DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2019

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 6 and 7, 2019, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2018 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2018 DoD P&T Committee meeting on February 1, 2019.

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 Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

Nonformulary 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. Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the CGRP antagonists, which provide a new mechanism for migraine headache prevention. The drugs in the subclass include erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm (Emgality). The CGRP antagonists are available as once monthly injections and were individually reviewed as new drugs at the August and November 2018 DoD P&T Committee meetings. All three products are FDA-approved for the preventive treatment of migraines in adults.

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

CGRP antagonists vs. oral preventive therapies

- Oral drugs, including the antiepileptics, beta-blockers and antidepressants, remain the first-line treatment for migraine headache prevention, based on the 2012/2015 American Academy of Neurology/American Headache Society (AHS) migraine prevention guidelines and the 2018 AHS consensus statement for instituting the new migraine treatments into clinical practice. CGRP antagonists are recommended following 2 or 3 trials of oral medications.
- A 2018 network meta-analysis from the Institute for Clinical and Economic Review (ICER) found that oral preventive treatment and CGRP antagonists decrease monthly migraine days (MMD) by approximately 2 days from baseline, compared to placebo. ICER also concluded that the evidence is inadequate to distinguish the net health benefit between treatment with the CGRP inhibitors versus oral preventive therapies (e.g., amitriptyline, topiramate, or propranolol).

CGRP antagonist vs. CGRP antagonist

- Although there are no head-to-head trials comparing erenumab, fremanezumab, or galcanezumab, there do not appear to be clinically relevant differences in efficacy, based on indirect comparisons. For episodic migraine, a meta-analysis showed similar improvements between the three CGRP antagonists in terms of change from baseline in MMD and the patients who had a ≥ 50% reduction in migraine days (50% responders) *(Zhu, et al., Neurological Sciences 2018*).
- The 2018 ICER network meta-analysis reported reductions in MMDs ranging from 1.2 to 1.9 days with the CGRP inhibitors for episodic migraine, with the odds of achieving a 50% response rate ranging from 1.7 to 2.7. For chronic migraine, the decrease in MMDs ranged from 1.3 to 2.4 days. ICER concluded the evidence was inadequate to distinguish the net health benefits among the three CGRP inhibitors.
- The FDA review noted that some patients treated with a CGRP antagonist experienced relatively large reductions in migraine headache days. However, there are no clinical characteristics to prospectively identify those patients most likely to respond to therapy. Additionally, there was a high placebo response rate noted in the individual trials used to gain FDA approval.
- Some distinguishing characteristics among the CGRP inhibitors are as follows:
  - Erenumab (Aimovig) is available in two dosages, 70 mg and 140 mg. There are no clear data to suggest that the two doses differ in their efficacy or safety.
  - Fremanezumab (Ajovy) is the only CGRP inhibitor approved for quarterly dosing in addition to monthly dosing. However, administration of three pens at the same time is required.
  - Galcanezumab (Emgality) requires a loading dose, administered as two pens at the same time.
  - All three products require refrigeration; however, advantages of Aimovig and Emgality include the ability to be stored up to 7 days at room temperature vs. only 24 hours with Ajovy.

Safety

- The CGRP antagonists have a relatively mild side effect profile, with injection site reactions the most commonly reported adverse event. Injection site reactions occurred at an incidence of 5.6% with Aimovig, 18%-23% with Emgality, and 45% with Ajovy.
- The ICER report concluded that there were no differences in the discontinuation rates due to adverse events among the CGRP inhibitors.
- There is concern for theoretical cardiovascular adverse events with long-term use of the CGRP antagonists. The FDA has required postmarketing surveillance for myocardial infarction and stroke for the class.

Other Factors

- Botulinum toxin (Botox) injection is approved for prevention of chronic migraine, but is not part of the TRICARE pharmacy benefit. Botulinum toxin has similar efficacy to the oral preventive medications and CGRP antagonists in chronic migraine patients, based on the 2018 ICER review.
- There is a high degree of interchangeability between the CGRP antagonists. However, there remains uncertainty regarding the long-term efficacy and safety of this new class of therapy. At least one CGRP inhibitor should be on the UF to meet the needs of the majority of patients in the MHS.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the CGRP Antagonist Prophylaxis agents. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that galcanezumab (Emgality) was the most cost-effective CGRP antagonist, followed by erenumab (Aimovig), and fremanezumab (Ajovy).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating galcanezumab (Emgality), erenumab (Aimovig), and fremanezumab (Ajovy) as uniform formulary demonstrated significant cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following for the CGRP Antagonist Prophylaxis agents, as outlined below, based on clinical and cost-effectiveness:
    - UF
        - erenumab injection (Aimovig)
        - fremanezumab injection (Ajovy)
        - galcanezumab injection (Emgality)

- NF
    - None

- Note: A CGRP product was not added to the BCF, due to the unknown long-term efficacy and safety data. The BCF selections in the migraine class include sumatriptan and rizatriptan.

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—PA criteria currently apply to the CGRP products, requiring a trial of at least one drug from two oral classes used for migraine prophylaxis, including antiepileptic medications, beta-blockers or antidepressants. PA criteria were originally recommended when the individual CGRP products were first evaluated as new drugs.

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the current manual PA criteria for all three CGRP antagonists in new users. The PA criteria and updates reflect the recommendations from the 2018 AHS Consensus Statement regarding candidates for a CGRP and assessment of response. (See Appendix C for the full criteria.)

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the existing quantity limits for the three CGRP antagonists. See Appendix D.

4. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR CGRP PROPHYLAXIS AGENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) excluding Aimovig, Ajovy, and Emgality from the Auto-Refill program administered by Express Scripts, Inc., at the TRICARE Mail Order Pharmacy, based on uncertainty regarding long-term safety and patient adherence.

5. ***COMMITTEE ACTION: UF, QL, PA AND AUTO-REFILL IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is May 29, 2019. Note that the recommendations for removal of the auto-refill requirements for the CGRP antagonists will occur 90 days after signing.

B. Oncological Agents – CYP-17 Inhibitors (CYP17) and 2nd-Generation Antiandrogens (2nd-Gen AA) Subclasses

Background—The P&T Committee evaluated the relative clinical effectiveness of two subclasses of drugs used for Prostate Cancer. The agents in the CYP17 inhibitor subclass include abiraterone acetate (Zytiga, generics) and abiraterone acetate micronized (Yonsa), while the 2nd-generation antiandrogen (AA) subclass is comprised of enzalutamide (Xtandi) and apalutamide (Erleada). The Committee reviewed new data available since the previous formulary decision in February 2015.

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

CYP17 Inhibitors Subclass

- The 2018 guidelines from the National Comprehensive Cancer Network (NCCN) included updated recommendations for metastatic castration-resistant prostate cancer (mCRPC). Abiraterone acetate micronized (Yonsa) used with methylprednisolone was added to the mCRPC algorithm. The guidelines continue to recommend abiraterone acetate (Zytiga, generics) with prednisone for this indication.
- The American Urological Association (AUA) guidelines for mCRPC were updated in 2018 and continue to include abiraterone with prednisone.
- Abiraterone acetate (Zytiga) and abiraterone acetate micronized (Yonsa) contain the same active ingredient. Both products must be co-administered with a corticosteroid to reduce the incidence and severity of mineralocorticoid excess (hypertension, hypokalemia, and fluid retention). Differences include that Zytiga is given with prednisone while Yonsa is administered with methylprednisolone.
- There is no clinical trial data available with Yonsa; FDA approval was based upon the clinical trial data with Zytiga and bioequivalence studies.
- There are no head-to-head comparative trials for the two abiraterone products. However, the NCCN guidelines recommend that either formulation can be used in place of the other.
- The micronized formulation of Yonsa results in a smaller tablet particle size; therefore, the dosages differ between the two preparations. Under fasting conditions, single doses of Yonsa 500 mg were equivalent to single doses of Zytiga 1,000 mg.
- Zytiga has an advantage of a lower tablet burden. Yonsa has an advantage in that it can be dosed without regard to meals, while Zytiga must be taken on an empty stomach.
- Generic formulations of Zytiga recently entered the market in December 2018, but the generics only include one tablet strength (250 mg).
- Based on available safety data, the FDA review of Yonsa concluded that there is no evidence that there are differences in safety between Zytiga and Yonsa. Both products have similar warnings and precautions for mineralocorticoid excess, adrenocortical insufficiency, and hepatotoxicity. The FDA review noted that adverse events occurred at similar rates between the two formulations.

- Overall, there is a high degree of therapeutic interchangeability between Zytiga and Yonsa. At least one CYP17 inhibitor is required on the formulary in order to meet the needs of MHS patients.

2nd-Generation AA Subclass

- Enzalutamide (Xtandi) and apalutamide (Erleada) are both FDA-approved for use in non-metastatic castration-resistant prostate cancer (nmCRPC). The 2018 NCCN and 2018 AUA guidelines also recommend both Xtandi and Erleada for nmCRPC. However, of the two 2nd-generation antiandrogens, only Xtandi has FDA approval for use in metastatic CRPC and is included in both the NCCN and AUA guidelines for mCRPC.
- FDA approval for the 2nd-generation AAs for non-metastatic CRPC was based on two randomized, placebo-controlled trials, PROSPER with Xtandi and SPARTAN with Erleada. Men with prostate-specific antigen (PSA) doubling times of ≤ 10 months were included in the trials.
    - Metastasis-free survival (MFS), defined as the delay in development of metastatic disease until metastasis is detected, was the primary endpoint used in both the PROSPER and SPARTAN trials. The study results showed that both 2nd-generation AAs provided a benefit in terms of MFS compared to placebo.
    - An indirect comparison of the two trials showed a similar effect on MFS. For Xtandi the median MFS was 36.6 months vs. 14.7 months with placebo, resulting in a 71% risk reduction for the endpoint. In comparison, with Erleada the median MFS was 40.5 months vs. 16.2 months with placebo, corresponding with a 72% risk reduction in the primary endpoint.
    - Although overall survival data are not yet mature, interim analyses indicate a trend toward improved survival with both drugs when compared to placebo.
- A 2018 ICER report concluded that, when compared to placebo, Erleada and Xtandi showed delays in disease progression and a trend toward improved survival in patients with non-metastatic CRPC, and were given an "A" rating.
- Xtandi and Erleada have relatively similar adverse effect profiles. Both drugs are associated with hypertension, fatigue, falls, fractures, and seizures.
- Although the PROSPER trial using Xtandi in patients with non-metastatic CRPC showed a disproportionate rate of adverse cardiac effects and death compared to placebo, this finding was not reproduced in other studies with Xtandi conducted in varying populations, including patients with non-metastatic hormone-sensitive prostate cancer (HSPC), metastatic HSPC, non-metastatic CRPC, and metastatic CRPC.
- Comparative effectiveness of Xtandi and Erleada, when used in non-metastatic CRPC, cannot be determined at this time, due to the lack of head-to-head trials.
- At least one 2nd-generation antiandrogen must be included on the formulary for MHS patients.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the prostate cancer agents. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

CYP17 Inhibitors

- CMA results for the CYP17 inhibitor subclass showed that abiraterone acetate micronized (Yonsa) was more cost-effective than abiraterone (Zytiga, and generics).
- BIA was performed for the CYP17 inhibitor subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating abiraterone acetate micronized (Yonsa) as formulary and step-preferred and abiraterone acetate (Zytiga, generics) as UF and non-step-preferred demonstrated the greatest cost avoidance for the MHS.

2nd-Generation AA Subclass

- CMA results for the 2nd-generation antiandrogen subclass showed that enzalutamide (Xtandi) was the most cost-effective 2nd-generation AA.
- BIA was performed for the 2nd-generation antiandrogen subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating enzalutamide (Xtandi) as formulary and step-preferred and apalutamide (Erleada) as UF and non-step-preferred demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following for the Prostate Cancer agents, as outlined below, based on clinical and cost-effectiveness:

   CYP 17 Inhibitor Subclass

   - UF and step-preferred
     - abiraterone acetate micronized (Yonsa)
   - UF and non-step-preferred
     - abiraterone acetate (Zytiga, generics)
   - NF
     - None

   2nd-Generation Antiandrogen Subclass

   - UF and step-preferred
     - enzalutamide (Xtandi)
   - UF and non-step-preferred
     - apalutamide (Erleada)
   - NF
     - None

- Note that a CYP17 or 2nd-generation AA agent was not added to the BCF. Bicalutamide (Casodex) will remain on the BCF for the Prostate 1 subclass.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Updated manual PA criteria for abiraterone acetate micronized (Yonsa) and abiraterone acetate (Zytiga, generics) were recommended by the P&T Committee (18 for, 0 opposed, 0 abstained, 0 absent). For both Yonsa and Zytiga/generics, the prescription must be written by an oncologist or urologist, and off-label use for non-localized disease was added. The Zytiga PA criteria were also updated to include step therapy, requiring a trial of Yonsa first, unless there is a contraindication, inadequate response, or adverse reaction to Yonsa, for all new and current users of Zytiga/generics (i.e., "no grandfathering" scenario). Additionally, for Zytiga, the 250 mg tablets are the preferred formulation, based on cost-effectiveness. All new and current users of Zytiga/generic 500 mg tablets will need to try the 250 mg tablets first. See Appendix C for full criteria.

   The Committee also recommended updating the current PAs for enzalutamide (Xtandi) and apalutamide (Erleada) to include the Xtandi step-therapy requirements. All new users (i.e., "grandfathering" scenario) of Erleada will require a trial of Xtandi first, unless contraindicated or if the patient has had an inadequate response or adverse reaction to previous use of Xtandi. Additionally, for nmCRPC, both Xtandi and Erleada will require patients to have documented prostate-specific antigen doubling time (PSADT) of ≤ 10 months, consistent with the trial design of PROSPER and SPARTAN. See Appendix C for full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updating the current quantity limits for Yonsa, Zytiga, Xtandi, and Erleada. See Appendix D.

4. ***COMMITTEE ACTION: TIER 1 COST-SHARE—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) lowering the current tier 2 cost-share for the CYP17 inhibitor abiraterone acetate micronized (Yonsa) and the 2nd-generation AA enzalutamide (Xtandi) to the generic Tier 1 cost-share.

   The authority for this recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate." Lowering the cost-share for both Yonsa and Xtandi will provide a greater incentive for beneficiaries to use the most cost-effective CYP 17 or 2nd-generation antiandrogen product, respectively, in the purchased care points of service.

5. ***COMMITTEE ACTION: UF, QL AND PA IMPLEMENTATION PERIOD—*** The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the P&T minutes at all points of service, and 2) DHA send letters to beneficiaries who are affected by the step decision in the CYP17 subclass (those patients currently on Zytiga, generics). Based on the P&T Committee's recommendation, the effective date is July 31, 2019.

V. SECTION 702, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2018: TRICARE TIER 4/NOT COVERED DRUGS PER 32 CFR 199.21(E)(3)

Background—An interim final rule implementing Section 702(b)(10) of the NDAA 2018 was published on December 11, 2018, and is found at: https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. The interim rule allows for complete exclusion of drugs from TRICARE pharmacy benefit coverage when certain criteria are met.

The interim rule amends 32 CFR 199.21(e)(3). The P&T Committee may recommend, and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Specifically, 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.

The P&T Committee was briefed on the above provisions at the February 2019 meeting. The Committee considered several factors when identifying candidates for complete exclusion from the TRICARE pharmacy benefit. These factors include, but are not limited to, the availability and quality of clinical efficacy evidence compared to alternative similar agents, determination of significant safety issues in which risks may outweigh potential benefit, identification of drugs that contain ingredients not covered by the TRICARE pharmacy benefit, or other negative concerns identified by regulatory authorities or nationally recognized expert organizations. The Committee also reviewed the practices regarding exclusion of drugs from several commercial, state, and Federal Government health care plans. Complete exclusion of drugs from the TRICARE pharmacy benefit will apply to both new and current users.

Relative Clinical and Cost Effectiveness Summary/Rationale for Complete Exclusion—The Committee reviewed clinical efficacy, safety, and cost-effectiveness data for four candidates considered for Tier 4/Not Covered status under the TRICARE pharmacy benefit program.

- **Diabetes Non-Insulin Drugs – Biguanides Subclass: metformin ER gastric retention 24 hours (Glumetza brand and generics)** is an extended release formulation of metformin approved in 2005. It uses a polymer-based oral drug delivery system that makes the tablet swell, which causes retention in the stomach. Clinical trials show

Glumetza is at least as efficacious as metformin immediate-release (IR) (Glucophage) in all measures of glycemic control. There is no evidence to suggest that differences in the extended-release properties of Glumetza confer any benefits in efficacy or safety compared to the other metformin ER formulations (Glucophage XR).

Overall conclusion: A significant cost difference exists between Glumetza and other generic metformin ER formulations (Glucophage XR), with no additional clinical benefit. The P&T Committee concluded that the needs of TRICARE beneficiaries can be met by other metformin ER or metformin IR products available on the Uniform Formulary.

- **Pain Agents – Combinations Subclass: naproxen/esomeprazole** (**Vimovo**) is a fixed-dose combination of two over-the-counter (OTC) drugs, a nonsteroidal anti-inflammatory drug (NSAID) and a proton pump inhibitor (PPI). The Committee agreed that use of fixed dose combination therapies offers patients a convenient formulation for improving adherence. However, this particular combination of an NSAID, which is typically targeted for short-term use, and a PPI, which has limited data to support use beyond eight weeks, is potentially harmful. There is no data to suggest that using other prescription or OTC NSAIDs concurrently with PPIs would not provide the claimed benefit of the individual ingredients found in Vimovo.

  Overall conclusion: The Committee concluded that Vimovo is not cost-effective relative to other NSAIDs and PPIs used concurrently. The needs of TRICARE beneficiaries can be met by the concurrent use of similar single ingredient OTC or prescription NSAIDs and PPIs available on the Uniform Formulary.

- **Pancreatic Enzyme Replacement Therapy: pancrelipase (Zenpep)** and the other pancreatic enzyme replacement therapies (PERTs) were reviewed for formulary status in May 2018. The Committee concluded there is a high degree of therapeutic interchangeability among the PERT products, and having one on the formulary is sufficient to meet the needs of Military Health System (MHS) patients. Creon was designated as the sole step-preferred PERT, and the cost-share was lowered to the generic Tier 1 cost-share to provide a greater incentive for beneficiaries to use the more cost effective PERT formulation. Zenpep was designated nonformulary and non-step-preferred, requiring a trial of Creon in all users. Zenpep provides very little to no clinical effectiveness relative to Creon or the other PERTs.

  Overall conclusion: The needs of TRICARE beneficiaries can be met by Creon and the other available PERTs.

- **Targeted Immunomodulatory Biologics (TIBs): brodalumab** (**Siliq**) is an injectable TIB approved for treating plaque psoriasis and is the only TIB that carries a black box warning for suicide. An FDA safety review of all clinical trials with Siliq reported 36 patients with attempted suicide, or suicidal ideation, and 6 patients with completed suicides. This safety risk is comparable to other biologic agents that the FDA denied marketing approval, and is significantly greater than any of Siliq's clinical comparators.

The drug also has Risk Evaluation and Mitigation Strategies (REMS) requirements that mandate certification of both prescribers and pharmacies.

Siliq was reviewed as a newly approved drug at the August 2017 DoD P&T Committee meeting and recommended for nonformulary status, with PA criteria requiring a trial of adalimumab (Humira) and secukinumab (Cosentyx) first.

Overall conclusion: The P&T Committee concluded that relative to the other nine TIBs that are FDA-approved to treat psoriasis, Siliq imposes a significant safety risk without offering any unique advantage in efficacy or in specific sub-populations. However, a subset of patients with plaque psoriasis will develop highly refractory disease, and Siliq may be of value as an alternate agent for patients who do not respond to other treatment options.

A. ***COMMITTEE ACTION: TRICARE TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) designating the following products as Tier 4/Not Covered under the TRICARE pharmacy benefits program.

- metformin ER gastric retention 24 hours (Glumetza brand and generics)
- naproxen/esomeprazole (Vimovo)
- pancrelipase (Zenpep) **Please refer to the signature page (pages 25-26) for the revised decision and new prior authorization criteria.**

B. ***COMMITTEE ACTION***: ***RECOMMENDATION MAINTAINING CURRENT NF STATUS FOR SILIQ***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current formulary status for brodalumab (Siliq). The Committee acknowledged Siliq's place in therapy for highly selected patients who are refractory to other treatment options. Siliq will remain NF and non-step-preferred, requiring a trial of Humira, Cosentyx, Stelara, Tremfya, Ilumya and Taltz first. The current PA will remain in place to mitigate risk of suicidal ideation.

C. ***COMMITTEE ACTION: TIER 4/NOT COVERED IMPLEMENTATION PERIOD***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) for pancrelipase (Zenpep), metformin ER gastric retention 24 hours (Glumetza brand and generics), and naproxen/esomeprazole (Vimovo): 1) an effective date of the first Wednesday after a 120-day implementation period at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is August 28, 2019.

VI. 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 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 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 2019 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. *COMMITTEE ACTION: UF/TIER 4/NOT COVERED RECOMMENDATION—*

The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
  - amifampridine (Firdapse) – Miscellaneous Neurological Agent for Lambert-Eaton Myasthenic Syndrome (LEMS)
  - baloxavir (Xofluza) – Antiviral for Influenza
  - cenegermin-bkbj ophthalmic solution (Oxervate) – Anti-Inflammatory Immunomodulatory Ophthalmic Agent for Neurotrophic Keratitis
  - elapegademase-lvlr IM injection (Revcovi) – Miscellaneous Metabolic Agent for Adenosine Deaminase Severe Combined Immune Deficiency (ADA-SCID)
  - gilteritinib (Xospata) – Oncological Agent for Acute Myelogenous Leukemia (AML)
  - glasdegib (Daurismo) – Oncological Agent for AML
  - inotersen injection (Tegsedi) – Miscellaneous Neurological Agent for Hereditary Transthyretin Amyloidosis
  - larotrectinib (Vitrakvi) – Oncological Agent for Solid Tumors
  - lorlatinib (Lorbrena) – Oncological Agent for Non-Small Cell Lung Cancer (NSCLC)
  - loteprednol ophthalmic suspension (Inveltys) – Ophthalmic Corticosteroid for Postoperative Inflammation
  - pegfilgrastim-cbqv injection (Udenyca) – White Blood Cell Stimulant and Biosimilar to Neulasta
  - riluzole oral suspension (Tiglutik) – Miscellaneous Neurological Agent for Amyotrophic Lateral Sclerosis (ALS)
  - tafenoquine 100 mg tablet (Arakoda) – Antimalarial Agent for Prophylaxis of Malaria
  - tafenoquine 150 mg tablet (Krintafel) – Antimalarial Agent for Prevention of Relapse and Radical Cure of Malaria
  - talazoparib (Talzenna) – Oncological Agent for Breast Cancer

- testosterone enanthate, subcutaneous (SQ) injection (Xyosted) – Androgens-Anabolic Steroids: Testosterone Replacement Therapies

- NF:
  - aripiprazole tablet with ingestible event marker (Abilify MyCite) – Atypical Antipsychotic
  - clobazam oral film (Sympazan) – Anticonvulsant-Antimania Agent for Lennox-Gastaut Syndrome
  - cyclosporine 0.09% ophthalmic solution (Cequa) – Anti-Inflammatory Immunomodulatory Ophthalmic Agent for Dry Eye Disease
  - desmopressin acetate sublingual (SL) tablet (Nocdurna) – Miscellaneous Endocrine Agent for Nocturia due to Nocturnal Polyuria
  - filgrastim vials (Granix) – White Blood Cell Stimulant and Biosimilar to Neupogen
  - halobetasol propionate 0.01% lotion (Bryhali) – High Potency Corticosteroid-Immune Modulator for Plaque Psoriasis
  - itraconazole 65 mg capsules (Tolsura) – Antifungal Agent
  - latanoprost (Xelpros) – Ophthalmic Prostaglandin
  - omadacycline (Nuzyra) – Tetracycline Antibiotic for Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
  - revefenacin nebulized solution (Yupelri) – Pulmonary-2: Long Acting Anti-Muscarinic Agent (LAMA) for Chronic Obstructive Pulmonary Disease (COPD)
  - rifamycin (Aemcolo) – Miscellaneous Gastrointestinal Antibiotic for Traveler's Diarrhea
  - sarecycline (Seysara) – Tetracycline Antibiotic for Acne Vulgaris

- Tier 4/Not Covered
  - halobetasol propionate 0.05% foam (Lexette) – corticosteroids-Immune Modulators – High Potency for Plaque Psoriasis:

    The topical corticosteroids were reviewed for formulary placement in August 2013. There is a high degree of therapeutic interchangeability within a particular potency category and vehicle. There are currently 28 other high-potency topical corticosteroids on the formulary, including 12 products formulated in a hair-friendly vehicle, including foam, gel, lotion, shampoo, and solution. The new foam formulation of Lexette offers no clinically meaningful advantages over the high-potency topical steroids available on the UF.

Overall conclusion: The P&T Committee concluded that Lexette provides little to no clinical benefit and its cost is prohibitive relative to the numerous formulary alternatives. Currently, the needs of TRICARE beneficiaries can be met by the 28 other formulary high-potency topical steroids.

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Abilify MyCite, Aemcolo, Bryhali, Cequa, Granix, Nocdurna, Nuzyra, Seysara, Sympazan, Tolsura, Xelpros, and Yupelri. See Appendix B for the full criteria.

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

- Oral Tetracycline Agents: Applying the same automated (step therapy) and manual PA criteria for sarecycline (Seysara) in new and current users that is currently in place for the other non-step-preferred oral tetracyclines. Patients must first try one generic doxycycline IR product, either the hyclate or monohydrate salt and one generic minocycline IR product first, before Seysara.
- Androgens-Anabolic Steroids: Testosterone Replacement Therapies: Applying new manual PA criteria for Xyosted SQ in new and current users. In addition to a trial of the step-preferred testosterone 2% topical gel (Fortesta), patients must also try one injectable testosterone product and meet the Risk Evaluation and Mitigation Strategies (REMS) requirements listed in the Xyosted product label regarding the risk of increases in blood pressure and potential increase in the risk of major adverse cardiovascular events (MACE).
- Applying manual PA criteria to new users of Abilify MyCite, Arakoda, Daurismo, Firdapse, Lorbrena, Oxervate, Talzenna, Tegsedi, Tolsura, Vitrakvi, and Xospata.
- Applying manual PA criteria to new and current users of Aemcolo, Cequa, Nocdurna, Tiglutik, and Yupelri.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***

- **New Drugs Recommended for UF or NF status:** The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1

absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday 30 days after signing of the minutes in all points of service.

- **New Drugs Recommended for Tier 4 status halobetasol propionate 0.05% foam (Lexette):** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) for Lexette 1) an effective date of the first Wednesday after a 120-day implementation period at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is August 28, 2019.

VII. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

a) Antihistamine-1: First generation and combinations – Dexchlorpheniramine 2 mg/5 mL oral solution (Ryclora)

Ryclora is a new liquid formulation of a dexchlorpheniramine, which had previously been removed from the market. The committee reviewed the oral liquid formulations of the non-sedating antihistamines. Cost-effective generic formulations of chlorpheniramine are available on the UF without a PA required, and low-cost OTC liquid formulations for fexofenadine and loratadine are widely available.

COMMITTEE ACTION: ANTIHISTAMINE-1: FIRST GENERATION AND COMBINATIONS DEXCHLORPHENIRAMINE MALEATE LIQUID (RYCLORA) MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for dexchlorpheniramine 2 mg/5 mL oral syrup (Ryclora) in new and current users, due to the significant cost differences and lack of clinically compelling benefits over generic alternatives. See Appendix C for the full criteria.

b) Hepatitis C Agents: Direct-Acting Agents (HCV DAAs): generic ledipasvir/sofosbuvir (authorized generic for Harvoni) and generic sofosbuvir/velpatasvir (authorized generic for Epclusa)

The P&T Committee most recently reviewed the HCV DAAs for formulary status in August 2018. Since the review, authorized generics for Harvoni and Epclusa entered the market in December 2018. An "authorized generic" is the brand company's own product repackaged and marketed as a generic drug. An authorized generic is considered therapeutically equivalent to the name brand drug because it is the same drug. The FDA does not consider authorized generics as AB-rated generic formulations.

COMMITTEE ACTION: GENERIC LEDIPASVIR/SOFOSBUVIR AND GENERIC SOFOSBUVIR/VELPATASVIR MANUAL PA CRITERIA— The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the authorized generic products ledipasvir/sofosbuvir and sofosbuvir/velpatasvir in new users, requiring a trial of the branded Harvoni or Epclusa, due to cost-effectiveness. The PA requirement will be removed when it is no longer cost advantageous. See Appendix C for the full criteria.

c) Skeletal Muscle Relaxants and Combinations: cyclobenzaprine 7.5 mg

Generic formulations of the skeletal muscle relaxant cyclobenzaprine are available in 5 mg, 7.5 mg, and 10 mg tablets. Cyclobenzaprine 7.5 mg tablets are significantly less cost-effective compared to the 5 mg or 10 mg strengths. Cost-effective generic formulations of cyclobenzaprine 5 mg and 10 mg and multiple comparable muscle relaxants (e.g., baclofen, methocarbamol) are available on the UF without PA required. The Committee did note that skeletal muscle relaxants are not considered first-line therapy for musculoskeletal conditions.

COMMITTEE ACTION: CYCLOBENZAPRINE 7.5 MG MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new and current users of cyclobenzaprine 7.5 mg tablets, due to the significant cost differences and lack of clinically compelling benefits compared with administering one and a half of a 5 mg tablet or using other generic muscle relaxants. See Appendix C for the full criteria.

2. Temporary specific Prior Authorization for Drugs Not Subject to 32 CFR 199.21(g)(5)—There are an increasing number of drugs approved by the FDA via Abbreviated New Drug Applications (ANDAs), rather than the traditional New Drug Application (NDA) process. These drugs do not qualify for review by the DoD P&T Committee under 32 CFR 199.219(g)(5) (e.g., innovator reviews or newly approved drug reviews). These ANDA-approved products commonly contain ingredients that are currently available in generic products or were included in formulations previously removed from the market. Additionally, the ANDA-approved products can be less cost-effective than formulary alternatives and provide little to no additional clinical benefit.

In order to respond quickly to market launch of ANDA-approved products where several cost-effective formulary alternatives are available, the DHA Pharmacy Operations Division requested administrative authority to place temporary specific Prior Authorization criteria on select ANDA-approved products. The pre-authorization requirement will help minimize patient impact by decreasing the number of patients potentially initiating treatment on such products.

The "temporary specific" criteria will require documentation by the provider as to why that drug is required rather than the available alternatives. The temporary specific PA

criteria will be implemented at the time of product launch or as soon as operationally possible. All temporary specific PA criteria will be reviewed by the DoD P&T Committee at the next meeting. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes at the next meeting. Letters will be sent to any existing utilizers of the identified drugs, if applicable.

COMMITTEE ACTION: NEWLY APPROVED DRUGS OUTSIDE OF 32 CFR 199.21(g)(5) RECOMMENDED TEMPORARY SPECIFIC PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) granting authority to the DHA POD to implement temporary specific PA criteria for those products identified as falling outside of 32 CFR 199.21(g)(5), prior to formal vote by the DoD P&T Committee at the following meeting.

3. **Updated Manual PA Criteria, Step Therapy, and MN Criteria**—Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications and safety. The updated manual PA and MN criteria as outlined below will apply to new users.

   a) **Cardiovascular Agents Miscellaneous: ivabradine (Corlanor)—**The Committee reviewed a request to allow an off-label use for ivabradine (Corlanor). Manual PA criteria have applied to Corlanor since November 2015, limiting use to the FDA indication to decrease the risk of hospitalization in patients with chronic heart failure. The Committee recommended updating the PA criteria to include treatment of patients with symptomatic inappropriate sinus tachycardia (IST) or postural tachycardia syndrome (POTS). The recommendation was based on supporting clinical trial data and the 2015 guidelines from the American College of Cardiology/American Heart Association/Heart Rhythm Society, which state that Corlanor is reasonable for ongoing management in patients with these conditions.

   b) **Cystic Fibrosis Agents: ivacaftor (Kalydeco)**—Kalydeco was first reviewed by the P&T Committee in July 2012, where PA was recommended, based on the package insert labeling. Additional updates were made in May 2014 and November 2018. The FDA has now approved Kalydeco for use in patients as young as 1 year of age, and the PA criteria were updated to reflect the new FDA-approved age range.

   c) **Gastrointestinal-2 Agents: Miscellaneous – rifaximin 200 mg (Xifaxan)—** Manual PA criteria were previously recommended for Xifaxan for Traveler's Diarrhea at the May 2013 P&T Committee meeting. The Xifaxan PA was updated to reflect the most recent update of the 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea, requiring a trial of azithromycin or ciprofloxacin.

   d) **Hematological Agents – Platelets: avatrombopag (Doptelet)**—Avatrombopag (Doptelet) and lusutrombopag (Mulpleta) are pre-procedure regimens for patients

with thrombocytopenia associated with liver disease. Mulpleta does not require dose adjustment; therefore, the P&T Committee updated the Doptelet PA criteria to require use of Mulpleta first, to reduce the risk of dosing errors with Doptelet.

e) **Immune Modulators Endocrine Agents: Miscellaneous – Desmopressin nasal spray (Noctiva)**—Noctiva nasal spray was most recently reviewed for formulary placement at the May 2018 DoD P&T Committee meeting. The PA criteria for Noctiva were updated to include a comprehensive list of safety concerns, and to mirror the PA criteria for the new drug desmopressin SL tablets (Nocdurna). The MN criteria were also updated.

f) **Targeted Immunomodulatory Biologics (TIBs): adalimumab (Humira) and anakinra (Kineret)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. The FDA recently granted new indications for Humira for moderate to severe hidradenitis suppurativa in patients 12 years and older, and for Kineret for systemic juvenile idiopathic arthritis, and the respective PAs were updated for these additional indications.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Kalydeco, Noctiva nasal spray, Xifaxan, Doptelet, Humira, Kineret, Corlanor; and also recommended updates to the MN criteria for Noctiva. (See Appendices B and C for the full criteria.)

B. Auto-Refill Requirements for Desmopressin (Nocdurna SL tabs and Noctiva nasal spray)

The new formulations of desmopressin, Noctiva and Nocdurna, have significant safety concerns, including hyponatremia, particularly in patients older than 65 years; drug interactions are also common. The 2019 update to the Beers criteria gives a strong recommendation to avoid use of desmopressin for treatment of nocturia and nocturnal polyuria, as safer alternatives are available. The Beers criteria aims to help reduce potentially inappropriate medication use in patients older than 65 years. Due to safety concerns, the P&T Committee recommended removing Noctiva and Nocdurna from the auto-refill program.

1. ***COMMITTEE ACTION: NOCTIVA AND NOCDURNA AUTO-REFILL PROGRAM RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing Nocdurna SL tablets and Noctiva nasal spray from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy.

C. QLs

QLs were reviewed for 7 drugs from drug classes where there are existing QLs, including the oncological agents, GI-2 agents, dry eye disease drugs, and LAMA. QLs were also discussed for 9 drugs where QLs are not currently in place.

1. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Aemcolo, Cequa, Daurismo, Firdapse, Krintafel, Lorbrena, Oxervate, Talzenna, Tegsedi, Tiglutik, Udenyca, Vitrakvi, Xofluza, Xospata, Xyosted, and Yupelri. See Appendix D for the QLs.

D. PA and QLs Implementation Periods

1. ***COMMITTEE ACTION: PA, MN, AUTO-REFILL RECOMMENDATION, AND QLs IMPLEMENTATION PERIOD—***The P&T Committee recommended the following implementation periods:

   - (18 for, 0 opposed, 0 abstained, 0 absent) New PAs for Ryclora, cyclobenzaprine 7.5 mg, authorized generic ledipasvir/sofosbuvir and authorized generic sofosbuvir/velpatasvir become effective 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for the cyclobenzaprine 7.5 mg and Ryclora if applicable, as new and current users will be subject to the PA.
   - (18 for, 0 opposed, 0 abstained, 0 absent) Updates to the current PA criteria for Kalydeco, Noctiva nasal spray, Xifaxan, Doptelet, Humira, Kineret, and Corlanor in new users, and the MN update to Noctiva nasal spray become effective 30 days after the signing of the minutes.
   - (18 for, 0 opposed, 0 abstained, 0 absent) Removal of Noctiva and Nocdurna from the Auto-Refill program administered by ESI become effective 90 days after the signing of the minutes. Letters will be mailed to patients affected by the decision.
   - (17 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 16 drugs listed in section VII, C, above, and in Appendix D, become effective on the first Wednesday three weeks after the signing of the minutes in all POS.

VIII. BRAND OVER GENERIC AUTHORIZATION FOR DIHYDROERGOTAMINE SPRAY/PUMP (MIGRANAL NASAL SPRAY)

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Migranal nasal spray product is more cost-effective than the AB-rated generic formulations for dihydroergotamine nasal spray, which were launched in December 2018. Therefore, the branded Migranal Nasal Spray product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Migranal Nasal Spray. The "brand over generic" requirement for Migranal Nasal Spray will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

A. ***COMMITTEE ACTION: MIGRANAL NASAL SPRAY BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) implementing the requirement to prefer the branded

Migranal Nasal Spray product over generic formulations. Manual PA criteria are required for generic dihydroergotamine mesylate in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Migranal Nasal Spray product cannot be used. (See Appendix C.)

B. ***COMMITTEE ACTION: MIGRANAL NASAL SPRAY BRAND COPAYMENT CHANGE—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) that the brand (Tier 2) formulary cost-share for Migranal Nasal Spray in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost-share.

IX. LINE EXTENSIONS

The P&T Committee clarified the formulary status for 3 product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) clarifying the formulary status of the following 3 products to reflect the current formulary status and applicable step therapy, PA criteria, MN criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday three weeks after signing of the minutes.

- Basal Insulin Analogs—Insulin degludec (Tresiba) is now available in vials. Insulin degludec in the pen formulation (Tresiba FlexTouch pen) is currently designated as NF and non-step-preferred, requiring a trial of insulin glargine 100 U/mL (Lantus) first. The P&T Committee recommended designating Tresiba vials as NF and non-step-preferred, with the same step therapy and manual PA requirements as the Tresiba FlexTouch pen. Tresiba vials will also be added to the EMMPI program.

- Hematological Agents—eltrombopag (Promacta) is now available in oral suspension packets. Promacta tablets have not yet been reviewed by the Committee for formulary status, and are currently designated as UF, since FDA approval occurred prior to August 2015 with the implementation of the innovator program. The new Promacta formulation will be designated as UF similar to the parent agent.

- TIBs—the new formulation of tocilizumab (Actemra) ACTPen autoinjector pen will be designated as NF and non-step-preferred, with the same MN, PA, and QLs as the Actemra prefilled syringe. See Appendix D for the QLs.

X. RE-EVALUATION OF NF GENERICS/EMMPI REQUIREMENTS

A. Second Generation Antihistamines: levocetirizine (Xyzal)

Antihistamines: levocetirizine (Xyzal, generics)—The P&T Committee reviewed the current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per unit, for generic levocetirizine (Xyzal). The P&T Committee agreed that, while the unit cost of generic levocetirizine has dropped significantly from the previous generic and brand cost, it is still substantially higher than generic OTC formulations of cetirizine and loratadine, both of which are on the Uniform Formulary. The P&T Committee also noted that generic levocetirizine is comparably priced at all 3 points of service and available from at least 13 manufacturers, suggesting stable generic prices or continued price decreases are likely, due to robust market competition.

1. ***COMMITTEE ACTION: LEVOCETIRIZINE FORMULARY STATUS AND IMPLEMENTATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) that levocetirizine (Xyzal, generics) remain NF but be exempted from the mail order requirement on the basis of comparable pricing at mail order versus MTFs or retail, effective the first Wednesday three weeks after the signing of the minutes. See Appendix F.

XI. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EMMPI)

See Appendix F for the mail order status of medications designated NF or UF during the February 2019 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the non-formulary to mail requirement. The implementation date for all EMMPI recommendations from the February 2019 meeting, including the newly approved drugs affected by the EMMPI, will be effective upon the first Wednesday three weeks after the signing of the minutes.

A. *COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS*

The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI program, for the reasons outlined in the table.

XII. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

At the November 2018 meeting, the P&T Committee designated Tobramycin Inhalation Solution Pak (NDC: 70644-0899-99) by Genericus, Inc. as not compliant with Section 703 requirements. After further review and comparison of tobramycin inhalation solution pak with the other available tobramycin inhalation products which do not include the nebulizer, the Committee recommended removing this drug from the Section 703 Non-Compliant Drug List and returning to its previous status of UF on the Uniform Formulary with no POS restrictions.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED UF***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) that the Section 703 non-compliant NDC of the following product return to its former UF status with no POS restrictions:

- Genericus, Inc.: tobramycin inhalation solution pak (*New Drug Application-authorized generic; NDC 70644-0899-99*) 300 mg/5 mL ampule-nebulizer

XIII. UF SUB-WORKING GROUP UPDATE: ALIGNING OVER-THE-COUNTER (OTC) FORMULARIES

At the retail pharmacy network and mail order pharmacy, OTC medications are limited to those explicitly included in the TRICARE pharmacy benefit (e.g., diabetic supplies, tobacco cessation agents), and those medications added to the Uniform Formulary and covered by TRICARE under provisions of 32 CFR 199.21(h)(5) as being cost-effective and clinically effective compared with other drugs in the same therapeutic class. These covered OTC products currently include omeprazole, loratadine, cetirizine, fexofenadine, levonorgestrel 1.5 mg (Plan B One-Step and its generics), and doxylamine 25 mg. By contrast, MTFs currently dispense a wide variety of OTC medications. A phased process that encompasses standardization across MTFs is underway.

As a first attempt to address standardization, the P&T Committee reviewed 7 low-use, non-FDA-approved products for potential removal from the MHS GENESIS OTC list: niacin, niacinamide, lactase, glucosamine/chondroitin, chlorhexidine/glycerin/he-cell (Maxilube jelly), surgical lubricant (Surgilube), and folic acid 1 mg OTC. The Committee reviewed the utilization of the 7 products at the MTFs and MHS Genesis host sites.

The P&T Committee noted the following:

- Niacin 500 mg tablet is available as a legend product (Niaspan, generics). Almost 90% of MTF OTC niacin prescriptions are for 500 mg tablets or capsules.
- Oral niacinamide is marketed as a food supplement. In addition to niacin deficiency, more than 25 other potential uses have been identified, including acne and rosacea.
- Lactase (e.g., Lactaid) is used for lactose intolerance in the small intestine.

- Glucosamine/chondroitin is marketed as a food supplement and used to slow degeneration of joint cartilage or alleviate joint pain. A number of clinical trials have assessed its efficacy for osteoarthritis (OA), with conflicting results. An assessment from the NIH National Center for Complementary and Integrative Health concludes that 1) evidence suggests chondroitin is not helpful for knee or hip pain; 2) it is unclear if glucosamine is helpful for OA knee pain; 3) it is unclear if either help with pain in other joints. The American College of Rheumatology's 2012 guideline "conditionally recommends" that patients with hip or knee OA not use glucosamine or chondroitin.
- Maxilube is marketed as a personal lubricant, while Surgilube is marketed as a lubricant for surgical and gynecological procedures. It is unclear why Surgilube is being dispensed as an outpatient pharmacy product.
- Folic acid 1 mg is also available as a legend product. Prescription formulations of folic acid 1 mg are available at all three points of service.

A. COMMITTEE ACTION: STATUS OF AGENTS ON THE MHS GENESIS OTC LIST—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing the following products from the MHS GENESIS OTC list: niacin, niacinamide, lactase, glucosamine/chondroitin, chlorhexidine/glycerin/he-cell (Maxilube jelly), surgical lubricant (Surgilube), and folic acid 1 mg.

B. COMMITTEE ACTION: IMPLEMENTATION—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 90 days following signing of the minutes. Letters will be sent to affected patients at MHS GENESIS MTFs.

XIV. BRAND OVERRIDE CRITERIA

Background—The committee reviewed generic over brand mandatory substitution policy. The committee affirmed currently applied appeals criteria.

A. *COMMITTEE ACTION: BRAND OVERRIDE CRITERIA RECOMMENDATION*—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) to maintain current override criteria for brand requests when generic products are available.

XV. DOD SPECIALTY DRUG PROGRAM

The P&T Committee was briefed on various aspects of the DoD Specialty Drug Program. The Committee recommended criteria to identify potential candidates for addition to or removal from the mail order specialty clinical services program. In order to manage the Specialty Drug program more efficiently, the DHA POD requested administrative authority to add or remove drugs or drug classes from the Clinical Services Drug List.

A. COMMITTEE ACTION: ADMINISTRATIVE AUTHORITY RECOMMENDATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) granting administrative authority to the DHA POD to add or remove drugs or drug classes from the Clinical Services Drug List prior to formal vote by the DoD P&T Committee. Any drugs added or removed from the Clinical Services Drug List will subsequently be presented at the next P&T Committee meeting.

XVI. ITEMS FOR INFORMATION

Annual Review of Newly Approved Drugs

The Committee was briefed on the utilization and cost trends 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, a total of 194 drugs have been reviewed, with 101 (52%) designated as UF and 93 (48%) designated as NF. A clinical summary of program to date was also provided. Challenges to maintaining the program include the increasing volume of new drug approvals from the FDA and the increasing number of specialized products, particularly oncology agents, requiring expertise for review. Updates on the metrics for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

XVII. ADJOURNMENT

The meeting adjourned at 1700 hours on February 7, 2019. The next meeting will be in May 2019.

Appendix A—Attendance: February 2019 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 and Nonformulary During the February 2019 DoD P&T Committee Meeting
Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary
Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☐ concurs with all recommendations.

☒ concurs with the recommendations, with the following modifications:

After taking into consideration the Beneficiary Advisory Panel non concurrence for Tier 4/Not covered status for Zenpep, and their recommendation to place a stricter PA on Zenpep, the following will occur:

1. Zenpep will retain Non formulary status.
2. New manual PA criteria will apply to all new and current users of Zenpep, to require a trial of all formulary and non formulary Pancreatic Enzyme Replacement Enzymes, with the exception for patients younger than 2 who will only require a trial of Creon.
3. Implementation will occur 90 days after signing, with affected beneficiaries notified via letter

Mr. Guy Kiyokawa
Deputy Director, DHA
for R.C. Bono, VADM, MC, USN,
Director

25 APR 19
Date

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

FEBRUARY 2019

UPDATED TABLE OF PRIOR AUTHORIZATION CRITERIA FOR ZENPEP AND THE OTHER PANCREATIC ENZYME REPLACEMENT PRODUCTS

Drug / Drug Class	Prior Authorization Criteria
Step-Preferred • Creon **Non-Step-Preferred** • Pancreaze • Pertzye • Viokace **Pancreatic Enzyme Replacement Therapy (PERT)**	Creon is the preferred Pancreatic Enzyme Replacement product; Prior Authorization is not required for Creon. Manual PA criteria apply to all new and current users of Pancreaze, Pertzye, and Viokace. All new and current users of a PERT are required to try Creon first, before receiving one of the non-step-preferred products. Manual PA criteria—Pancreaze, Pertzye, and Viokace is approved if any of the following criteria are met: • The patient has failed an adequate trial of Creon, defined as at least 2 dose adjustments done over a period of at least 4 weeks OR • The patient is ≤ 2 years old and a sufficient trial of Creon was unsuccessful OR • For Viokace: the patient requires an uncoated tablet due to actual or suspected dissolution issues with enteric coating of Creon Prior authorization does not expire.
Step-Preferred • Creon **Non-Step-Preferred** • Zenpep **Pancreatic Enzyme Replacement Therapy (PERT)**	Creon is the preferred Pancreatic Enzyme Replacement product; Prior Authorization is not required for Creon. Manual PA criteria apply to all new and current users of Zenpep. All new and current users of a PERT are required to try Creon first, before receiving one of the non-step-preferred products. Additionally all new and current users of Zenpep are required to try Pertzye, Pancrease, and Viokace. Manual PA criteria—Zenpep is approved if ALL of the following criteria are met: For patients 2 years of age or younger • The patient has had a sufficient trial of Creon and treatment was unsuccessful For patients older than 2 years of age • The patient has failed an adequate trial of Creon, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND • The patient has failed an adequate trial of Pancreaze, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND • The patient has failed an adequate trial of Pertzye, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND • The patient has failed an adequate trial of Viokace; defined as at least 2 dose adjustments done over a period of at least 4 week; document the dates tried _____. OR the patient is between 2 and 19 years of age and requires a dosage strength that is not available with Viokace. Prior authorization does not expire.

Appendix A—Attendance: February 2019 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Mr. David Bobb	Chief, DHA Pharmacy Operations Division
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Shaun Carstairs, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
COL Clayton Simon, MC	TRICARE Regional Office Representative
Kelly Echevarria, PharmD for Jennifer Zacher, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Brian Wheeler	DHA, Deputy General Counsel
Eugene Moore, PharmD, BCPS for Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Ms. Kimberlymae Wood	DHA Contract Operations Division
Ms. Yvette Dluhos	DHA Contract Operations Division
LCDR Jason Galka	DLA Troop Support
CPT Zachary Leftwich, MSC	Army Medical Department Center and School (AMEDDC&S)
Maj Thomas Robinson	Brooke Army Medical Center (BAMC) Resident

Appendix A—Attendance (continued)

Others Present	
CDR Heather Hellwig, 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
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Christina Andrade, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
Robert Conrad, PharmD	DHA Formulary Management Branch
Brian Beck, PharmD	DHA Purchased Care Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Cortney Raymond	DHA Formulary Management Branch Contractor

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• aripiprazole tablet with ingestible event marker (Abilify MyCite) **Antipsychotic Agents: Atypical**	• Formulary agents likely to result in therapeutic failure **Formulary Alternatives:** aripiprazole, Abilify Maintena
• clobazam oral film (Sympazan) **Anticonvulsants-Antimania Agents**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • No alternative formulary agent (patient has difficulty swallowing tablets or oral suspension) **Formulary Alternatives:** clobazam tablets and suspension (Onfi)
• cyclosporine 0.09% ophthalmic (Cequa) **Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Immunomodulatory Agents**	• Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** cyclosporine 0.05% (Restasis/multidose), lifitegrast 5% (Xiidra)
• desmopressin sublingual tab (Nocdurna) **Endocrine Agents Miscellaneous**	• Use of formulary agents has resulted in therapeutic failure **Formulary Alternatives:** generic desmopressin nasal, oral desmopressin tab (DDAVP, generics)
• desmopressin nasal spray (Noctiva) **Endocrine Agents Miscellaneous**	**February 2019 updates are in bold** • **Use of formulary agents has resulted in therapeutic failure** • ~~**No alternative formulary agent: Patient is an adult and requires treatment for nocturnal polyuria**~~ • **Formulary Alternatives:** generic desmopressin nasal, oral desmopressin tab (DDAVP, generics)
• filgrastim vials (Granix) **Hematological Agents: WBC Stimulants**	• Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** Granix prefilled syringes, Neupogen, Zarxio
• halobetasol propionate 0.01% lotion (Bryhali) **Corticosteroids-Immune Modulators: High Potency**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Use of formulary agents is contraindicated **Formulary Alternatives:** Topical clobetasol propionate 0.5% (Clobex, Olux, Temovate, generics), halobetasol propionate (Halonate, generics), desoximetasone (Topicort, generics), fluocinonide 0.05% (non-Vanos products), betamethasone dipropionate augmented (Diprolene/-AF, generics)
• itraconazole 65 mg tabs (Tolsura) **Antifungals**	• Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** itraconazole 100 mg capsules or itraconazole 10 mg/mL solution

Drug / Drug Class	Medical Necessity Criteria
• latanoprost 0.005% ophthalmic emulsion (Xelpros) **Glaucoma Agents**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • All formulary agents resulted in therapeutic failure **Formulary Alternatives:** latanoprost 0.005% ophthalmic solution (generic Xalatan), bimatoprost (generic 0.03% Lumigan)
• omadacycline (Nuzyra) **Antibiotics: Tetracycline**	• Use of formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** doxycycline, linezolid, moxifloxacin, levofloxacin
• revefenacin (Yupelri) **Pulmonary-2: Long Acting Anti-Muscarinic Agents (LAMAs)**	• Use of all formulary and non-formulary agents have resulted in therapeutic failure (Spiriva Respimat/Handihaler, Tudorza Pressair, Incruse Ellipta, Seebri Neohaler) **Formulary Alternatives:** Spiriva Respimat/Handihaler, Tudorza Pressair, Incruse Ellipta, and Seebri Neohaler
• rifamycin (Aemcolo) **Gastrointestinal-2: Miscellaneous**	• Use of formulary agents resulted in therapeutic failure **Formulary Alternatives:** ciprofloxacin, azithromycin, and rifaximin
• sarecycline (Seysara) **Antibiotics: Tetracycline**	• Patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic minocycline products **Formulary Alternatives:** minocycline IR 50 mg or 100 mg
• insulin degludec vials (Tresiba) **Insulins: Basal**	• Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus), insulin glargine (Toujeo)
• tocilizumab (Actemra ACTPen) **Targeted Immunomodulatory Biologics (TIBs) – Non-tumor Necrosis Factor Inhibitors**	• Use of adalimumab (Humira) is contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) has resulted in therapeutic failure • The patient is transitioning from IV tocilizumab (Actemra IV) **Formulary Alternatives:** Humira (BCF)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• erenumab-aooe injection (Aimovig)
• fremanezumab-vfrm injection (Ajovy)
• galcanezumab-gnlm injection (Emgality)
 	
Migraine Agents: CGRP Prophylaxis
	February 2019 updates are in BOLD and strikethrough.
	
	Manual PA criteria apply to all new users of Aimovig, Ajovy, or Emgality.
	
	Manual PA Criteria: Aimovig, Ajovy, or Emgality is approved if all criteria are met:
	• Patient ≥ 18 years old and not pregnant
	• Must be prescribed by or in consultation with a neurologist
	• **The patient also meets one of the following:**
	  • **Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR**
	  • Patient has **episodic migraine at a rate** ~~a migraine diagnosis with~~ of at least 8 migraine days per month for 3 months **OR**
	  • **Patient has a diagnosis of chronic migraine**
	• 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:
	  • Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
	  • Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, **timolol**
	  • Prophylactic antidepressants: amitriptyline, **duloxetine, nortriptyline,** venlafaxine
	• **Patient is not currently on botulinum toxin or patient must not have received a botulinum toxin injection within the last 2 months**
	• Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed
	• For Emgality, a loading dose will be allowed
	
	Non-FDA-approved uses are NOT approved.
	PA expires after 6 months.
	
	Renewal Criteria: coverage will be approved indefinitely for continuation of therapy if **one of the following apply:**
	• ~~The patient has shown improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication)~~
	• **Note that in order to go through renewal criteria, the patient must have satisfied the initial PA criteria**
	• **The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR**
	• **The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:**
	  • **Migraine Disability Assessment (MIDAS)**
	  • **Reduction of ≥ 5 points when baseline score is 11–20**
	  • **Reduction of ≥ 30% when baseline score is > 20**
	  • **Headache Impact Test (HIT-6)**
	  • **Reduction of ≥ 5 points**
	  • **Migraine Physical Functional Impact Diary (MPFID)**
	  • **Reduction of ≥ 5 points**

Drug / Drug Class	Prior Authorization Criteria

• abiraterone acetate micronized (Yonsa)
 	
Oncological Agents: CYP-17 Inhibitors
	February 2019 updates are in BOLD and strikethrough.
	
	Manual PA criteria apply to all new users of Yonsa.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Age ≥ 18 years**
	• **Prescribed by or in consultation with an oncologist or urologist**
	• Provider is aware that Yonsa may have different dosing and food effects than other abiraterone acetate products (medication errors and overdose warning)
	~~• Patient has documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)~~
	~~• Patient has documented diagnosis of metastatic high-risk castration-sensitive prostate cancer (mCSPC)~~
	• **Patient has documented diagnosis of non-localized disease including:**
	  • **Metastatic castration-resistant prostate cancer (mCRPC)**
	  • **Metastatic castration-sensitive prostate cancer (mCSPC)**
	  • **Regional disease (T_xN1M0) OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	  • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
	• Patient must receive concomitant therapy with methylprednisolone
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	
	Other non-FDA-approved uses are NOT approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• abiraterone acetate (Zytiga, generics)
 	
Oncological Agents: CYP-17 Inhibitors
	February 2019 updates are in BOLD and strikethrough.
	
	Manual PA criteria apply to **all new and current users** of Zytiga and generics.
	
	***DoD will allow the clinical PA to provide information for the 250 mg or 500 mg tablets. Currently, the 250 mg tablets are the preferred agent, so if the provider is willing to write for the 250 mg tablets, then a new prescription will need to be written – but the PA will not need to be filled out more than once.**
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Yonsa is the Department of Defense's preferred CYP-17 Inhibitor agent.**
	  • **Has the patient tried Yonsa?**
	  OR
	  • **Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Yonsa that is not expected to occur with the requested agent?**
	• **Age ≥ 18 years**
	• **Prescribed by or in consultation with an oncologist or urologist**
	• ~~Patient has documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)~~
	• ~~Patient has documented diagnosis of metastatic high-risk castration-sensitive prostate cancer (mCSPC)~~
	• **Patient has documented diagnosis of non-localized disease including:**
	  • **Metastatic castration-resistant prostate cancer (mCRPC)**
	  • **Metastatic castration-sensitive prostate cancer (mCSPC)**
	  • **Regional disease (T_xN1M0) OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	  • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
	• Patient must receive concomitant therapy with prednisone
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	• **Zytiga 250 mg is the DoD's preferred strength. Is the prescription for Zytiga 250 mg OR will the prescription be changed to the 250 mg?**
	  • **Note: If the prescription is being changed to the 250 mg strength, please submit a new prescription with this PA form**
	  OR
	  • **Please state why the patient cannot take multiple 250 mg tablets to achieve the patient's daily dose (fill-in blank)**
	
	Other non-FDA-approved uses are NOT approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• enzalutamide (Xtandi)
 	
Oncological Agents: 2nd-Gen Antiandrogens
	February 2019 updates are in BOLD.
	
	Manual PA criteria apply to all new users of Xtandi.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Age ≥ 18 years**
	• **Prescribed by or in consultation with an oncologist or urologist**
	• Patient has documented diagnosis of **metastatic OR non-metastatic** castration-resistant prostate cancer (CRPC)
	  • If used in non-metastatic castration-resistant prostate cancer (nmCRPC), patient must have: prostate specific antigen doubling time **(PSADT) ≤ 10 months OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	  • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	
	Other non-FDA-approved uses are NOT approved.
	PA does not expire.

• apalutamide (Erleada)
 	
Oncological Agents: 2nd-Gen Antiandrogens
	February 2019 updates are in BOLD.
	
	Manual PA criteria apply to all new users of Erleada.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen agent.**
	  • **Has the patient tried Xtandi?**
	  OR
	  • **Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Xtandi that is not expected to occur with Erleada**
	• **Age ≥ 18 years**
	• Prescribed by or in consultation with an oncologist or urologist
	• Patient has documented diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND**
	  • Negative CT scan of abdomen/pelvis and/or negative bone scan, **AND**
	  • **PSADT ≤ 10 months OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	• **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.**
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	
	Other non-FDA-approved uses are NOT approved.
	PA expires in 1 year.
	
	Renewal PA Criteria: Coverage will be approved for 1 year for continuation of therapy if:
	• Patient continues to be metastases-free
	• No toxicities have developed
	• Patient has not progressed onto subsequent therapy (such as abiraterone ~~[Zytiga]~~)

Drug / Drug Class	Prior Authorization Criteria
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	Manual PA applies to all new users of Firdapse. Manual PA Criteria: Firdapse is approved if: • Age ≥ 18 years old • Drug is prescribed by an oncologist or neurologist • Has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS) Non-FDA-approved uses are NOT approved. PA does not expire.
• aripiprazole tablet with ingestible event marker (Abilify MyCite) **Antipsychotic Agents: Atypical**	Manual PA criteria apply to all new users of Abilify MyCite. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient must have documented attempt to use generic aripiprazole tablets, with non-compliance documented in prescriber notes. Prescriber notes must also document the prescriber's attempted medication adherence counseling. • Patient must have documented trial of at least 12 weeks of Abilify Maintena first • Provider acknowledges that FDA labeling states the ability of Abilify MyCite to improve patient compliance or modify aripiprazole dosage has not been established. Non-FDA-approved uses are NOT approved. PA does not expire.
• cenegermin-bkbj ophthalmic solution (Oxervate) **Anti-inflammatory Immunomodulatory Ophthalmic Agents**	Manual PA criteria apply to all new users of Oxervate. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 2 years • Patient has a documented diagnosis of neurotrophic keratitis • Drug is prescribed by a cornea specialist or ophthalmologist • Patient does not wear contact lenses during treatment course Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• cyclosporine 0.09% ophthalmic (Cequa) **Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Immunomodulatory Agents**	**February 2019 criteria for Cequa are in BOLD.** PA criteria apply to all **new and current** users. A new user is defined as a patient who has not filled a prescription for **Cequa** in the past 120 days. • If there is no Restasis, **Cequa**, or Xiidra prescription in the past 120 days, a manual PA is required. <u>Manual PA Criteria:</u> Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • **For Cequa: the patient is ≥ 18 years old** • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: • Positive symptomatology screening for moderate to severe dry eye disease from an appropriate measure • At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ 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) • Concomitant use of Restasis, **Cequa**, or Xiidra is NOT allowed. **Non-FDA-approved uses for Cequa are NOT approved.** PA expires in one year. <u>Renewal Criteria:</u> Coverage will be approved indefinitely if all criteria are met: • The drug is prescribed by an ophthalmologist or optometrist. • The patient must have documented improvement in ocular discomfort. • The patient must have documented improvement in signs of dry eye disease.

• desmopressin sublingual (SL) tab (Nocdurna) • desmopressin nasal spray (Noctiva) **Endocrine Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Nocdurna. **Manual PA criteria apply to all new users of Noctiva Nasal Spray; Noctiva Nasal Spray updates are in BOLD** Manual PA Criteria: Coverage is approved if all criteria are met: • For Nocdurna: Age ≥ 18 years old • For Nocdurna: For females: must use 27.7 mcg dosage; for males: must use 55.3 mcg dosage • For Noctiva Nasal Spray: Age ≥ 50 years old (Only the low dose is allowed for pts > 65 years old) • Patient has nocturia defined as having ≥ 2 nocturnal voids nightly for ≥ 6 months • Causes of nocturia have been evaluated and nocturnal polyuria is confirmed with a 24-hour urine collection • **Patient has tried non-pharmacologic techniques or lifestyle interventions to manage the nocturia (e.g., nighttime fluid restriction, avoidance of caffeine and alcohol, earlier timing of medications, leg elevation and/or use of compression stockings)** • **The patient has tried oral desmopressin acetate tablets (DDAVP tablets, generics)** • Patient is not currently taking any of the following medications: – Loop diuretics, alpha$_1$-adrenoceptor antagonists, 5-alpha reductase inhibitors (ARIs), thiazide diuretics, anticholinergics, antispasmodics, sedative/hypnotic agents, NSAIDs, SSRIs, SNRIs, antidepressants, anti-epileptics, opioids, or SGLT2s – Systemic or inhaled corticosteroids or lithium • Prescribed by a urologist, a geriatrician, an endocrinologist, or a **nephrologist** • **Provider must supply most recent serum sodium and date** – **Sodium _____mEq/mL Date_____** • Patient has normal sodium (135-145 meq/L) prior to initiation, recheck sodium after one week of therapy, and another sodium recheck at 1 month • **Provider acknowledges that patients over 65 years old are at greater risk of hyponatremia and has advised the patient about this significant safety concern** • Patient does not have the following conditions for both Noctiva Nasal Spray and Nocdurna: – **Renal impairment (eGFR < 50 mL/min)** – **Hyponatremia or history of hyponatremia** – **Polydipsia** – **Nocturnal enuresis** – **SIADH** – **Congestive heart failure** – **Uncontrolled hypertension or uncontrolled diabetes mellitus** – **Interstitial cystitis** – **Chronic prostatitis/chronic pelvic pain syndrome** – **Suspicion of bladder outlet obstruction (BOO) or urine flow <5 mL/sec** – **Surgical treatment, including transurethral resection, for BOO or benign prostatic hyperplasia within the past 6 months** – **Urinary retention or a post-void residual volume in excess of 250 mL as confirmed by bladder ultrasound performed after suspicion of urinary retention** – **Current or a history of urologic malignancies (e.g., urothelium, prostate, or kidney cancer)** – **Genitourinary tract pathology (e.g., infection or stone in the bladder and urethra causing symptoms)** – **Neurogenic detrusor activity (detrusor overactivity)** – **Suspicion or evidence of cardiac failure** – **History of obstructive sleep apnea** – **Hepatic and/or biliary diseases** – **Treatment with another investigational product within 3 months prior to initiating therapy** – **Known alcohol or substance abuse** – **Work or lifestyle that may have interfered with regular nighttime sleep**

Drug / Drug Class	Prior Authorization Criteria
	AND • **Patient does not have the following conditions for Noctiva Nasal Spray** – **acute or chronic rhinitis (for Noctiva nasal spray only)** – **atrophy of nasal mucosa (for Noctiva nasal spray only**) Non-FDA-approved uses are NOT approved. PA expires ~~in 6 months~~ **4 months.** Renewal Criteria: Coverage will be approved for an additional 6 months if all of the following apply: • **Note that in order to go through renewal criteria, the patient must have satisfied the initial PA criteria** • Patient has not developed any of the conditions above • **Patient is not taking any of the medications mentioned above** • Patient has shown a reduction in nocturia episodes
• gilteritinib (Xospata) **Oncological Agents: Acute Myelogenous Leukemia**	Manual PA criteria apply to all new users of Xospata. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 18 • Has laboratory evidence of relapsed or refractory acute myeloid leukemia with a Ferline McDonough Sarcoma (FMS)-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test • The patient will be monitored for posterior reversible encephalopathy syndrome (PRES), prolonged QTc, and pancreatitis • Patient is not pregnant or actively trying to become pregnant • Prescribed by or in consultation with a hematologist/oncologist Non-FDA-approved uses are NOT approved. PA does not expire.
• glasdegib (Daurismo) **Oncological Agents: Acute Myelogenous Leukemia**	Manual PA criteria apply to all new users of Daurismo. Manual PA Criteria: Coverage is approved if all criteria are met: • Treatment of newly diagnosed acute myeloid leukemia (in combination with low-dose cytarabine) in adult patients who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy. • Provider acknowledges and patient has been informed that limitations of use include that this drug has not been studied in patients with severe renal impairment or moderate to severe hepatic impairment. • Patient is not pregnant or actively trying to become pregnant • Patient will be monitored for febrile neutropenia and QTc prolongation • Prescribed by or in consultation with a hematologist/oncologist Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• inotersen injection (Tegsedi) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Tegsedi. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 18 and has genetically confirmed transthyretin mutation resulting in familial amyloidotic polyneuropathy (FAP) stage 1 or 2 hereditary transthyretin-mediated amyloidosis (hTTRA) • Has polyneuropathy secondary to hereditary transthyretin-mediated amyloidosis with either 1) a polyneuropathy disability (PND) score ≤ IIIB or 2) a Neuropathy Impairment Score between 10 and 130 • Provider and patient are both registered and enrolled with the Tegsedi Risk Evaluation and Mitigation Strategies (REMS) program • Patient has no evidence of thrombocytopenia • Patient does not have chronic kidney disease (CKD) stage 3b and has no history of glomerulonephritis • The provider will monitor the patient's platelet counts and renal and hepatic function • Patient will take an oral Vitamin A supplement at the recommended daily allowance • Provider is aware and patient is informed of the following potential adverse drug reactions: stroke, encephalitis, carotid arterial dissection, hypercoagulability and thrombosis (venous and arterial), QRS prolongation and other arrhythmias, elevated liver-associated enzymes, autoimmune hepatitis, primary biliary cirrhosis, biliary obstruction, glomerulonephritis, nephrotic syndrome, interstitial nephritis, thrombocytopenia, idiopathic thrombocytopenia (ITP), antineutrophil cytoplasmic antibody-associated (ANCA) vasculitis, and hypersensitivity • Prescribed by or in consultation with a specialist that manages hereditary transthyretin amyloidosis (e.g., cardiologist, geneticist, neurologist) • Concomitant use of Onpattro and Tegsedi is not allowed Non-FDA-approved uses are NOT approved. PA does not expire.
• itraconazole 65 mg caps (Tolsura) **Antifungals**	Manual PA applies to all new users of Tolsura. Manual PA Criteria: Tolsura is approved if: • Patient has one of the following diagnoses: ▪ Histoplasmosis ▪ Pulmonary or Extrapulmonary Blastomycosis ▪ Pulmonary or Extrapulmonary Aspergillosis AND • For histoplasmosis or blastomycosis: ▪ Patient has had serious side effects with generic itraconazole 100 mg tablets/capsules OR ▪ Patient has failed drug treatment with generic itraconazole 100 mg tabs/capsules • For aspergillosis ▪ Patient has had serious side effects with generic itraconazole 100 mg tablets/capsules and amphotericin B OR ▪ Patient has failed drug treatment with generic itraconazole 100 mg tabs/capsules and amphotericin B Non-FDA-approved uses are NOT approved including onychomycosis. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• larotrectinib (Vitrakvi) capsules and oral solution **Oncological Agents**	Manual PA criteria apply to all new users of Vitrakvi capsules and oral solution. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient diagnosed with a solid tumor that: ▪ has a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, ▪ is metastatic **OR** where surgical resection is likely to result in severe morbidity, AND ▪ has no satisfactory alternative treatments OR that has progressed following such treatment(s). • Larotrectinib (Vitrakvi) is prescribed by or in consultation with a hematologist/oncologist • For Vitrakvi oral solution: in addition to the above criteria, the patient has difficulty swallowing the capsules Non-FDA-approved uses are NOT approved. PA does not expire.
• lorlatinib (Lorbrena) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of Lorbrena. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by or in consultation with hematologist or oncologist • Patient has a diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer • Patient has experienced disease progression on one of the following treatments: – crizotinib (Xalkori) and at least one other ALK inhibitor – alectinib (Alecensa) as a first-line agent – ceritinib (Zykadia) as a first-line agent **OR** • **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND** • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation** Non-FDA-approved uses are NOT approved. PA does not expire.
• revefenacin (Yupelri) **Pulmonary-2: Long Acting Anti-Muscarinic Agents (LAMAs)**	Manual PA is required for all new and current users of Yupelri. Manual PA Criteria: Yupelri is approved if all criteria are met: • The patient has a diagnosis of chronic obstructive pulmonary disease • The patient has tried and failed an adequate course of a nebulized Short-Acting Muscarinic Antagonist (e.g., ipratropium) • The patient has tried and failed an adequate course of Spiriva Respimat • The patient has tried and failed an adequate course of therapy with at least one of the following dry powder inhalers: Tudorza Pressair, Incruse Ellipta, Spiriva Handihaler, or Seebri Neohaler OR • The patient cannot generate the peak inspiratory flow needed to activate at least one of the following dry powder inhalers: Tudorza Pressair, Incruse Ellipta, Spiriva Handihaler, or Seebri Neohaler Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rifamycin (Aemcolo) **GI-2: Miscellaneous**	Manual PA criteria apply to all new and current users of Aemcolo. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 18 • Patient has a diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* • Patient does not have diarrhea complicated by fever and/or bloody stool • Patient does not have diarrhea due to pathogens other than noninvasive strains of *E. coli* • Patient has tried and failed a 3-day trial of ciprofloxacin unless a contraindication exists or patient has tried and failed azithromycin unless a contraindication exists Non-FDA-approved uses are NOT approved including but not limited to diarrhea-predominant irritable bowel syndrome (IBS-D), non-alcoholic steatohepatitis (NASH), small intestine bacterial overgrowth (SIBO), and inflammatory bowel disease (IBD). PA renewal not allowed. A new prescription will require a new PA to be submitted.
• riluzole oral suspension (Tiglutik) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Tiglutik. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is diagnosed with amyotrophic lateral sclerosis • Patient has dysphagia/swallowing dysfunction Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• sarecycline (Seysara)
 	
Antibiotics: Tetracycline
	February 2019 criteria specific to Seysara are in BOLD.
	
	PA applies to both new and current users of Seysara.
	
	Automated PA Criteria:
	• Patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) AND one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 days
	
	Manual PA Criteria: If automated PA criteria are not met, the non-step-preferred product is allowed if:
	
	Acne Vulgaris or Rosacea
	• For Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Mondoxyne NL, or Okebo: The patient has tried and had an inadequate response to or failed to tolerate the following:
	  ◦ one generic immediate-release doxycycline product (hyclate or monohydrate salt) AND
	  ◦ one generic immediate-release minocycline product
	
	• For Solodyn or generic minocycline ER, Minolira, **or Seysara:** The patient has acne with inflammatory lesions AND
	  ◦ the patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events
	
	Susceptible Infections
	• For Doryx, Doryx MPC, Acticlate, and Okebo: if used for susceptible infections, the patient has failed or had clinically significant adverse events to generic IR doxycycline
	
	Non-FDA-approved uses are NOT approved.
	PA expires in 1 year.
	
	Renewal Criteria:
	• Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Mondoxyne NL, Okebo, Solodyn or generic minocycline ER, or Minolira will be approved for an additional year, if:
	  ▪ The patient's therapy has been re-evaluated within the last 12 months
	  ▪ The patient is tolerating treatment, and there is continued medical need for the medication
	  ▪ The patient has had disease stabilization or improvement in disease on therapy
	• **Seysara: PA renewal is not allowed; repeat courses will require a new PA to be submitted**

Drug / Drug Class	Prior Authorization Criteria
• tafenoquine (Arakoda) **Antimalarials**	Manual PA criteria apply to all new users of tafenoquine (Arakoda). Manual PA Criteria: Coverage will be approved for tafenoquine (Arakoda) if all criteria are met: • Age ≥ 18 and Arakoda is being prescribed for malaria chemoprophylaxis • Patient has a contraindication or intolerance to both atovaquone-proguanil (Malarone) and doxycycline (e.g., pregnancy) • Patient does not have a major psychiatric disorder to include but not limited to: – Active or recent history of depression – Generalized anxiety disorder – Psychosis or schizophrenia – Post-Traumatic Stress Disorder or Traumatic Brain Injury • Patient does not have a history of seizures or vestibular disorders • Patient does not have a cardiac conduction abnormality • Patient has been tested and is negative for glucose 6 phosphate dehydrogenase (G6PD) deficiency • The above information must be documented in the patient's medical record, and the patient must be educated on Arakoda adverse effects and dosing Non-FDA-approved uses are NOT approved. PA expires after 2 years. PA renewal is not allowed; repeat courses will require a new PA to be submitted.
• talazoparib (Talzenna) **Oncological Agents: Breast Cancer**	Manual PA criteria apply to all new users of Talzenna. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by or consultation with a hematologist or oncologist • Patient has a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) and human epidermal growth factor receptor 2-negative (HER2-) breast cancer Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• testosterone enanthate SQ injection (Xyosted)
 	
Androgens-Anabolic Steroids: Testosterone Replacement Therapies
	February 2019 criteria specific to Xyosted are in BOLD
	
	Manual PA criteria apply to all new and current users of Xyosted.
	
	Manual PA for Xyosted requires a trial of the step-preferred product, Fortesta **and one injectable testosterone product**
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Age ≥ 18 years and male
	• Patient has documentation of experiencing signs and symptoms usually associated with hypogonadism
	• **Xyosted is prescribed for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies**
	• Diagnosis of hypogonadism is confirmed and evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions
	• Patient has one of the following criteria:
	  • Patient has tried Fortesta (testosterone 2% gel) **AND an injectable testosterone formulation for a minimum of 90 days AND** failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after Fortesta application or the injectable testosterone formulation) **AND** without improvement in symptoms
	  – OR –
	  • **Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta that is not expected to occur with the Xyosted autoinjector**
	• **The provider has considered the patient's baseline cardiovascular risk and ensured blood pressure is adequately controlled before initiating Xyosted and periodically during the course of treatment (based on the product's boxed warning of increased risk of major adverse cardiovascular events and hypertension).**
	• **Patient does not have any of the following:**
	  • **Carcinoma of the breast or suspected carcinoma of the prostate**
	
	Non-FDA-approved uses are NOT approved.
	Not approved for concomitant use with other testosterone products.
	PA does not expire.

• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**February 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Doptelet. Manual PA Criteria: Avatrombopag (Doptelet) is approved if all criteria are met: • Age ≥ 18 years • **The patient has tried and failed, or has a contraindication to, or is expected to have an intolerance to lusutrombopag (Mulpleta)** • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet count less than 50 x 10^9/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • The drug is prescribed by or in consultation with a gastroenterologist Non-FDA-approved uses are NOT approved. PA expires in 60 days.

Drug / Drug Class	Prior Authorization Criteria
• cyclobenzaprine 7.5 mg (generic) **Skeletal Muscle Relaxants and Combinations**	Manual PA criteria apply to all new and current users of cyclobenzaprine 7.5 mg tablets or capsules. Manual PA Criteria: Coverage will be approved for cyclobenzaprine 7.5 mg tablets if all criteria are met: • Cyclobenzaprine 7.5 mg tablets have been identified as having cost-effective alternatives. The provider must describe why cyclobenzaprine 7.5 mg is required as opposed to available alternatives, including generic cyclobenzaprine 5 mg tablets and cyclobenzaprine 10 mg tablets • (blank write in) Non-FDA-approved uses are NOT approved. PA does not expire.
• dexchlorpheniramine 2 mg/5 mL oral syrup (Ryclora) **Anthistamine-1: First Generation and Combinations**	Manual PA criteria apply to all new and current users of dexchlorpheniramine liquid (Ryclora). Manual PA Criteria: Coverage will be approved for dexchlorpheniramine liquid if all criteria are met: • Ryclora liquid has been identified as having cost-effective alternatives. The provider must describe why Ryclora is required as opposed to available alternatives (chlorpheniramine liquid, loratadine liquid, cetirizine liquid and fexofenadine liquid). Non-FDA-approved uses are NOT approved. PA does not expire.
• dihydroergotamine nasal spray/pump **Migraine Agents**	Manual PA criteria apply to all new users of generic dihydroergotamine (DHE) nasal spray. Note that brand Migranal nasal spray is the preferred product in the DoD. Manual PA Criteria—Coverage for generic DHE nasal spray is approved if the following criteria is met: • The provider has provided patient-specific justification as to why the brand Migranal nasal spray cannot be used.
• insulin degludec vials (Tresiba) **Basal Insulins**	Manual PA criteria apply to all new users of Tresiba vials. Manual PA Criteria: Tresiba is approved if ALL criteria are met: • Patient is age ≥ 1 year • The provider must explain why the patient cannot use Lantus (fill in the blank) • The provider must explain why the patient cannot use Toujeo (fill in the blank) Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ivabradine (Corlanor) **Miscellaneous Cardiovascular Agents**	Manual PA criteria apply to all new users of Corlanor. **Updates from the February 2019 meeting are in bold.** Manual PA Criteria: Corlanor is approved **if all of the following criteria are met:** **For Heart Failure with reduced ejection fraction** • The drug is prescribed by a cardiologist or heart failure specialist. • The patient has a diagnosis of stable, symptomatic heart failure with left ventricular ejection fraction ≤ 35%, is in sinus rhythm, and has a resting heart rate > 70 beats per minute. • The patient has heart failure symptoms despite maximal therapy of a beta blocker therapy that has been shown to have survival benefit in heart failure. ▪ Note that acceptable heart failure beta blockers and target doses include the following: metoprolol succinate ER 200 mg QD; carvedilol 25 mg BID or 50 mg BID if > 85 kg; carvedilol ER 80 mg QD; bisoprolol 10 mg QD (bisoprolol is not FDA-approved for heart failure but has proven efficacy in a large clinical trial) • OR the patient has a contraindication to beta blocker use ▪ Note that the contraindication must be listed on the Prior Authorization form. • **OR the patient has tried and experienced intolerance to a heart failure beta blocker (metoprolol succinate, carvedilol, carvedilol, bisoprolol)** **For inappropriate sinus tachycardia or postural tachycardia syndrome** • **The drug is prescribed by a cardiologist** • **The patient has a diagnosis of postural orthostatic tachycardia syndrome (POTS) and/or inappropriate sinus tachycardia (IST)** **Non-FDA-approved uses other than IST or POTS are NOT approved.** Prior authorization does not expire.
• ivacaftor (Kalydeco) **Cystic Fibrosis Agents**	**February 2019 updates are in BOLD and strikethrough.** Manual PA criteria apply to all new users of Kalydeco. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient ~~is 24 months~~ **has a diagnosis of cystic fibrosis and is being prescribed for an age appropriate population according to the FDA indication** • Patient is not homozygous for the F508del mutation in the CFTR gene • The patient has a specific CF-related gene mutation that has been detected by an FDA-approved test • **Kalydeco will not be used concomitantly or at the same time as Orkambi or Symdeko** • What is the gene mutation? (fill in the blank) Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rifaximin 200 mg (Xifaxan) **Gastrointestinal-2 Agents: Miscellaneous**	**February 2019 updates for the indication of Traveler's Diarrhea are in BOLD. No changes were made for the indications of hepatic encephalopathy or diarrhea-predominant irritable bowel syndrome (IBS-D).** Manual PA criteria apply to all new users of Xifaxan 200 mg for TD. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 12 years • Patient has a diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* • Patient does not have diarrhea complicated by fever and/or bloody stool • Patient does not have diarrhea due to pathogens other than noninvasive strains of *E. coli* • Patient has tried and failed a 3-day trial of ciprofloxacin unless a contraindication exists **or patient has tried and failed azithromycin unless a contraindication exists** **Non-FDA-approved uses are NOT approved including: small intestinal bacterial overgrowth (SIBO), non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), spontaneous bacterial peritonitis (SBP), functional dyspepsia, diabetes, cirrhosis (ascites/alcohol-related), graft vs host disease, primary sclerosing cholangitis, Celiac disease, ulcerative colitis, Crohn's disease, diverticular disease, bowel preparation, constipation, colorectal cancer prevention, opioid-induced constipation, chronic abdominal pain, or other disease states.** **PA renewal is not allowed; no refills allowed**
• ledipasvir/sofosbuvir (Harvoni authorized generic) **Hepatitis C Virus - Direct Acting Antivirals Subclass (HCV DAAs)**	**Manual PA criteria apply to all new users of ledipasvir/sofosbuvir (authorized generic for Harvoni).** Manual PA Criteria: Ledipasvir/sofosbuvir authorized generic products are approved if all of the following criteria are met: • The brand Harvoni formulation is preferred over the authorized generic product. Please provide a patient-specific justification as to why the brand Harvoni product cannot be used in this patient. (Fill in the blank) AND the patient must meet the following criteria for a HCV DAA product: • ≥ 18 years of age • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of hepatitis C virus infection • The HCV genotype is documented. (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires in 1 year.

Drug / Drug Class	Prior Authorization Criteria
• sofosbuvir/velpatasvir (**Epclusa** authorized generic) **Hepatitis C Virus - Direct Acting Antivirals Subclass (HCV DAAs)**	**Manual PA criteria apply to all new users of sofosbuvir/velpatasvir (authorized generic for Epclusa).** Manual PA Criteria: sofosbuvir/velpatasvir authorized generic products are approved if all of the following criteria are met: • The brand Epclusa formulation is preferred over the authorized generic product. Please provide a patient-specific justification as to why the brand **Epclusa** product cannot be used in this patient. (Fill in the blank) AND the patient must meet the following criteria for a HCV DAA product: • ≥ 18 years of age • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of hepatitis C virus infection • The HCV genotype is documented. (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires in 1 year.

Drug / Drug Class	Prior Authorization Criteria
• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs) – Tumor Necrosis Factor (TNF) Inhibitors**	Prior Authorization criteria originally approved August 2014 and implemented February 18, 2015. PA updated November 2015, November 2016, and November 2018 to reflect indication changes. **February 2019 updates are in BOLD** Manual PA criteria apply to all new users of Humira. <u>Manual PA Criteria</u>: Coverage is approved for Humira if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy. • Moderate to severely active Crohn's disease (CD). • Moderate to severely active ulcerative colitis (UC). • Moderate to severe hidradenitis suppurativa (HS). • Non-infectious intermediate, posterior, and panuveitis. Coverage approved for pediatric patients ≥ 6 years with: • Moderate to severely active Crohn's disease. Coverage approved for pediatric patients ≥ 12 years with: • **Moderate to severe hidradenitis suppurativa (HS).** Coverage approved for pediatric patients 2-17 years with: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA). • Non-infectious intermediate, posterior, and panuveitis. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? • AS only: Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Coverage for off-label uses not listed above. Please provide diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara) abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Drug / Drug Class	Prior Authorization Criteria
• anakinra (Kineret) **Targeted Immunomodulatory Biologics (TIBs) – Non-Tumor Necrosis Factor (TNF) Inhibitors**	**February 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Kineret. <u>Manual PA Criteria:</u> Coverage is approved for Kineret if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis Coverage approved for pediatric patients (all ages) with (Trial of Humira not required.): • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) • Cryopyrin Associated Period Syndrome (CAPS) or • **Systemic Juvenile Idiopathic Arthritis (sJIA)** • Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications. Has the patient tried Humira? • The patient has a contraindication to Humira (adalimumab) OR • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are NOT approved. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (**Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).**

Drug / Drug Class	Prior Authorization Criteria
• tocilizumab (Actemra ACTPen) **Targeted Immunomodulatory Biologics (TIBs) – Non-tumor Necrosis Factor Inhibitors**	Manual PA criteria apply to all new users of Actemra ACTPen, similar to other Actemra formulations. <u>Manual PA Criteria</u>: If automated criteria are not met: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs). • Giant cell arthritis (GCA) (Trial of Humira not required.) Coverage approved for pediatric patients ≥ 2 years with: • Active polyarticular juvenile idiopathic arthritis (PJIA) • Systemic juvenile idiopathic arthritis (SJIA) • Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications. • The patient has a contraindication to Humira (adalimumab) OR • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • Patient has been stable on an IV Actemra with continuous use in the last 3 months and needs to transition to the SQ formulation of Actemra. • Patient's platelet count is ≥ 100,000 per mm³ AND ALT/AST ≤ 1.5 times ULN • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are NOT approved. Prior Authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• fremanezumab-vfrm (Ajovy) **CGRP Prophylaxis Subclass**	▪ Retail: 1 syringe per fill (allow multiple copays for multiple refills) ▪ MTF/Mail: 3 syringes per fill Note that the QL changes will be implemented when the PA is implemented 30 days after signing of the minutes.
• galcanezumab-gnlm (Emgality) **CGRP Prophylaxis Subclass**	▪ Retail: 1 syringe or pen per fill; 2 syringes allowed for loading dose in PA (allow multiple copays for multiple refills) ▪ MTF/Mail: 3 syringes or pens per fill Note that the QL changes will be implemented when the PA is implemented 30 days after signing of the minutes.
• erenumab-aooe (Aimovig) 70 mg and 140 mg **CGRP Prophylaxis Subclass**	▪ Retail: 1 syringe or pen per fill (allow multiple copays for multiple refills) ▪ MTF/Mail: 3 syringes per fill Note that the QL changes will be implemented when the PA is implemented 30 days after signing of the minutes.
• abiraterone acetate micronized (Yonsa) • abiraterone acetate (Zytiga, generics) **Oncological Agents: CYP-17 Inhibitors**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply Note that the QL changes will be implemented when the PA is implemented 90 days after signing of the minutes.
• enzalutamide (Xtandi) • apalutamide (Erleada) **Oncological Agents: 2nd-Generation Antiandrogens**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply
• baloxavir marboxil (Xofluza) **Antivirals**	▪ MTF/Mail/Retail: 1 package per fill ▪ No refills allowed
• cenegermin-bkbj (Oxervate) **Anti-inflammatory Immunomodulatory Ophthalmic Agents**	▪ MTF/Mail/Retail: 56-day supply

Drug / Drug Class	Quantity Limits
• cyclosporine 0.09% ophthalmic (Cequa) **Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Immunomodulatory Agents**	▪ Retail: 60 vials (1 carton) per fill ▪ MTF/Mail: 180 vials (3 cartons) per fill
• gilteritinib (Xospata) **Oncological Agents: Acute Myelogenous Leukemia**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• glasdegib (Daurismo) **Oncological Agents: Acute Myelogenous Leukemia**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• inotersen injection (Tegsedi) **Neurological Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply
• ivacaftor (Kalydeco) tablets **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 30-day supply
• larotrectinib (Vitrakvi) capsules **Oncological Agents**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• larotrectinib (Vitrakvi) oral solution **Oncological Agents**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• lorlatinib (Lorbrena) **Oncological Agents: Lung Cancer**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• pegfilgrastim-cbqv (Udenyca) **Hematological Agents: White Blood Cell Stimulants**	▪ Retail: 1 syringe per fill and 21-day supply ▪ MTF/Mail: 2 syringes per fill and 45-day supply
• revefenacin (Yupelri) **Pulmonary-2: Long Acting Muscarinic Antagonists (LAMAs)**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply

Drug / Drug Class	Quantity Limits
• rifamycin (Aemcolo) **Gastrointestinal-2 Agents: Miscellaneous**	▪ MTF/Mail/Retail: 12 tabs per fill ▪ No refills allowed
• riluzole oral suspension (Tiglutik) **Neurological Agents Miscellaneous**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• testosterone enanthate (Xyosted) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	▪ Retail: 4 syringes per fill and 28-day supply ▪ MTF/Mail: 12 syringes per fill and 84-day supply
• talazoparib (Talzenna) **Oncological Agents: Breast Cancer**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• tafenoquine (Krintafel) **Antimalarials**	▪ MTF/Mail/Retail: 2 tabs per fill

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
amifampridine (Firdapse)	Neurological Agents Miscellaneous	• None	Lambert-Eaton myasthenic syndrome (LEMS)	• Firdapse is the first FDA-approved drug for the treatment of LEMS in the United States. • Amifampridine was previously approved by the European Commission as an orphan drug in December of 2002. • The active ingredient was previously available as a compounded formulation, which is no longer available, given the FDA approval of Firdapse. • Firdapse may cause seizures, including in patients with no prior history. • Use Firdapse with caution in patients with uncontrolled asthma and in patients with congenital QT syndromes or a prolonged QT interval. • Firdapse is the first-line option for a very rare disorder, but should be only be prescribed with a diagnosis of LEMS by an oncologist or neurologist.	• UF • Do not add to EMMPI list
aripiprazole tablet with ingestible event marker (Abilify MyCite)	Antipsychotic Agents: Atypical	• Aripiprazole oral tab • Abilify Maintena ER monthly depot	Bipolar I disorder, irritability with autistic disorder, major depressive disorder, schizophrenia, Tourette's	• Abilify MyCite is a new formulation of aripiprazole that contains an ingestible event marker (IEM) to monitor adherence and a patch to collect the data. • This is the first drug approved using the IEM technology. • Despite its marketing strategy to improve patient adherence, no studies assessing patient adherence were conducted with Abilify MyCite. • Aside from the ability to send data to HCPs, Abilify MyCite provides no compelling advantage over existing formulary agents.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
baloxavir (Xofluza)	Antivirals	• oseltamivir (Tamiflu)	Influenza	• Xofluza is the first polymerase acidic endonuclease inhibitor and fourth FDA-approved agent for Influenza virus strains A and B. • It is given as a single dose given within 48 hours for the treatment of acute, uncomplicated influenza in patients 12 years and older. • Approval occurred via an expedited 505(b) pathway. • In 2 clinical efficacy trials, Xofluza treatment at the recommended dose resulted in a statistically significant shorter time to alleviation of symptoms compared with placebo by about 24 hours (50 hrs with Xofluza vs. 78 hrs with placebo). • In 1 clinical efficacy trial, there was no difference in the time to alleviation of symptoms between subjects who received Xofluza and oseltamivir; both drugs alleviated symptoms by 54 hours. • Compared to placebo, Xofluza does not produce an increased adverse event profile. • Xofluza reduces flu symptoms for the same duration as Tamiflu, is administered as a single dose, and has a mild side effect profile, but is lacking data regarding pediatric efficacy and prophylactic studies.	• UF • Do not add to EMMPI list
cenegermin-bkbj ophthalmic solution (Oxervate)	Antiinflammatory Immunomodulatory Ophthalmic Agents	• None	Neurotrophic keratitis	• Oxervate is a biologic ophthalmic solution that is recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (NK). • Oxervate is the first drug approved for NK. • Clinical trials were conducted in relatively small numbers of patients; however, rates of complete corneal healing were statistically significant compared to vehicle. • Long-term safety has not been established. • Most common ADRs include eye pain, ocular hyperemia, eye inflammation, and increased lacrimation. • Oxervate demonstrated superior healing rates and has a unique place in therapy for this rare ocular condition.	• UF • Do not add to EMMPI list
clobazam oral film (Sympazan)	Anticonvulsants-Antimania Agents	• clobazam (Onfi) tablets and suspension	Indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older	• Clobazam (as a tablet, oral suspension, or film) is one option for adjunctive treatment of patients with Lennox-Gastaut Syndrome. • Sympazan is a new oral film formulation that has comparable bioavailability to clobazam tablets (Onfi) and oral suspension. • Approved based on bioequivalence with Onfi tablets and two adjunctive treatment studies showing statistically significant improvement in drop seizures. • Sympazan provides no compelling advantage over clobazam tablets and suspension.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
cyclosporine 0.09% ophthalmic solution (Cequa)	Antiinflammatory Immuno-modulatory Ophthalmic Agents: Ophthalmic Immuno-modulatory Agents	• cyclosporine 0.05% ophthalmic emulsion (Restasis unit dose and multidose) • lifitegrast 5% ophthalmic solution (Xiidra)	Dry eye disease	• Cequa is the third medication approved for the treatment of dry eye disease and the second cyclosporine ophthalmic for dry eye disease after Restasis. • Although Cequa is statistically superior to placebo based on the Schirmer Tear Test, it did not meet the minimal clinically important difference (MCID) for this endpoint versus placebo. • Similar safety profile to Restasis and Xiidra. • No compelling advantages over existing medications.	• NF • Add to EMMPI list
desmopressin acetate SL tablet (Nocdurna)	Endocrine Agents Miscellaneous	• desmopressin oral tab • desmopressin nasal • Noctiva nasal	Nocturia due to nocturnal polyuria	• Nocdurna is a new sublingual formulation of desmopressin indicated for nocturia due to nocturnal polyuria in adults. • Nocdurna was evaluated in a 4-week and two 12-week placebo-controlled, phase III studies. • Sex-specific dosing of Nocdurna was statistically superior to placebo in reducing the average number of nocturic episodes per night from baseline; however, clinical relevance is questionable. • Significant placebo effect. • Three initial studies submitted to the FDA did not lead to approval. • Significant safety concerns exist, including a black box warning for risk of hyponatremia and drug interactions; there is an increased risk of serious AEs with increased age. • There is little to no clinical benefit of Nocdurna and significant safety concerns exist.	• NF • Add to EMMPI list
elapegademase-lvlr IM injection (Revcovi)	Metabolic Replacement Agents Miscellaneous	• pegademase bovine (Adagen) IM solution	Adenosine deaminase severe combined immune deficiency (ADA-SCID)	• Revcovi is the second drug available to treat ADA-SCID. • Two small, open-label studies showed improvements in disease severity and immune function. • Revcovi provides an additional option to treat a very rare disorder.	• UF • Do not add to EMMPI list
tbo-filgrastim (Granix vials)	Hematological Agents: WBC stimulants	• Granix syringes • Neupogen • Zarxio • Nivestym	Neupogen Biosimilar	• Granix is a biosimilar to Neupogen. • The vials are a new formulation in addition to the previously available pre-filled syringes. • No new clinical data was submitted for approval of the vials. • Provides no compelling clinical advantages over existing filgrastim formulary agents.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
gilteritinib (Xospata)	Oncological Agents: Acute Myelogenous Leukemia	• midostaurin (Rydapt)	AML, FLT3 mutation	• Second kinase inhibitor indicated for AML with an FLT3 mutation, but first for relapsed/remitting AML. • Three trials supporting efficacy with interim analysis of phase III RCT, ADMIRAL, showing superior efficacy to salvage chemo regimens. • Extensive safety profile but not significantly different from other kinase inhibitors. • Overall well tolerated with rare serious adverse events requiring discontinuation.	• UF • Do not add to EMMPI list
glasdegib (Daurismo)	Oncological Agents: Acute Myelogenous Leukemia	• None	AML	• First-in-class agent for AML inhibiting Sonic Hedgehog (SHH) pathway. • Approved for use in newly diagnosed AML alongside low-dose cytarabine in select populations including patients ≥ 75 years old and those who cannot tolerate intensive standard-of-care induction regimens, e.g. 7+3 (cytarabine + daunorubicin). • Limitations include insufficient data to determine impact of severe renal impairment (50% renal clearance) and moderate to severe hepatic impairment (83% metabolized primarily via CYP3A4).	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
halobetasol propionate 0.01% lotion (Bryhali)	Corticosteroids-Immune Modulators: High Potency	• clobetasol 0.05% cream & ointment • fluocinonide 0.05% cream & oint (Lidex) • betamethasone dipropionate augmented 0.05% cream, ointment, **gel,** & **lotion** (Diprolene, Diprolene AF, generics) • clobetasol 0.05% **solution**, **foam**, **gel**, **shampoo**, **lotion,** & spray (Clobex, Olux) • **halobetasol propionate 0.05%** cream, ointment, **foam,** & combinations (Halonate, Ultravate, generics)	Plaque psoriasis	• Bryhali is another formulation of halobetasol propionate in a lotion formulation. • There are 28 other high-potency topical corticosteroid options on the BCF and UF and at least 12 other agents that are appropriate for scalp use. • Topical steroids are highly interchangeable within potency classes (e.g., high, medium and low) and vehicle (e.g., lotion, foam, shampoo). • Bryhali has little to no clinical benefit relative to similar drugs on the formulary.	• NF • Add to EMMPI list
halobetasol propionate 0.05% foam (Lexette)	Corticosteroids-Immune Modulators: High Potency	• Same comparators as Bryhali	Plaque psoriasis	• Lexette is another formulation of halobetasol propionate in a foam vehicle. • There are 28 other high-potency topical corticosteroid options on the BCF and UF and at least 12 other agents that are appropriate for scalp use. • Topical steroids are highly interchangeable within potency classes (e.g., high, medium, low) and vehicle. • Lexette has little to no clinical benefit relative to similar drugs on the formulary.	• Tier 4 (Not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
inotersen injection (Tegsedi)	Neurological Agents Miscellaneous	• patisiran (Onpattro) – medical benefit	Hereditary Transthyretin Amyloidosis	• Second siRNA treatment for hereditary transthyretin (hTTR) amyloidosis; first pharmacy benefit agent. • Indicated for neuropathy secondary to hTTR amyloidosis. • Statistically and clinically meaningful efficacy in lowering transthyretin levels. • Significant safety concerns include a disproportionate death rate in the Tegsedi arm, numerous serious ADRs, and a black box warning and REMS program.	• UF • Do not add to EMMPI list
itraconazole 65 mg capsules (Tolsura)	Antifungals	• itraconazole 100 mg caps and 200 mg tablets (Sporanox)	Fungal infections in adults including blastomycosis, histoplasmosis, and aspergillosis.	• Tolsura is the third itraconazole formulation available currently on the US market including one suspension and 100 mg capsule. • Administration of Tolsura (2 x 65 mg capsules) with food results in exposures similar to those achieved when itraconazole 2 x 100 mg capsule is administered with food. • No new efficacy studies were submitted for Tolsura FDA approval. • Tolsura carries traditional itraconazole warnings and precautions and provides little to no clinical benefit relative to similar drugs on the formulary.	• NF • Do not add to EMMPI list
larotrectinib (Vitrakvi)	Oncological Agents	• None	Kinase inhibitor for solid tumors	• New multi-kinase inhibitor designated as first-in-class agent. • First oncologic agent approved for molecular target absent a cancer subtype. • Promising results but studies are limited. • Overall, well tolerated with favorable safety profile relative to many intensive chemotherapeutic regimens.	• UF • Do not add to EMMPI list
latanoprost 0.005% ophthalmic emulsion (Xelpros)	Glaucoma Agents	• latanoprost 0.005% ophthalmic solution (Xalatan) • latanoprostene bunod 0.024% ophthalmic solution (Vyzulta)	Glaucoma or ocular hypertension (HTN)	• Third prostaglandin analog without benzalkonium chloride (BAK) as its preservative. • Xelpros was approved through the 505(b)(2) pathway and is the third latanoprost-like agent approved by the FDA. • No new efficacy data was published, and the package insert suggests similar efficacy and safety compared with Xalatan. • This is another option for patients with BAK allergy or sensitivity. Other BAK-free agents are tafluprost and travoprost. • Despite being BAK-free, Xelpros provides no compelling advantages over current available therapy.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lorlatinib (Lorbrena)	Oncological Agents: Lung Cancer	• alectinib (Alecensa) • crizotinib (Xalkori) • ceritinib (Zykadia) • brigatinib (Alunbrig)	Anaplastic lymphoma kinase (ALK)-positive, metastatic, non-small cell lung cancer (NSCLC) patients who have progressed after one of the following: 1. crizotinib and one other ALK inhibitor 2. alectinib as first-line ALK inhibitor therapy 3. ceritinib as first-line ALK inhibitor therapy	• Fifth ALK inhibitor (ALK-I) available to treat NSCLC. • First third-generation ALK-I indicated for patients with ALK inhibitor resistance. • Indicated for patients who have progressed after second-generation ALK-I treatment, with or without prior crizotinib. • Evaluated for efficacy in 1 single-arm, open-label study, NCT01970865. • As second-line therapy, lorlatinib provided an objective response in 47% of patients. • When used as a third-line agent, lorlatinib demonstrated a 38.7% objective response. • There are currently no head-to-head studies with other ALK inhibitors. • Has a higher risk of weight gain (16%), hypercholesterolemia (66%), and hypertriglyceridemia (45%) and a lower risk of interstitial lung disease (< 1%), compared to other ALK inhibitors. • Lorlatinib provides an additional treatment option for ALK+ NSCLC and is the first agent approved for third-line care or second-line after a second-generation ALK inhibitor.	• UF • Do not add to EMMPI list
loteprednol 1% ophthalmic suspension (Inveltys)	Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Anti-inflammatory Agents	• loteprednol 0.5% (Lotemax) • prednisolone 1% (Pred Forte)	For the treatment of post-operative inflammation and pain following ocular surgery	• Inveltys is another formulation of loteprednol for post-surgery pain and inflammation. • Clinical trials showed superiority at decreasing inflammation and pain compared to placebo at day 15. • Inveltys is the only BID formulation in the ophthalmic anti-inflammatory subclass. All others are typically dosed QID. • No compelling clinical advantage over available agents, other than less frequent dosing.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
omadacycline (Nuzyra)	Antibiotics: Tetracycline	• doxycycline 100 mg tablets	Community-acquired bacterial pneumonia (CABP)/acute bacterial skin and skin structure infections (ABSSSI)	• Nuzyra is a novel tetracycline with potent broad-spectrum activity against infectious pathogens that cause CABP or ABSSSI. • Like doxycycline, omadacycline's pharmacokinetic profile allows for once-daily dosing and lung penetration and lacks requirements for renal dose adjustments. • Requires administration on an empty stomach similar to other tetracyclines/doxycycline. • Three Phase III non-inferiority trials: OASIS, OASIS-2, and OPTIC studies compared Nuzyra in head-to-head vs standard-of-care agents for CABP and ABSSSI. • Similar safety profile to doxycycline with nausea and vomiting occurring most frequently. • Nuzyra coverage mimics other tetracyclines: no *C. diff.*-associated diarrhea was observed in clinical trials; coverage includes gram-positive, gram-negative, atypical, aerobic, and anaerobic bacteria. • In the OPTIC trial, omadacycline was associated with a higher mortality rate (n=8; 2%) compared to moxifloxacin (n=4; 1%). The FDA is requiring additional postmarketing studies regarding mortality difference. • There are numerous cost-effective antibiotics available on the formulary that do not carry additional safety risk.	• NF • Do not add to EMMPI list
pegfilgrastim-cbqv injection (Udenyca)	Hematological Agents: WBC Stimulants	• Neulasta • Fulphila	Biosimilar to Neulasta	• Udenyca is a biosimilar to Neulasta. • No new clinical data was submitted for approval of Udenyca. • Provides no compelling clinical advantages over existing formulary pegfilgrastims.	• UF • Add to EMMPI list
revefenacin nebulized solution (Yupelri)	Pulm-2: LAMAs	• tiotropium soft mist inhaler (Spiriva Respimat) • glyco-pyrrolate nebulized solution (Lonhala Magnair)	For the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	• Sixth LAMA and the second nebulized LAMA but provides no advantage over Spiriva Respimat, a soft mist inhaler (SMI), which does not require inspiratory flow of ≥ 60 L/min. • In RCTs, the increases in trough FEV_1 with Yupelri were superior to the increases seen with placebo. • Yupelri provides no compelling clinical advantages over other agents in the class.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
rifamycin (Aemcolo)	GI-2: Miscellaneous	• ciprofloxacin 500 mg BID x 3 days or 750 mg once • azithromycin 1 gm once • rifaximin 200 mg TID x 3 days	Traveler's diarrhea	• Aemcolo is a new non-systemically absorbed oral antibiotic indicated for the treatment of traveler's diarrhea caused by non-invasive strains of *E. coli* in adults. Mechanism is similar to rifaximin (Xifaxin), which is also indicated for traveler's diarrhea. • Available in an enteric-coated tablet that delivers the active ingredient to the distal small bowel and colon. • Dosing is 2 x 194 mg tablets given twice daily for 3 days. • One placebo-controlled study showed the time to last unformed stool was about 24 hours sooner with Aemcolo versus placebo (26 hours vs. 68 hours). Clinical cure was seen in 81.4% of Aemcolo-treated subjects compared to 56.9% with placebo. Both endpoints were statistically significant. • Has not been compared head-to-head with other agents indicated for traveler's diarrhea. • ADR profile is benign. • IDSA guidelines currently recommend use of either a fluoroquinolone or azithromycin, depending on susceptibility patterns and travel history. • Aemcolo offers an additional treatment option for traveler's diarrhea; however, it provides no compelling clinical advantages over existing formulary agents.	• NF • Do not add to EMMPI list
riluzole oral suspension (Tiglutik)	Neurological Agents Miscellaneous	• riluzole oral tablets	Amyotrophic lateral sclerosis (ALS)	• Tiglutik is a new formulation of riluzole in an oral suspension approved for ALS. • No new clinical trials were conducted on riluzole oral suspension; pharmacokinetics demonstrated equivalence with oral tablets. • Riluzole has the potential for off-label use, including in psychiatric disorders. • Riluzole oral suspension provides an option other than crushing tablets for patients with dysphagia/swallowing difficulties.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
sarecycline (Seysara)	Antibiotics: Tetracycline	• doxycycline 100 mg • minocycline 100 mg	Acne	• Sarecycline is a narrow spectrum tetracycline-derived antibiotic approved for the treatment of moderate to severe acne. • Doxycycline IR generics and minocycline IR generics are step-preferred in this class. • 21st tetracycline agent approved for moderate to severe acne vulgaris studied in patients aged 9–45 years. • Once-daily dosing, pregnancy restrictions, and dose adjustments are similar to doxycycline or minocycline; Seysara has less gram-negative coverage. • There are no head-to-head trials of sarecycline vs other tetracycline agents to show improved efficacy, safety, or clinical importance of surpassing bacterial resistance mechanisms. • Use beyond 12 weeks and safety beyond 12 months have not been established. • Although Seysara may provide a theoretical benefit, acne vulgaris is rarely cultured to investigate resistance, and there are many cost-effective alternatives on the formulary. • Seysara provides little to no clinical benefit over formulary alternatives.	• NF • Add to EMMPI list
tafenoquine 100 mg tablet (Arakoda)	Antimalarials	• doxycycline • atovaquone/ proguanil (Malarone) • mefloquine	Antimalarial for chemoprophylaxis	• New formulation of tafenoquine approved for chemoprophylaxis of malaria that is dosed once weekly. • Arakoda was evaluated in 2 trials. In a phase III trial, Arakoda was non-inferior to mefloquine in 615 patients. In a phase IIb trial, Arakoda was more effective at treating malaria compared to placebo. • The most common ADRs include dizziness, GI complications, headache, psychiatric events, and decreased hemoglobin. • Arakoda-specific ADR includes increased alanine aminotransferase (ALT). • Arakoda showed non-inferiority in a head-to-head trial vs mefloquine, allows for weekly dosing, and no cases of resistance have been seen to date; however, it has a similar lead time to doxycycline and Malarone, both which have a mild side effect profile. • Arakoda offers a compelling clinical advantage in terms of weekly dosing and its ability to kill all types of plasmodium, but there is insufficient data regarding adverse events, particularly surrounding psychiatric adverse events.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tafenoquine 150 mg tablet (Krintafel)	Antimalarials	• primaquine	Antimalarial for prevention of relapse/radical cure	• Krintafel is a new formulation of tafenoquine indicated for radical cure of *P. vivax* malaria in combination with a second antimalarial agent; it is NOT approved for malaria prophylaxis. • Krintafel has a higher relapse-free rate than chloroquine plus primaquine or primaquine alone. • The most common ADRs include dizziness, GI complications, headache, psychiatric events, and decreased hemoglobin. • The tafenoquine resistance profile is unknown; however, some multidrug-resistant strains of malaria have been successfully treated with tafenoquine in combination with another agent. • Krintafel currently provides an additional option for curing of malaria relative to other drugs on the formulary.	• UF • Do not add to EMMPI list
talazoparib (Talzenna)	Oncological Agents: Breast Cancer	• olaparib (Lynparza)	Treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer	• Talzenna is the fourth available PARP inhibitor and the second PARP inhibitor indicated for breast cancer; however, it is the only PARP inhibitor option that can be used regardless of chemotherapy history. • The primary endpoint of progression-free survival was statistically significant in comparison to standard chemotherapy treatment in the EMBRACA trial. • The secondary endpoint of overall survival was not statistically significant compared to chemotherapy. • No head-to-head studies with other PARP inhibitors were conducted. • Most common ADRs (> 20% occurrence) include: anemia, neutropenia, thrombocytopenia, decreased appetite, headache, nausea, vomiting, diarrhea, alopecia, and fatigue. • Talazoparib provides a minimal improvement to progression-free survival, without a statistically significant mortality benefit. • The PARP inhibitor appeared to be very effective at enhancing quality of life; however, the quality of life metrics were exploratory and not designed to appropriately detect significance. • This drug offers minimal advantages in clinical efficacy relative to existing treatment options.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
testosterone enanthate, SQ injection (Xyosted)	Androgens-Anabolic Steroids: Testosterone Replacement Therapies	**Injectables (vial):** •T. enanthate •T. cypionate •T. undecanoate (Med benefit) **Non-injectables:** •Fortesta gel •Androderm patch •Androgel •Natesto nasal spray	Male testosterone replacement therapy	• Xyosted is the fourth testosterone replacement therapy (TRT) injection on the market and first autoinjector for subcutaneous use. • Xyosted is dosed once weekly for subcutaneous administration in the abdominal region. • Unlike the other TRTs, Xyosted requires monitoring for HTN due to boxed warnings of: ↑ risk of HTN and ↑ risk for major adverse CV events (MACE). • Other than being a self-injectable drug, it provides no compelling advantage over other injectable and non-injectable testosterone products available on the formulary.	• UF and non-step-preferred • Add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary During the February 2019 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Do NOT Add to the Mail Order Requirement (Excepted from Mail Order Requirement)
February 2019	**Basal Insulins:** ▪ insulin degludec (Tresiba) vials **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Assuming mail order availability:* ▪ testosterone enanthate SQ injection (Xyosted) ▪ pegfilgrastim injection (Udenyca) **Designated NF:** *No reason to exempt from EMMPI requirement:* ▪ sarecycline (Seysara) ▪ revefenacin (Yupelri) ▪ desmopressin acetate sublingual (Nocdurna) ▪ filgrastim (Granix) vials ▪ halobetasol propionate 0.01% lotion (Bryhali) ▪ clobazam oral film (Sympazan) ▪ latanoprost 0.005% ophthalmic emulsion (Xelpros) ▪ cyclosporine 0.09% ophthalmic solution (Cequa)	**2nd-generation antihistamines** *Comparable pricing at mail order vs MTFs or retail:* ▪ levocetirizine (Xyzal; generics) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Not yet clear if feasible to provide through mail order:* ▪ elapegademase (Revcovi) ▪ cenegermin ophthalmic solution (Oxervate) ▪ talazoparib (Talzenna) ▪ lorlatinib (Lorbrena) ▪ larotrectinib (Vitrakvi) ▪ glasdegib (Daurismo) ▪ gilteritinib (Xospata) ▪ inotersen (Tegsedi) ▪ tafenoquine (Arakoda) for malaria prophylaxis ▪ amifampridine (Firdapse) limited distribution ▪ riluzole oral suspension (Tiglutik) *Drugs for acute or limited duration use*: ▪ baloxavir (Xofluza) for influenza ▪ tafenoquine (Krintafel) for radical cure of *Plasmodium vivax* malaria ▪ loteprednol ophthalmic (Inveltys), for inflammation and pain after ocular surgery **Drugs designated NF:** *Acute use exception applies:* ▪ rifamycin (Aemcolo) for traveler's diarrhea ▪ omadacycline (Nuzyra) for CABP and ABSSSI ▪ itraconazole 65 mg capsules (Tolsura) for invasive fungal infections *Existing exception applies:* ▪ aripiprazole tablet with ingestible event marker (Abilify MyCite), antipsychotic exception

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2019	**Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass**	UF Class Review	▪ None. Note that a CGRP was not selected for the BCF. ▪ Sumatriptan and rizatriptan are currently on the BCF for treatment of migraines.	▪ erenumab-aooe injection (Aimovig) ▪ fremanezumab-vfrm injection (Ajovy) ▪ galcanezumab-gnlm injection (Emgality)	▪ None	Pending signing of the minutes / 30 days The effective date is May 29, 2019.	▪ Manual PA criteria applies to all new users	▪ See Appendix C for PA criteria.
Feb 2019	**Prostate Cancer Agents: CYP-17 Inhibitors Subclass and 2nd-Generation Antiandrogen Subclass**	UF Class Review Class previously reviewed in Feb 2015	▪ None. Note that no BCF selection was made for the 2 subclasses. ▪ bicalutamide (Casodex, generics) are currently on the BCF for prostate cancer. (Feb 2015)	CYP-17 Inhibitors *Step-preferred* ▪ abiraterone acetate micronized (Yonsa) *Non-step-preferred* ▪ abiraterone acetate (Zytiga, generics) 2nd-Generation Antiandrogens *Step-preferred* ▪ enzalutamide (Xtandi) *Non-step-preferred* ▪ apalutamide (Erleada)	▪ None	Pending signing of the minutes / 90 days The effective date is July 31, 2019.	▪ Manual PA required ▪ QLs apply	▪ Yonsa and Xtandi will be Tier 1 copay/cost-shared. ▪ See Appendix C for full PA criteria and step therapy requirements.

TRICARE Formulary Search tool: http://www.express-scripts.com/tricareformulary

Appendix H—Table of Abbreviations

Term	Definition	Term	Definition
AA	Antiandrogen	CKD	chronic kidney disease
AASLD	American Association for the Study of Liver Diseases	CMA	cost minimization analysis
ABSSSI	acute bacterial skin and skin structure infection	COPD	chronic obstructive pulmonary disease
ADA-SCID	adenosine deaminase severe combined immune deficiency	CV	cardiovascular
ADR	adverse reaction	CYP 17	cytochrome P450 17α−hydroxylase/17,20-lyase enzyme
AE	adverse event	DAA	direct-acting antiviral
AHS	American Headache Society	DHA	Defense Health Agency
ALK	anaplastic lymphoma kinase	DHE	dihydroergotamine
ALS	amyotrophic lateral sclerosis	DMARD	disease-modifying anti-rheumatic drug
ALT	alanine aminotransferase	DoD	Department of Defense
AML	Acute Myelogenous Leukemia	DR	delayed release
ANCA	antineutrophil cytoplasmic antibody-associated	ECF	Extended Core Formulary
ANDA	abbreviated new drug application	EGFR	epidermal growth factor receptor
ARI	alpha reductase inhibitor	EMMPI	The Expanded MTF/Mail Pharmacy Initiative
AS	ankylosing spondylitis	ER	extended release
AST	aspartate aminotransferase	ESI	Express Scripts, Inc.
AUA	American Urological Association	FAP	familial amyloid polyneuropathy
BAK	benzalkonium chloride	FDA	U.S. Food and Drug Administration
BCF	Basic Core Formulary	FEV_1	forced expiratory volume in one second
BIA	budget impact analysis	FMB	Formulary Management Branch
BOO	bladder outlet obstruction	FMS FLT3	Ferline McDonough Sarcoma-like tyrosine kinase 3 mutation
CABP	community-acquired bacterial pneumonia	FY	fiscal year
CAPS	Cryopyrin Associated Period Syndrome	G6PD	glucose-6-phosphate dehydrogenase
CD	Crohn's Disease	gBRCAm	germline BRCA-mutated
CF	cystic fibrosis	GCA	giant cell arthritis
CFR	Code of Federal Regulations	GI	gastrointestinal
CFTR	cystic fibrosis transmembrane conductor regulator	GnRH	gonadotropin-releasing hormone
CGRP	calcitonin gene-related peptide	HCP	health care provider
CHF	chronic heart failure	HCV	hepatitis C virus

Term	Definition	Term	Definition
HER2-	human epidermal growth factor receptor 2 negative	NAFLD	non-alcoholic fatty liver disease
HIT-6	Headache Impact Test	NASH	non-alcoholic steatohepatitis
HS	hidradenitis suppurativa	NCCN	National Comprehensive Cancer Network
HSPC	hormone-sensitive prostate cancer	NDA	New drug application
HTN	hypertension	NDAA	National Defense Authorization Act
hTTRA	hereditary transthyretin amyloidosis	NDC	National Drug Code
IBD	inflammatory bowel disease	NF	nonformulary
IBS-D	diarrhea-predominant irritable bowel syndrome	NIH	National Institutes of Health
ICER	Institute for Clinical and Economic Review	NK	neurotrophic keratitis
IDSA	Infectious Diseases Society of America	nmCRPC	non-metastatic castration-resistant prostate cancer
IEM	ingestible event marker	NOMID	Neonatal-Onset Multisystem Inflammatory Disease
IM	intramuscular	NSAID	nonsteroidal anti-inflammatory drug
IR	immediate release	NSCLC	non-small cell lung cancer
IST	inappropriate sinus tachycardia	NTRK	neurotrophic tropomyosin receptor kinase
ITP	immune thrombocytopenic purpura	OA	osteoarthritis
IV	intravenous	OTC	over-the-counter
LAMA	long-acting muscarinic antagonist	P&T	Pharmacy and Therapeutics
LEMS	Lambert-Eaton myasthenic syndrome	PA	prior authorization
LGS	Lennox-Gastaut syndrome	PARP	poly ADP-ribose polymerase
MACE	major adverse cardiovascular events	PERT	Pancreatic Enzymes Replacement Therapy drug class
MCID	minimal clinically important difference	PJIA	polyarticular juvenile idiopathic arthritis
mCRPC	metastatic castration-resistant prostate cancer	PND	polyneuropathy disability
mCSPC	metastatic castration-sensitive prostate cancer	POD	Pharmacy Operations Division
MFS	metastasis-free survival	POS	point of service
MHS	Military Health System	POTS	postural tachycardia syndrome
MIDAS	Migraine Disability Assessment	PPI	proton pump inhibitor
MMD	monthly migraine days	PRES	posterior reversible encephalopathy syndrome
MN	medical necessity	Ps	plaque psoriasis
MPFID	Migraine Physical Functional Impact Diary	PsA	psoriatic arthritis
MTF	Military Treatment Facility	PSA	prostate-specific antigen

Term	Definition	Term	Definition
PSADT	prostate-specific antigen doubling time	SNRI	serotonin and norepinephrine reuptake inhibitor
QL	quantity limit	SQ	subcutaneous
RA	Rheumatoid arthritis	SSRI	selective serotonin reuptake inhibitor
RCT	randomized controlled trial	TB	tuberculosis
REMS	Risk Evaluation and Mitigation Strategies	TD	traveler's diarrhea
SBP	spontaneous bacterial peritonitis	TIBs	targeted immunomodulatory biologics
SGLT2	sodium-glucose cotransporter-2 inhibitor	TNF	tumor necrosis factor
SHH	Sonic Hedgehog	TRT	testosterone replacement therapy
SIADH	syndrome of inappropriate antidiuretic hormone secretion	UC	Ulcerative colitis
SIBO	small intestinal bacterial overgrowth	UF	Uniform Formulary
siRNA	small interfering Ribonucleic Acid	ULN	upper limit normal
SJIA	systemic juvenile idiopathic arthritis	WBC	White blood cell
SL	sublingual	XR	extended release
SMI	soft mist inhaler		