

**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 2021 and 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 (Erbix)]. 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.
 - *Baqsimi* 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 (Livtency) – 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, Incivree, 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 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:



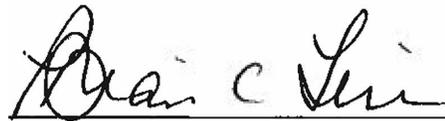
John P. Kugler, M.D., MPH
DoD P&T Committee Chair

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

Appendix A—Attendance

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

Appendix A—Attendance

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

Appendix A—Attendance

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Newly Approved Drugs MN Criteria	
<ul style="list-style-type: none"> • maralixibat (Livmarli) <p>Metabolic Agents- Miscellaneous</p>	<ul style="list-style-type: none"> • All five formulary agents (ursodiol, cholestyramine, rifampin, naltrexone, and at least 1 antihistamine) have resulted in therapeutic failure <p>Formulary alternatives: ursodiol, cholestyramine, diphenhydramine, rifampin, naltrexone</p>
<ul style="list-style-type: none"> • ropeginterferon alfa-2b-njft injection (Besremi) <p>Hematological Agents</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from at least 1 formulary agent • At least 1 formulary agent has resulted in therapeutic failure <p>Formulary alternatives: hydroxyurea, Pegasys</p>
<ul style="list-style-type: none"> • carbidopa/levodopa IR scored tab (Dhivy) <p>Parkinson’s Agents</p>	<ul style="list-style-type: none"> • Formulary agents have resulted in therapeutic failure • No alternative formulary agent: Patient cannot achieve the dose with generic IR carbidopa/levodopa <p>Formulary alternatives: generic IR carbidopa/levodopa</p>
<ul style="list-style-type: none"> • atogepant (Qulipta) <p>Migraine Agents</p>	<ul style="list-style-type: none"> • Formulary agents resulted in therapeutic failure <p>Formulary alternatives: Nurtec ODT, Aimovig, Emgality, Ajovy</p>
<ul style="list-style-type: none"> • lonapegsomatropin-tcgd injection (Skytrofa) <p>Growth stimulating agents</p>	<ul style="list-style-type: none"> • Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from <u>all</u> formulary agents <p>Formulary alternatives: Norditropin (step-preferred), Omnitrope, Zomacton</p>
<ul style="list-style-type: none"> • varenicline nasal solution (Tyrvaya) <p>Ophthalmic: Dry Eye</p>	<ul style="list-style-type: none"> • Formulary agents have resulted in therapeutic failure <p>Formulary alternatives: cyclosporine 0.05% (Restasis/Multidose), lifitegrast 5% (Xiidra)</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug Pas	
<ul style="list-style-type: none"> • asciminib (Scemblix) <p style="text-align: center;">Oncological Agents</p>	<p>Manual PA criteria apply to all new users of Scemblix</p> <p><u>Manual PA criteria:</u> Scemblix is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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: _____. <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • avacopan (Tavneos) <p style="text-align: center;">Hematological Agents</p>	<p>Manual PA criteria apply to new users of Tavneos.</p> <p><u>Manual PA criteria:</u> Tavneos is approved initially for 6 months if all criteria are met:</p> <ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> 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): <ul style="list-style-type: none"> 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 <p>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</p> <p><u>Renewal criteria</u> (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:</p> <ul style="list-style-type: none"> • 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

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • atogepant (Qulipta) <p>Migraine Agents</p>	<p>Changes from February 2022 meeting are in strikethrough.</p> <p>Manual PA criteria apply to all new users of Qulipta.</p> <p><u>Manual PA criteria:</u> Qulipta is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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., Ubrelyv, 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: <ul style="list-style-type: none"> ○ 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 ○ 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: <ul style="list-style-type: none"> ○ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate ○ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol ○ 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 <ul style="list-style-type: none"> ○ erenumab-aooe (Aimovig) ○ fremanezumab-vfrm (Ajovy) ○ galcanezumab-gnlm (Emgality) <p>Non-FDA-approved uses are not approved. Prior Authorization expires after 6 months.</p> <p><u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Migraine Disability Assessment (MIDAS) <ul style="list-style-type: none"> • 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
-------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> lonapegsomatropin-tcgd injection (Skytrofa) <p>Growth Stimulating Agents</p>	<p>Manual PA criteria apply to all new users of Skytrofa</p> <p>The provider acknowledges that Norditropin is the Department of Defense's preferred somatropin agent.</p> <p><u>Manual PA criteria:</u> Skytrofa is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Patient has a contraindication to Norditropin OR Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Skytrofa <p>*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.</p> <p>AND</p> <ul style="list-style-type: none"> Patient requires a less than daily dosing regimen due to needle intolerance or aversion <p>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.</p> <p>Prior authorization expires in 1 year; provider must fill out a new PA.</p>
<ul style="list-style-type: none"> maralixibat (Livmarli) <p>Metabolic Agents-Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Livmarli.</p> <p><u>Manual PA criteria:</u> Livmarli is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> ursodiol cholestyramine rifampin naltrexone At least one antihistamine (e.g. Atarax, Benadryl, etc.) <p>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.</p> <p>Prior Authorization expires after 6 months.</p> <p><u>Renewal criteria</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved for an additional six months if the following apply:</p> <ul style="list-style-type: none"> Patient must demonstrate significant improvement in pruritus symptoms.

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> ropeginterferon alfa-2b-njft injection (Besremi) <p>Hematological Agents</p>	<p>Manual PA criteria apply to all new users of Besremi.</p> <p><u>Manual PA criteria:</u> Besremi is approved for 1 year if all criteria are met:</p> <ul style="list-style-type: none"> 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) <p>Non-FDA-approved uses are NOT approved including myeloproliferative neoplasms, essential thrombocythemia (ET), or adult T-cell leukemia (ATL).</p> <p>Prior Authorization expires after 1 year.</p> <p><u>Renewal criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage is approved for an additional year if the following criteria are met:</p> <ul style="list-style-type: none"> Patient has a documented improvement in symptoms
<ul style="list-style-type: none"> topiramate oral solution (Eprontia) <p>Anticonvulsants- Antimania Agents</p>	<p>Manual PA criteria apply to all new users of Eprontia.</p> <p><u>Manual PA criteria:</u> Eprontia is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> For epilepsy monotherapy: Partial onset seizure or primary generalized tonic-clonic seizures in patients 2 years of 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) <p>Non-FDA-approved uses are not approved</p> <p>Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • carbidopa/levodopa IR scored tab (Dhivy) <p>Parkinson’s Agents</p>	<p>Manual PA criteria apply to all new users of Dhivy</p> <p><u>Manual PA criteria:</u> Dhivy is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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) <p>Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> • varenicline nasal solution (Tyrvaya) <p>Ophthalmic: Dry Eye</p>	<p>Manual PA criteria apply to all new users of Tyrvaya.</p> <p><u>Manual PA criteria:</u> Tyrvaya is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Positive symptomology screening for 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: <ul style="list-style-type: none"> ○ 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]) ○ 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: <ul style="list-style-type: none"> ○ Patient has tried and failed an adequate course (at least 6 weeks) of treatment of lifitegrast or cyclosporine treatment <p>Non-FDA-approved uses are not approved. Prior Authorization expires after 1 year</p> <p><u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely if all criteria are met:</p> <ul style="list-style-type: none"> ○ 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 C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> vosoritide (Voxzogo) <p>Growth Stimulating Agents: Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Voxzogo.</p> <p><u>Manual PA criteria:</u> Voxzogo is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> 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 <p>Non-FDA-approved uses are not approved. Prior Authorization expires after 1 year; provider must fill out a new PA..</p>
<ul style="list-style-type: none"> fenofibrate 120 mg tablets (Fenoglide) <p>Antilipidemics-2: Fenofibrates</p>	<p>Manual PA criteria applies to new and current users of fenofibrate 120 mg tablets (Fenoglide).</p> <p><u>Manual PA Criteria:</u> Fenoglide 120 mg tablets are approved if all criteria are met:</p> <ul style="list-style-type: none"> 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 (<i>fill-in blank</i>) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> indomethacin suppository (Indocin) <p>Pain Agents: NSAID</p>	<p>Manual PA criteria applies to new and current users of indomethacin suppositories (Indocin).</p> <p><u>Manual PA Criteria:</u> diclofenac 25 mg tablet is approved if all criteria are met:</p> <ul style="list-style-type: none"> 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 (<i>fill-in blank</i>) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> prenatal MVI (Neonatal Plus) <p>Vitamins: Prenatal</p>	<p>Manual PA criteria applies to new and current users of prenatal MVI (Neonatal Plus).</p> <p><u>Manual PA Criteria:</u> Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, or Neonatal Plus is approved if all criteria are met:</p> <ul style="list-style-type: none"> 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 (<i>fill-in blank</i>) <p>Non-FDA-approved uses are NOT approved. Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> testosterone cypionate and testosterone enanthate IM injections <p>Androgens-Anabolic Steroids: Testosterone Replacement Therapies</p>	<p><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></p> <p>Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections.</p> <p>Manual PA Criteria: testosterone cypionate and testosterone enanthate IM injections are approved if all criteria are met:</p> <ul style="list-style-type: none"> Coverage approved for male patients if: <ul style="list-style-type: none"> 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 <p>OR</p> <ul style="list-style-type: none"> Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if: <ul style="list-style-type: none"> 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 <p>Non-FDA-approved uses are NOT approved. Not approved for concomitant use with other testosterone products. Prior Authorization does not expire.</p>
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • dasiglucagon SC injection (Zegalogue) • glucagon injection (Gvoke Hypopen and Pre-Filled Syringe) <p>Antidotes-Overdose Agents: Hypoglycemia Agents</p>	<ul style="list-style-type: none"> ▪ 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)
<ul style="list-style-type: none"> • glucagon kit (Glucagon Emergency) • glucagon powder for injection (GlucaGen Hypokit and GlucGen Diagnostic) <p>Antidotes-Overdose Agents: Hypoglycemia Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 2 kits per fill
<ul style="list-style-type: none"> • asciminib (Scemblix) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • atogepant (Qulipta) <p>Migraine Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 30 tabs/30 days ▪ MTF/Mail: 90 tabs/90 days
<ul style="list-style-type: none"> • avacopan (Tavneos) <p>Hematological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • maralixibat (Livmarli) <p>Metabolic Agents- Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • varenicline nasal solution (Tyrvaya) <p>Ophthalmic: Dry Eye</p>	<ul style="list-style-type: none"> ▪ Retail: 1 package (2 bottles in each package) in 30 days ▪ MTF/Mail: 3 packages (2 bottles in each package) in 90 days
<ul style="list-style-type: none"> • vosoritide (Voxzogo) <p>Growth Stimulating Agents: Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
<p>asciminib (Scemblix)</p> <p>Oncological Agents: Chronic Myelogenous Leukemia</p>	<ul style="list-style-type: none"> • bosutinib (Bosulif) • ponatinib (Iclusig) 	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • UF
<p>atogepant (Qulipta)</p> <p>Migraine Agents</p>	<ul style="list-style-type: none"> • Emgality • Ajovy • Aimovig • Nurtec ODT 	<ul style="list-style-type: none"> • Tablet-10/30/60mg • Dosing- 10, 30, or 60 mg by mouth once daily w/wo food 	Preventive treatment of episodic migraine in adults	<ul style="list-style-type: none"> • >5%: constipation, nausea, fatigue 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • NF
<p>avacopan (Tavneos)</p> <p>Hematological Agents</p>	<ul style="list-style-type: none"> • prednisone • cyclophosphamide • azathioprine • mycophenolate • rituximab 	<ul style="list-style-type: none"> • 10 mg capsules • 30 mg (three caps) by mouth BID with food 	Microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)	<ul style="list-style-type: none"> • >5%: HA, HTN, N/V/D, rash, fatigue, upper abdominal pain, dizziness, increased creatinine, and paresthesia 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • UF

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
carbidopa/levodopa (Dhivy) Parkinson's Agents	<ul style="list-style-type: none"> Carbidopa/levodopa IR tab 25 mg/100 mg Carbidopa/levodopa ODT tab 25 mg /100 mg 	<ul style="list-style-type: none"> 25 mg carbidopa/100 mg levodopa scored oral tablet 	Parkinson's disease (PD)	<ul style="list-style-type: none"> Same as other carbidopa/levodopa formulations 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> NF
celecoxib oral solution (Elyxyb) Pain Agents: NSAIDs	<ul style="list-style-type: none"> celecoxib capsules diclofenac powder packet (Cambia) ibuprofen naproxen APAP/aspirin/caffeine 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> ADR > 2% and greater than placebo: Dysgeusia (3%) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Tier 4/Not covered
lonapegsomatropin-tcgd injection (Skytrofa) Growth Stimulating Agents	<ul style="list-style-type: none"> Genotropin Norditropin 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Most common ADRs (≥5%) in peds: viral infection, pyrexia, cough, N/V/D, hemorrhage, abdominal pain, and arthralgia and arthritis 	<ul style="list-style-type: none"> Skytrofa is a long-acting somatotropin 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 	<ul style="list-style-type: none"> NF and non-step-preferred

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
marabavir (Livtency) Antivirals	<ul style="list-style-type: none"> • ganciclovir • valganciclovir • foscarnet • cidofovir 	<ul style="list-style-type: none"> • 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%: <ul style="list-style-type: none"> • Taste disturbance (46%) • Nausea (21%) • Diarrhea (19%) • Vomiting (14%) • Fatigue (12%) 	<ul style="list-style-type: none"> • Livtency 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 	<ul style="list-style-type: none"> • UF
maralixibat (Livmarli) Metabolic Agents- Miscellaneous	<ul style="list-style-type: none"> • cholestyramine • rifampin • hydroxyzine • naltrexone • odevixibat (Bylvay) 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • ≥ 5%: V/D, abdominal pain, fat soluble vitamin deficiency (FSVD), liver enzyme abnormalities, GI bleeding, bone fractures 	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • NF

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
<p>ropeginterferon alfa-2b-njft injection (Besremi)</p> <p>Hematological Agents</p>	<ul style="list-style-type: none"> hydroxyurea peginterferon alfa-2a injection (Pegasys) ruxolitinib (Jakafi) busulfan (Myleran) 	<ul style="list-style-type: none"> 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	<p>Common ADRs (>40%) reported:</p> <ul style="list-style-type: none"> influenza-like illness arthralgia fatigue pruritus nasopharyngitis musculoskeletal pain 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> NF
<p>topiramate oral solution (Eprontia)</p> <p>Anticonvulsants-Antimania Agents</p>	<ul style="list-style-type: none"> topiramate IR 200 mg tablet topiramate ER capsule topiramate ER 200 mg capsule (Qudexy XR) 	<ul style="list-style-type: none"> 25 mg/ml in 473 ml bottle Varies depending on age and indication 	Epilepsy, migraine, Lennox-Gastaut	<ul style="list-style-type: none"> Epilepsy >10%: paresthesia, anorexia, speech, fatigue, dizziness, nervous, slowing, vision, fever Migraine >5%: paresthesia, hypoesthesia, anorexia, memory, taste, N/D, abd pain, URI 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> UF
<p>varenicline nasal solution (Tyrvaya)</p> <p>Ophthalmic: Dry Eye</p>	<ul style="list-style-type: none"> Restasis Restasis multi-dose Cequa Xiidra 	<ul style="list-style-type: none"> 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	<p>Most common AEs (incidence > 5% of patients): sneezing (82%), cough (16%), throat irritation (13%), and instillation-site (nose) irritation (8%)</p>	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> NF

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

Generic (Trade)	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					<ul style="list-style-type: none"> • 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 	
<p>vosoritide injection (Voxzogo)</p> <p>Growth Stimulating Agents: Miscellaneous</p>	<ul style="list-style-type: none"> • Growth hormone therapy (off-label) 	<ul style="list-style-type: none"> • 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 	<p>Increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses</p>	<p>Most common adverse reactions (>10%) are injection site erythema, injection site swelling, vomiting, injection site urticaria, arthralgia, decreased blood pressure, and gastroenteritis</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • UF

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

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program if NF, Exempted from Mail Order Requirement)
February 2022	<p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated NF: <i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:</i></p> <ul style="list-style-type: none"> varenicline nasal solution (Tyrvaya) <p><i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, pending availability at mail, and pending final cost:</i></p> <ul style="list-style-type: none"> lonapegsomatropin-tcqd injection (Skytrofa) ropeginterferon alfa-2b-njft injection (Besremi) <p>Line Extensions Designated UF <i>Similar/parent agent already on list (all new strengths or dosage forms):</i></p> <ul style="list-style-type: none"> dupilumab syringe (Dupixent) 	<p>Drug Class Reviews <i>Acute use exception applies</i></p> <ul style="list-style-type: none"> glucagon (Baqsimi, Gvoke, Zegalogue) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Drugs in class not currently represented on EMMPI List and comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> asciminib (Scemblix) topiramate oral solution (Eprontia) <p><i>Not yet clear if feasible to provide through mail:</i></p> <ul style="list-style-type: none"> avacopan (Tavneos) marabavir (Livtency) <p><i>Not yet clear if feasible to provide through mail and final cost pending:</i></p> <ul style="list-style-type: none"> vosoritide injection (Voxzogo) <p>Designated NF: <i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> maralixibat (Livmarli) carbidopa/levodopa IR scored tab (Dhivy) <p><i>Exception due to comparable pricing at mail order vs MTFs or retail and similar agents not on list:</i></p> <ul style="list-style-type: none"> atogepant (Qulipta) <p>Line Extensions Designated UF <i>Similar/parent agent not on list:</i></p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> celecoxib oral solution (Elyxyb) 	<ul style="list-style-type: none"> celecoxib tablets ibuprofen naproxen diclofenac numerous other NSAIDs or combo products 	<ul style="list-style-type: none"> Month day, (120 days)
Nov 2021	Antianxiety Agents: Benzodiazepines	<ul style="list-style-type: none"> lorazepam ER capsule (Loreev XR) 	<ul style="list-style-type: none"> lorazepam IR tablets alprazolam IR and XR tablets 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Nov 2021	Migraine Agents	<ul style="list-style-type: none"> dihydroergotamine mesylate nasal spray (Trudhesa) 	<ul style="list-style-type: none"> DHE nasal spray sumatriptan nasal and oral rizatriptan zolmitriptan eletriptan 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Aug 2021	Antilipidemic-1s	<ul style="list-style-type: none"> rosuvastatin/ezetimibe (Roszet) 	<ul style="list-style-type: none"> rosuvastatin with ezetimibe atorvastatin with ezetimibe simvastatin/ezetimibe (Vytorin) evolocumab (Repatha) alirocumab (Praluent) 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
May 2021	Anticonvulsants-Antimania Agents	<ul style="list-style-type: none"> levetiracetam (Elepsia XR) 	<ul style="list-style-type: none"> levetiracetam ER lamotrigine XR topiramate ER 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Corticosteroids-Immune Modulators: High Potency	<ul style="list-style-type: none"> clobetasol propionate 0.05% lotion metered dose pump (Impeklo) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene/betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> June 15, 2022 (120 days)

Appendix H—Not Covered Drugs and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	<ul style="list-style-type: none"> budesonide ER 9 mg capsules (Ortikos) 	<ul style="list-style-type: none"> budesonide ER tablets (Entocort EC, generics) other corticosteroids 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Corticosteroids	<ul style="list-style-type: none"> dexamethasone 20 mg tablets (Hemady) 	<ul style="list-style-type: none"> dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	<ul style="list-style-type: none"> fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) 	<ul style="list-style-type: none"> 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]) 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	<ul style="list-style-type: none"> fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) 	<ul style="list-style-type: none"> fluticasone/salmeterol (Advair Diskus) fluticasone/salmeterol (Advair HFA) fluticasone/vilanterol (Breo Ellipta) [non formulary] mometasone/formoterol (Dulera) [non formulary] 	<ul style="list-style-type: none"> June 2 2021

Appendix H—Not Covered Drugs and Therapeutic Alternatives

Minutes & Recommendations of the DoD P&T Committee Meeting February 9-10, 2022

Appendix H—Not Covered Drugs and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
			<ul style="list-style-type: none"> budesonide/formoterol (Symbicort) [non formulary] fluticasone/salmeterol (AirDuo Respiclick) [non formulary] 	
Nov 2020	Calcium Channel Blockers	<ul style="list-style-type: none"> levamlodipine (Conjupri) 	<ul style="list-style-type: none"> amlodipine felodipine nifedipine diltiazem verapamil 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	GI-2 Agents	<ul style="list-style-type: none"> metoclopramide nasal spray (Gimoti) 	<ul style="list-style-type: none"> metoclopramide oral tablet (Reglan generics) metoclopramide oral solution (Reglan, generics) metoclopramide orally disintegrating tablet (Reglan ODT) 	<ul style="list-style-type: none"> June 2 2021
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% solution clobetasol 0.05% solution, shampoo fluocinonide 0.05% solution calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% ointment, cream, solution clobetasol 0.05% ointment, cream fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> February 24, 2021

Appendix H—Not Covered Drugs and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 health.mil website.

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

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Analgesics and Combinations (reviewed May 2019, acetaminophen 325 mg tablet updated May 2021)		
Feb 2022	<p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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) <p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 30671 - benzocaine/menthol 20 %-0.5 % AEROSOL (Topical) (Dermoplast) • 30730 - dibucaine 1 % OINT. (G) (Topical) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 00740 - benzocaine 20 % SPRAY (e.g., Hurrricane Spray) • 12200 - benzocaine 20 % GEL (GRAM) (e.g., Orajel) • 29244 - benzocaine 20 % SPRAY (Hurrricane One Spray)
Antibacterials		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 30011 - chlorhexidine gluconate 4 % LIQUID (e.g., Hibiclens) • 45334 - povidone-iodine 10 % SOLUTION (e.g., Betadine) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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)

Appendix I—MHS GENESIS OTC Text List

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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 21311 - bacitracin/polymyxin B sulfate 500-10K/G OINT. (G)
Antiemetic-Antivertigo Agents		
Feb 2022	RETAIN these GCNs <ul style="list-style-type: none"> • 18301 - meclizine HCl 12.5 MG TABLET • 18312 - meclizine HCl 25 MG TAB CHEW 	REMOVE these GCNs <ul style="list-style-type: none"> • 18302 - meclizine HCl 25 MG TABLET
Antifungals (Topical antifungals reviewed Aug 19; vaginal antifungals reviewed Nov 20)		
Feb 2022	Already reviewed (RETAIN) Topical antifungals <ul style="list-style-type: none"> • 30370 - clotrimazole 1 % CREAM (G) • 62498 - terbinafine HCl 1 % CREAM (G) • 30310 - tolnaftate 1 % POWDER Vaginal antifungals <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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

Appendix I—MHS GENESIS OTC Text List

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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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 <p>NOTE: OTC versions of cetirizine, loratadine, and fexofenadine tablets are available at all points of service on the DoD pharmacy benefit</p>	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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	<p>ADD these GCNs</p> <ul style="list-style-type: none"> • 46432 – famotidine 10 MG TABLET 	
Antiinfectives : Anti-Helminthics (pyrantel pamoate reviewed Aug 20)		
Feb 2022	<p>Already reviewed (RETAIN):</p> <ul style="list-style-type: none"> • 43170 - pyrantel pamoate 50 MG/ML ORAL SUSP 	
Antiinfectives : Miscellaneous		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 44520 -permethrin 1 % LIQUID (e.g., Nix) • 91071 -piperonyl butoxide/pyrethrins 4%-0.33% SHAMPOO (e.g., Rid) 	
Antilipidemics-2 : Dietary Supplements		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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

Appendix I—MHS GENESIS OTC Text List

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
Antiplatelet-Hemorrhologic Agents : Pain Miscellaneous (reviewed Aug 2020)		
Feb 2022	Already reviewed (RETAIN) <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 34577 - dextrose/dextrin/maltose 24 G/31 G GEL (GRAM) (e.g., Insta-glucose) 	
Compounding Supplies		
Feb 2022		REMOVE these GCNs <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • 30942 - hydrocortisone 1 % CREAM (G) • 30951 - hydrocortisone 1 % OINT. (G) • 30942 - hydrocortisone/aloe vera 1 % CREAM (G) 	

Appendix I—MHS GENESIS OTC Text List

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	<p>ADD these GCNs</p> <ul style="list-style-type: none"> • 17802 - dextromethorphan polistirex 30 MG/5 ML SUS ER 12H (e.g., Delsym) <p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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/pseudoephedrine HCl 600MG-60MG TAB ER 12H (e.g., Mucinex-D) • 89731 - guaifenesin/pseudoephedrine 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 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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		<p>REMOVE these NDCs</p> <ul style="list-style-type: none"> • 65702012810 - prothrombin time test strips STRIP
Dietary Supplements		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 24536 - ubidecarenone 200 MG CAPSULE (e.g., Coenzyme Q10) • 95128 - ubidecarenone 100 MG CAPSULE (e.g., Coenzyme Q10) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 49232 - ubidecarenone 30 MG CAPSULE (e.g., Coenzyme Q10)

Appendix I—MHS GENESIS OTC Text List

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	<p>RETAIN these NDCs Sharps containers:</p> <ul style="list-style-type: none"> • 08080143699 - container,empty EACH • 08290305487 - container,empty EACH • 08290305488 - container,empty EACH • 08290305490 - container,empty EACH • 08290323487 - container,empty EACH 	<p>REMOVE these NDCs</p> <ul style="list-style-type: none"> • 38779879503 - adapter cap for bottle EACH • 08290305489 - container,empty EACH • 00283118520 - medical supply, miscellaneous EACH • 63323000130 - vial,empty VIAL • 49502020801 - inhaler,assist device,accessory EACH • 49502020802 - inhaler,assist device,accessory EACH • 49502020803 - inhaler,assist device,accessory EACH <p>Note: inhaler spacers are covered under the pharmacy benefit at all points of service</p>
Durable Medical Equipment		
Feb 2022		<p>REMOVE these NDCs</p> <ul style="list-style-type: none"> • 00573304001 - cold-hot pack EACH
Electrolyte-Mineral-Trace Element Replacement (Calcium products reviewed Feb 20): Iron Replacement		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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 (Novaferum drops)
Electrolyte-Mineral-Trace Element Replacement (Calcium products reviewed Feb 20): Calcium, Magnesium, Potassium, Zinc		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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

Appendix I—MHS GENESIS OTC Text List

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
	<ul style="list-style-type: none"> • 97145 - zinc sulfate 50(220)MG CAPSULE <p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 08420 - bismuth subsalicylate 262 MG TAB CHEW • 26970 - bismuth subsalicylate 262MG/15ML ORAL SUSP (e.g., Kaopectate) • 08550 - loperamide HCl 2 MG TABLET 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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

Appendix I—MHS GENESIS OTC Text List

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	<p>Currently on list (to be reviewed in May 22)</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 08260 - simethicone 40MG/0.6ML DROPS SUSP • 08281 - simethicone 80 MG TAB CHEW • 08282 - simethicone 125 MG TAB CHEW 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 94652 - simethicone 180 MG CAPSULE
Keratolytics		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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)

Appendix I—MHS GENESIS OTC Text List

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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 07950 - magnesium hydroxide 400 MG/5ML ORAL SUSP (e.g., Milk of Magnesia) <p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 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		<p>Remove these NDCs</p> <ul style="list-style-type: none"> • 38779737402 - topical cream metered-dose dev EACH
Nasal Allergy Agents: Corticosteroids (reviewed Feb 21)		
Feb 2022	<p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 34062 - oxymetazoline 0.05% spray (e.g., Afrin) 	<p>REMOVE these GCNs</p> <p>None at this meeting; however, the following will be removed as a result of the Feb 21 review:</p> <ul style="list-style-type: none"> • 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)

Appendix I—MHS GENESIS OTC Text List

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	<p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 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	<p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 27956 - hypromellose 0.3 % GEL (GRAM) • 31880 - sodium chloride 5 % OINT. (G) • 31923 - sodium chloride 5 % DROPS 	
Oral Care Agents : Oxidizing Agents		
Feb 2022		<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 34401 - carbamide peroxide 6.5 % DROPS (e.g., Debrox) 	
Pain Agents : Pain Miscellaneous (reviewed May 19)		
Feb 2022	<p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> • 35743 - ibuprofen 200 MG TABLET • 35749 - ibuprofen 100 MG TAB CHEW • 35930 - ibuprofen 100 MG/5ML ORAL SUSP 	

Appendix I—MHS GENESIS OTC Text List

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 <ul style="list-style-type: none"> • 99006 - coal tar 2 % OINT. (G) (e.g., Elta Tar)
Respiratory Agents Miscellaneous (reviewed Feb 21)		
Feb 2022	Already reviewed (RETAIN) <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 03121 - sodium chloride 1 G TABLET 	REMOVE these GCNs <ul style="list-style-type: none"> • 26657 - sodium chloride 1000 MG TABLETSOL
Sedative-Hypnotic Agents : Ethanolamines		
Feb 2022	RETAIN these GCNs <ul style="list-style-type: none"> • 11730 - doxylamine succinate 25 MG TABLET <p>Note: Doxylamine is on the DOD pharmacy benefit and available at all three points of service</p>	
Skin Preps : Antiseptics		
Feb 2022	ADD these GCNs <ul style="list-style-type: none"> • 28780 - alcohol antiseptic pads MED. PAD 	REMOVE these GCNs <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • 23373 - capsaicin 0.1 % CREAM (G) • 33560 - capsaicin 0.025 % CREAM (G) 	REMOVE these GCNs <ul style="list-style-type: none"> • 23615 - coal tar 1 % SHAMPOO (e.g, T-Gel) REMOVE these NDCs <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 36519 - lanolin,anhydrous OINT. (G) • 32838 - petrolatum,white OINT PACK • 98544 - zinc oxide 12.8% OINT. (G) (e.g, Triple Paste)

Appendix I—MHS GENESIS OTC Text List

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
	<ul style="list-style-type: none"> 23565 - zinc oxide 16 % OINT. (G) (e.g., Boudreauxs) 	
Skin Preps (no subclass)		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> 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) <p>Currently on list (rectal products, to be reviewed in May 22)</p> <ul style="list-style-type: none"> 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	<p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> 68738 - melatonin 3 MG TABLET 99671 - melatonin 5 MG TABLET 	<p>REMOVE these GCNs None at this meeting; however, the following will be removed as a result of the May 21 review:</p> <ul style="list-style-type: none"> 94035 – melatonin 1 mcg tablet spray 13448 – melatonin 5 mg SL tablet 31649 – melatonin 10 mg MPHASE
Urinary Agents Miscellaneous		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> 12000 - sod phos di, mono/K phos mono 250 MG TABLET (e.g., K-Phos Neutral) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> 14065 - potassium citrate/citric acid 1100-334/5 SOLUTION (e.g., Polycitra-K)
Vitamins : Fat Soluble (vitamin D products reviewed Feb 20)		
Feb 2022	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> 94161 - vitamin A 10000 UNIT CAPSULE 15257 - vitamin E (dl,tocopheryl acet) 90 MG CAPSULE 14683 - vitamin E (dl,tocopheryl acet) 180 MG CAPSULE <p>Already reviewed (RETAIN)</p> <ul style="list-style-type: none"> 00223 - cholecalciferol (vitamin D3) 25 MCG TABLET 26416 - cholecalciferol (vitamin D3) 10(400)/ML DROPS 53740 - cholecalciferol (vitamin D3) 10 MCG TABLET 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> 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

Appendix I—MHS GENESIS OTC Text List

DoD P&T Meeting	RETAIN or ADD to the MHS GENESIS OTC List	REMOVE from the MHS GENESIS OTC List
	<ul style="list-style-type: none"> • 93242 - cholecalciferol (vitamin D3) 125 MCG CAPSULE • 94411 - ergocalciferol (vitamin D2) 200 MCG/ML DROPS 	
Vitamins : Multivitamins (Renal & Ocular)		
Feb 2022	<p>ADD these GCNs 35396 - vit C/E/Zn/coppr/lutein/zeaxan 250MG-90MG CAPSULE (Preservision AREDS 2)</p> <p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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	<p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 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) 	<p>REMOVE these GCNs</p> <ul style="list-style-type: none"> • 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	<p>ADD these GCNs</p> <ul style="list-style-type: none"> • 46129 - PNV151/Fe/FA/o3/dha/epa/fish 27-800-260 CAPSULE (Prenatal Multi-DHA) <p>RETAIN these GCNs</p> <ul style="list-style-type: none"> • 30909 - PNV no.95/ferrous fum/folic ac 28MG-0.8MG TABLET • 44966 - prenatal no.137/iron/folic acid 27MG-0.8MG TABLET • 30958 - prenatal vits96/iron fum/folic 27MG-0.8MG TABLET <p>Note: numerous legend prenatal vitamins are dispensed at all three points of service</p>	

Appendix I—MHS GENESIS OTC Text List

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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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