 mg strength) on average • Most common ADRs are GI-related including nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion (dyspepsia), and stomach (abdominal) pain • Warnings and contraindications are similar to the GLP1RA class • Ongoing studies for Mounjaro are numerous and include use for weight loss in those without diabetes, NASH, and heart failure with preserved ejection fraction • Mounjaro is the first dual-acting GLP1/GIP agonist approved for adults with T2DM and has shown a clinically significant improvement in glycemic control as well as weight loss with similar ADRs to the GLP1RAs • Given that other GLP1RAs have an additional indication for CV risk reduction, true utility of Mounjaro remains unclear until the CVOT (SURPASS-CVOT) is completed	• NF • Add to EMMI list

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
May 2022	**Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF** *Similar agents are already on list* • daridorexant (Quviviq) **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • amlodipine oral solution (Norliqva) • cyclosporine 0.1% ophth emulsion (Verkazia) • insulin glargine solostar authorized biologic • tapinarof 1% cream (Vtama) • testosterone undecanoate 112.5 mg caps (TLando) • tirzepatide (Mounjaro)	**Beta Blockers** *Comparable pricing at mail order vs MTFs or retail:* • nebivolol (Bystolic; generics) **Drug Class Reviews** **Designated UF:** **OABs** *Comparable pricing at mail order vs MTFs or retail:* • mirabegron (Myrbetriq) • mirabegron (Myrbetriq Granules) • vibegron (Gemtesa) **Antidepressants/Non-Opioid Pain Drugs** *Comparable pricing at mail order vs MTFs or retail* • vortioxetine (Trintellix) • vilazodone (Viibryd) **Designated NF:** **Antidepressants/Non-Opioid Pain Drugs** *Comparable pricing at mail order vs MTFs or retail:* • paroxetine mesylate (Pexeva) • duloxetine DR (Drizalma sprinkle) • levomilnacipran (Fetzima) • milnacipran (Savella) • bupropion hydrobromide XR (Aplenzin) • gabapentin ER 24 hr tablets (Gralise) • gabapentin enacarbil (Horizant) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Not yet clear if feasible to provide through mail:* • alpelisib (Vijoice) • edaravone ORS (Radicava) • mavacamten (Camzyos) *Acute use exception applies* • amoxicillin; vonoprazan (Voquezna Dual Pak) • amoxicillin; clarithromycin; vonoprazan (Voquezna Triple Pak) *Drugs in class not currently represented on EMMPI List* • ganaxolone oral suspension (Ztalmy) **Designated NF:** *Not yet clear if feasible to provide through mail:* • leuprolide SC injection (Camcevi) *Comparable pricing at mail order vs MTFs or retail:* • donepezil patch (Adlarity)

Appendix G—Implementation Dates*

Upon signing: October 26, 2022

Two weeks after signing: November 9, 2022

30 Days after Signing: November 30, 2022

60 days after signing: December 28, 2022

90 days after signing: January 5, 2023

Termination of NDAA 2018 Medication Adherence Pilot: December 31, 2022 (as per statute)

120 Days after signing: March 1, 2023

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

Appendix H—Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
August 2022	Skeletal Muscle Relaxants	• baclofen oral solution (Lyvispah)	• baclofen oral solution (Ozobax) • baclofen oral suspension (Fleqsuvy) • baclofen tablets	• 120 days
August 2022	Acne Agents: Topical Acne & Rosacea	• benzoyl peroxide 5% cream (Epsolay)	• benzoyl peroxide gel OTC and Rx versions • azaleic acid 15% gel (Finacea gel) • metronidazole 1% gel • brimonidine 0.33% gel (Mirvaso) • ivermectin 1% cream (Soolantra) • minocycline 1.5% topical foam (Zilxi) • minocycline 4% foam (Amzeeq) • minocycline 50 mg tablets	• 120 days
May 2022	Nephrology Agents Miscellaneous	• budesonide (Tarpeyo)	• prednisone • methylprednisolone • budesonide delayed release capsules (Entocort EC, generics)	• November 30, 2022 (120 days)
May 2022	Narcotic Analgesics and Combinations	• celecoxib/ tramadol (Seglentis)	• tramadol • celecoxib	• November 30, 2022 (120 days)
May 2022	Anticholinergics-Antispasmodics	• glycopyrrolate (Dartisla ODT)	• glycopyrrolate tablets • glycopyrrolate oral solution (Cuvposa) • omeprazole • famotidine	• November 30, 2022 (120 days)
May 2022	Endocrine Agents Miscellaneous	• levoketoconazole (Recorlev)	• ketoconazole • metyrapone (Metopirone) • osilodrostat (Isturisa) • pasireotide (Signifor LAR -medical benefit)	• November 30, 2022 (120 days)
May 2022	Diuretics	• torsemide 20 mg and 60 mg tablets (Soaanz)	• torsemide • furosemide • bumetanide • ethacrynic acid	• November 30, 2022 (120 days)
May 2022	Acne Agents: Topical Acne & Rosacea	• tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twyneo)	• tretinoin cream • benzoyl peroxide cream	• November 30, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
February 2022	Pain Agents: NSAIDs	• celecoxib oral solution (Elyxyb)	• celecoxib tablets • ibuprofen • naproxen • diclofenac • numerous other NSAIDs or combos	• August 24, 2022 (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	• lorazepam ER capsule (Loreev XR)	• lorazepam IR tablets • alprazolam IR and XR tablets	• June 15, 2022 (120 days)
Nov 2021	Migraine Agents	• dihydroergotamine mesylate nasal spray (Trudhesa)	• DHE nasal spray • sumatriptan nasal and oral • rizatriptan • zolmitriptan • eletriptan	• June 15, 2022 (120 days)
Aug 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)

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms.

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

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

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

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Vitamins Fat Soluble		
May 2022	**Add these GCNs** • 99882 vitamin D3 (cholecalciferol) 2000 unit caps • 12309 vitamin D3 (cholecalciferol) 2000 unit tabs • 98425 vitamin D3 (cholecalciferol) 50,000 unit caps **Retain these GCNs** • 53740 vitamin D3 (cholecalciferol) 400 unit tabs • 00223 vitamin D3 (cholecalciferol) 1000 unit tabs • 93242 vitamin D3 (cholecalciferol) 5000 unit caps • 26416 vitamin D3 (cholecalciferol) 400 unit/mL drops • 94411 vitamin D3 (cholecalciferol) 8000 unit/mL drops Note: Vitamin D2 (ergocalciferol) 50,000 unit caps are legend and available at all 3 points of service.	

DoD P&T Committee Updates to Approval Authorities
Note that updates are in **bold** font.

Table 1. Processes and Recommendation/Approval Authorities For August 2022 DoD P&T Committee Meeting

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 and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting.** ▪ 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., HandiHaler 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 for TPharm4, 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. ▪ **FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA approved devices or supplies and determination as to whether a new FDA approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination made to consider for coverage, timeline for review by DoD P&T Committee. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit.** ▪ **Designating "line extension" devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the**

	DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
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). ▪ **The Director may approve devices or supplies as recommended by the P&T Committee and the BAP; however approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit.** ▪ **Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with prior authorization criteria and implementation plans as recommended by the DoD P&T Committee and BAP.**
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, **device or supply** or class of medications, devices or supplies; 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, **devices or supplies.** ▪ Addition or deletion of medications, **devices or supplies** listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes, **devices or supplies** 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, **devices or supplies** from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, **devices or supplies** 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.

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS
November 2022

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on November 2nd and 3rd, 2022.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of August 2022 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the August 2022 DoD P&T Committee meeting on October 26, 2022.

B. Clarification of Previous Minutes:

1. **August 2022 Meeting**

   - **Antidepressants and Non-Opioid Pain—Add to TPharm5 Rapid Response program:** Updated Prior Authorizations (PA) were recommended for the 9 branded products in the class. These drugs will be added to the TPharm5 Rapid Response/Safety Net program, which will provide additional outreach to beneficiaries who have not received a prescription after an initial PA reject.

   - **Sunset of the Medication Adherence Pilot—rosuvastatin copay:** Patients who have filled rosuvastatin prescriptions will receive an additional letter informing them of the co-pay increase from $0 to the generic Tier-1 copay when the pilot terminates on December 31, 2022.

2. **May 2022—Glucagon-Like Peptide 1-Receptor Agonists (GLP1-RA):** Corresponding updates were made to the PA criteria for the combination GLP1-RA/insulin products (Soliqua and Xultophy) to remove Bydureon as the step-preferred products and to add Trulicity and Ozempic as the formulary products.

3. **February 2022 Meeting—MHS GENESIS OTC Test List—benzocaine/menthol lozenges shortage:** Due to a shortage of Cepacol lozenges (GCNs 30354, 30355 on the list), Chloraseptic Max and Cloraseptic Sore Throat. (GCNs 31986, 97495) were added to the list, based on actual MTF purchasing patterns.

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 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 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are

assessed. 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 nonformulary (NF) medication.

NF medications are generally restricted to the mail order program pursuant to 32 CFR 199.21(h)(3)(i) and (ii). Additionally, the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (9) and NDAA 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

IV. UF DRUG CLASS REVIEWS

A. Atopy Agents—Oral Janus Kinase Inhibitor (JAK-1) Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the oral JAK inhibitors approved for treating atopic dermatitis, commonly known as eczema. The drugs in the subclass include upadacitinib (Rinvoq), and abrocitinib (Cibinqo). This is the first time the oral JAK inhibitor subclass has been reviewed for formulary status.

The Atopy Class is a newly created drug class with a variety of agents indicated for atopic dermatitis (AD) and other disease states. It is comprised of products with differing mechanisms of action for treating eczema, including JAK inhibitors [Rinvoq, Cibinqo, and topical ruxolitinib (Opzelura)]; interleukin antagonists [dupilumab (Dupixent), benralizumab (Fasenra), mepolizumab (Nucala), and omalizumab (Xolair)]; calcineurin inhibitors [pimecrolimus (Elidel), tacrolimus (Protopic, generic)], and a phosphodiesterase-type 4 (PDE-4) inhibitor [crisaborole (Eucrisa)]. There is a mix of oral, injectable and topical formulations in the class. The oral JAK inhibitors, tofacitinib (Xeljanz) and baricitinib (Olumiant), will remain in the Targeted Immunomodulatory Biologics (TIBs) class, as they are not approved for treating atopic dermatitis.

Rinvoq and Cibinqo differ markedly in their FDA-approved indications. Rinvoq is approved for a variety of conditions, to include atopic dermatitis (moderate-severe), rheumatoid arthritis (moderate-severe), psoriatic arthritis, ulcerative colitis, and ankylosing spondylitis, while Cibinqo is solely approved for atopic dermatitis (moderate-severe). *(Note that the new Rinvoq indication for non-radiographic axial spondyloarthritis will be reviewed at the February 2023 P&T Committee meeting).*

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 1 abstained, 2 absent) the following:

Professional Treatment Guidelines

- Standard first-line treatments for atopic dermatitis include topical therapies (e.g., calcineurin inhibitors and topical corticosteroids) and consideration of phototherapy before initiating systemic therapies.

- The International Eczema Council 2017 guidelines summarize considerations for initiating systemic treatment options for treating atopic dermatitis. Patients with moderate-to-severe atopic dermatitis should be given appropriate topical therapies and disease management education. In patients with persistent symptoms, consideration for alternative diagnoses and phototherapy, if appropriate, is warranted. Patients who continue to have persistent moderate-to-severe atopic dermatitis symptoms despite the above measures are appropriate candidates for systemic therapy.

Efficacy

- There are no head-to-head trials comparing Rinvoq and Cibinqo. FDA approval was based on several randomized controlled trials (RCT) conducted for each medication.
- For both products, RCTs demonstrated statistically significant achievement of reduction in Investigator Assessment and Eczema Area Severity Index (EASI) scores (which measures the extent and severity of disease) for atopic dermatitis compared to placebo.
- A 2022 JAMA Dermatology network meta-analysis (NMA) assessed new systemic treatment options for atopic dermatitis, and included several RCTs for Rinvoq and Cibinqo, along with other products approved for this indication.
    - The NMA concluded the higher strengths of Rinvoq 30 mg and Cibinqo 200 mg daily were associated with slightly improved scores than Dupixent 300 mg given every other week (standard adult dosage). Rinvoq 15 mg daily was associated with similar scores to standard dose Dupixent, while Cibinqo 100 mg daily was associated with slightly worse scores.
- A 2021 Institute for Clinical and Economic Review (ICER) NMA also evaluated newer systemic treatment options for atopic dermatitis. The results reported that Rinvoq 30 mg was more likely to achieve a 75% reduction in the Eczema Area Severity Index (EASI-75) score thresholds than Cibinqo 200 mg or other systemic interventions, including Dupixent. However Rinvoq 30 mg was not statistically superior to Cibinqo 200 mg in achieving EASI-75 thresholds.

Safety

- Pooled trial data show that Rinvoq and Cibinqo have similar discontinuation rates due to adverse events, both reported at 5%. Rinvoq is associated with a higher proportion of adverse events related to upper respiratory infection and acne, while Cibinqo carries a higher risk for nausea.
- Rinvoq and Cibinqo both require similar pre-treatment and post-treatment screenings. The black box warnings are identical for both products, and include serious infection, increased all-cause mortality, malignancy, major adverse

cardiac events, and thrombosis. Of note, this black box warning was issued as a result of increased safety signals from another JAK inhibitor, Xeljanz, during studies conducted in patients with rheumatoid arthritis.

- For Rinvoq, the RCTs enrolled sufficient numbers of patients from special populations (e.g., geriatric, pediatric, compromised renal or hepatic function), resulting in a recommendation for dose modification for geriatric patients and an indication for pediatric patients; additionally, dose reduction is required in severe renal failure patients. Cibinqo currently has insufficient geriatric and pediatric data and must be avoided in severe renal and hepatic failure.

Individual Agents

- *upadacitinib (Rinvoq):* Advantages of Rinvoq include FDA-approval for diseases other than atopic dermatitis. For atopic dermatitis, Rinvoq is approved for adults and for children as young as 12 years of age and weighing more than 40 kilograms. Additional indications are under investigation.
- *abrocitinib (Cibinqo):* Cibinqo's product labeling is limited to treating atopic dermatitis in adults, and there is insufficient data for treating special populations.

Overall Conclusions

- When treating atopic dermatitis, indirect comparisons from NMAs suggest higher doses of Rinvoq and Cibinqo are somewhat more effective than Dupixent. Direct efficacy comparisons of Rinvoq and Cibinqo have yet to be conducted.
- In terms of efficacy, there is a high degree of therapeutic interchangeability between Rinvoq and Cibinqo. In terms of safety, there is a moderate degree of therapeutic interchangeability as each medication carries a few unique adverse events, and long-term safety will need to be further defined for both agents.
- In order to meet the needs of MHS beneficiaries, one oral JAK inhibitor is required for treatment of atopic dermatitis.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and also conducted a cost minimization analysis (CMA) and budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 2 absent) the following

- CMA results showed upadacitinib (Rinvoq) was more cost effective than abrocitinib (Cibinqo), based on designating Rinvoq as UF and Cibinqo as NF.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA

results showed that designating upadacitinib (Rinvoq) as UF, with abrocitinib (Cibinqo) as NF demonstrated the most cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following:
    - UF
        - upadacitinib (Rinvoq) *moves from NF to UF*
    - NF
        - abrocitinib (Cibinqo) remains *NF*
    - Tier 4 (Not covered) – None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***PA criteria were originally recommended when the individual oral JAK inhibitors were first evaluated by the Committee as new drugs. The current PA criteria for both Rinvoq and Cibinqo require trial of topical medications (corticosteroid and a topical calcineurin inhibitor), first, consistent with professional guidelines for treating atopic dermatitis.

    The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining the current manual PA criteria for Rinvoq, and updates to the manual PA criteria for Cibinqo in new users. Note that for Rinvoq, the current PA requirements for indications other than atopic dermatitis still apply (e.g., a trial of Humira is still required before Rinvoq in patients with arthritis).

    The updated PA criteria for Cibinqo in new users will now include the requirement for a trial of the injectable interleukin antagonist Dupixent, and a trial of Rinvoq; this is in addition to a trial of a topical corticosteroid and a topical calcineurin inhibitor. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining the medical necessity criteria currently in place for Cibinqo. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QL)—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining the specialty quantity limits for Rinvoq and Cibinqo which was recommended at the August 2022 DoD P&T Committee meeting, and will include a 60 day supply at all points of service. See Appendix D for the full QLs.

5. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS —*** The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining Rinvoq on the EMMPI program and adding Cibinqo to the EMMPI program.

6. ***COMMITTEE ACTION: UF, MN, PA, EMMPI and IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. See Appendix G for the actual implementation dates.

B. Hematological Agents—Red Blood Cell (RBC) Stimulants Erythropoietins Subclass

Background—This is the first formulary review for the erythropoietin RBC stimulants. The three marketed erythropoietin alfa products are epoetin alfa (Epogen and Procrit), and epoetin alfa-epbx (Retacrit). Epogen and Procrit are the reference biologics, while Retacrit is the biosimilar. *(See Biosimilar section on pages 23-24 for additional information).* Retacrit was reviewed as an innovator drug in August 2018 and designated as UF. Note that darbepoetin alfa (Aranesp) was not included in the class review.

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

Background

- Epogen, Procrit and Retacrit all have the same FDA-approved indications, including for treating anemia caused by chronic kidney disease, zidovudine therapy, or chemotherapy, and to reduce the need for RBC transfusions in patients undergoing elective, non-cardiac surgery. There are several well-accepted off-label uses.
- These products are available in vials ranging from 2,000 units/mL to 40,000 units/mL. Epogen is not available in a 40,000 units/mL vial.

Professional Treatment Guidelines

- Clinical practice guidelines in the field of nephrology and oncology address the place in therapy for RBC stimulants and the selection of biosimilars. There is no preference for any one erythropoietin agent, either a reference product or a biosimilar, over the others. There is a lack of evidence that any one erythropoietin product is superior to another.
    - The 2012 Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guideline for anemia in chronic kidney disease recommend erythropoietin agents in patients with anemia who have exhausted all other

means of correcting anemia (iron administration, inflammatory states) and who wish to avoid excessive blood transfusions or symptoms of anemia. No one specific product is recommended, and an individual agent should be chosen based on the balance of pharmacokinetic/pharmacodynamics profiles, safety, clinical outcome data, costs and availability.

- The 2019 American Society of Clinical Oncology/American Society of Hematology guidelines state that erythropoietin stimulating agents may be used in individuals with chemotherapy-induced anemia who have incurable cancer and whose hemoglobin is less than 10 g/dL. The expert panel considers epoetin beta, epoetin alfa, darbepoetin alfa, and biosimilar epoetin alfa-epbx equivalent with respect to effectiveness and safety.

Efficacy

- A large retrospective study in patients with chronic kidney disease evaluated switching between originator and biosimilar epoetin alfa products. The results showed that there were no reported differences in safety or efficacy outcomes when patients were switched between the biosimilar and originator products (Belleudi 2019).

Safety

- The adverse event profiles for the epoetin alfa products differ based on indication. Commonly reported side effects include upper respiratory tract infection, headache, diarrhea, bone and joint pain, and injection site irritation.

Overall Conclusions

- Overall, there is a high degree of therapeutic interchangeability between Epogen, Procrit and Retacrit, as there are no clinically meaningful differences between the reference drug products and the biosimilar.
- In order to meet the needs of MHS beneficiaries, at least one erythropoietin RBC stimulant is required on the formulary.

Relative Cost-Effectiveness Analysis and Conclusion—P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that epoetin alfa-epbx (Retacrit) was more cost effective than epoetin alfa (Epogen, Procrit).
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating epoetin alfa-epbx (Retacrit) as UF and step-preferred, with epoetin alfa (Epogen, Procrit) as UF and non-step-preferred, generated 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 step-preferred
     - epoetin alfa -epbx (Retacrit)
   - UF non-step-preferred
     - epoetin alfa (Epogen)
     - epoetin alfa (Procrit)
   - NF – None
   - Tier 4 (Not covered) – None
   - Note that for Procrit and Epogen a trial of Retacrit is required

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) PA criteria for Epogen and Procrit. A trial of Retacrit will be required first in new users, unless the patient has failed therapy with or cannot tolerate it. See Appendix C for full criteria.

3. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining Epogen, Procrit and Retacrit on the EMMPI program.

4. ***COMMITTEE ACTION: UF, PA, EMMPI IMPLEMENTATION PERIOD*—**The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. (See Appendix G for the actual implementation date.)

V. NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) AND NEW MEDICAL DEVICES

The products were divided into three groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Aspruzyo, Hyftor, Ryaltris, Vivjoa, and Zoryve; Group 2 was comprised of the 2 medical devices, FreeStyle Libre 3 and Omnipod 5, and Group 3 included Tascenso, Sotyktu, Xaciato, Zonisade and Entadfi.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 16 for, 0 opposed, 0 abstained, 2 absent; Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0

absent; and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved pharmaceutical agents.

Addition of new medical devices to the TRICARE pharmacy benefit is also reviewed in this section. Medical devices are primarily covered by the TRICARE medical benefit, and any additions to the TRICARE pharmacy benefit are not meant to replace this pathway for procuring medical devices. See the August 2022 DoD P&T Committee meeting minutes (found at https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Pharmacy-Operations/DOD-PT-Committee/Meeting-Minutes) for details regarding the clinical and cost effectiveness review of new medical devices. The Committee identified two medical devices for review at this meeting, Omnipod 5 and FreeStyle Libre 3.

See Appendix E for the complete list of newly approved pharmaceutical agents reviewed at the November 2022 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended: Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and for Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent; the following:

    - UF
        - FreeStyle Libre 3 - Therapeutic Continuous Glucose Monitoring System (CGMS); new version of a CGMS for monitoring diabetes. Note that as part of this recommendation FreeStyle Libre 3 was added to the TRICARE pharmacy benefit.
        - Omnipod 5 – Miscellaneous insulin device; new version of an External Insulin Infusion Pump for administering insulin. Note that as part of this recommendation Omnipod 5 was added to the TRICARE pharmacy benefit. Additionally, due to noncompliance with the Trade Agreements Act, Omnipod 5 is excluded from the TRICARE Mail Order pharmacy and MTF points of service; it is available at retail pharmacies.
        - sirolimus 0.2% topical gel (Hyftor) – Immunosuppressives; a topical treatment for facial angiofibromas associated with tuberous sclerosis complex (TSC)
        - zonisamide oral suspension (Zonisade) – Anticonvulsant-Antimania Agents; new liquid formulation of zonisamide
    - NF:
        - clindamycin 2% vaginal gel (Xaciato) – Antibiotic; vaginal formulation for treating bacterial vaginosis

- deucravacitinib (Sotyktu) – Targeted Immunomodulatory Biologics (TIBs); an oral tyrosine kinase 2 (TYK2) inhibitor used for systemic treatment of moderate-to-severe plaque psoriasis. Note that as part of this recommendation Sotyktu will be added to the Rapid Response program.
- fingolimod orally dissolving tablet (Tascenso ODT) – Oral Miscellaneous Multiple Sclerosis Agents; new oral disintegrating formulation of fingolimod for patients 10 years of age or older who weigh less than 40 kg
- oteseconazole (Vivjoa) – Antifungal; for treatment of recurrent vulvovaginal candidiasis (RVVC) in females who are not of reproductive potential
- ranolazine ER granule (Aspruzyo Sprinkles) – Miscellaneous Cardiovascular Agent; a new sprinkle formulation for treating chronic angina
- roflumilast 0.3% cream (Zoryve) – Psoriasis Agents; topical phosphodiesterase 4 (PDE-4) for treatment of plaque psoriasis

- Tier 4 (Not covered): The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents. See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
  - finasteride/tadalafil (Entadfi) – Benign Prostatic Hyperplasia (BPH) Agents; combination product of two drugs already available as in generic formulations, a PDE-5 inhibitor and a 5-alpha reductase inhibitor
    - Entadfi was recommended for Tier 4 placement as it has little to no additional clinical effectiveness relative to similar agents in the class, and the needs of TRICARE beneficiaries are met by available alternative agents. Alternatives include finasteride, dutasteride, and tadalafil tablets.
  - olopatadine/mometasone nasal spray (Ryaltris) – Nasal Allergy Agents – Corticosteroids; combination product of two drugs available in generic formulations, a nasal steroid and a nasal antihistamine
    - Ryaltris was recommended for Tier 4 placement as it has little to no additional clinical effectiveness relative to similar agents in the class, the needs of TRICARE beneficiaries are met by available alternative agents, and it

contains at least one ingredient that is not covered under the TRICARE benefit (e.g., OTC drug combo product). Alternatives include other legend and OTC treatments formulations for allergic rhinitis: azelastine (Astelin, Astepro), olopatadine (Patanase) flunisolide (Nasarel), fluticasone propionate (Flonase), ipratropium (Atrovent), fluticasone/azelastine (Dymista), budesonide (Rhinocort), triamcinolone (Nasacort), mometasone (Nasonex), beclomethasone (Beconase AQ, QNASL), ciclesonide (Omnaris, Zetonna).

2. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for clindamycin 2% vaginal gel (Xaciato), deucravacitinib (Sotyktu), fingolimod ODT (Tascenso ODT), oteseconazole (Vivjoa), ranolazine ER granule (Aspruzyo Sprinkles), and roflumilast 0.3% cream (Zoryve). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: PA CRITERIA—*** The P&T Committee recommended Group 1: 17 for, 0 opposed, 0 abstained, 1 absent; Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent; and Group 3: 15 for, 2 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Applying automated and manual PA criteria to new users of Sotyktu. A trial of both Humira and Cosentyx will be required for the treatment of moderate to severe plaque psoriasis.
- Applying manual PA criteria to new users of Tascenso ODT. The PA will require an alternate dosage form of a sphingosine-1 phosphate (S1p) receptor modulator to treat MS to be used first.
- Applying manual PA criteria to new users of Vivjoa for recurrent vulvovaginal candidiasis. Failure of a previous six-month course of oral fluconazole is required.
- Applying manual PA criteria to new users of Aspruzyo Sprinkle, Zonisade, Zoryve, and Hyftor, consistent with the existing PA requirements for using alternate dosage forms for readily available generic tablets.
- Applying PA criteria to new users of FreeStyle Libre 3 and Omnipod 5, consistent with what is already in place for the earlier versions of these two medical devices.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs) —***The P&T Committee recommended (Group 1: 17 for, 0 opposed, 0 abstained, 1 absent; Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3:

18 for, 0 opposed, 0 abstained, 0 absent; Group 3: 15 for, 2 opposed, 0 abstained, 1 absent) QLs for Xaciato, Sotyktu, Tascenso ODT, Vivjoa, Hyftor, FreeStyle Libre 3, and Omnipod 5. The reasons for the QLs were due to existing QLs for the class, or due to recommended treatment course durations. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI—***The P&T Committee recommended (Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

6. ***COMMITTEE ACTION: UF, TIER 4, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (Group 1 and Group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and Group 2 for the medical devices Omnipod 5 and FreeStyle Libre 3: 18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

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

Addendum to the UF recommendation for tadalafil oral suspension (Tadliq) – Pulmonary Arterial Hypertension (PAH) drugs –alternative dosage form of a PDE-5 inhibitor: Tadliq was initially recommended for Tier 4 placement. However, after the DoD P&T Committee meeting was held, specialist feedback supported off-label use to treat children with congenital heart disease who have failed sildenafil therapy. An electronic vote was taken to determine whether Tadliq should be designated as nonformulary, with PA and MN criteria, and an implementation of 2 weeks.

COMMITTEE ACTION: ADDENDUM TO UF, PA, MN and IMPLEMENTATION RECOMMENDATION FOR TADALAFIL ORAL SUSPENSION (TADLIQ)—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) nonformulary status for Tadliq.

- NF:
    - tadalafil oral suspension (Tadliq), Pulmonary Arterial Hypertension (PAH) drugs; alternative dosage form

The Committee also recommended PA criteria in new and current users and MN criteria, with implementation occurring the first Wednesday 2 weeks after signing of the minutes at all points of service. See appendices B and C for the MN and PA criteria.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) Glaucoma Agents: Cholinergics/Cholinesterase Inhibitors—echothiophate ophthalmic solution (Phospholine Iodide)—Phospholine Iodide was reviewed as part of the Ophthalmic Glaucoma Agents class review in February 2007 and was designated as UF. At that time, it was considered a third-line treatment for glaucoma with a unique niche in therapy. In May 2021, national supplies of Phospholine Iodide were depleted after the sole manufacturer discontinued production. A new manufacturer has started producing Phospholine Iodide and it is now significantly less cost effective than prior to market withdrawal. MHS provider feedback relayed that this product is rarely used and recommended prior authorization criteria to ensure appropriate use.

COMMITTEE ACTION: ECHOTHIOPHATE OPHTHALMIC SOLUTION (PHOSPHOLINE IODIDE) NEW PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria in new users of Phospholine Iodide, in order to restrict use to optometrists with a glaucoma specialty, or ophthalmologists. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

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

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

a) **Narcotic Analgesics and Combinations—oxycodone 2.5-, 5-, 7.5-, and 10 mg/acetaminophen 300 mg tablets and oxycodone 10 mg/acetaminophen 300 mg/5 mL oral solution—**The fixed dose combination of oxycodone/acetaminophen (Percocet, generic) is a narcotic pain reliever, commonly combined with 325 mg of acetaminophen. Numerous cost-effective generic formulations, are available along with several other short-acting opioids (e.g., hydrocodone/acetaminophen, codeine/acetaminophen, oxycodone IR, etc.). Alternatives in an oral solution include oxycodone 5 mg/acetaminophen 325 mg/5mL and oxycodone 5 mg/5 mL. The various combinations of oxycodone/acetaminophen 300 mg are not cost effective compared to other available short-acting opioids.

b) **Antidepressants: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs):—venlafaxine besylate 112.5 mg tablets—** Venlafaxine hydrochloride (HCl) is available in a variety of doses in both capsules and tablets including 37.5 mg and 75 mg dosages which can be taken together to obtain a dose of 112.5 mg. Venlafaxine HCl is more cost-effective than the venlafaxine besylate 112.5 mg formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for oxycodone/acetaminophen 300 mg tablets and solution in new and current users, and venlafaxine besylate 112.5 mg tablets in new users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to patients affected by the new oxycodone/acetaminophen PA. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA criteria for several drugs, due to new FDA-approved indications or expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for the full criteria.

a) **Cystic Fibrosis Agents—lumacaftor/ivacaftor oral granules (Orkambi)—** Manual PA criteria were updated to expand the age indication for patients with Cystic Fibrosis as young as 1 year of age. Orkambi was previously indicated for children over the age of 2.

b) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass—ibrutinib (Imbruvica)**

i. **Pediatric chronic graft versus host disease (cGVHD):** Manual PA criteria were updated to include the expanded age indication in pediatric patients age 1 year and older with cGVHD after failure of one or more lines of systemic therapy.

ii. **Capsules and tablet formulations:** Manual PA criteria were also revised for the Imbruvica tablet formulation, which previously required a trial of

Imbruvica capsules first, due to cost-effectiveness (See the May 2018 the DoD P&T Committee meeting minutes). Due to recent pricing changes, the requirement for a trial of Imbruvica capsules prior to using the 420 mg and 560 mg tablets will be removed. Note that a trial of capsules will continue to be required before use of the lower strength Imbruvica tablets (140 mg and 280 mg tablets). The PA updates will apply to new patients.

c) **Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists—relugolix/estradiol/norethindrone (Myfembree) and elagolix (Orilissa)**—The manual PA criteria were updated for Myfembree to expand use for treating moderate to severe pain associated with endometriosis. Myfembree when used for this indication will require a trial of nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives first; this is also required for a similar agent already approved for endometriosis, elagolix (Orilissa). Additionally, the PA expiration section of the Orilissa PA was updated to more closely align with the Myfembree PA. Both PAs are now approved for a lifetime expiration of 24 months without a need for renewal, according to the package insert limits for 2 years of therapy.

d) **Oncological Agents: Lung Cancer—crizotinib (Xalkori)—**Manual PA criteria were updated to expand use to adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is anaplastic lymphoma kinase-positive.

e) **Oncological Agents: 2nd-Generation Antiandrogens—darolutamide (Nubeqa)—**The manual PA criteria were updated to allow use for the treatment of adult patients with metastatic hormone-sensitive prostate cancer in combination with docetaxel. The current step-therapy requirements for the class will still apply; a trial of enzalutamide (Xtandi) is required first unless the patient has a contraindication, inadequate response, or adverse reaction to Xtandi.

f) **Oncological Agents: Acute Myelogenous Leukemia (AML)—ivosidenib (Tibsovo)—**Manual PA criteria were updated to expand use in combination with azacitidine for the treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

g) **Oncological Agents—pemigatinib (Pemazyre)—**The manual PA criteria were updated to include a new indication for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor (FGFR1) rearrangement

h) **Oncological Agents—trametinib (Mekinist)**—The manual PA criteria were updated to expand use for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. Note that this indication is approved under accelerated approval based on overall response rate and duration of

response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

i) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors —risankizumab On-Body Injector (Skyrizi OBI)**—PA criteria have applied to Skyrizi since August 2019 for the original indication of moderate-to-severe plaque psoriasis in adults who are candidates for phototherapy or systemic therapy. An expanded indication for psoriatic arthritis was reviewed at the February 2022 DoD P&T Committee meeting.

   Skyrizi's package labeling was recently expanded to include adults with moderately to severely active Crohn's disease. The new OBI is solely approved for Crohn's disease, and Skyrizi syringes and pens are only indicated for plaque psoriasis and psoriatic arthritis. In pivotal trials, Skyrizi was only compared to placebo, and practice guidelines do not yet mention Skyrizi's role in therapy for Crohn's disease. Step-therapy applies to the TIB class, requiring a trial of Humira first. In addition, the other Skyrizi indications (plaque psoriasis and psoriatic arthritis) require a trial of Cosentyx and Stelara first. Since Cosentyx is not approved for Crohn's disease, the step therapy will only require a trial of Humira and Stelara when Skyrizi is used for Crohn's disease. The current PA for the pen and syringe formulations of Skyrizi will also be updated to exclude use for Crohn's disease, consistent with package labeling.

j) **TIBs: Non-TNF Inhibitors—ustekinumab (Stelara)—**Manual PA criteria were updated for Stelara for treating active psoriatic arthritis to now include patients 6 to 17 years of age. Although there is currently a step-therapy for Stelara requiring a trial of Humira first, this will not apply to pediatric patients, as Humira is not indicated for active psoriatic arthritis in this patient population. This is similar to the current PA criteria for Stelara for the pediatric plaque psoriasis indication (e.g., a trial of Humira first is not required).

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Orkambi, Imbruvica, Myfembree, Orilissa, Xalkori, Nubeqa, Tibsovo Pemazyre, Mekinist, Skyrizi, and Stelara.in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

4. Updated PA Criteria for Reasons other than new Indications: Androgens-Anabolic Steroids: Testosterone Replacement Therapies- testosterone cypionate and testosterone enanthate injection

At the February 2022 DoD P&T Committee meeting, a new PA was placed on injectable versions of testosterone cypionate and testosterone enanthate, allowing use in adult males with hypogonadism and transgender males 16 years of age and older. Implementation of this PA occurred in July 2022. Updated criteria were recommended during the November 2022 P&T Committee as noted below.

Additional updates will be considered for all dosage forms, including the injectable form, of testosterone during the February 2023 class review. The following PA revisions were recommended:

1. Allow children less than one year of age to bypass the PA via an age edit. This will account for use in micropenis, which is typically treated with three doses of injectable testosterone within the first year of life.
2. Allow for use in males (assigned male at birth) if they are less than 18 years old and the prescription is written by or in consultation with a pediatric endocrinologist.
3. Allow for use in breast cancer in females if the medication is prescribed by an oncologist. Injectable testosterone is FDA-approved for use in breast cancer in females.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PLAN FOR THE TESTOSTERONE REPLACEMENT THERAPIES—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for the testosterone replacement therapies in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

5. Updated PA Criteria for Removal of Indication

Over the past several months, the FDA has removed certain indications from several oncology drugs due to safety issues. The P&T Committee recommended updates to the PAs below, based on recent FDA action.

a) Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)—The indication for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy has been removed, due to an increased risk of death. Other Lynparza indications remain for ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer.

b) Oncologic Agents - Multiple Myeloma—ixazomib (Ninlaro) —A new limitation of use states that Ninlaro is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials due to an increased risk of death. The indication for use in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy remains

COMMITTEE ACTION: LYNPARZA and NINLARO-UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) to

remove the Lynparza indication for the treatment of adult patients with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. The new limitation of use for Ninlaro about not using this drug in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials will be incorporated into the Ninlaro PA. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

B. Quantity Limits

1. **Newly approved drugs:** See pages 11-12 for the QLs for the Newly Approved drugs, which are outlined in Appendix. D.
2. **Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon (Baqsimi nasal, and Gvoke, Zegalogue and Glucagon injections)–**The QLs for these products were increased to allow for situations such as school use, summer camp, and multiple caregiver's homes. The new QLs are 6 kits/fill at all points of service (Retail, TRICARE Mail Order, and MTF).
3. **Migraine Agents: Oral Calcitonin-Gene Related Peptide (CGRP) Antagonists: ubrogepant (Ubrelvy)–**QLs for Ubrelvy were updated to account for a larger bottle size recently introduced from the manufacturer.
4. **SARS-CoV-2 treatments: nirmatrelvir and ritonavir kit (Paxlovid)**–The committee recommended to update the QLs to allow for one treatment course per 90 days at all points of service, which will align with other commercial health plans. The Committee will continue to monitor the emerging research and practice guidance, and revise accordingly, if needed.

COMMITTEE ACTION: QLs AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the QLs as discussed above, with implementation occurring 2 weeks after signing of the minutes. See Appendix D for the QLs.

C. Line Extensions

The P&T Committee clarified the formulary status for three product line extensions 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) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors—** designating **acalabrutinib (Calquence)** tablets with the same formulary status (UF), QL and PA as the parent Calquence capsules.

b) **Diabetes Non-insulin: Glucagon-like Peptide-1 Receptor Agonists (GLP1RAs)—**designating **semaglutide (Ozempic) 2mg** injection as NF, with the same formulary status (NF) and PA as the parent Ozempic 0.5 and 1 mg injections

COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the formulary status and PA status for the line extension products as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BCF CLARIFICATION: CONTRACEPTIVES

There is currently at least one BCF agent for all categories of oral contraceptives and emergency contraceptives; there are three categories (injection, contraceptive patch, and vaginal contraceptive ring) that do not currently have a BCF agent. Clinical evidence, utilization trends, and cost data informed the selection of generic Xulane patch, NuvaRing vaginal ring, and Depo-Provera injection as the recommended BCF agents for these three categories adding to the MTF availability of contraceptive care.

COMMITTEE ACTION: CONTRACEPTIVES ADDED TO THE BCF AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) adding the most cost-effective generic version of the following contraceptive agents to the BCF: norelgestromin 150 mcg/ethinyl estradiol 35 mcg transdermal system (Xulane; equivalent to the discontinued Orto-Evra patch), etonogestrel 0.12 mg/EE/ethinyl estradiol 15 mcg vaginal ring (NuvaRing), and medroxyprogesterone acetate 150 mg/vial (Depo-Provera), with implementation occurring 2 weeks after signing of the minutes. Note that the Depo-SubQ Provera 104 injection will remain designated as UF, but was not added to the BCF.

VIII. CHANGE IN COPAY: TIER 1 COPAY

A copay change from the current tier 2 copay to the tier 1 copy was recommended for two products, a narcotic antagonist and an emergency contraceptive.

a) **Emergency Contraceptives: ulipristal acetate (Ella)**: Ella was added to the BCF at the August 2018 DoD P&T Committee meeting and is currently available at the Tier 2 copay. Ella was recommended for Tier 1 status to provide a high-value medication at a lower cost to beneficiaries

b) **Narcotic Antagonists: naloxone injection 5 mg/0.5 mL (Zimhi)**: Zimhi was recommended for Tier 1 status as it is a high value and cost-effective reversal agent for opioids. Commercial health plans commonly lower naloxone copays, and another new naloxone formulation, Kloxxado, was designated with the tier 1 copay at the November 2021 DoD P&T Committee meeting.

COMMITTEE ACTION: TIER 1 COPAY FOR ZIMHI AND ELLA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0

opposed, 1 abstained, 1 absent) applying the Tier 1 copay to Zimhi and Ella, with implementation occurring 2 weeks after signing of the minutes.

The authority for the above recommendations is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the 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. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes."

IX. RE-EVALUATION OF NF GENERICS/EMMPI REQUIREMENTS: Alzheimer's Agents, 2nd Generation Antihistamines, and Proton Pump Inhibitors

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The historical standard for reevaluating generically available Tier 3/NF agents for return to formulary status was established at the May 2007 DoD P&T Committee meeting and reiterated in the DoD P&T Committee meeting minutes from November 2012. To summarize, generic products must be "A-rated" as listed in the Orange Book as therapeutically equivalent to the reference product, available in stable and sufficient supply, and the NF agent must be cost effective relative to similar agents on the Uniform Formulary, defined as a weighted average cost per day (or alternative measure) less than or equal to similar agents in the UF class.

The P&T Committee discussed the above standard and agreed that considerations in addition to relative cost should be taken into consideration when discussing formulary status changes. Additionally, reassessing relative clinical and cost effectiveness of generically available Tier 3/NF agents could result in changes to other formulary management tools, including manual and step prior authorizations, quantity limits, and status on the Maintenance Drug List (EMMPI program). Other considerations may include but are not limited to place in therapy and clinical evidence relative to formulary options; desire for a broader choice of formulary options; administrative burden; volume of use; likelihood of inappropriate use if formulary management tools are removed; and the requirement that Tier 3/NF agents generally be filled only at Mail.

The DoD P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30-day equivalent prescriptions for three drugs from the Alzheimer's Agents, 2nd Generation Antihistamines, and Proton Pump Inhibitors (PPIs), when compared to their respective formulary alternatives.

a) ***Alzheimer's Agents (Cholinesterase Inhibitors): donepezil 23 mg (Aricept 23 mg, generics)***—Donepezil 23 mg tabs were compared to formulary alternatives, including galantamine tabs, galantamine 24h ER caps, rivastigmine caps, and rivastigmine

transdermal patch. The P&T Committee concluded that, although the weighted average cost per 30-day equivalent prescription for donepezil 23 mg tabs is currently somewhat higher than donepezil 5 or 10 mg tablets or orally dissolving tablets, it is within the range of other formulary options. In addition, there is currently low utilization of the 23 mg tab, which is unlikely to substantially increase in volume.

b) 2nd Generation Antihistamines: levocetirizine (Xyzal, generics); desloratadine (Clarinex, generics) —Levocetirizine and desloratadine were compared to formulary alternatives, including cetirizine, loratadine, and fexofenadine (which are included on the Uniform Formulary as covered OTCs). The P&T Committee concluded that the two generically available desloratadine products (the 5 mg tab and 2.5- and 5-mg rapidly dissolving tabs), as well as levocetirizine 2.5 mg/5 mL oral solution, are still substantially more costly than the formulary alternatives. Generic levocetirizine 5 mg tabs, on the other hand, are now comparable in price to generic fexofenadine 180 mg, which is on the Uniform Formulary. Of particular note in this class is that many products are available in both OTC and legend versions; desloratadine is the only remaining product that is legend-only. The P&T Committee also noted that the cost of generic desloratadine 5 mg tabs is lower at retail network pharmacies than at MTFs or Mail Order. Utilization of desloratadine rapidly dissolving tabs is very low.

c) PPIs (Tabs/Caps subclass): lansoprazole (Prevacid, generics)—The Tier 3/NF agents lansoprazole 15 and 30 mg caps were compared to formulary alternatives, including tab or cap formulations of omeprazole, pantoprazole, rabeprazole, and esomeprazole, all of which are on the UF. Additional formulary tools apply to the Tabs/Caps subclass: a step PA requires a trial of either omeprazole or pantoprazole prior to receiving rabeprazole or esomeprazole, while a manual PA requiring a trial of all UF agents applies to the two Tier 3/NF agents, lansoprazole, and omeprazole/sodium bicarb caps. Dexlansoprazole (Dexilant, generics) is Tier 4/not covered.

The P&T Committee noted that while generic lansoprazole capsules are still more costly than omeprazole or pantoprazole, they are less costly than esomeprazole, which is on the UF. In addition, the cost of generic lansoprazole caps is lower at retail network pharmacies than at MTFs or Mail Order.

COMMITTEE ACTION: FORMULARY STATUS, EMMPI STATUS AND IMPLEMENTATION—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes. (See Appendix F for implementation dates).

- *Alzheimer's Agents (Cholinesterase Inhibitors):* Return donepezil 23 mg tabs to UF status; remove from the EMMPI program

- *2nd Generation Antihistamines: levocetirizine (Xyzal, generics); desloratadine (Clarinex, generics)*
  - Return levocetirizine 5 mg tabs to UF status
  - Maintain levocetirizine 2.5 mg/5 mL solution as Tier 3/NF

- Maintain all desloratadine products (5 mg tabs, 2.5 and 5 mg rapidly dissolving tabs, and desloratadine/PSE [Clarinex D 12H]) as Tier 3/NF, but exempt desloratadine 5 mg tabs and the 2.5 and 5 mg rapidly dissolving tabs from the mail order requirement on the basis of cost effectiveness and remove them from the Maintenance Drug List

- *Proton Pump Inhibitors (Tabs/Caps subclass): lansoprazole (Prevacid, generics)*
  - Return lansoprazole 15 and 30 mg caps to UF status, remove them from the EMMPI program and remove the manual PA, but place them behind the step in the same status as rabeprazole and esomeprazole
  - Maintain omeprazole/sodium bicarb caps as Tier 3/NF

X. TIER 4/NOT COVERED RE-REVIEW: REVIEW OF CURRENT TIER 4 PRODUCTS AND RAPID ACTING INSULINS—INSULIN ASPART/NIACINAMIDE (FIASP)

If the P&T Committee determines that a pharmaceutical agent provides very little or no clinical effectiveness relative to similar agents, it may recommend complete or partial exclusion of that agent from the TRICARE pharmacy benefits program. Drugs designated as Tier 4/Not Covered status are not available at the MTFs or Mail Order points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies**.**

With respect to the pharmaceutical agents currently designated as Tier 4/Not Covered, the P&T Committee concluded that there is a lack of new clinical data that supports a specific clinical need for these products which is not met by formulary agents. Additionally, there is a lack of new clinical data to challenge the conclusion that the current Tier 4/Not Covered drug offer little or no clinical effectiveness relative to formulary agents.

Rapid Acting Insulins: insulin aspart/niacinamide (Fiasp)—The P&T Committee reviewed specific data regarding the July 1, 2020 implementation of Tier 4/Not Covered status for insulin aspart/niacinamide (Fiasp) as well as new clinical evidence published after the November 2019 DoD P&T Committee evaluation of the rapidly-acting insulins.

For insulin aspart/niacinamide (Fiasp), the P&T Committee concluded that:

- Fiasp is a formulation of insulin aspart that contains niacinamide, a form of vitamin B3.
- Although Fiasp has a faster onset of action of approximately 2.5 minutes, the change in pharmacokinetic profile does not show a clinically significant difference in A1C or post-prandial blood glucose compared to insulin aspart (Novolog).

- There is no data to show that Fiasp is superior to other rapid-acting insulins. Pivotal studies demonstrated that Fiasp is non-inferior when compared to Novolog, but did not show superiority.
- New data since 2019 evaluating use of Fiasp in insulin pumps found Fiasp was comparable to insulin aspart (Novolog) in term of efficacy and safety, but failed to demonstrate any significant differences in glycemic control (i.e., time-in-range as measured by continuous glucose monitoring). Limitations of the data include small patient enrollment and short study duration.
- There is no new data to change the previous clinical conclusion that Fiasp provides very little to no clinical effectiveness for treating diabetes relative to formulary rapid acting insulins.

COMMITTEE ACTION: FIASP TIER 4 STATUS—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent), to maintain Tier 4/Not Covered status for insulin aspart/niacinamide (Fiasp).

XI. PROCESS FOR REVIEWS OF BIOLOGICS AND BIOSIMILARS

The DoD P&T Committee reviews newly approved drugs per 32 CFR 199.21(g)(5) to include new drugs approved through the 505(b) New Drug Applications (NDA) as well as 351(a) Biologics License Applications (BLA) pathways. These two pathways have follow-on approvals. For NDA pathway drugs, generic drugs are approved and listed in the Orange Book. BLA products also have follow-on products approved as 351(k) biosimilars or 351(k) interchangeable products and are listed in the Purple Book. Although these processes are similar, there are distinct differences in the approvals of biosimilars. The Committee reviewed these processes and recommended a procedure of reviewing these products as they are approved.

The Committee concluded the following regarding biologics and their biosimilars.

- By FDA approval and definition, biosimilars are equally safe and efficacious. This provides strong competition within products for biosimilar drug classes.
- Not all biosimilars are cost-effective when compared to the reference biologic.
- Biosimilars can be in direct competition to other biologics, and Utilization Management (UM) Tools can be effectively applied.
- Currently there are a limited number of interchangeable biosimilars marketed. States will allow for individual pharmacies to interchange biosimilars under certain circumstances, to include notifying the provider. There are slight differences between individual states in documentation requirements.
- Unbranded biologics are marketed under the same 351(a) BLA as the reference product. These unbranded biologics can have differing formulary status

compared to their reference product. Unbranded biologics will be reviewed by the DoD P&T Committee as either a newly approved drug, a line extension, or using other UM tools.

- Current UM tools are routing prescription utilization to the most cost-effective agents. This is seen in the basal insulin class.
- Interchangeable biosimilars will not default to a generic Tier 1 copay, but the DoD P&T Committee can make this decision to make certain biosimilar products Tier 1.

The P&T Committee discussed and approved a process of reviewing biologics and biosimilars for inclusion on the DoD Uniform Formulary. Newly approved biosimilars will be reviewed using the new drug process outlined in 32 CFR 199.21(g)(5). Biosimilars will not default to the Tier 1 generic copay. Unbranded Biologics will either be treated like a New Drug, as a line extension, or managed using other UM tools. Interchangeable products approved under the 351(k) pathway can still have a PA requiring trial of a step preferred product. The Committee will continue to evaluate this process for future improvements.

COMMITTEE ACTION: ***PROCESS FOR REVIEWING BIOLOGICS AND BIOSIMILARS—***The P&T Committee recommended (17 for, 0 against, 0 abstained, 1 absent) that newly approved biosimilars will be reviewed using the new drug process outlined in 32 CFR 199.21(g)(5). Biosimilars will default to Tier 2 or Tier 3 copays depending on formulary placement. Unbranded Biologics will either be treated like a New Drug, as a line extension, or managed using other UM tools.

XII. ITEMS FOR INFORMATION

A. Post-Implementation Review: White Blood Cell (WBC) Stimulants: The Committee reviewed utilization and cost trends for the WBC Stimulants, which were reviewed for formulary placement in August 2020. The WBC Stimulants class review resulted in significant and sustained cost avoidance for the MHS. Savings from UF class reviews can vary based on competition, comparator interchangeability, and other market factors (and many were observed with this class). Class reviews can create or maintain conditions (e.g., step therapy) where future agents are placed behind a step and subject to prior authorization. Formulary management tools can increase market share of cost-effective agents and drive reductions in total cost, observed outcomes may vary. Optimum scenarios were selected and implemented during this review.

B. Addition of Solu-Cortef 100 mg Act-O-Vials (GCN 028302) to the TRICARE Pharmacy Benefit: Hydrocortisone sodium succinate (Solu-Cortef) was not previously part of the TRICARE pharmacy benefit, due to the requirement for IV/IM administration. Due to several requests from the field using the DHA 111 form, and supporting information from the 2016 Endocrine Society guidelines for primary adrenal insufficiency which

recommends every patient have a glucocorticoid injection kit for emergency use, the Solu-Cortef Act-O-Vials were added to the TRICARE Pharmacy benefit at all three points of service. Quantity limits of two vials per prescription fill will also apply. Solu-Cortef is also available under the TRICARE Medical benefit.

C. Annual MHS Prescribing and Cost Trends: The Committee was briefed on various aspects of MHS prescribing and cost trends, including overall trends and spends, the top 25 drug classes, and increasing specialty spend. During Fiscal Year 2022, the DoD P&T Committee performed 8 drug class reviews (comprised of 15 subclasses), 55 new drug reviews, and approximately 81 UM actions. A significant amount of time was spent implementing the 2021 formulary recommendations which were affected by the BAP delay. One major accomplishment was completion of the MHS GENESIS OTC list.

XIII. ADJOURNMENT

The meeting adjourned at 1615 hours on November 3, 2022. The next meeting will be in February, 2023.

Appendix A—Attendance: November 2-3, 2022 DoD P&T Committee Meeting:
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 2022 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

Brian C. Lein, MD
Assistant Director,
Healthcare Administration
for Telita Crosland LTG, MC, USA
Director

31 Jan 2023
Date

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, Col (Ret), MC, USA	Army Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
COL Aatif Sheik, MSC	Army, Pharmacy Consultant
LCDR Caitlin Cruz for CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CAPT Tiffany Cline for CAPT Bridgette Faber, MSC Day #1 AM	Navy, Pharmacy Consultant
CAPT Bridgette Faber, MSC Day #1 PM and Day #2	Navy, Pharmacy Consultant
Lt Col Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Maj Burke Wilson for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD	Physician at Large, DHA
LTC Jason Burris, MC	Army, Oncology Physician
Ms. Beth Days	Oncology Pharmacist
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
COL Yang Xia	TRICARE Latin America and Canada
Nonvoting Members Present	

Megan Gemunder, DHA	Attorney Advisor, Contract Law
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Dean Valibhai, PharmD	TPharm5 Clinical COR
Eugene Moore, PharmD	TPharm4 Clinical COR
Lt Col Francisco Boral	Defense Logistics Agency
Maj Charles (Josh) Stallings	Defense Logistics Agency
Guests	
Ms. Marsha Peterson	Contracting Officer
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Sydney Roman	DHA Contracting
Ms. Victorkia Reed	DHA Contracting, TPharm5
Mr. Dwight Bonham	DHA Contracting, COR TPharm5
Others Present	
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
David Folmar, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, RPh	DHA Formulary Management Branch Contractor
Michael Lee, RPh	DHA Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA Formulary Management Branch Contractor
CDR Marie Manteuffel	TDY PHS Pharmacist to the FMB

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• **abrocitinib (Cibinqo)** **Atopy Agents: Oral JAK-I Inhibitors**	**Updates are in bold** • Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives: upadacitinib (Rinvoq),** dupilumab (Dupixent), topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus), high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
New Drugs MN Criteria	
• **clindamycin 2% vaginal gel (Xaciato)** **Antibiotics**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** metronidazole (oral tabs, vaginal gel), clindamycin (vaginal cream)
• **deucravacitinib tablets (Sotyktu)** **Targeted Immunomodulatory Biologics (TIBs)**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** apremilast (Otezla), secukinumab (Cosentyx), adalimumab (Humira)
• **fingolimod ODT (Tascenso)** **Multiple Sclerosis: Miscellaneous Oral Agents**	• Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** fingolimod capsules (Gilenya, generics), siponimod (Mayzent), ponesimod (Ponvory), ozanimod (Zeposia)
• **oteseconazole (Vivjoa)** **Antifungals**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** fluconazole (Diflucan, generics)
• **ranolazine ER granule (Aspruzyo Sprinkles)** **Cardiovascular Agents Miscellaneous**	• No alternative formulary agent - patient cannot swallow tablets **Formulary alternatives:** ranolazine ER tablets (Ranexa, generics)

• **roflumilast 0.3% cream (Zoryve)** **Psoriasis Agents**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** moderate to high potency topical corticosteroids (e.g., betamethasone, clobetasol, fluocinonide), topical calcineurin inhibitors (i.e., pimecrolimus, tacrolimus)
• **tadalafil oral suspension (Tadliq)** **PAH**	• No alternative formulary agent: patient cannot take sildenafil and requires an additional therapeutic agent for PAH **Formulary Alternatives**: sildenafil suspension, tadalafil tablets

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	

• abrocitinib (Cibinqo)
 	
Atopy Agents: Oral JAK-I Inhibitors
	Updates from Nov 2022 are in bold and strikethrough
	
	Manual PA criteria apply to all new users of abrocitinib (Cibinqo).
	
	Manual PA criteria: abrocitinib (Cibinqo) is approved if all criteria are met:
	• Patient is 18 years of age or older
	• Medication is prescribed by an allergist, dermatologist, or immunologist
	• Drug is used to treat moderate to severe atopic dermatitis
	• **The patient's disease is not adequately controlled with other systemic drug products including biologics (ex Dupixent) OR it is inadvisable to use other systemic drug products including biologics**
	• Patient failed, has a contraindication, or intolerability to one medication in EACH of the following **four ~~two~~** categories:
	  • Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
	  • Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
	  • **Injectable interleukin antagonist: dupilumab (Dupixent)**
	  • **Oral JAK: upadacitinib (Rinvoq)**
	• Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy
	• Patient has had a negative TB test in the last 12 months (or is adequately managed)
	• Patient has no history of venous thromboembolism (VTE)
	• Provider is aware of the boxed FDA warnings
	• Patient does not have neutropenia (ANC < 1000)
	• Patient does not have lymphocytopenia (ALC < 500)
	• Patient does not have anemia (Hgb < 8 mg/dL)
	• Patient is not taking a concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulatory agents
	
	Non-FDA-approved uses are not approved.
	PA expires in 1 year. Renewal PA criteria will be approved indefinitely.
	
	Renewal criteria: (initial TRICARE PA approval is required for renewal) The patient's disease severity has improved and stabilized to warrant continued therapy

• **upadacitinib (Rinvoq)** **Atopy Agents: Oral JAK-I Inhibitors**	**Note that there were no changes to the current Rinvoq criteria for the other indications (RA, PsA, Ulcerative Colitis or Ankylosing Spondylitis – see the August 2022 P&T Committee meeting minutes for the full criteria)** Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq ER). Manual PA Criteria: Rinvoq is approved if all criteria are met: ***For Atopic Dermatitis*** • The patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient's disease is not adequately controlled with other systemic drug products, including biologics (for example, Dupixent) **OR it is inadvisable to use other systemic drug products including biologics** • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: o For patients 18 years of age or older; high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) o For patients 12 to 17 year of age: any topical corticosteroid ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy *For all indications* • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved. PA expires in 1 year for atopic dermatitis. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, or ankylosing spondylitis. Renewal criteria: (initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if the following apply: Atopic Dermatitis - The patient's disease severity has improved and stabilized to warrant continued therapy
• **epoetin alfa (Epogen)** • **epoetin alfa (Procrit)** **RBC Stimulants: Erythropoietins**	Manual PA criteria apply to all new users of epoetin alfa (Procrit and Epogen) Manual PA Criteria: Coverage will be approved if all criteria are met: • Provider acknowledges that epoetin alfa-epbx (Retacrit) is the preferred epoetin alfa for TRICARE and is available without a PA • The patient has experienced an inadequate response or • The patient has had an adverse reaction to Retacrit that is not expected to occur with Procrit or Epogen Prior Authorization does not expire

Newly Approved Drug PAs	
• **deucravacitinib tablets (Sotyktu)** **Targeted Immunomodulatory Biologics (TIBs)**	Step therapy and manual PA criteria apply to all new users of Sotyktu Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) and secukinumab (Cosentyx) 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, Sotyktu is approved if all criteria are met: • The provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira and Cosentyx AND: • The patient had an inadequate response to Humira and Cosentyx OR • The patient experienced an adverse reaction to Humira and Cosentyx that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira and Cosentyx • Patient is 18 years of age or older • Patient has diagnosis of moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, or corticosteroids) • 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 TIB agents • Provider acknowledges the FDA safety alerts and boxed warnings and precautions associated with Sotyktu Non-FDA-approved uses are not approved PA does not expire
• **fingolimod ODT (Tascenso)** **Multiple Sclerosis: Miscellaneous Oral Agents**	Manual PA criteria apply to all new users of Tascenso ODT. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is ≥ 10 years and weighs ≤ 40 kg • Patient has a documented diagnosis of a relapsing form of multiple sclerosis (MS) • Medication is prescribed by a neurologist • Patient has tried and failed or has a contraindication (i.e., swallowing difficulties) to fingolimod capsule • Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunomide [Aubagio]) • Patients of childbearing potential agree to use effective contraception during treatment and for 2 months after stopping therapy • Patient has not failed a course of another S1p receptor modulator (e.g., Gilenya, Mayzent, Zeposia, Ponvory) • Provider acknowledges that all recommended Tascenso ODT monitoring has been completed and the patient will be monitored throughout treatment as recommended in the package insert. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), pulmonary function tests (PFTs), blood pressure, skin assessments and macular edema screening as indicated. Non-FDA approved uses are not approved, including for patients weighing > 40 kg PA does not expire.

• **oteseconazole (Vivjoa)** **Antifungals**	Manual PA criteria apply to all new users of Vivjoa. Manual PA Criteria: Coverage is approved if all criteria are met: • The prescription is written by a gynecologist • Patient is post-menopausal OR post-menarchal and not of reproductive potential (i.e., history of tubal ligation, salpingo-oophorectomy, or hysterectomy) • Patient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC) confirmed by microscopy, nucleic acid amplification testing (NAAT) testing, or culture. RVVC is defined as greater than or equal to four acute episodes of symptomatic vulvovaginal candidiasis within a one year period • Patient has experienced therapeutic failure, contraindication, or intolerance to a six month maintenance course of oral fluconazole. Non FDA-approved uses are not approved PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA
• **ranolazine ER granule (Aspruzyo Sprinkles)** **Cardiovascular Agents Miscellaneous**	Manual PA criteria apply to all new users of Aspruzyo Sprinkle Manual PA criteria: Coverage is approved if all criteria are met: • The patient is 18 years of age or older • The patient has a diagnosis of chronic angina • Provider must document why the patient requires Aspruzyo Sprinkle and cannot take ranolazine ER tablets *(write in)* Non-FDA approved uses are not approved. PA does not expire

• **roflumilast 0.3% cream (Zoryve)**
 	
Psoriasis Agents
	Manual PA criteria apply to all new users of Zoryve.
	
	Manual PA criteria: Coverage is approved if all criteria are met:
	• Patient is 12 years of age or older
	• The medication is being prescribed by, or in consultation with, a dermatologist
	• The patient has a diagnosis of plaque psoriasis
	• The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following:
	  • A topical corticosteroid
	  ▪ For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) OR
	  ▪ For patients 12 to 17 year of age: any topical corticosteroid
	  • A topical calcineurin inhibitor (i.e., tacrolimus, pimecrolimus)
	
	Non-FDA approved uses are not approved.
	PA does not expire.

• **sirolimus 0.2% gel (Hyftor)** **Immunosuppressives**	Manual PA criteria apply to all new users of Hyftor Manual PA criteria: Coverage is approved if all criteria are met: • Hyftor is prescribed by or in consultation with a dermatologist or other provider experienced in tuberous sclerosis treatment • Patient has a documented diagnosis of facial angiofibroma associated with Tuberous Sclerosis Complex (TSC) • Provider acknowledges the recommendation to monitor for hyperlipidemia during treatment Non-FDA approved uses are not approved. PA does not expire

• **zonisamide oral suspension (Zonisade)** **Anticonvulsants-Antimania Agents**	Manual PA criteria apply to all new users of Zonisade Manual PA Criteria: Coverage is approved if all criteria are met: • Provider acknowledges generic zonisamide capsule are available to TRICARE patients and do not require a PA • Medication is prescribed by a neurologist • Patient has diagnosis of partial-onset epilepsy • Patient requires a liquid formulation due to swallowing difficulty • Patient has tried and failed or has a contraindication to at least one formulary anti-epileptic drug Non-FDA approved uses are not approved. PA does not expire
• **tadalafil oral suspension (Tadliq)** **PAH**	Manual PA criteria apply to new and current users of Tadliq. Automated PA Criteria: PA does not apply to patients younger than 18 years of age (age edit) AND if the patient has filled a prescription for sildenafil oral suspension at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. If automated criteria are not met: Manual PA Criteria: Tadliq is approved if all criteria are met: • Tadliq is prescribed by a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 pulmonary arterial hypertension (PAH) ▪ Patient has had a right heart catheterization (documentation required) ▪ Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH • Patient is not receiving other PDE-5 inhibitors, nitrates, or riociguat (Adempas) concomitantly • Patient requires a liquid formulation due to swallowing difficulty AND • Patient has had an adequate trial and failure OR has had an adverse reaction to sildenafil Non-FDA-approved uses are not approved, including for erectile dysfunction or for benign prostatic hyperplasia (BPH) Prior authorization does not expire.
• **Freestyle Libre 3** **CGM: Therapeutic Continuous Glucose Monitoring Systems**	**Updates from the current CGMS PA criteria are in bold** Manual PA criteria apply to all new users of Dexcom G6, FreeStyle Libre2, or **FreeStyle Libre 3**. Patients who have previously received a CGM under the TRICARE medical benefit (e.g., DME) must still fill out the prior authorization criteria below in order to receive these CGMs under the TRICARE pharmacy benefit. Note: other CGM systems are not part of the TRICARE pharmacy benefit but may be covered through the TRICARE DME process. Manual PA criteria: Coverage is approved if all criteria are met: • The patient has a diagnosis of Type 1 diabetes mellitus OR Type 2 diabetes mellitus • One of the following situations applies: • Patient is using basal and prandial insulin injections; OR • Patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR

	• Patient has Type 2 diabetes mellitus and is receiving insulin therapy and has a history of severe hypoglycemia episodes requiring medical intervention • **CGM** is prescribed by an endocrinologist or diabetes specialist • **Diabetes management expert is defined as: licensed independent practitioner experienced in the management of insulin dependent diabetics requiring basal and bolus dosing or a pump and familiar with the operation and reports necessary for proper management of continuous glucose monitoring systems. This is a self-certification.** • Documentation from the patient record must be submitted with all of the following: • Diagnosis • Medication history, including use of insulin • Completion of a comprehensive diabetes education program for the patient • Patient agrees to wear CGM as directed • Patient agrees to share device readings with managing healthcare professional for overall diabetes management • Patient meets the following age requirements • Dexcom G6: Patient is 2 years of age or older • FreeStyle Libre 2 **or FreeStyle Libre 3**: Patient is 4 years of age or older • Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips, with the goal of minimizing/discontinuing use Initial prior authorization expires in 1 year PA renewal will be required annually <u>Renewal criteria</u>: Coverage will be approved on a yearly basis if all of the following apply (Note that initial TRICARE PA approval is required for renewal) • Confirmation that the patient has seen an endocrinologist or diabetes specialist at least once within the past year • Confirmation that the patient has utilized CGM daily • Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips at every visit, with the goal of minimizing/discontinuing use • Patients with T2DM continue to require daily basal and prandial insulin injections • Patient continues to agree to share data with managing healthcare professional for the purposes of clinical decision making
• **Omnipod 5** **Insulins: Miscellaneous Insulin Devices**	Note that Omnipod 5 is currently only available at retail pharmacies. Manual PA criteria apply to all new users of Omnipod 5 pods and kits <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Note: Current utilization of Omnipod 3 and 4 is not automatic approval for Omnipod 5. A new PA is required for Omnipod 5 • Omnipod 5 is prescribed by or in consultation with an endocrinologist • The patient has a documented diagnosis of Type 1 diabetes mellitus • Patient meets one of the following: • The patient is on an insulin regimen of 3 or more injections per day using both basal and prandial insulin and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy *OR* • Patient is utilizing another insulin-pump device and is switching to Omnipod 5 • 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 <u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Omnipod 5 is approved for 1 year for continuation of therapy if all criteria are met

	• Patient has been successful with therapy as shown by increased time in range (TIR), improved A1c, *OR* • Patient has experienced decreases in hypoglycemic episodes
Utilization Management New PAs	
• **echothiophate (Phospholine Iodide)** **Glaucoma Agents: Cholinergics/ Cholinesterase Inhibitors**	Manual PA criteria apply to all new users of Phospholine Iodide. Manual PA criteria: Phospholine Iodide is approved if all the following criteria are met: • The provider acknowledges that most other eye drops for glaucoma are available to TRICARE patients without a prior authorization. Providers are encouraged to consider changing the prescription to a different glaucoma agent if appropriate. • The prescription is written by an optometrist with a glaucoma specialty or an ophthalmologist Prior authorization does not expire.
• **oxycodone 2.5-, 5-, 7.5-, and 10 mg/ acetaminophen 300 mg tablet** • **oxycodone 10 mg/acetaminophen 300 mg/5 mL oral solution** **Narcotic Analgesics and Combinations**	Manual PA criteria apply to all new and current users of oxycodone/acetaminophen 300 mg tablets and solution. Manual PA criteria: Oxycodone/acetaminophen 300 mg tablets and solution are approved if all criteria are met: • Provider acknowledges other oxycodone/acetaminophen formulations, including oxycodone/acetaminophen 325 mg tablets and solution are available without requiring prior authorization. • The provider must explain why the patient can't take a different oxycodone/acetaminophen formulation. (*write-in*) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• **venlafaxine besylate 112.5 mg tablet** **Antidepressants: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)**	Manual PA criteria apply to all new users of venlafaxine besylate 112.5 mg tablet. Manual PA criteria: Venlafaxine besylate 112.5 mg tablet is approved if all criteria are met: • Provider acknowledges other formulations of venlafaxine, including venlafaxine hydrochloride are available without requiring prior authorization. • The provider must explain why the patient can't take a different formulation of venlafaxine. (*write-in)* Non-FDA-approved uses are not approved. Prior authorization does not expire.

Utilization Management Updated PAs	

• **lumacaftor/ivacaftor oral granules (Orkambi)**
 	
Cystic Fibrosis Agents
	Updates from the November 2022 meeting are in bold and strikethrough.
	
	Manual PA criteria apply to all new users of Orkambi granules.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Orkambi is prescribed for the treatment of cystic fibrosis in an age appropriate patient population according to the product label.
	  • For Orkambi granules – the patient is between the ages of ~~**two**~~ **1** to 5 years; or the patient is older than 5 years with documented swallowing difficulties
	  • For Orkambi tablets – the patient is 6 years of age or older
	• The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected/confirmed by an FDA-approved test
	• Concomitant use of Orkambi granules with Orkambi tablets is not allowed.
	• Concomitant use of Orkambi granules or tablets is not allowed with ivacaftor (Kalydeco) or tezacaftor/ivacaftor (Symdeko).
	
	Non-FDA-approved uses are not approved, including:
	• Patients who are heterozygous for the F508del mutation in the CFTR gene
	
	PA does not expire.

• **ibrutinib capsules and tablets (Imbruvica)**
 	
Leukemia and Lymphoma Agents: BTKis
	Updates from the November 2022 meeting are in bold.
	
	Manual PA is required for new users of Imbruvica capsules and tablets.
	
	Manual PA Criteria: Imbruvica is approved if all criteria are met:
	• The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for TRICARE patients (**at the 140 mg and 280 mg strengths**).
	• If the Rx is for Imbruvica tablets at the 140 mg or 280 mg strengths, 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 or **for the higher strengths of Imbruvica tablets (420 mg and 560 mg),** please continue with the PA criteria below.
	• Drug is prescribed by or in consultation with a hematologist/oncologist
	• **Patient is 1 to 17 years of age with a diagnosis of chronic graft-versus-host disease OR**
	• Patient is 18 years of age or older
	• 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.
• **relugolix/estradiol/ norethindrone (Myfembree)** **Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists**	**Updates from the November 2022 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Myfembree. <u>Manual PA criteria</u>: Myfembree is approved if all criteria are met: • Patient is 18 years of age or older • Patient is a premenopausal woman • Patient has a diagnosis of: ▪ Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **OR** ▪ **Moderate to severe pain association with endometriosis AND** • **Patient has had inadequate relief after at least three months of therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) or NSAIDs are contraindicated** **AND** • 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)**~~

	• **Provider is aware of drug interactions with Myfembree and oral P-gp inhibitors (e.g., erythromycin) and combined P-gp and strong CYP3A inducers (e.g., rifampin) and will counsel patient on these interactions as appropriate** 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.**
• **elagolix (Orilissa)** **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	**Updates from the November 2022 meeting are in bold and strikethrough.** Manual PA applies to all new users of elagolix (Orilissa). <u>Manual PA Criteria</u>: Elagolix is approved if all criteria are met: • The patient is 18 years of age or older • Patient is a premenopausal woman with endometriosis • Patient has had inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, unless contraindicated • 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 severe hepatic impairment (Child-Pugh Class C) • Patient does not have osteoporosis • Patient is on concurrent calcium supplementation. • Patient is not using Orilissa concomitantly with cyclosporine or gemfibrozil Non-FDA approved uses are not approved. **~~PA Expiration 9 months; Renewal expiration 24 months.~~ Prior authorization expires after 24 months (lifetime expiration). Cumulative treatment with Orilissa and Myfembree will not exceed 24 months during the patient's lifetime.** **~~<u>Renewal Criteria</u>: PA will be approved for an additional 15 months (lifetime usage not to exceed 24 months) if all criteria are met~~** **~~• The patient meets the original PA criteria~~** **~~• Patient does not have moderate hepatic impairment (Child-Pugh Class B);~~** **~~Patient is taking the Orilissa 150 mg dose (note that the 200 mg dose is only approved for up to 6 months)~~**
• **crizotinib (Xalkori)** **Oncological Agents: Lung Cancer**	**Updates from the November 2022 meeting are in bold.** Manual PA criteria apply to all new users of crizotinib (Xalkori). <u>Manual PA Criteria</u>: Xalkori is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following diagnoses: ▪ Metastatic non-small cell lung cancer (NSCLC) AND • Tumors are anaplastic lymphoma kinase (ALK) positive OR ROS1-positive (as detected by an approved test) ▪ Relapsed or refractory systemic anaplastic large cell lymphoma (ALK) positive AND • Patient is 1 year of age and older or a young adult (Note – limitation of use: safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory systemic ALK-positive anaplastic large cell lymphoma) ▪ **Unresectable, recurrent, or refractory inflammatory myofibroblastic tumor in patients 1 year of age or older AND** • **Tumors are ALK-positive**

	▪ 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 including neoplastic diseases. Prior authorization does not expire.
• **darolutamide (Nubeqa)** **Oncological Agents: 2nd-Generation Antiandrogens**	**Updates from the November 2022 meeting are in bold.** Manual PA is required for all new users of Nubeqa. Manual PA Criteria: Nubeqa is approved if all criteria are met: • Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. The patient is required to try Xtandi first. **OR** • Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Nubeqa AND • Patient is 18 years of age or older AND • Drug is prescribed by or in consultation with an oncologist or urologist AND • Patient has diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) AND • The patient has had a negative CT scan of abdomen/pelvis and/or negative bone scan AND • Prostate-specific antigen doubling time (PSADT) is ≤ 10 months OR • **Patient has a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel** • 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: _____ • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non-FDA-approved uses are not approved. PA expires in 1 year. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Nubeqa is approved for 1 year for continuation therapy if all criteria are met: • The patient continues to be metastases-free • The patient has not progressed onto subsequent therapy (such as abiraterone)
• **ivosidenib (Tibsovo)** **Oncological Agents: Acute Myelogenous Leukemia**	**Updates from the November 2022 meeting are in bold.** Manual PA criteria apply to all new users of ivosidenib (Tibsovo). Manual PA Criteria: Tibsovo is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has a diagnosis of: ▪ Relapsed/refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by a FDA-approved test OR ▪ Patient has newly diagnosed AML **AND is using Tibsovo as monotherapy OR in combination with azacitidine (Vidaza)** and is aged 75 years of age or older OR has comorbidities that preclude use of intensive induction chemotherapy with a susceptible IDH1 mutation as detected by a FDA-approved test OR ▪ Patient has previously treated, locally advanced, or metastatic cholangiocarcinoma with an IDH1 mutation as detected by a FDA approved test OR ▪ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • The patient will be monitored for differentiation syndrome

	• The patient will be monitored for Guillain-Barre syndrome Other Non-FDA-approved uses are not approved Prior Authorization does not expire.
• **pemigatinib tablets (Pemazyre)** **Oncological Agents**	**Updates from the November 2022 meeting are in bold.** Manual PA is required for all new users of Pemazyre. Manual PA Criteria: Pemazyre is approved if all criteria are met: • The patient has a diagnosis of pathologically confirmed unresectable or advanced/metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test OR • **The patient has a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement** • Patient is 18 years of age of older • Prescribed by or in consultation with a hematologist/oncologist • Patient will be monitored for ophthalmologic disorders including pre-treatment screening for retinal disorders. • Patient will be monitored for hyperphosphatemia. • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment. • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy. • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. Non-FDA approved uses are not approved except as noted above. Prior authorization does not expire.
• **trametinib (Mekinist)** **Oncological Agents**	**Updates from the November 2022 meeting are in bold.** Manual PA criteria apply to all new users of Mekinist. Manual PA criteria: • Coverage will be approved if all criteria are met: ▪ Treatment (alone or in combination with dabrafenib [Tafinlar]) of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation; OR ▪ In combination with dabrafenib (Tafinlar), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation ▪ **For the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options** • Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy • Combination with dabrafenib (Tafinlar) for locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) Non-FDA-approved uses are not approved. Prior Authorization does not expire.

• **risankizumab On-Body Injector (Skyrizi OBI)** **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the November 2022 meeting are in bold and strikethrough (from the current PA for Skyrizi for plaque psoriasis or psoriatic arthritis).** PA criteria apply to all new users of **Skyrizi OBI. The patient must have tried Humira and Stelara~~, and Cosentyx~~.** Manual PA Criteria: Skyrizi **OBI** is approved if all criteria are met: • The patient has a contraindication or has had an inadequate response to Humira, ~~**Cosentyx**~~, AND Stelara OR • The patient has had an adverse reaction to Humira, ~~**Cosentyx,**~~ AND Stelara that is not expected with the requested non-step-preferred TIB AND • Patient is 18 years of age or older • ~~**The patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy**~~ • **The patient is diagnosed with moderately to severely active Crohn's disease** • Patient has tried and had an inadequate response to non-biologic systemic therapy (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • Coverage NOT provided for concomitant use with other TIBs, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, or Xeljanz/Xeljanz XR • The patient has had a negative TB test result in past 12 months (or TB is adequately managed) ~~**Non-FDA-approved uses are not approved.**~~ **Use of the on-body injector for non-FDA-approved indications, plaque psoriasis or psoriatic arthritis is not approved. Providers should fill out the PA for Skyrizi pen and syringes for indications other than Crohn's disease.** PA does not expire.
• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the November 2022 meeting are in bold.** Note that Humira is the Department of Defense's preferred targeted biologic agent. 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, coverage is approved for Stelara if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis **(patients between the ages of 6 and 17 may receive Stelara for active psoriatic arthritis without the requirement to try Humira first)** • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy (patients between the ages of 6 and 17 may receive Stelara for plaque psoriasis without the requirement to try Humira first) • Moderate to severe active Crohn′s disease who have failed or intolerant to immunomodulators, corticosteroids, or Humira. Alternatively, for moderate to severe ulcerative colitis (UC); infliximab may be used first in lieu of Humira • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept

	(Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), apremilast (Otezla), or rituximab (Rituxan Non-FDA approved uses are not approved. PA does not expire.
• **testosterone cypionate** • **testosterone enanthate** **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the November 2022 meeting are in bold and strikethrough.** **PA does not apply to patients less than 1 year of age (age edit)** Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections. <u>Manual PA Criteria</u>: testosterone cypionate and testosterone enanthate IM injections are approved if all criteria are met: • Coverage approved for male patients **(patients male at birth)** if: ▪ **Patient is younger than 18 years of age if:** • **Prescription is written by or in consultation with a pediatric endocrinologist OR** ▪ Patient is 18 years of age or older AND • Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND • Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND • The patient does not have prostate cancer AND • The patient is experiencing symptoms usually associated with hypogonadism OR • Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if: ▪ Patient has diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to the most current edition of the DSM ▪ Patient is an adult, or is 16 years or older ▪ Patient has experienced puberty to at least Tanner stage 2 ▪ Patient has no signs of breast cancer AND ▪ For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND ▪ Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) OR • **Coverage approved for females if:** ▪ **Patient has diagnosis of breast cancer** ▪ **Prescription is written by or in consultation with an oncologist** Non-FDA-approved uses are NOT approved. Not approved for concomitant use with other testosterone products. Prior Authorization ~~**does not expire**~~ **expires in 1 year** **<u>Renewal Criteria</u>: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if one of the following apply:** • **The patient has had a positive response to therapy** • **The risks of continued therapy do not outweigh the benefits**

Drug / Drug Class	Quantity Limits
• **abrocitinib (Cibinqo)** • **upadacitinib (Rinvoq)** **Atopy Agents: Oral JAK-1 Inhibitors**	▪ Retail/MTF/Mail: 60-days supply
• **clindamycin 2% vaginal gel (Xaciato)** **Antibiotics**	▪ Retail/MTF/Mail: 1 carton per fill
• **deucravacitinib tablets (Sotyktu)** **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail/MTF/Mail: 60 day supply
• **oteseconazole (Vivjoa)** **Antifungals**	▪ Retail/MTF/Mail: 1 package per fill
• **sirolimus 0.2% gel (Hyftor)** • **Immunosuppressives**	▪ Retail: 3 tubes/30 days ▪ MTF/Mail: 9 tubes/90 days
• **Freestyle Libre 3** **CGM: Therapeutic Continuous Glucose Monitoring System**	▪ Sensors: o Retail: 2 sensors in 28 days o MTF/Mail: 6 sensors in 84 days
• **Omnipod 5** **Insulins: Miscellaneous Insulin Devices**	▪ Retail: o Omnipod 5: 15 pods/30 days o Omnipod 5 Kit: 1 kit/2 years
• **glucagons (Baqsimi, Gvoke, Zegalogue, and Glucagon)** **Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents**	▪ Zegalogue and Gvoke: Retail/MTF/Mail: 6 syringes/pens per fill (three two-pack or six individual packs) ▪ Baqsimi: Retail/MTF/Mail: 6 nasal spray units per fill (three two-pack or six individual)
• **ubrogepant (Ubrelvy)** **Migraine Agents: Oral CGRP Antagonists**	▪ Retail: 16 tablets/30 days ▪ MTF/Mail: 48 tablets/90 days

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• clindamycin 2% vaginal gel (Xaciato) **Antibiotics**	• metronidazole tabs • tinidazole tabs • metronidazole vaginal gel • clindamycin vaginal cream • secnidazole granule (Solosec)	• Each applicator of 5 gram of gel contains 100 mg clindamycin • One user-filled disposable applicatorful administered intravaginally as a single dose	Bacterial vaginosis (BV) for female patients age ≥12 years of age	• vulvovaginal candidiasis (17% treatment vs. 4% placebo) • vulvovaginal discomfort (6% treatment vs. 5% placebo)	• Single dose clindamycin phosphate vaginal gel • Xaciato was evaluated in one study; the primary endpoint of clinical cure at day 21 – 30 Test of Cure visit was statistically greater in comparison to placebo • Lower peak serum levels and systemic exposure to clindamycin with vaginal application, relative to oral or IV clindamycin formulations • Xaciato offers an additional option for the treatment of BV, and one-time dosing may enhance patient compliance: however, alternative formulary agents are also available • As of time of review, no head to head studies with other BV treatments to inform if formulation and/or shortened treatment duration imparts benefit relative to existing formulary agents	• NF • Do not add to EMMPI list
• deucravacitinib tablets (Sotyktu) **Targeted Immuno-modulatory Biologics (TIBs)**	• adalimumab (Humira) • apremilast (Otezla) • secukinumab (Cosentyx)	• 6 mg tabs • Dosing: 6 mg PO QD	for adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	• URI • increased CPK • herpes simplex • mouth ulcers • folliculitis • acne	• New MOA: tyrosine kinase 2 (TYK2) inhibitor • RCTs demonstrated statistically significant improvement of Sotyktu for achieving PASI-75 scores vs. placebo and Otezla at week 16; with additional maintenance of response in patients who continued treatment with Sotyktu through week 52 • Well tolerated with nasopharyngitis and upper respiratory infections reported as most frequently reported adverse effects • Sotyktu mediates its effects via Tyrosine Kinase 2 Inhibitor (TYK2) as member of the JAK family of proteins; JAK inhibitors carry a black box safety warning and it is currently unknown whether Sotyktu may be associated with these same potential adverse events • Sotyktu provides another oral systemic treatment options for moderate to severe plaque psoriasis	• NF and Non-Step Preferred • Add to EMMPI list

• fingolimod ODT (Tascenso) **Multiple Sclerosis: Miscellaneous Oral Agents**	• fingolimod capsule (Gilenya) • siponimod (Mayzent) • ozanimod (Zeposia) • ponesimod (Ponvory)	• Form/Strength: ODT, 0.25 mg • Dosing: 0.25 mg PO QD	Relapsing forms of MS, to include clinically isolated syndrome, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg	• headache • elevated LFT • diarrhea • cough • influenza • sinusitis • back pain • abdominal pain • extremity pain	• Tascenso offers a pediatric, ODT formulation of fingolimod for patients 10 years of age and older and weighing < 40 kg • There is no new clinical data for Tascenso ODT; approval based on 505(b)(2) and demonstrated bioequivalence to fingolimod capsules; active ingredient approved by the FDA since 2010 • Fingolimod 0.25 mg dose was evaluated in one pediatric study using oral capsules; the primary end point of reducing the annualized relapse rate was statistically significant in comparison to interferon beta-1a IM injections • Tascenso ODT offers a pediatric indication compared to other S1P modulators for MS treatment • It carries the same daily dosing schedule, and has a mid-range half-life compared to other S1P modulators • In addition to standard CBC, LFT, and skin cancer screenings; fingolimod is the only S1PM that recommends a baseline and 3 month fundoscopic exam after starting treatment • Among S1PM, rare reports of PRES and PML have been reported with fingolimod use • Provides little compelling advantages over other S1p receptor modulators other than being a pediatric dose for those 10 years of age and older and weighing < 40 kg	• NF • Do not add to EMMPI list

• olopatadine/mometasone nasal spray (Ryaltris) **Nasal Allergy Agents: Corticosteroids**	• olopatadine (Patanase) • mometasone furoate (Nasonex) • azelastine/ fluticasone propionate (Dymista) • fluticasone (Flonase)	• Available as a nasal spray: 665 mcg of olopatadine HCl and 25 mcg of mometasone furoate in each spray (240 sprays per bottle) • Dosing: 2 sprays/nostril BID	Treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older	ADRs ≥1%: • dysgeusia • epistaxis • nasal discomfort	• Combination of intranasal antihistamine and intranasal corticosteroid that demonstrates modest nasal relief vs. placebo & monotherapy • rTNSS and iTNSS change from baseline were statistically significant as compared to placebo and monotherapy • Intranasal antihistamine provides quick onset of action for symptom relief (15 minutes), but can use single ingredient products for this effect • Ryaltris has not been compared to azelastine and fluticasone nasal spray (Dymista) • Provides little to no compelling clinical advantage over existing agents	• Tier 4/Not Covered
• oteseconazole (Vivjoa) **Antifungals**	• fluconazole (Diflucan)	• 150 mg capsules; 18 count blister pack per wallet, 1 wallet per carton • **Day 1**: Vivjoa 600 mg, **Day 2**: Vivjoa 450 mg, **Day 14**: Vivjoa 150 mg QW for 11 weeks • fluconazole/ oteseconazole dosing - **Day 1/Day 4/Day 7**: fluconazole 150mg, **Day 14 - Day 20**: oteseconazole 150 mg QD, **Day 28**: oteseconazole 150 mg QW for 11 weeks; take with food, swallow whole	Recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential	ADRs >2%: • headache (7.4%) • nausea (3.6%)	• Reduces incidence of recurrent vulvovaginal candidiasis (RVVC) in non-childbearing females • Significantly longer half-life (138 days) relative to other azoles • In 3 pivotal trials, Vivjoa had a statistically significantly lower rate of infection recurrence than placebo; was not directly compared to fluconazole for maintenance therapy • Shorter treatment duration and fewer drug interactions than fluconazole • Has not been associated with QT prolongation • Vivjoa is contraindicated in females of reproductive potential; may cause fetal harm • Embryofetal toxicity concerns limit Vivjoa's utility; likely to be used as a second-line medication for RVVC	• NF • Do not add to EMMPI list

• ranolazine ER granule (Aspruzyo Sprinkles) **Cardiovascular Agents Miscellaneous**	• amlodipine • metoprolol succinate XL • ranolazine ER tabs • metoprolol succinate sprinkle (Kapspargo)	• ER granules in sachets of 500 or 1000 mg • 500 mg BID; max: 1,000 mg BID	Chronic angina	• dizziness (6.2%) • headache (5.5%) • constipation (4.5%) • nausea (4.4%) • Do not consume EtOH – rapid release of drug from granules; AE risk	• Aspruzyo is a new "sprinkle" formulation of ranolazine ER tab which has similar BID dosing as ranolazine ER tabs • It is allowed for NG or G tube administration per manufacturer's label • No new clinical data is available; approval was based on data from Ranexa • Provides no compelling clinical advantages over ranolazine ER tablets, other than convenience to patients who cannot swallow tablets	• NF • Do not add to EMMPI list
• roflumilast 0.3% cream (Zoryve) **Psoriasis Agents**	• 0.005% calcipotriene (Dovonex) • 0.005%/ 0.064% calcipo-betameth (Taclonex) • 1% pime-crolimus (Elidel) • 1% tapinarof (Vtama) • apremilast (Otezla)	• Form/Strength: cream, 0.3% • Dosing: Apply topically QD	Topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older	• diarrhea, headache, insomnia, nausea, site pain, URI, UTI	• MOA: topical phosphodiesterase 4 inhibitor • Evaluated in 2 unpublished studies; significant reduction in IGA scores in comparison to vehicle cream. No head-to-head studies with other agents (as of time of review) • Unclear duration of use; extension study (ARQ-151-306) in subjects ≥2 years of age final report submission due June 2025 • FDA deferred pediatric studies for ages 2 – 5 years and 6 to 11 years, given recruitment challenges • Zoryve offers an additional option for the treatment of plaque psoriasis, however numerous alternative formulary agents are available • Use is currently limited to a single indication and place in therapy is currently unknown	• NF • Add to EMMPI list

• sirolimus 0.2% gel (Hyftor) **Immunosuppressives**	• no pharmacy benefit alternatives	• Form/Strength: Topical gel (0.2%) in a 10 g tube; 2 mg sirolimus/1 g • Dosing: Apply to affected areas on face BID	Treatment of facial angiofibroma associated with tuberous sclerosis (TSC) in adults and pediatric patients 6 years of age and older	• Dry skin, irritation, pruritus, acne, acneiform dermatitis, ocular hyperemia, skin hemorrhage, skin irritation	• Topical treatment for facial angiofibromas associated with tuberous sclerosis complex (TSC) • Demonstrates efficacy for reducing the size and erythema of facial angiofibromas associated with TSC from one pivotal trial vs placebo; no head to head studies available • Therapeutic effects dissipate once medication is discontinued – long term therapy required • Long term extension studies demonstrated low discontinuation rates due to adverse effects with continued therapeutic benefit during daily administration. Found no advantage of combining oral and topical mTOR inhibitors • Hyftor provides an alternative to non-pharmacologic options (e.g., lasers) for removal of angiofibromas associated with TSC	• UF • Do not Add to EMMPI
• finasteride/ tadalafil (Entadfi) **Benign Prostatic Hyperplasia (BPH) Agents**	• finasteride tab • tadalafil tab	• Fixed dose capsule of finasteride 5 mg and tadalafil 5 mg • One capsule orally once daily for up to 26 weeks	Initial treatment of the signs and symptoms of (BPH) in men with enlarged prostates for up to 16 weeks	• >2%: back pain, headache, dyspepsia, influenza • Contraindications: Use with any form of organic nitrate; hypersensitivity; pregnancy; use with guanylate cyclase stimulators	• Approved via the 505b2 pathway • Individual components are available as generics in the dosages found in the fixed-dose combination product • One placebo controlled, 26-week trial in 696 patients reported improvement in the signs and symptoms of BPH, as measured by the International Prostate Symptom Score (IPSS) at 12 weeks. • The IPSS results were not clinically significant, as they did not meet the minimally clinically important difference of at least 3 point change in the IPSS • Provides little to no clinical benefit compared to using finasteride and/or tadalafil	• Tier 4/Not Covered
• tadalafil oral suspension **Pulmonary Arterial Hypertension (PAH): PDE-5 Inhibitor**	• sildenafil tab (Revatio) • sildenafil susp (Revatio) • tadalafil tab (Adcirca, Alyq)	• Form/Strength: oral suspension, 20mg/5ml • Dosing: 40 mg (10mL) PO QD	Pulmonary Arterial Hypertension (PAH)	• headache	• Approved to treat PAH WHO Group 1) to improve exercise ability. • Tadliq is the second PDE5 inhibitor available as an oral suspension • No new clinical studies are available for Tadliq, approved via 505(b)(2) • Package insert in the special populations sections state safety and effectiveness in pediatrics not established • Provides little to no clinical advantage relative to existing formulary alternatives	• NF

• zonisamide oral suspension (Zonisade) **Anticonvulsants -Antimania Agents**	• zonisamide capsules (Zonegran)	• Form/Strength: suspension, 100 mg/5 mL	Adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years and older	• somnolence, anorexia, dizziness, ataxia, irritability, memory and concentration difficulty	• Zonisade is another formulation of zonisamide used for treatment of partial onset epilepsy • Zonisade was approved via 505(b)(2) and demonstrated bioequivalence to zonisamide capsules; no new clinical data • Zonisade provides an alternative treatment formulation for partial onset epilepsy and provides no significant clinical advantage compared to existing agents	• UF • Do not add to EMMPI

• Freestyle Libre 3
 	
CGMS: Therapeutic Continuous Glucose Monitoring System
	• FreeStyle Libre 2
	• Dexcom G6
		• 1 sensor applied every 14 days	Continuous Glucose Monitoring	• Refer to product labeling for information	• FreeStyle Libre 3 is the 3rd CGMS available through the pharmacy benefit.
					• Advantages over FreeStyle Libre 2 include:
					  • Real-time glucose results automatically displayed every minute on smartphone
					  • Real-time glucose alarms with current glucose and trend arrow, viewable in the alarm notification
					  • Sensor stores up to 14 days of glucose data, so decreased risk of lost data
					  • Smaller, thinner, and more discreet Sensor
					  • Bluetooth connection range increased by 50% between Sensor and App (33 feet)
					• Data is lacking with FreeStyle Libre 3 to show effectiveness in increasing Time-In-Range (TIR)
					• Other than eliminating the need for patient to scan the sensor at least every 8 hours, FreeStyle Libre 3 provides little compelling clinical advantage over existing CGMs
						• UF
						• EMMPI – not applicable

• Omnipod 5 **Insulins: Miscellaneous insulin devices**	• Omnipod Generation 3 pods • Omnipod Generation 4 DASH • Vgo • Medtronics hybrid closed loop insulin deliver system • Tandem hybrid closed loop insulin deliver system	• Used as part of system with software algorithm and an integrated CGM • Apply pod with u100 insulin every 3 days	Delivers insulin through pod system in children and adults 2 years of age and older who have Type 1 diabetes mellitus	• Refer to product labeling for information	• Omnipod 5 is the 4th available tubeless insulin delivery device through the pharmacy benefit (Others are the Omnipod classic, Omnipod Dash, V-go) • It is the 3rd hybrid closed loop system available (insulin delivery, CGM data and an algorithm to monitor both). Others available through the medical benefit are Tandem product and the Medtronics product. • Type 1 Diabetics: Omnipod 5 data shows a decrease in A1c and an increase in Time in Range (TIR). Indirect comparison shows similar results to other hybrid closed loop systems and when compared to Omnipod 4 there are similar lowering of A1c. • Type 2 Diabetes: Data is lacking for Omnipod 5 to show effectiveness in lowering A1c and increasing TIR. • Studies lack rigor typically seen in medication reviews in that there are small numbers of patients studied, short duration of the study (longest was 90 days), and a lack of an active comparison group. Studies with Omnipod 5 did not compare to another closed system and did not compare to other tubeless systems • MHS providers relayed they would like a device on the formulary that allows for overnight coverage (hybrid closed loop), is tubeless, and available for children • Omnipod 5 provides little compelling clinical advantage over existing devices/supplies other than combining a hybrid closed loop system and a tubeless insulin delivery system	• UF • EMMPI – not applicable • Due to noncompliance with the Trade Agreements Act, Omnipod 5 is excluded from mail order and military treatment facilities (MTFs)

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
November 2022	**Drug Class Reviews** **Atopy** **Designated UF:** • upadacitinib (Rinvoq) *(already on the program)* **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • abrocitinib (Cibinqo) **RBC Stimulants: Erythropoietins** **Designated UF:** *Already on the program* • Epogen (*already on the program)* • Procrit (*already on the program)* • Retacrit (*already on the program)* **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF** *Similar agents are already on list* • deucravacitinib (Sotyktu) **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • roflumilast 0.3% cream (Zoryve) **Line Extensions** • Ozempic 2 mg	**Alzheimer's Agents** *Comparable pricing at mail order vs MTFs or retail:* • donepezil 23 mg (Aricept 23 mg generics) **2nd Generation Antihistamines** *Comparable pricing at mail order vs MTFs or retail:* • desloratadine 5 mg tabs • desloratadine 2.5 mg and 5 mg rapidly dissolving tabs (Clarinex generics **Proton Pump Inhibitors** *Comparable pricing at mail order vs MTFs or retail:* • lansoprazole (Prevacid generics) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF:** *Comparable pricing at mail order vs MTFs or retail:* • ranolazine ER sprinkle (Aspruzyo) *Consistent with others in the class* • Zonisamide oral suspension (Zonisade) *New Medical Devices* • FreeStyle Libre 3 • Omnipod 5 † **Designated NF:** *Acute use exception* • clindamycin phosphate vaginal gel (Xaciato) • oteseconazole (Vivjoa)

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (9) and NDAA 2015, which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

† For pharmaceutical agents that are non-Trade Agreement Act compliant, dispensing is limited to retail pharmacies.

Implementation Dates*

Upon signing: January 31, 2023

Two weeks after signing: February 15, 2023

30 Days after Signing: March 8, 2023

60 days after signing: April 5, 2023

90 days after signing: May 10, 2023 (moved from May 3rd due to the quarterly P&T Committee meeting)

120 Days after signing: May 31, 2023

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
November 2022	Benign Prostatic Hyperplasia Agents; 5-alpha Reductase Inhibitors	• finasteride/ tadalafil (Entadfi)	• finasteride tab • dutasteride tab • tadalafil tab	• 120 days
November 2022	Nasal Allergy Agents: Corticosteroids	• olopatadine 665 mcg /mometasone 25 mcg nasal spray (Ryaltris Nasal Spray)	• azelastine (Astelin, Astepro) • olopatadine (Patanase) • fluticasone/azelastine (Dymista) • fluticasone propionate (Flonase) • mometasone (Nasonex) • ipratropium (Atrovent) • budesonide (Rhinocort) • triamcinolone (Nasacort) • beclomethasone (Beconase AQ, QNASL) • ciclesonide (Omnaris, Zetonna) • flunisolide (Nasarel)	• 120 days
August 2022	Skeletal Muscle Relaxants	• baclofen oral solution (Lyvispah)	• baclofen oral solution (Ozobax) • baclofen oral suspension (Fleqsuvy) • baclofen tablets	• March 1, 2023 (120 days)
August 2022	Acne Agents: Topical Acne & Rosacea	• benzoyl peroxide 5% cream (Epsolay)	• benzoyl peroxide gel OTC and Rx versions • azaleic acid 15% gel (Finacea gel) • metronidazole 1% gel • brimonidine 0.33% gel (Mirvaso) • ivermectin 1% cream (Soolantra) • minocycline 1.5% topical foam (Zilxi) • minocycline 4% foam (Amzeeq) • minocycline 50 mg tablets	• March 1, 2023 (120 days)
May 2022	Nephrology Agents Miscellaneous	• budesonide (Tarpeyo)	• prednisone • methylprednisolone • budesonide delayed release capsules (Entocort EC, generics)	• November 30, 2022 (120 days) • Implementation delayed
May 2022	Narcotic Analgesics and Combinations	• celecoxib/ tramadol (Seglentis)	• tramadol • celecoxib	• November 30, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2022	Anticholinergics-Antispasmodics	• glycopyrrolate (Dartisla ODT)	• glycopyrrolate tablets • glycopyrrolate oral solution (Cuvposa) • omeprazole • famotidine	• November 30, 2022 (120 days)
May 2022	Endocrine Agents Miscellaneous	• levoketoconazole (Recorlev)	• ketoconazole • metyrapone (Metopirone) • osilodrostat (Isturisa) • pasireotide (Signifor LAR -medical benefit)	• November 30, 2022 (120 days)
May 2022	Diuretics	• torsemide 20 mg and 60 mg tablets (Soaanz)	• torsemide • furosemide • bumetanide • ethacrynic acid	• November 30, 2022 (120 days)
May 2022	Acne Agents: Topical Acne & Rosacea	• tretinoin 0.1%/ benzoyl peroxide 3% topical cream (Twyneo)	• tretinoin cream • benzoyl peroxide cream	• November 30, 2022 (120 days)
February 2022	Pain Agents: NSAIDs	• celecoxib oral solution (Elyxyb)	• celecoxib tablets • ibuprofen • naproxen • diclofenac • numerous other NSAIDs or combos	• August 24, 2022 (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	• lorazepam ER capsule (Loreev XR)	• lorazepam IR tablets • alprazolam IR and XR tablets	• June 15, 2022 (120 days)
Nov 2021	Migraine Agents	• dihydroergotamine mesylate nasal spray (Trudhesa)	• DHE nasal spray • sumatriptan nasal and oral • rizatriptan • zolmitriptan • eletriptan	• June 15, 2022 (120 days)
Aug 2021	Antilipidemic-1s	• rosuvastatin/ ezetimibe (Roszet)	• rosuvastatin with ezetimibe • atorvastatin with ezetimibe • simvastatin/ezetimibe (Vytorin)	• June 15, 2022 (120 days)

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			• evolocumab (Repatha) • alirocumab (Praluent)	
May 2021	Anticonvulsants-Antimania Agents	• levetiracetam (Elepsia XR)	• levetiracetam ER • lamotrigine XR • topiramate ER	• June 15, 2022 (120 days)

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms.

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

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