DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2018

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 7 and 8, 2018, 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 2017 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2017 DoD P&T Committee meeting on January 31, 2018.

2. **Clarification to the November 2017 Quantity Limits at the Military Treatment Facilities (MTFs):** Quantity limits are defined as any quantity restriction, including quantity limits, collective limits and day supply limits. Additionally, unless otherwise directed by the DoD P&T Committee, quantity restrictions at the MTFs are to be established the same way as in the Mail Order.

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. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) Subclass

Background—The GLP1RAs were most recently reviewed in August 2015, with exenatide once weekly (Bydureon) and albiglutide (Tanzeum) selected for UF and step-preferred status,

with all the other GLP1RAs designated as NF and non step-preferred. Since the last review, two new products have been approved, an exenatide once weekly autoinjector (Bydureon BCise), and semaglutide (Ozempic). The GLP1RA combinations with insulin were not included in this review.

Voluntary market discontinuation of Tanzeum is expected in August 2018. The purpose of this review is to select a second step-preferred UF agent to replace the formulary position currently held by Tanzeum.

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

- Metformin remains the first-line treatment in all patients with type 2 diabetes mellitus (T2DM) unless there are contraindications.
- The new Bydureon BCise autoinjector formulation is easier to self-administer than the Bydureon pen. It is comparable to Bydureon in lowering A1c.
- When used as monotherapy or in combination with other oral agents, the GLP1RAs decrease hemoglobin A1c (A1c) on average approximately 1% to 2% from baseline. Overall, differences in A1c between the GLP1RAs are not clinically relevant.
    - However, in one study (SUSTAIN-3), semaglutide (Ozempic) was statistically and clinically superior to exenatide once weekly (Bydureon) in glycemic control, as semaglutide lowered A1c by 1.5% from baseline compared to 0.9% with exenatide. Limitations to the SUSTAIN-3 study include its open label, active comparator design; it was not designed to show superiority.
    - In the open-label, active comparator SUSTAIN-7 study, semaglutide was statistically superior to dulaglutide (Trulicity) in glycemic control, as it reduced A1c by 1.5-1.8% from baseline compared to 1.1-1.4% with dulaglutide. However, the differences in change in A1c between semaglutide and dulaglutide were not considered clinically relevant, as the change in A1c between the two drugs was less than 0.5%.
- Patients are likely to experience weight loss with use of any GLP1RA.
- Cardiovascular outcomes trials (CVOTs) evaluating the effects on endpoints, including CV mortality, non-fatal myocardial infarction, and stroke, have been completed with four of the products: liraglutide (Victoza) in the LEADER trial, Ozempic in SUSTAIN-6, Bydureon in the EXSCEL trial, and lixisenatide (Adlyxin) in the ELIXA trial. Trials are currently ongoing with dulaglutide (Trulicity) in the REWIND trial and Tanzeum in the HARMONY-OUTCOME trial.
- Liraglutide (Victoza) is the only GLP1RA that has an additional indication to reduce CV risk in patients with established CV disease, based on the LEADER trial. However, given the differences in patient populations in the CVOTs, it is difficult to directly compare one GLP1RA to another in terms of CV benefit.

- In the four CVOTs, the association of GLP1RAs with retinopathy has been a concern, however this was a secondary outcome, and the trials were underpowered to adequately assess worsening retinopathy. Additional studies are needed to definitively determine the long-term effects of GLP1RAs on diabetic retinopathy.
- Gastrointestinal (GI) effects of nausea, vomiting, and diarrhea are the most commonly reported adverse effects with the class. The incidence of nausea varies based on dosing, with higher doses resulting in more nausea. Bydureon has the lowest incidence of nausea at 14%, compared to Ozempic (16-20%), Trulicity (12-21%), Victoza (23%), Adlyxin (29%), and exenatide twice daily (Byetta) (35%).
- Victoza, Adlyxin, and Ozempic have an advantage in offering a smaller needle size for patient convenience. One disadvantage of Bydureon and Bydureon BCise is the larger needle size.
- Bydureon, Bydureon BCise, Trulicity, and Ozempic, have the advantage of once weekly dosing, while Victoza and Adlyxin are dosed once daily, and Byetta is dosed twice daily. Potential advantages of Bydureon and Bydureon BCise include that they are the only GLP1RAs that do not require dosage titration.
- Trulicity, Victoza, and Ozempic require no dose adjustment in renal insufficiency.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the GLP1RAs. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that exenatide once weekly (Bydureon and Bydureon BCise) were the most cost-effective agents, followed by dulaglutide (Trulicity), exenatide twice daily (Byetta), semaglutide (Ozempic), liraglutide (Victoza), and lixisenatide (Adlyxin).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating exenatide (Bydureon and Bydureon BCise) and dulaglutide (Trulicity) as formulary and step-preferred, with exenatide twice daily (Byetta), semaglutide (Ozempic), liraglutide (Victoza), and lixisenatide (Adlyxin) as NF and non step-preferred demonstrated the largest estimated cost avoidance for the Military Health System (MHS).

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

    - UF and step-preferred
        - exenatide once weekly (Bydureon and Bydureon BCise)
        - dulaglutide (Trulicity)

    - NF and non step-preferred

- albiglutide (Tanzeum)
- exenatide twice daily (Byetta)
- liraglutide (Victoza)
- lixisenatide (Adlyxin)
- semaglutide (Ozempic)

- This recommendation includes step therapy which requires a trial of exenatide once weekly (Bydureon or Bydureon BCise) and dulaglutide (Trulicity) prior to use of the NF, non step-preferred GLP1RA drugs in all new and current users.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining exenatide once weekly (Bydureon) and adding exenatide once weekly autoinjector (Bydureon BCise) to the BCF.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—PA criteria currently apply to the GLP1RAs subclass. Currently, a trial of metformin or a sulfonylurea is required prior to use of a GLP1RA, and use of the step-preferred GLP1RAs are also required prior to the non step-preferred products. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the requirement for a trial of a sulfonylurea, and maintaining the metformin step, based on the treatment guidelines from several diabetes associations where metformin is preferred due to its positive effects on glycemic control, safe adverse effect profile, and minimal cost. Additionally sulfonylureas are no longer considered first line therapy for diabetes. The Committee also recommended updating the existing manual PA criteria so that new and current GLP1RA users must try the step-preferred products, Bydureon or Bydureon BCise and Trulicity, prior to using Tanzeum, Byetta, Victoza, Adlyxin, or Ozempic. Use of the non step-preferred products is allowed if the patient has had an inadequate response to the step-preferred GLP1RAs. See Appendix C for the full criteria.

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

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) quantity limits for liraglutide (Victoza) to limit use to the FDA-labeled indication for diabetes mellitus. See Appendix D.

6. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) adding semaglutide (Ozempic) to the EMMPI program, as

the other GLP1RAs are currently on the EMMPI list. See Appendix F.

7. ***COMMITTEE ACTION: UF, and PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is July 25, 2018.

B. Anti-Inflammatory Immunomodulatory Ophthalmics: Ophthalmic Immunomodulatory Agents Subclass

Background—Cyclosporine 0.05% ophthalmic emulsion (Restasis) and lifitegrast 5% ophthalmic solution (Xiidra) are the two products in this subclass, which are both approved to treat dry eye disease. Prior authorization criteria currently apply to both drugs.

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

- Ocular surface inflammation and damage are characteristic of moderate to severe dry eye disease. Restasis and Xiidra are both approved for dry eye disease, but their mechanisms of action differ.
- Both drugs are dosed twice daily. Xiidra's onset of action can occur as soon as two weeks following initiation of therapy, however peak effect will not likely occur until after 12 weeks of therapy. In contrast, Restasis' onset of action may take up to six months. Over-the-counter (OTC) ocular lubricants can be used concomitantly with both Restasis and Xiidra.
- Both Restasis and Xiidra in individual placebo-vehicle controlled trials have shown reductions in signs and symptoms of dry eye disease using different endpoints. There are no head-to-head trials between Restasis and Xiidra. It is difficult to determine the clinical relevance of these changes, and dry eye disease is a progressive condition that waxes and wanes. Recent treatment guidelines for dry eye disease do not favor one product over another (American Academy of Ophthalmology 2017; Dry Eye Workshop II 2017).
- There are no published studies evaluating efficacy when patients are switched from one product to another.
- While the clinical studies that led to FDA approval had low patient dropout rates, most trials were of short duration. An analysis of MHS prescription claims showed that approximately 70% of patients fill prescriptions for less than six months of therapy.
- The safety profiles of Restasis and Xiidra are most commonly associated with ocular burning and stinging. Lifitegrast causes dysgeusia in 16% of patients. There are no apparent serious concerns.
- There is a moderate degree of therapeutic interchangeability with Restasis and Xiidra, as there is a variable response to these drugs in practice. To meet the needs of DoD

beneficiaries, at least one ophthalmic immunomodulatory agent is needed to treat the majority of patients with dry eye syndrome.

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

- CMA showed that Restasis and Xiidra were cost effective in the various formulary scenarios.
- BIAs with corresponding sensitivity analyses were performed on all formulary scenarios.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:
    - UF:
        - cyclosporine 0.05% ophthalmic emulsion (Restasis)
        - lifitegrast 5% ophthalmic solution (Xiidra)
    - NF: None
    - Note that a BCF product was not selected for the subclass. The BCF drugs will remain Pred Forte and Pred Mild in the Anti-Inflammatory Immunomodulatory Ophthalmic Agents class.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) revising the existing manual PA criteria for both Restasis and Xiidra. The drugs must be prescribed by an ophthalmologist or optometrist, the diagnosis of dry eye disease must be documented, and a trial of two OTC ocular lubricants is now required. The revised PA criteria will apply to new patients and existing users who have not filled a prescription for Restasis or Xiidra in the past 120 days. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR OPHTHALMIC IMMUNOMODULATORY DRUGS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) excluding Restasis and Xiidra from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, due to the MHS claims analysis showing 70% of patients do not continuously fill prescriptions beyond six months.

C. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is July 25, 2018.

D. Osteoporosis Drugs*:* Parathyroid Hormone (PTH) Analogs

Background—The P&T Committee evaluated the PTH analogs for treatment of osteoporosis; this subclass has not previously been reviewed for formulary status, although the full class was reviewed in 2008. The subclass consists of two injectable products, teriparatide (Forteo) and abaloparatide (Tymlos), which are both approved for the treatment (and not for the prevention) of osteoporosis in postmenopausal women at high risk for fracture.

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

- Both abaloparatide (Tymlos) and teriparatide (Forteo) have potential benefit in reducing fracture risk in high-risk patients or those with a history of fragility fractures, regardless of whether they were treated with bisphosphonates or not.
- With regard to fracture risk reduction, both Tymlos and Forteo have comparable efficacy for vertebral and non-vertebral fracture risk reduction in patients at high risk for fractures, compared to placebo. A 2016 trial (ACTIVE) reported the risk difference of new vertebral fractures with abaloparatide versus placebo was 3.6%, with a number needed to treat (NNT) of 28, compared to a risk difference of 3.4% with teriparatide versus placebo (NNT 29).
- In terms of changes in bone mineral density, both Tymlos and Forteo produced a statistically significant increase in bone mineral density at 18 months compared to placebo at the hip, femoral neck, and lumbar spine (ACTIVE trial).
- Both PTH analogs have similar adverse drug reaction profiles. Both drugs are limited to cumulative lifetime use of two years based on findings of osteosarcoma associated with use of teriparatide in rodent studies. However, a 2017 meta-analysis from the Institute for Clinical and Economic Review reported extensive real world clinical experience with teriparatide (Forteo) in postmenopausal women without identification of any new adverse events.
- In terms of other factors, Tymlos does not require refrigeration, while Forteo must be kept refrigerated. Forteo has additional indications for men with high fracture risk and for treatment of glucocorticoid-induced osteoporosis in patients at high risk for fracture.
- There is a high degree of interchangeability between Forteo and Tymlos.

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

- CMA results showed that Forteo was the more cost-effective PTH analog, followed by Tymlos.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Forteo as formulary and step-preferred, with Tymlos as NF and non step-preferred demonstrated the largest estimated cost avoidance for the MHS.

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

    - UF and step-preferred: teriparatide (Forteo)
    - NF and non step-preferred: abaloparatide (Tymlos)
    - This recommendation includes step therapy, which requires a trial of teriparatide in new patients, prior to use of abaloparatide.
    - Note that a BCF product was not selected for the Parathyroid Hormone Analogs Subclass

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for new users of Forteo and Tymlos, consistent with the package labeling for indications and safety. Additionally, the step therapy requirements will be included in the manual PA. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Tymlos. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for Forteo and Tymlos. See Appendix D.

5. ***COMMITTEE ACTION: UF, AND PA IMPLEMENTATION PERIOD—*** The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is June 27, 2018.

D. Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones (ACTH)

Background—The P&T Committee evaluated the ACTH subclass, which is comprised of injectable corticotropin. Injectable corticotropin has been commercially available since 1952, but now is only marketed as a proprietary product, H.P. Acthar Gel. This is the first formulary review of the subclass, but manual PA criteria have applied to H.P. Acthar Gel since December 2013.

H.P. Acthar Gel is a highly purified natural product of adrenocorticotropin derived from porcine pituitary gland. H. P. Acthar gel carries FDA indications for treatment of infantile spasms (West Syndrome) and treatment of exacerbations of multiple sclerosis (MS). The label also states that H.P. Acthar Gel "may" be used for a wide variety of other disorders, but does not explicitly state that it is indicated for those disorders. This language is in the context of the drug's initial approval in 1952, prior to the higher standards demonstrating clinical

effectiveness mandated by the Kefauver-Harris Amendment of the Food Drug and Cosmetic Act in 1962.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) the following for H.P. Acthar Gel:

- Infantile Spasms
  - Optimal treatment of infantile spasms involves early hormonal therapy.
  - Evidence supports both glucocorticoid-dependent as well as glucocorticoid-independent pathways in the treatment of infantile spasms.
  - A comprehensive review of the evidence in infantile spasms suggests that the clinical effectiveness of high-dose oral corticosteroids (e.g., prednisone) is non-inferior to that of ACTH. Evidence also supports that some patients refractory to high-dose oral corticosteroids will respond to ACTH.
  - Trial evidence is supported by numerous Level 1 systematic reviews and meta-analyses with low to moderate quality evidence.
  - The most common adverse effects of ACTH in infantile spasms leading to intervention, dose-reduction, or discontinuation include infection and irritability. The adverse effects are typically transitory in relation to treatment duration.
- MS Exacerbation
  - Professional treatment guidelines clearly and unanimously define the standard of care for treating MS exacerbations with intravenous (IV) methylprednisolone.
  - A comprehensive review of the evidence in MS suggests that the clinical effectiveness of high-dose oral corticosteroids is equivalent to or superior to that of ACTH.
  - A 2013 Cochrane review concluded that onset of treatment in an MS exacerbation is irrelevant to the exacerbation outcome. The evidence is insufficient to determine the impact of hormonal therapies on future exacerbation prevention and is also insufficient to determine the impact of hormonal therapies on long-term disability.
  - There is limited evidence to delineate adverse event profiles between ACTH and methylprednisolone. Head-to-head clinical trials have shown that the adverse reactions with ACTH and methylprednisolone are equivalent. Methylprednisolone is associated with a higher propensity for GI and psychiatric effects, while ACTH has a higher propensity for causing weight gain and edema.
  - Clinical trial evidence is supported by numerous Level 1 systematic reviews and meta-analyses with low to moderate quality evidence.
- Other Uses

  A comprehensive review of the evidence for all of the disease states where H.P. Acthar Gel "may" be used failed to identify well-controlled studies of clinically meaningful endpoints that substantively determined H.P. Acthar Gel's efficacy, maximum-tolerated dose, toxicity, and safety as compared with standard means of treatment. Therefore, the evidence for H.P. Acthar Gel failed to establish clinical effectiveness for those

conditions. H.P. Acthar Gel is unsupported by the literature in the following conditions:

- Rheumatologic disorders: systemic lupus erythematosus, inflammatory myopathies (including dermatomyositis and polymyositis), psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, and ankylosing spondylitis
- Dermatologic diseases: erythema multiforme (of any severity), Stevens-Johnson syndrome, and Toxic Epidermal Necrolysis (TEN) syndrome
- Allergic states: serum sickness
- Ophthalmic diseases: severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, birdshot choroiditis, chorioretinitis, anterior segment inflammation, scleritis, conjunctivitis, and Opsoclonus Myoclonus syndrome
- Respiratory diseases: sarcoidosis
- Nephrotic syndromes, including focal segmental glomerulosclerosis (FSGS), idiopathic membranous nephropathy, IgA nephropathy, membranoproliferative glomerulonephritis (MPGN), and monoclonal diffuse proliferative glomerulonephritis, and any other non-nephrotic edematous state
- Other neurologic disease: amyotrophic lateral sclerosis (ALS), MS (not related to exacerbation of MS), optic neuritis (not related to exacerbation of MS), and neurosarcoidosis
- Any other indication outside of the medically necessary indications of infantile spasms and MS exacerbation

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) that H.P. Acthar Gel was significantly more costly than its clinical comparators.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) the following, based on clinical and cost effectiveness:
    - UF: injectable corticotropin (H.P. Acthar Gel)
    - NF: None
    - Note that a BCF product was not selected for the Adrenocorticotropic Hormones Subclass.
2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for new and current users of H.P. Acthar Gel for treatment of infantile spasms (West Syndrome) in infants less than 24 months of age who are unresponsive to

high-dose steroids. Manual PA criteria are also recommended for new and current users of H.P. Acthar Gel with MS exacerbation who have failed or who are intolerant to an adequate trial of IV or oral corticosteroids. PA renewal will be allowed for infantile spasms; however, PA review will be required for each occurrence of MS exacerbation.

H.P. Acthar Gel is not approved for use of any other condition outside of infantile spasms or MS exacerbation. H.P. Acthar Gel's efficacy for the other indications listed above in the clinical effectiveness conclusion has not been established and/or remains unproven. Experimental and investigational use of H.P. Acthar Gel for these other conditions is not medically necessary and is therefore excluded from TRICARE coverage. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) quantity limits for H.P. Acthar Gel. See Appendix D.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is June 27, 2018.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Part 1: 16 for, 0 opposed, 0 abstained, 0 absent; Part 2: 15 for, 0 opposed, 0 abstained, 1 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 2018 P&T Committee meeting, a brief summary of their clinical attributes, their formulary recommendations, and see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

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

- UF:
    - acalabrutinib (Calquence) – Oral Oncologic Agent for Mantle Cell Lymphoma
    - benznidazole – Miscellaneous Anti-Infective for Chagas Disease
    - dolutegravir/rilpivirine (Juluca) – Antiretrovirals for Human Immunodeficiency Virus (HIV)
    - emicizumab-kxwh (Hemlibra) – Antihemophilic Factors

- letermovir (Prevymis) Antivirals

- NF:
  - coagulation factor IX, recombinant (Rebinyn) – Antihemophilic Factors
  - dapagliflozin/saxagliptin (Qtern) – Non-Insulin Diabetes Drugs – Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor
  - fluticasone propionate 93 mcg nasal spray (Xhance) – Nasal Allergy Drugs – Corticosteroids
  - house dust mite allergen extract (Odactra) – Immunological Agents Miscellaneous: Oral Agents
  - latanoprostene bunod ophthalmic solution (Vyzulta) – Glaucoma Drugs
  - minocycline ER (Ximino) – Antibiotics: Tetracyclines
  - sodium picosulfate/magnesium oxide/anhydrous citric acid (Clenpiq) – Laxatives-Cathartics-Stool Softeners
  - spironolactone 25 mg/5 mL oral suspension (CaroSpir) – Diuretics

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (Part 1: 15 for, 0 opposed, 1 abstained, 0 absent; Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Rebinyn, Qtern, Xhance, Odactra, Vyzulta, Ximino, Clenpiq, and CaroSpir. See Appendix B for the full criteria.

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

- Applying the same manual PA criteria for dapagliflozin/saxagliptin (Qtern) in new and current users, as is currently in place for the other non step-preferred SGLT2 inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors. Patients must first try the step-preferred SGLT2 inhibitor empagliflozin (Jardiance).
- Applying the same manual PA criteria for minocycline ER (Ximino) in new and current users, as is currently in place for the other non step-preferred tetracyclines. Patients must first try formulary step-preferred agents.
- Applying manual PA criteria to new users of Odactra, Hemlibra, and Calquence, and for new users of CaroSpir who are over 12 years old.
- Applying manual PA criteria to new and current users of Xhance and Vyzulta.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (Part 1: 15 for, 0 opposed, 1 abstained, 0 absent;

Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

a) **Corticosteroids-Immune Modulator Agents—Corticosteroid Subclass: Prednisone Delayed Release (Rayos)**

Rayos is a branded formulation of delayed release (DR) prednisone that has the same indications as immediate release (IR) prednisone, which was approved in 1955. It is dosed once daily, similar to IR prednisone, and has the same safety profile. Cost-effective generic formulations of prednisone and other glucocorticoids are available on the UF without PA required.

(1) ***COMMITTEE ACTION: PREDNISONE DR (RAYOS) MANUAL PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) manual PA criteria for Rayos due to the significant cost differences and lack of clinically compelling benefits between Rayos and generic prednisone. New and current users of Rayos are required to try generic prednisone IR and a second corticosteroid first. See Appendix C for the full criteria.

b) **Antivirals: Acyclovir/Hydrocortisone 5%/1% Cream (Xerese), Penciclovir 1% Cream (Denavir), and Acyclovir 50 mg buccal tablet (Sitavig)**

The committee reviewed three treatments for herpes labialis (cold sores). Xerese is a branded combination of acyclovir/hydrocortisone cream that has an equivalent efficacy and safety profile as the separate ingredients applied individually. Denavir is a branded penciclovir 1% cream that is indicated for treatment of recurrent cold sores, while Sitavig is a buccal tablet formulation of acyclovir. Cost-effective generic formulations of acyclovir cream and the oral antiviral agents (e.g., acyclovir, valacyclovir) used for treating herpes labialis are available on the UF without PA required.

(1) ***COMMITTEE ACTION: XERESE, DENAVIR, AND SITAVIG MANUAL PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) manual PA criteria for Xerese, Denavir, and Sitavig due to the significant cost differences and lack of clinically compelling benefits compared with generic topical and oral antivirals. New and current users of these products are required to try generic acyclovir cream and oral antiviral agents first. See Appendix C for the full criteria.

2. **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 PAs outlined below will apply to new users.

    a) **Targeted Immunomodulatory Biologics (TIBs): Tofacitinib (Xeljanz/Xeljanz XR) and Ixekizumab Injection (Taltz)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Xeljanz was originally approved for treating rheumatoid arthritis, while Taltz was originally approved for plaque psoriasis and was reviewed as a new drug in May 2016. PA criteria were updated to add the additional indication for active psoriatic arthritis in adults for Xeljanz, Xeljanz XR, and Taltz.

    b) **GI-2 Miscellaneous Agents: Plecanatide (Trulance)**—Trulance was reviewed as a new drug in May 2017 and indicated for chronic idiopathic constipation, with manual PA criteria recommended. The PA criteria were updated to add the additional FDA indication for treatment of irritable bowel syndrome with constipation (IBS-C), with the requirement for a trial of linaclotide (Linzess) before approval of plecanatide for IBS-C.

    c) **Female Hypoactive Sexual Desire Disorder Agents: Flibanserin (Addyi)**—Addyi was reviewed in November 2015 with manual PA criteria recommended. The PA criteria were updated to add an expiration date of three months, with renewal PA criteria ensuring efficacy and safety.

    d) **Antidepressants and Non-Opioid Pain Syndrome Agents: Pregabalin (Lyrica) PA and MN Criteria**—Step therapy and manual PA criteria have applied to Lyrica since it was originally reviewed for formulary placement in November 2011, with the most recent update occurring in May 2017. The additional indication for treatment of neuropathic pain associated with spinal cord injury after a trial of gabapentin and duloxetine was added to the PA criteria. The MN criteria for Lyrica were also updated to reflect the PA requirement of a trial of gabapentin and duloxetine.

    e) **Acne Agents—Topical Acne and Rosacea Agents: Dapsone Gel 5% and 7.5% (Aczone) MN Criteria**—Aczone and topical acne agents were reviewed in August 2016 and manual PA criteria updated in August 2017 to reflect the labeled indication of both male and female patients. The MN criteria for Aczone 7.5% were updated to also reflect the labeled indication of both genders.

    f) **Antibiotics: Tetracyclines—**The PA criteria for the tetracyclines, which were originally reviewed in February 2017, was updated to include renewal criteria, with an expiration date of 365 days.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) updates to the manual PA criteria for Xeljanz, Xeljanz XR, Taltz, Trulance, Addyi, and Lyrica; updated PA renewal criteria for the tetracyclines; and updates to the MN criteria for Lyrica and Aczone. All updated criteria apply to new users of these agents. See Appendices B and C for the full criteria.

B. QLs—QLs were reviewed for three drugs from drug classes where there are existing QLs, including the oncologic agents, antiemetics, nasal steroids, and five new drugs where QLs are not currently in place.

1. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) QLs for Calquence, Stelara, Xhance, Sitavig, Hemlibra, Neulasta, Emend, and Prevymis. See Appendix D for the QLs.

C. Naloxone Removal of Refill Limitations—When the Committee reviewed the narcotic antagonists in August 2016, no refills were allowed (i.e., a new prescription was required for every fill) in order to ensure the patient would be seen by the provider after an opioid overdose. Subsequently, the MHS Pain Management Working Group (MHS PMWG) reviewed this requirement and noted the widespread availability of naloxone from most pharmacies (based on state laws) allows for dispensing of naloxone without a prescription. The MHS PMWG is now requesting to allow refills for naloxone.

1. ***COMMITTEE ACTION: NALOXONE REFILL LIMITATIONS—***The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) removing the "no refill" limits currently in place for all naloxone formulations. Refills will be allowed as noted on the prescription.

D. PA, MN, QLs, and Removal of Naloxone Refill Limitations Implementation Periods

1. ***COMMITTEE ACTION: PA, MN, QLs, AND NALOXONE REFILL LIMITATIONS IMPLEMENTATION PERIODS—***The P&T Committee recommended the following implementation periods:

   - (11 for, 0 opposed, 0 abstained, 5 absent) The new manual PA for Rayos, Xerese, Denavir, and Sitavig become effective on the first Wednesday after a 90-day implementation period in all points of service. Additionally, the P&T Committee recommended DHA send letters to the beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is July 25, 2018.
   - (12 for, 0 opposed, 0 abstained, 4 absent) Updates to the current PAs for Taltz, Xeljanz/Xeljanz XR, Addyi, Trulance, and Lyrica; the MN criteria for Aczone and Lyrica; and the renewal criteria for the tetracyclines become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.

- (11 for, 0 opposed, 0 abstained, 5 absent) The QLs for the 14 drugs listed in section VI, B, above, and in Appendix D become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.
- (14 for, 0 opposed, 0 abstained, 4 absent): Removal of the "no refill" limitations for all naloxone formulations become effective on the first Wednesday two weeks after signing of the minutes in all points of service.

VII. BRAND OVER GENERIC AUTHORIZATION FOR SILDENAFIL TABLETS (VIAGRA)

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Viagra product is more cost effective than the AB-rated generic formulations for sildenafil, which were launched in December 2017. The manufacturer of Viagra has offered a Distribution and Pricing Agreement (DAPA). Therefore, the branded Viagra 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 Viagra. The "brand over generic" requirement for Viagra will be removed administratively when it is no longer cost effective compared to the AB-rated generics.

A. ***COMMITTEE ACTION: VIAGRA BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA—***The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) implementing the requirement to prefer the branded Viagra product over generic formulations. Manual PA criteria are required for generic sildenafil in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Viagra product cannot be used. (See Appendix C.)

B. ***COMMITTEE ACTION: VIAGRA BRAND COPAYMENT CHANGE—***The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) that the brand (Tier 2) formulary cost share for Viagra in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share.

The authority for the last recommendation is codified in 32 CFR 199.21(j)(3):

> [W]hen a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for five 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 (12 for, 0 opposed, 0 abstained, 4 absent) clarifying the formulary status of the following five products to reflect the current formulary status, and applicable step therapy, PA criteria, MN criteria, and QLs for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- Pulmonary Arterial Hypertension Agents—Endothelin Receptor Agonists: Bosentan (Tracleer) 32.5 mg tablet for solution is designated formulary on the UF, which is the same as bosentan (Tracleer) 62.5 mg and 125 mg tablets.

- Pulmonary-1 Agents—Inhaled Corticosteroids: The new beclomethasone dipropionate HFA (QVAR RediHaler) inhaler is designated as NF, non step-preferred and requires manual PA, which is the same as the QVAR parent agent. Additionally, QLs will also apply. See Section VI, B, above, on page 15, and Appendix D for the QLs.

- Antidepressants and Non-Opioid Pain Syndrome Agents: Pregabalin extended release (Lyrica CR) is designated NF, non step-preferred with the same MN and PA criteria as the pregabalin (Lyrica) parent agent. (See Section VI, A, 2d above, on page 14, Appendix B for updated Lyrica MN criteria, and Appendix C for updated Lyrica PA criteria.)

- Oncologic Agents for Non-Small Cell Lung Cancer: Brigatinib (Alunbrig Initiation Pack) is designated as formulary, similar to Alunbrig.

- Anticoagulant Agents—Oral Anticoagulant Subclass: Apixaban (Eliquis Initiation Pack) initiation pack is designated as formulary on the UF, similar to the Eliquis parent agent.

- GI-2 Miscellaneous Agents: Linaclotide (Linzess) 72 mcg tablet is designated formulary on the UF, similar to Linzess 145 mcg.

IX. 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 during the February 2018 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the February 2018 meeting, including the newly-approved drugs

affected by the EMMPI, will be effective on the first Wednesday two weeks after the signing of the minutes.

A. Newly-Approved Drugs per 32 CFR 199.21(g)(5)

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

   The P&T Committee recommended (Day 1 AM: 15 for, 0 opposed, 1 abstained, 0 absent; Day 1 PM: 15 for, 0 opposed, 0 abstained, 1 absent):

   a) **Add**: None

   b) **Do Not Add:**

   - Juluca (HIV medication); not currently required to go to Mail Order (i.e., not on the EMMPI list)
   - Prevymis (for cytomegalovirus infection) and benznidazole (Chagas disease); due to limited treatment duration
   - Hemlibra and Calquence, since it is not feasible or unclear if feasible to provide via mail order

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

   The P&T Committee recommended (Day 1 AM: 15 for, 0 opposed, 1 abstained, 0 absent; Day 1 PM: 15 for, 0 opposed, 0 abstained, 1 absent):

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: Vyzulta, Qtern, Odactra, and CaroSpir.

   b) **Do Not Add:** The previously established exception from the mail order requirement for acute use agents applies to Rebinyn and Clenpiq. The following agents may not be feasible to provide through mail order and should be excepted pending further information: fluticasone propionate 93 mcg nasal spray (Xhance) and minocycline ER capsules (Ximino).

B. Status of Other Medications on the EMMPI List

1. ***COMMITTEE ACTION: ADDITION OF AGENTS TO EMMPI LIST***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) to add flibanserin (Addyi) to the EMMPI list.

X. ITEMS FOR INFORMATION

A. New MHS Pharmacy Copayments

The Committee was briefed on the new MHS pharmacy copayments that were implemented on February 1, 2018. Refer to https://www.tricare.mil/pharmacycosts for the new copayments.

B. Second 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. A total of 113 drugs were evaluated, with 56 remaining as NF, and 57 designated as UF. Updates on the metrics for the newly-approved drugs will be presented periodically at upcoming P&T Committee meetings.

XI. ADJOURNMENT

The meeting adjourned at 1400 hours on February 8, 2018. The next meeting will be in May 2018.

Appendix A—Attendance: February 2018 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 Nonformulary During the February 2018 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:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

24 APR 2018
Date

Appendix A—Attendance: February 2018 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner for Mr. David Bobb	Chief, DHA Pharmacy Operations Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
Col James Jablonski, MC	Air Force, Physician at Large
LTC John Poulin, MC	Army, Physician at Large
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Mr. Joe Canzolino	Department of Veterans Affairs
Col Angela Mysliwiec	TRICARE Regional Office Representative
Voting Members Absent	
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Nonvoting Members Present	
Ms. Leigh Bradley (SES)	General Counsel, DHA
Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
CAPT Robert Hayes	Indian Health Service
Ms. Yvette Dluhos	DHA Contract Operations Division
Capt Kevin Bourne	Defense Logistics Agency Troop Support
Mr. Jason Wray	Defense Logistics Agency Troop Support

Appendix A—Attendance (continued)

Others Present	
Lt Col Ronald Khoury, MC	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
David Folmar, PharmD	DHA Formulary Management Branch
LCDR Scott Raisor	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
CPT Zachary Leftwich, MSC	DHA Formulary Management Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Robert Conrad, PharmD	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Brian Beck, PharmD	DHA Purchased Care Branch
Rukshar Banu	Student, University of Incarnate Word

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• albiglutide (Tanzeum) • exenatide twice daily (Byetta) • liraglutide (Victoza) • lixisenatide (Adlyxin) • semaglutide (Ozempic) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Use of <u>both</u> formulary agents (Bydureon/Bydureon BCise and Trulicity) have resulted in significant adverse effects that are not expected to occur with use of the non-preferred products **Formulary Alternatives:** exenatide once weekly (Bydureon and Bydureon BCise), dulaglutide (Trulicity)
• abaloparatide subcutaneous injection (Tymlos) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	• The patient has experienced significant adverse effects from formulary agent • No alternative formulary agent: the patient cannot comply with refrigeration requirement for the formulary alternative **Formulary Alternatives:** teriparatide (Forteo)
• coagulation factor IX, recombinant (Rebinyn) **Antihemophilic Factors**	• Use of the formulary products is contraindicated and treatment with other antihemophilic factors is not clinically appropriate • The patient has experienced adverse effects from the formulary antihemophilic factors **Formulary Alternatives:** Idelvion, Alprolix
• dapagliflozin/saxagliptin (Qtern) **Non-Insulin Diabetes Drugs: SGLT2 Inhibitors**	• The patient has experienced significant adverse effects from empagliflozin that is not expected to occur with dapagliflozin **Formulary Alternatives:** sitagliptin (Januvia, Janumet, Janumet XR); empagliflozin (Jardiance, Glyxambi, Synjardy, Synjardy XR)
• fluticasone propionate 93 mcg nasal spray (Xhance) **Nasal Allergy Drugs: Corticosteroids**	• Use of at least two formulary and nonformulary nasal allergy drugs has resulted in therapeutic failure **Formulary Alternatives:** azelastine 137 mg nasal inhaler, flunisolide, fluticasone propionate 50 mcg nasal inhaler (generic Flonase), mometasone (generic Nasonex), beclomethasone (Beconase AQ)
• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	• At least two formulary agents, including a nasal steroid, AND either a nasal antihistamine, oral antihistamine, or leukotriene receptor antagonist has resulted in therapeutic failure • No alternative formulary agent – the patient has allergic rhinitis and allergic asthma and has persistent asthma exacerbations despite use of inhaled corticosteroids, and their asthma is controlled (defined as an FEV1 >70%) **Formulary alternatives:** fluticasone propionate 50 mcg nasal inhaler (generic Flonase), azelastine 137mcg nasal inhaler, cetirizine, loratadine, montelukast

Drug / Drug Class	Medical Necessity Criteria
• latanoprostene bunod ophthalmic solution (Vyzulta) **Glaucoma Agents:**	• The patient has experienced significant adverse effects from two formulary agents **Formulary Alternatives:** latanoprost (generic Xalatan), bimatoprost (generic 0.03% Lumigan)
• minocycline ER (Ximino) **Antibiotics: Tetracyclines**	• The patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic minocycline immediate release products **Formulary alternatives:** minocycline IR 50 mg or 100 mg
• sodium picosulfate/magnesium oxide/anhydrous citric acid (Clenpiq) **Laxatives-Cathartics-Stool Softeners**	• No alternative formulary agent – the patient requires a sodium picosulfate/Mg oxide/citric acid bowel prep formulation and cannot comply with the mixing requirement for PrePopik **Formulary alternatives:** PrePopik
• spironolactone 25 mg/5 mL oral suspension (CaroSpir) **Diuretics**	• No alternative formulary agent – the patient requires an aldosterone blocker/potassium-sparing diuretic and cannot take tablets **Formulary alternatives:** spironolactone, eplerenone, amiloride, HCTZ/triamterene, amiloride/HCTZ, spironolactone/HCTZ
• pregabalin (Lyrica) • pregabalin ER (Lyrica CR) **Antidepressants and Non-Opioid Pain Syndrome Agents**	**Changes from the February 2018 meeting are in BOLD** • Use of **both** formulary agents **(gabapentin and duloxetine)** have resulted in therapeutic failure **Formulary Alternatives:** gabapentin and duloxetine
• dapsone 7.5% gel (Aczone) **Acne Agents: Topical Acne and Rosacea Agents**	**Changes from the February 2018 meeting are in BOLD** • Patient ~~**is an adult female with**~~ **has** inflammatory acne who has tried AND failed or experienced significant adverse effects from at least three formulary agents, including combination therapy with clindamycin and benzoyl peroxide **Formulary Alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and sulfacetamide sodium/sulfur lotion

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Step-Preferred • exenatide once weekly (Bydureon/Bydureon BCise) • dulaglutide (Trulicity) **Non Step-Preferred** • albiglutide (Tanzeum) • exenatide twice daily (Byetta) • liraglutide (Victoza) • lixisenatide (Adlyxin) • semaglutide (Ozempic) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	Changes from the February 2018 meeting are in strikethrough; additionally, Trulicity has replaced Tanzeum as the second step-preferred GLP1RA. All new users of a GLP1RA are required to try metformin ~~or a sulfonylurea (SU)~~ before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin ~~or a sulfonylurea~~ first. The requirement to try a sulfonylurea is now removed. Additionally, Bydureon/Bydureon BCise and Trulicity are now the preferred agents in the GLP1RA subclass. New and current users of the non step-prefrred products, Tanzeum, Byetta, Victoza, Adlyxin, and Ozempic, must try Bydureon/Bydureon BCise and Trulicity first. Manual PA criteria—Bydureon/Bydureon BCise, Trulicity, Tanzeum, Byetta, Victoza, Adlyxin, or Ozempic is approved (i.e., a trial of metformin ~~or SU~~ is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus. • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis ~~• The patient has experienced any of the following issues on a SU:~~ ~~o hypoglycemia requiring medical treatment~~ • The patient has had inadequate response to metformin ~~or a SU~~ • The patient has a contraindication to metformin ~~or a SU~~ AND In addition to the above criteria regarding metformin ~~and SU~~, the following PA criteria would apply specifically to new and current users of Tanzeum, Byetta, Victoza, Adlyxin, and Ozempic: • The patient has had an inadequate response to Bydureon/Bydureon BCise and Trulicity. Off-label uses are not approved. Prior Authorization does not expire.
• cyclosporine 0.05% ophthalmic emulsion (Restasis) • lifitegrast 5% ophthalmic solution (Xiidra) **Anti-Inflammatory Immunomodulatory Ophthalmics: Ophthalmic Immunomodulatory Agents Subclass**	**February 2018 updates are in BOLD** **PA criteria apply to all new and current users of Restasis or Xiidra. A new user is defined as a patient who has not filled a prescription for Restasis or Xiidra in the past 120 days.** • **If there is no Restasis or Xiidra prescription in the past 120 days, a manual PA is required.** Manual PA criteria: Coverage is approved if all the criteria are met: • **The drug is prescribed by an ophthalmologist or optometrist AND** • The patient is ≥ 18 years old AND • **A diagnosis of Moderate to Severe Dry Eye Disease is supported by both of the criteria below:** o **Positive symptomology screening for moderate to severe dry eye disease from an appropriate measure AND** o **At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) AND** • **Patient must try and fail the following:** o **At least 1 month of one ocular lubricant used at optimal dosing and**

Drug / Drug Class	Prior Authorization Criteria
	frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc], polyvinyl alcohol [Liquitears, Refresh Classic, etc], or wetting agents [Systame, Lacrilube} o **Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol, etc.) AND** • Concomitant use of Restasis and Xiidra is NOT allowed. • Restasis is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) Off-label uses for Xiidra are not approved. Off-label uses for Restasis, other than those listed above, are not approved. PA expires in 365 days. **Renewal Criteria: 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.**
• teriparatide (Forteo) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	Manual PA criteria apply to new users of Forteo. Manual PA criteria—Forteo is approved if **ALL** of the following criteria are met: • The patient is ≥ 18 years old • The drug is prescribed for treatment of osteoporosis, and not for prevention of osteoporosis. • The patient has one of the following diagnoses: o Patient is a postmenopausal female with osteoporosis, OR o The patient is male with primary or hypogonadal osteoporosis, OR o The patient has osteoporosis associated with sustained systemic glucocorticoid therapy (e.g., > 6 months use of >7.5mg/day prednisone or equivalent) AND • Patient has one of the following: o The patient is at high risk for fracture, defined as one of the following: ▪ history of osteoporotic fracture ▪ multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) ▪ documented bone mineral density (BMD) T-score of -2.5 or worse ▪ has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • Cumulative treatment with Forteo will not exceed 24 months during the patient's lifetime AND • Patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton) Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. Prior Authorization may not be renewed.

Drug / Drug Class	Prior Authorization Criteria
• abaloparatide (Tymlos) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	Manual PA criteria apply to new users of Tymlos. Manual PA criteria—Tymlos is approved if **ALL** of the following criteria are met: • The drug is prescribed for treatment of osteoporosis, and not for prevention of osteoporosis. • The patient is a postmenopausal female with osteoporosis at high risk for fracture as defined by one of the following: o history of osteoporotic fracture o multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) o documented bone mineral density (BMD) T-score of -2.5 or worse o has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • Cumulative treatment with Tymlos will not exceed 24 months during the patient's lifetime AND • The patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton) AND • **The patient cannot comply with the refrigeration requirement for Forteo.** Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. Prior Authorization may not be renewed.
• injectable corticotropin (H.P. Acthar Gel) **Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones (ACTH)**	Note: the provider may call ESI to expedite prior authorization review Manual PA criteria apply to all new and current users of H.P. Acthar Gel. Manual PA criteria—H.P. Acthar Gel PA will be approved if all of the following criteria are met for either treatment of infantile spasms or treatment of exacerbation in patients with multiple sclerosis. 1) Infantile Spasms (West Syndrome): • The patient is < 24 months old AND • The patient is diagnosed with infantile spasms with electroencephalogram-confirmed hypsarrhythmia AND • The patient has tried a 2-week course of high-dose (40-60 mg/day) prednisone/prednisolone for any episode of infantile spasms and has failed therapy as evidenced by continued signs/symptoms of either spasms or hypsarrhythmia on EEG AND • H.P. Acthar Gel is prescribed by or in consultation with a pediatric neurologist with expertise in the management of infantile spasm. Prior Authorization expires in 30 days. Renewal Criteria: Coverage will be approved for an additional 365 days for infantile spasms if all criteria are met: • The patient is < 24 months old AND • The patient has demonstrated a clinical response to H.P. Acthar Gel as defined by cessation of both previous characteristic spasms AND hypsarrhythmia on EEG within 2 weeks of starting H.P. Acthar Gel AND • The patient has not previously demonstrated intolerance to H.P. Acthar Gel,

Drug / Drug Class	Prior Authorization Criteria
	defined as the patient requiring discontinuation of H.P. Acthar Gel therapy. 2) Multiple Sclerosis Exacerbation: • The patient is an adult older than 18 years of age diagnosed with multiple sclerosis AND • The patient is diagnosed with an exacerbation of multiple sclerosis OR optic neuritis as a specific exacerbation of multiple sclerosis AND • The patient has failed or is intolerant to an adequate trial of IV/PO corticosteroids (e.g., 1000 mg methylprednisolone IV x 5-14 days OR oral equivalent) for the present exacerbation. o Note that anticipated hypercortisolism and other non-emergent side effects (e.g., non-emergent hyperglycemia, weight gain, non-urgent/emergent hypertension, edema, paresthesias, insomnia, constipation, diarrhea, hyperphagia, anorexia, nasal/sinus congestion, acne, and menstrual irregularities, etc.) do not meet the threshold for authorization of this PA. Similarly, if the patient has had emergent or life-threatening adverse effects to high-dose corticosteroids, H.P. Acthar gel is contraindicated. AND • H.P. Acthar Gel is prescribed by or in consultation with a neurologist. Prior Authorization expires in 30 days. PA Renewal is not authorized for multiple sclerosis exacerbation. 3) Other uses: PA will be not be approved for any condition other than infantile spasms in infants less than 24 months of age or MS exacerbation, including, but not limited to the following: optic neuritis not related to MS exacerbation, Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, Ankylosing Spondylitis, Dermatomyositis, Polymyositis, Juvenile Idiopathic Arthritis, Erythema Multiforme (any severity), Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis Syndrome, Serum Sickness, Keratitis, Iritis, Iridocyclitis, Uveitis, Choroiditis, Birdshot choroiditis, Chorioretinitis, anterior segment inflammation, Nephrotic Syndrome including focal segmental glomerulosclerosis (FSGS), idiopathic membranous nephropathy, IgA nephropathy, membranoproliferative glomerulonephritis (MPGN), and monoclonal diffuse proliferative glomerulonephritis, non-nephrotic edematous states, sarcoidosis, gout, scleritis, or conjunctivitis.
• acalabrutinib (Calquence) **Oncological Agents**	Manual PA criteria apply to all new users of Calquence. <u>Manual PA criteria</u>—Coverage will be approved if all criteria are met: • The patient is ≥ 18 years AND • The patient has pathologically confirmed mantle cell lymphoma, with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 AND • The patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec Off-label uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• dapagliflozin/saxagliptin (Qtern) **Non-Insulin Diabetes Drugs: SGLT2 Inhibitors**	Manual PA criteria apply to all new and current users of Qtern. Manual PA criteria—Coverage will be approved if all criteria are met: • The patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin AND • The patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, and Synjardy XR) and had an inadequate response or experienced significant adverse events, or have a contraindication to empagliflozin AND • The patient must have tried one of the preferred DPP-4 inhibitors (Januvia, Janumet, and Janumet XR) and had inadequate response or experienced significant adverse events, or have a contraindication to sitagliptin. Off-label uses are not approved. Prior authorization does not expire.
• emicizumab-kxwh (Hemlibra) **Antihemophilic Factors**	Manual PA criteria apply to all new users of Hemlibra. Manual PA criteria—Coverage will be approved if all criteria are met: • The patient must have a documented diagnosis of Hemophilia A AND • The patient must have a history of a high titer of factor VIII inhibitor (greater than or equal to 5 Bethesda units per mL) AND • The patient must NOT have been treated within the last 12 months for thromboembolic disease, or have current signs of, thromboembolic disease AND • Hemlibra must be prescribed by or in consultation with a hematologist. Off-label uses are not approved. Prior authorization does not expire.
• fluticasone propionate 93 mcg nasal spray (Xhance) **Nasal Allergy Agents: Corticosteroids**	Manual PA criteria apply to all new and current users of Xhance. Manual PA criteria—Coverage will be approved if all criteria are met: • Patient has nasal polyps AND • Patient must have tried and failed at least two of the following: azelastine 137 mcg nasal spray (generic Astelin), flunisolide nasal spray, fluticasone propionate 50 mcg nasal spray (generic Flonase), or ipratropium nasal spray (Atrovent nasal spray) AND • Patient has tried and failed mometasone (Nasonex) OR beclomethasone (Beconase) Off-label uses are not approved. Prior authorization does not expire.
• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	Manual PA criteria apply to all new users of Odactra. Manual PA criteria—Coverage will be approved if all criteria are met: • Odactra is prescribed by an allergist/immunologist AND • The patient is between the ages of 18 and 65 years AND • The patient has a diagnosis of house dust mite (HDM) allergic rhinitis confirmed with either a positive skin test or an *in vitro* test for pollen-specific for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites AND o The patient's symptoms of allergic rhinitis have not been controlled with a nasal corticosteroid (e.g., fluticasone) AND at least one of the following: oral antihistamine, nasal antihistamines, or a leukotriene receptor antagonist (montelukast) OR o The patient has a diagnosis of HDM-related allergic rhinitis and allergic asthma that has not responded to an adequate trial of inhaled steroids, and the patient's FEV1 >70% AND • The patient has received the first dose in the office setting and was observed for

Drug / Drug Class	Prior Authorization Criteria
	30 minutes with no allergic reactions noted AND • The patient has a prescription for self-administered SC epinephrine AND • The patient does not have a history of severe local allergic reaction to sublingual immunotherapy AND • Patient is not receiving co-administered SC immunotherapy AND • Patient does not have severe, uncontrolled, unstable asthma Other off-label uses other than allergic asthma are not approved. PA expires in 6 months. Renewal Criteria: Coverage will be approved indefinitely if the patient has responded positively to treatment and is not receiving co-administered SC immunotherapy and does not have severe, uncontrolled, unstable asthma.
• latanoprostene bunod ophthalmic solution (Vyzulta) **Glaucoma Agents:**	Manual PA criteria apply to all new and current users of Vyzulta. Manual PA criteria—Coverage will be approved if all criteria are met: • Patient must have a diagnosis of open angle glaucoma OR ocular hypertension • Patient is ≥16 years old • Patient has tried and failed at least two ophthalmic prostaglandin glaucoma agents (e.g., latanoprost, bimatoprost) Off-label uses are not approved. Prior authorization does not expire.
• minocycline ER (Ximino) **Antibiotics: Tetracyclines**	PA criteria apply to all new and current users of Ximino. Automated PA Criteria: • Patient has filled a prescription for one generic IR doxycycline (either the 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, Ximino is allowed if: • The patient has acne with inflammatory lesions AND • The patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events Off-label uses are not approved. Prior authorization expires in 365 days. Renewal criteria: Ximino will be approved for an additional 365 days, if: • The patient's therapy has been re-evaluated within the last 12 months • The patient is tolerating treatment and there continues to be a medical need for the medication • The patient has disease stabilization or improvement in disease while on therapy
• spironolactone 25 mg/5 mL oral suspension (CaroSpir) **Diuretics**	Manual PA criteria apply to all new users of CaroSpir who are over 12 years old. Manual PA criteria—Coverage will be approved if all criteria are met: • The patient has heart failure, hypertension or edema from cirrhosis AND • The provider must write in why the patient requires CaroSpir and cannot take an aldosterone blocker / potassium-sparing diuretic in a tablet formulation o Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience Non-FDA approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• prednisone delayed release (Rayos) **Corticosteroids-Immune Modulators: Corticosteroids Subclass**	Manual PA criteria apply to all new and current users of Rayos. Note that PA is not required for generic prednisone; providers are encouraged to consider changing the prescription to generic prednisone. Manual PA criteria—Coverage for Rayos will be approved if: • The provider writes in why the patient requires delayed release prednisone and why patient cannot take immediate release prednisone • Acceptable responses are approved if ALL of the criteria are met: o The patient has a diagnosis of rheumatoid arthritis AND o The patient medical history includes trial and failure of both: ▪ generic prednisone AND ▪ at least one generic oral corticosteroid (e.g., dexamethasone, methylprednisolone, etc.) Off-label uses are not approved. Prior Authorization does not expire.
• acyclovir/ hydrocortisone 5%/1% cream (Xerese) **Antivirals**	Note: DoD Formulary products include topical or oral antiviral agents. Consider alternate agents first, such as acyclovir oral/topical or valacyclovir oral tablets. This PA is only approved for treatment of immunocompetent patients 6 years and older with recurrent herpes labialis (not approved for prophylaxis). Manual PA criteria apply to all new and current users of Xerese. Manual PA criteria—Coverage for Xerese is approved if: • The provider writes in why the patient requires Xerese and why they cannot take oral antivirals or cannot use acyclovir 5% cream and hydrocortisone 1% cream separately. • Acceptable responses are approved if ALL of the criteria are met: o Tried and failed topical acyclovir 5% cream and hydrocortisone 1% cream separately AND o Treatment failure of one of the following: oral acyclovir, valacyclovir, or famciclovir Off-label uses are not approved. Prior Authorization does not expire.
• penciclovir cream 1% (Denavir) • acyclovir 50mg buccal tablet (Sitavig) **Antivirals**	Note: DoD Formulary products include topical or oral antiviral agents. Consider alternate agents first, such as acyclovir oral/topical or valacyclovir oral tablets. This PA is only approved for treatment of immunocompetent patients 12 years and older with recurrent herpes labialis (not approved for prophylaxis). Manual PA criteria apply to all new and current users of Denavir or Sitavig. Manual PA criteria—Coverage for Denavir or Sitavig is approved if: • The provider writes in why the patient requires Denavir or Sitavig and why they cannot take oral antivirals or cannot use acyclovir 5% cream. • Acceptable responses are approved if ALL of the criteria are met: o Tried and failed topical acyclovir 5% cream AND o Treatment failure of one of the following: oral acyclovir, valacyclovir, or famciclovir Off-label uses are not approved. Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• plecanatide (Trulance) **GI-2 Miscellaneous Drugs**	**Changes from February 2018 meeting are in BOLD and will apply to new users of Trulance.** Manual PA Criteria—Coverage approved if: 1. Patient is ≥ 18 years of age AND 2. Patient has clinically diagnosed chronic idiopathic constipation **OR IBS-C** AND 3. Patient does not have gastrointestinal obstruction AND **4.** Patient has failed or is intolerant to linaclotide (Linzess) **AND ONE OF THE FOLLOWING:** **1. If started on Linzess 145 mcg and intolerant due to diarrhea, must have trialed 72 mcg strength OR** **2. If started on Linzess 72 mcg and inadequate response, must try and have failed 145 mcg strength AND** 5. Dual therapy with another guanylate cyclase-C agonist is not allowed. Off-label uses are not approved. PA expires in one year. Renewal PA criteria for new and current users: After one year, PA must be resubmitted. Continued use of Trulance will be approved if there has been improvement in constipation symptoms and NO dual therapy with another guanylate cyclase-C agonist. Renewal PA criteria is limited to one year.
• flibanserin (Addyi) **Female Hypoactive Sexual Desire Disorder Agents—Mixed Serotonin Agonist/Antagonists**	**Changes from the February 2018 meeting are in BOLD and apply to new and current users of Addy.** Manual PA criteria apply to all new and current users of Addyi. Manual PA criteria—Coverage for Addyi is approved if: • The drug is prescribed for a premenopausal female with HSDD not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance AND • The patient does not have current alcohol use • The patient does not have hepatic impairment (Child-Pugh score ≥6) • The patient is not receiving concomitant therapy with a moderate or strong CYP3A4 inhibitor (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil) AND • The prescription is written by a provider who is certified/enrolled in the flibanserin REMS program. • Note that contraindications to the use of flibanserin include concurrent alcohol, moderate or strong CYP3A4 inhibitors, and hepatic impairment **Off label uses are not approved.** **~~PA does not expire~~ PA expires after three months.** **Renewal PA criteria:** PA will be approved indefinitely if the patient continues to exhibit clinical benefit, continues to be premenopausal, and continues to abstain from alcohol.

• pregabalin (Lyrica) • pregabalin ER (Lyrica CR) **Antidepressants and Non-Opioid Pain Syndrome Agents**	**Changes from the February 2018 meeting are in BOLD and will apply to new users of Lyrica.** Manual PA criteria—coverage will be approved if: • Indication: Seizure disorder and post-herpetic neuralgia o The patient has a contraindication to gabapentin that is not expected to occur with Lyrica o The patient experienced adverse events with gabapentin that are not expected to occur with Lyrica o The patient previously responded to Lyrica and changing to gabapentin would incur unacceptable risk OR • **Indication:** Non-seizure related disorder (diabetic peripheral neuropathy, fibromyalgia **or neuropathic pain associated with spinal cord injury)** o The patient has tried and failed gabapentin therapy (trial of Gralise or Horizant does not qualify) **AND** o **Patient has tried and failed duloxetine** OR o The patient has a contraindication to gabapentin or **duloxetine** that is not expected to occur with pregabalin OR o The patient experienced adverse events with gabapentin or **duloxetine** that are not expected to occur with pregabalin OR o The patient previously responded to pregabalin and changing to gabapentin or **duloxetine** would incur unacceptable risk **Off-label uses are not approved.** PA does not expire.
• All non step-preferred tetracyclines, including: • minocycline ER 45 mg, 90 mg, 135 mg ER (generics) • minocycline DR 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn) • minocycline ER capsule 45mg, 90mg, 135mg (Ximino) **Antibiotics: Tetracyclines**	**Changes from February 2018 meeting are in BOLD** **Renewal PA criteria apply to both new and current users of non-preferred tetracycline oral agents.** PA expires in 365 days. **Renewal PA criteria: PA will be renewed for an additional 365 days if the following:** • **Patient's therapy has been re-evaluated within the last 12 months** • **Patient is tolerating treatment and there continues to be a medical need for the medication** • **Patient has disease stabilization or improvement in disease while on therapy**
• sildenafil generic for Viagra **Phosphodiesterase-5 (PDE-5) Inhibitors**	Manual PA criteria apply to all new users of generic Viagra. Note that brand Viagra is the preferred phosphodiesterase-5 inhibitor product in the DoD. Manual PA Criteria—Coverage for generic Viagra is approved if the following criteria is met: • The provider has provided patient-specific justification as to why the brand Viagra product cannot be used. • Acceptable reasons include the following, which have occurred or are likely to occur with the branded Viagra product: allergy to the branded Viagra; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• liraglutide (Victoza) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	▪ MTF/Mail: 9 pens/90-day supply ▪ Retail: 3 pens/30-day supply
• teriparatide (Forteo) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	▪ MTF/Mail: 3 prefilled pens/84-day supply ▪ Retail: 1 prefilled pen/28-day supply
• abaloparatide (Tymlos) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	▪ MTF/Mail: 3 prefilled pens/90-day supply ▪ Retail: 1 prefilled pen/30-day supply
• injectable corticotropin (H.P. Acthar Gel) **Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones**	▪ MTF/Mail/Retail: 14-day supply
• acalabrutinib (Calquence) **Oncologic Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	Note: revised from default TIB agent rules, Nov 2017 meeting ▪ MTF/Mail/Retail: 56-day supply
• fluticasone propionate (Xhance) **Nasal Allergy Drugs**	▪ MTF/Mail: 3 bottles/90-day supply ▪ Retail: 1 bottle/30-day supply
• acyclovir buccal tablet (Sitavig) **Antiviral Agents**	▪ MTF/Mail/Retail: 2 tablets/28-day supply
• emicizumab-kxwh (Hemlibra) **Antihemophilic Factors**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• pegfilgrastim (Neulasta) **White Blood Cell Stimulants:**	Note: revised from July 2004 meeting ▪ MTF/Mail: 8 syringes/56-day supply ▪ Retail : 4 syringes/28-day supply
• aprepitant (Emend) **Antiemetic/Antivertigo Agents**	Note: revised from July 2004 meeting ▪ MTF/Mail: 16 capsules/56-day supply ▪ Retail: 8 capsules/28-day supply
▪ letermovir (Prevymis) **Antiviral Agents**	▪ MTF/Mail/Retail: 30-day supply

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

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
acalabrutinib (Calquence)	Oncological Agents	Imbruvica	100 mg capsules; 100 mg every 12 hrs	Adult patients with Mantle Cell Lymphoma (MCL) who have received at least one prior therapy	Serious: hemorrhage, infections, Afib, secondary primary malignancies, headache, diarrhea, bruising, fatigue, myalgia	• **Provides 2nd, more selective Bruton Tyrosine Kinase inhibitor for treatment of MCL** • Possibly less associated toxicity given less off-target effects • Accelerated approval based on overall response rates (ORR) and pending additional studies to verify benefit • Being studied as 1st line treatment for MCL in combination with rituximab
benznidazole	Anti-Infectives: Miscellaneous	None	12.5mg and 100mg oral tablets; dosed by weight	Pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by *Trypanosoma cruzi*	AEs are common. abdominal pain, nausea, vomiting, rash, decreased appetite, headache, and increased transaminases	• **First FDA-approved medication for Chagas Disease**; Orphan drug designation • Available since 1971 for investigational drug use by the Centers for Disease Control • One other investigational agent, Nifurtimox, has been available outside the U.S. since 1965 • **Significant risk for mild and severe AEs** • Definition of clinical 'cure' and clinical infection remains controversial
coagulation factor IX, recombinant (Rebinyn)	Antihemophilic Factors	• Alprolix • Idelvion	Age, weight, indication based dosing; 500, 1000, 2000 IU per vial	Adults and children with hemophilia B for 1) On-demand treatment and control of bleeding episodes; 2) Perioperative management of bleeding	Most common: itching/site reactions, few serious events; monitor for embolism/thrombosis, hypersensitivity; neutralizing antibodies	• **Provides 3rd extended half-life factor IX, achieved through pegylation** • For on-demand and perioperative use, but not indicated for routine prophylaxis or immune tolerance induction in Hemophilia B • Indication for routine prophylaxis blocked by exclusivity by another product; not assessed by FDA for that potential and likely off-label use • Concerns regarding long-term use in children given pegylation products depositing in choroid plexus and potential neurocognitive effects/development
dolutegravir/ rilpivirine (Juluca)	Antiretrovirals	• Complera • Triumeq • Tivicay plus Truvada • Atripla	dolutegravir 50mg/ rilpivirine 25mg tablets; one tablet a day	HIV To replace current antiretroviral regimen in virologically suppressed patients who are on a stable antiretroviral regimen for at least 6 months	Most common: nasopharyngitis, headache, upper respiratory tract infection, diarrhea, back pain	• Provides 4th single tablet regimen (STR) option for HIV • **First 2-drug combination (vs 3-drug) for HIV** • Both ingredients with established efficacy and safety profiles and generally well tolerated • Rilpivirine requires an acidic environment for absorption • **Anticipated place in therapy: for patients virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for >6 months with no history of treatment failure or resistance**

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
emicizumab-kxwh (Hemlibra)	Antihemophilic Factors	• FEIBA • Novo-Seven RT • Obizur • High dose factors	Load: 3 mg/kg SubQ qwk for 4 wks, Maintenance: 1.5 mg/kg q wk;30 mg, 60 mg, 105 mg, 150 mg vials	Routine prophylaxis to prevent or reduce the frequency of bleeding episode in adult and pediatric patients with hemophilia A with factor VIII inhibitors	Serious: thrombotic microangiopathy, thromboembolism; injection site reactions, headache, arthralgia, pyrexia, diarrhea, myalgia	• **Provides 1st factor IXa and factor X-directed bispecific humanized monoclonal antibody that acts to replace factor VIII** • **Significant advance in therapy**
fluticasone propionate 93 mcg nasal spray (Xhance)	Nasal Allergy Drugs: Corticosteroids	• fluticasone propionate (Flonase) • mometasone (Nasonex)	nasal spray	For the treatment of nasal polyps in patients 18 years of age or older	Similar to others in class: epistaxis, septal ulceration, sinusitis, headache	• Xhance is only indicated for nasal polyps for adults ≥18; is not approved for allergic rhinitis • Contains the same active ingredient as Flonase but has a different indication • Mometasone is another product indicated for nasal polyps • **No compelling advantage over existing UF agents**
house dust mite (HDM) allergen extract (Odactra)	Immunological Agents — Miscellaneous: Oral Agents	Nasal Allergy Drugs • fluticasone propionate (Flonase) • flunisolide (Nasarel), generic • azelastine 137 mg (Astelin), • generic ipratropium (Atrovent) • montelukast	10 mg SL tablets QD dosing year round	Adults age 18-65 as immunotherapy for HDM-induced allergic rhinitis, with or without conjunctivitis	• Black box warning for anaphylaxis and severe laryngopharyngeal restriction • Itching of the nose/ears • Swelling of the mouth, lips, tongue • Ulceration/sores in the mouth	• **1st sublingual immunotherapy (SLIT) for HDM allergy-related allergic rhinitis/conjunctivitis** • Diagnosis must be confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae or Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts • 1st dose must be administered by health care professional with experience in allergy/allergic reactions • Need co-prescription with injectable epinephrine • Moderately effective in reducing symptoms of HDM-related allergic rhinitis • **In patients with HDM-related allergic asthma, Odactra may reduce the risk of asthma exacerbations and is recommended in the GINA 2017 asthma guidelines as an add-on to ICS therapy (off-label use)**
latanoprostene bunod ophthalmic solution (Vyzulta)	Glaucoma Agents	• latanoprost (Xalatan) • bimatoprost (Lumigan)	ophthalmic solution	For the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension	Mild • Conjunctival hyperemia 6% • Eye irritation 3% • Instillation pain 2%	• Latanoprostene bunod is metabolized to latanoprost and nitric oxide (NO); both products suggested to decrease intraocular pressure (IOP) • Unclear if dual mechanism of action improves efficacy over other ophthalmic prostaglandins • **Studies used clinically inferior comparators in phase 3 trials** • **No compelling advantage over existing UF agents**

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
letermovir (Prevymis)	Antivirals	• ganciclovir • valganciclovir	240 mg, 480 mg tablets; 240mg/12mL, 480/24mL vial for injection; Dosing: 480mg daily x 100 days	Prophylaxis of cytomegalovirus (CMV) infection and treatment in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)	Generally mild: • Diarrhea • Nausea • Fever	• **New antiviral indicated for prophylaxis and treatment of CMV infection in adults undergoing a HSCT** • Well-established generic competitors with increased adverse events profile • Letermovir has important drug-drug interactions that must be assessed before initiation of therapy • Overall, letermovir was well tolerated, with a minimal safety issues • **For centers that use CMV prophylaxis in high-risk patients, letermovir would be favored over other agents**
minocycline ER capsules (Ximino)	Antibiotics: Tetracyclines	• minocycline generic • minocycline ER generic • Solodyn ER	minocycline ER 45mg, 90mg, 135mg capsules	Inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older	≥1%: Generally mild: • Headache • Fatigue • Dizziness • Pruritus	• No new studies were submitted to the FDA for this product • No studies of added benefit in acne vulgaris of treatment by capsule vs tablet were performed • **No compelling advantage over existing UF agents**
dapagliflozin/ saxagliptin (Qtern)	Non-Insulin Diabetes Drugs: SGLT2 Inhibitors	SGLT2s • canagliflozin • dapagliflozin • **empagliflozin** DPP4s • alogliptin • linagliptin • saxagliptin • **sitagliptin**	dapagliflozin 10mg/ saxagliptin 5 mg oral tablet	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus with inadequate control with dapagliflozin or who are on the combo already	>10%: URTIs 1-10%: HA, dyslipidemia, hypoglycemia, diarrhea, UTI, localized fungal infections, back pain, arthralgia, renal insufficiency	• **Fixed-dose combination (FDC) of dapagliflozin and saxagliptin** • Evaluated in 1 trial showing the 2 drug combination reduced A1c more than a single agent but without a clinically significant difference between groups • **Contains 2 nonformulary and non step-preferred agents** • **Aside from providing a FDC, adds no compelling clinical advantage over existing UF agents**
semaglutide (Ozempic)	Non-Insulin Diabetes Drugs: GLP1RAs	• exenatide once weekly • exenatide twice daily • liraglutide • albiglutide • lixisenatide • dulaglutide	SubQ injectable • Pre-filled multi-dose pen • Strengths: 0.25mg, 0.5mg, 1mg	Adjunct to diabetes and exercise in type 2 diabetes mellitus	Black box warning: risk of thyroid C-cell tumors (like most in the class) ≥5%: nausea, vomiting, diarrhea, constipation, abdominal pain	• **7th approved GLP1RA and the 4th once weekly formulation** • Compared head-to-head with Bydureon and Trulicity • No clinically relevant difference in A1c or other secondary endpoints • **Step therapy change after Feb 2018 meeting will require a trial of Bydureon/BCise and Trulicity firs,t before use of non step- preferred agents**

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
sodium picosulfate; magnesium oxide; anhydrous citric acid (Clenpiq)	Laxatives-Cathartics-Stool Softeners	• GoLytely • OsmoPrep • Prepopik	Split-dose method: one dose evening before procedure; one dose morning of procedure 2 bottles of 160 mL each	Osmotic laxative indicated for cleansing the colon in adults prior to colonoscopy	Contraindicated if severe renal dysfunction (creatinine clearance <30 mL/min) abdominal pain and bloating, dehydration, hypermagnesemia, hyponatremia, N/V/D, proctalgia, rash, itching, seizures	• **Same ingredients as Prepopik, but is pre-mixed oral solution vs powder** • Does not require mixing with water – ready to drink • Mechanism combines a stimulant effect (sodium picosulfate) to increase motility with, hyperosmotic effect (magnesium oxide and citric acid) to induce diarrhea • More tolerable than PEG-containing regimens (GoLytely) • Disadvantages include the risk of electrolyte disturbances; has not been as well studied as PEG-containing regimens, and higher cost compared to magnesium-containing regimens • **No clinical advantages over other bowel prep products other than it is a low volume pre-mixed bowel prep**
spironolactone oral suspension (CaroSpir)	Diuretics	• spironolactone tabs • amiloride • amiloride/ HCTZ • spironolactone/ HCTZ • triamterene/ HCTZ	25 mg/5 mL oral suspension; 118 mL and 473 mL bottles; banana flavored	• hypertension (add on therapy) • heart failure • edema caused by cirrhosis	• hyperkalemia • fluid/electrolyte imbalance • worsening renal function • gynecomastia	• Aldosterone receptor blocker, potassium-sparing diuretic • No clinical trial data – 505b(2) pathway approval • Package insert states “not therapeutically equivalent to Aldactone” • Limited to doses <100 mg due to pharmacokinetic profile; may cause unexpectedly high spironolactone levels • Convenience formulation for a commercially-prepared product • No pediatric indications • **No compelling advantages over existing UF agents**

Appendix F—Mail Order Status of Medications Designated Nonformulary During the February 2018 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
Feb 2018	**Non-Insulin Diabetes Drugs: GLP1RAs** (Note: the class as a whole is on the EMMPI list) ▪ semaglutide (Ozempic) **Newly-Approved Drugs per 32 CFR 199.21(g)(5)** ▪ latanoprostene bunod ophthalmic solution (Vyzulta) ▪ dapagliflozin/saxagliptin (Qtern) ▪ house dust mite allergen extract sublingual tablets (Odactra) ▪ spironolactone oral suspension (CaroSpir) **Other** ▪ flibanserin (Addyi)	**Newly-Approved Drugs per 32 CFR 199.21(g)(5)** **Acute use exception applies:** ▪ coagulation factor IX, recombinant (Rebinyn) ▪ sodium picosulfate/magnesium oxide/anhydrous citric acid (Clenpiq) **Other: Feasibility exception applies (unavailable at mail order):** ▪ fluticasone propionate 93 mcg nasal spray (Xhance) ▪ minocycline ER capsules (Ximino)

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 2018	**Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) Subclass**	UF Class Review Class previously reviewed Nov 2010 Nov 2012 Aug 2015	BCF Step-Preferred ▪ exenatide once weekly injection (Bydureon) ▪ exenatide once weekly autoinjector (Bydureon BCise)	UF Step-Preferred ▪ dulaglutide (Trulicity)	NF Non Step-Preferred ▪ albiglutide (Tanzeum) ▪ exenatide twice daily (Byetta) ▪ liraglutide (Victoza) ▪ lixisenatide (Adlyxin) ▪ semaglutide (Ozempic)	Pending signing of the minutes / 90 days The effective date is July 25, 2018	Manual PA criteria required for all new and current users of a GLP1RA	▪ Must try metformin first in all new users of any GLP1RA unless a contraindication exists ▪ Must try Bydureon/BCise and Trulicity first before use of a nonformulary, non step-preferred GLP1RA ▪ Tanzeum market D/C in Aug 2018 ▪ See Appendix C
Feb 2018	**Anti-Inflammatory Immuno-modulatory Ophthalmic Drugs: Ophthalmic Immuno-modulatory Subclass**	UF Class review Class previously reviewed Feb 2016	▪ BCF: none in subclass ▪ prednisolone ophthalmic suspension is BCF (Pred Mild, Pred Forte)	UF ▪ cyclosporine 0.05% ophthalmic emulsion (Restasis) ▪ lifitegrast 5% ophthalmic solution (Xiidra)	None	Pending signing of the minutes / 90 days The effective date is July 25, 2018	Manual PA criteria applies to all new patients defined as not having filled Xiidra or Restasis in the last 120 days	▪ A trial of two different artificial tears products required first ▪ See Appendix C

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 2018	**Osteoporosis Drugs: Parathyroid Hormone Analogs Subclass**	UF Class Review Subclass not reviewed; Class Reviewed June 2013	▪BCF: none in the subclass ▪alendronate is BCF for the bisphos-phonates	<u>UF and Step-Preferred</u> ▪ teriparatide injection (Forteo)	<u>NF Non Step-Preferred</u> ▪ abaloparatide injection (Tymlos)	Pending signing of the minutes / 60 days The effective date is June 27, 2018	Manual PA and QL apply	▪ A trial of Forteo is required in all new Tymlos patients ▪ See Appendix C
Feb 2018	**Cortico-steroids-Immune Modulators: Adreno-corticotropic Subclass**	UF Class Review Not previously reviewed	▪BCF: none in the subclass ▪prednisone and prednisolone are on the BCF	<u>UF</u> ▪ repository corticotropin injection (H.P. Acthar Gel)	Not Applicable	Pending signing of the minutes / 60 days The effective date is June 27, 2018	PA and QLs apply	▪ Prior Authorization applies for infantile spasms and multiple sclerosis exacerbation; other uses not covered ▪ See Appendix C

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

Appendix H—Table of Abbreviations

A1c	hemoglobin A1c
ACTH	adrenocorticotropic hormones
ADR	adverse drug reaction
AE	adverse event
Afib	atrial fibrillation
AKC	atopic keratoconjunctivitis
ALS	amyotrophic lateral sclerosis
ARR	absolute risk reduction
BCF	Basic Core Formulary
BIA	budget impact analysis
BMD	bone mineral density
BPA	blanket purchase agreement
CFR	Code of Federal Regulations
CIC	chronic idiopathic constipation
CMA	cost minimization analysis
CMV	cytomegalovirus
CVD	cardiovascular disease
CVOTs	cardiovascular outcomes trials
DAPA	Distribution and Pricing Agreement
DHA	Defense Health Agency
DoD	Department of Defense
DPP-4	dipeptidyl peptidase-4 inhibitor
DR	delayed release
ECF	Extended Core Formulary
EEG	electroencephalography
EHR	electronic health record
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FDC	fixed-dose combination
FEV1	forced expiratory volume in one second
FSGS	focal segmental glomerulosclerosis
FY	Fiscal Year
GI	gastrointestinal
GINA	Global Initiative for Asthma
GLP1RA	glucagon-like peptide-1 receptor agonist
GvHD	graft versus host disease
HA	heachche
HCTZ	hydrochlorothiazide
HDM	house dust mite
HIV	human immunodeficiency virus
HSDD	hypoactive sexual desire disorder
HSCT	hematopoietic stem cell transplant
IBS-C	irritable bowel syndrome – constipation predominant
ICER	Institute for Clinical and Economic Review

IOP	intraocular pressure
IR	immediate release
IV	intravenous
MCL	mantle cell lymphoma
MHS	Military Health System
MHS PMWG	Military Health System Pain Management Work Group
MI	myocardial infarction
MN	medical necessity
MPGN	membranoproliferative glomerulonephritis
MS	multiple sclerosis
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NF	nonformulary
NNT	number needed to treat
NO	nitric oxide
NSCLC	non-small cell lung cancer
ORR	overall response rates
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PDE-5	phosphodiesterase-5
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PT	patient
PTH	parathyroid hormone
QLs	quantity limits
REMS	Risk Evaluation and Mitigation Strategies
SC/SQ	subcutaneous
SGLT2	sodium glucose co-transporter 2 inhibitor
SL	sublingual
SLIT	sublingual immunotherapy
STR	single table regimen
T2DM	type 2 diabetes mellitus
TEN	Toxic Epidermal Necrolysis Syndrome
TIBs	targeted immunomodulatory biologics
TX	treatment
UF	Uniform Formulary
URTI	upper respiratory tract infection
UTI	urinary tract infection
VA	U.S. Department of Veterans Affairs
VKC	vernal keratoconjunctivitis
XR/SR	extended/sustained release