DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
May 2024

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 1st and 2nd, 2024.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February 2024 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the February 2024 DoD P&T Committee meeting on April 22nd, 2024.

B. Clarification of previous meeting minutes

- **February 2024**
  - **Growth Hormone Stimulating Agents—Norditropin**: Patients affected by the copay change for Norditropin from the Tier 1 to the Tier 2 copay will receive letters.
  - **Continuous Glucose Monitoring Systems (CGMS)—FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6 and Dexcom G7:** The PA updates for the CGMS were originally set to implement at 60-days after signing (June 26th), however, implementation occurred early at 30-days after signing (May 29th).
  - **Oncological—crizotinib (Xalkori) pellets:** The quantity limits will be 30 days at all points of service, similar to Xalkori tablets. Additionally, an age edit will apply to children 12 years of age and younger; they will not have to go through the prior authorization PA process.
  - **Lidocaine patch (Lidocan II/III**) are designated as uniform formulary (UF) with a default PA; they are not on the basic core formulary (BCF).

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 completely excluded pharmaceutical agents were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and completely excluded pharmaceutical agent recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those

outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018, permanently codified at 10 USC 1074g (a)(10). Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the TRICARE Mail Order Pharmacy (TMOP)in accordance with 10 USC 1074g (a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (a)(9), added by Section 702(c)(2) of the NDAA for FY 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the TMOP.

IV. UF DRUG CLASS REVIEWS

A. Insulins: Basal Insulin Analogs

Background—The Basal Insulin subclass was last reviewed at the August 2017 DoD P&T Committee meeting, and branded insulin glargine (Lantus) was designated as step-preferred. Since the last review, several biosimilars and unbranded biologics are now marketed.

There is significant biosimilar presence for the Basal Insulins. A biosimilar is defined by the Food and Drug Administration (FDA) as a biological product that is approved based on data demonstrating it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. The DoD P&T Committee at the November 2022 meeting concluded that by FDA approval and definition, biosimilars are equally safe and efficacious which provides strong competition within products for drug classes with biosimilars. Not all biosimilars are cost effective when compared to their reference product. Unbranded biologics are marketed under the same 351(a) Biologic License Application (BLA) as the reference product. These unbranded biologics can have differing formulary status compared to their reference product.

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

Products

- The branded products in the Basal Insulins subclass include insulin glargine (Lantus), insulin detemir (Levemir), insulin glargine U-300 (Toujeo), insulin degludec (Tresiba U-100, Tresiba U-200), and three other branded insulin glargine products, Basaglar, Semglee, and Rezvoglar. Several biosimilars and unbranded biologics for glargine and degludec are available.
- The products are all supplied as prefilled disposable pens. In addition, vials are available for all the products with the exception of Toujeo, Basaglar, and Rezvoglar.

- Market discontinuation will occur this year for insulin detemir (Levemir) and insulin glargine (Semglee). Market supply disruptions have also affected the subclass.

Clinical Practice Guidelines

- Professional treatment guidelines for both Type 1 diabetes mellitus (T1DM) and Type 2 diabetes mellitus (T2DM) from the American Diabetes Association (ADA) do not state a preference for one basal insulin analog over another. Similar recommendations are made by the American Association of Clinical Endocrinology (ACCE) and by the United Kingdom National Institute for Health and Care Excellence (NICE).
- For pregnancy and gestational diabetes, the ADA and American College of Obstetrics and Gynecology prefer insulin glargine, detemir, and neutral protamine Hagedorn (NPH) over other basal insulins, based on long marketing history and not due to efficacy or safety concerns.
- For children, the ADA and the International Society for Pediatric and Adolescent Diabetes recommend basal insulins over other insulins, but no preference is stated for a particular product.

Efficacy

- There was no new compelling data to change the 2017 efficacy conclusion that while basal insulins differ in pharmacokinetic properties such as duration of action and dosing frequency, this variance does not translate into improved glycemic control or hemoglobin A1C improvements compared to one another.

Safety

- For T1DM, systematic reviews and meta-analyses in pediatric and nonpregnant adult patients comparing insulin detemir to insulin glargine, insulin degludec to insulin detemir, or insulin degludec to insulin glargine did not find clinically relevant differences for outcomes, including rates of hypoglycemia.
- Similar results were found for systematic reviews and meta-analyses in nonpregnant adult patients with T2DM when comparing insulin glargine or insulin detemir to NPH insulin.

Individual Product Characteristics

- **insulin glargine (Lantus)** is the reference biologic for insulin glargine. Advantages include availability in a prefilled pen, cartridge and vial, and approval for both adult and pediatric administration without a lower age limit. Lantus is well-accepted for use in pregnant patients. It is available in 100 units per milliliter (mL) which provides 80 units as the maximum dose. Lantus has a long history as the preferred MHS basal insulin dating back to 2010.

    - Unbranded insulin glargine U-100 is available.

- **insulin glargine U-300 (Toujeo)** is a concentrated insulin glargine product containing 300 units per mL in two prefilled reusable pen options. It is approved for pediatric patients down to age six. Compared to Lantus, Toujeo offers a longer half-life (19 hours vs. 12 hours) and longer duration of action (24-36 hours vs. 24 hours). Toujeo is available in a SoloStar pen which administers up to 80 units per dose, and a Max SoloStar pen which administers up to 160 units per dose.
    - Unbranded insulin glargine U-300 SoloStar and Max SoloStar are available.
- **insulin glargine (Basaglar)** is considered a "follow-on" insulin (originally approved by the 505(b)(2) pathway but through FDA administrative action is deemed a BLA ~~on~~ as of March 23, 2020) and is not a true biosimilar to Lantus, although the data to support approval included a series of clinical studies to demonstrate similarity to the insulin (Lantus). Basaglar has the same amino acid and pH as Lantus. Basaglar has the same amino acid and pH as Lantus.
    - Basaglar is also available as a TempoPen. The TempoSystem consists of a phone app, glucometer, Tempo Smart Button, and Tempo Insulin Pen. The TempoPen provides no additional benefit as compared to KwikPen formulations. The TempoSystem is not a TRICARE pharmacy benefit and is not currently covered under the TRICARE medical benefit.
- **insulin glargine (Semglee), insulin glargine-yfgn (Semglee), insulin glargine-aglr (Rezvoglar)** are biosimilars of Lantus. Semglee is available in both pens and vials. Semglee and Rezvoglar are interchangeable with Lantus. The branded insulin glargine (Semglee) formulation will be discontinued.
    - Unbranded insulin glargine-yfgn is available.
- **insulin degludec (Tresiba)** is the reference product for insulin degludec and offers a long duration of action up to 42 hours which allows for flexibility with regard to time of administration. Tresiba is available in both a U-100 and U-200 concentration. The U-100 pen administers up to 80 units per single injection and the U-200 pen administers up to 160 units per single injection.
    - Both concentrations are available as unbranded biologic products.
- **insulin detemir (Levemir)** is the reference insulin detemir product. Detemir requires twice daily dosing. Market discontinuation will occur in 2024. There are no biosimilar nor unbranded products available.

Other Factors

- The basal insulins are rated as pregnancy category C, with the exception of detemir which is rated as pregnancy category B.
- There is no compelling evidence to support use of one basal product over another in either pregnancy or pediatric patients per current guidelines.

Overall Clinical Conclusion

- There is no new meaningful clinical evidence to change the previous conclusions from 2017 formulary review.
- Per the definition of a biosimilar product, there are no clinically meaningful differences between the reference drug product and the biosimilar, allowing for a high degree of therapeutic interchangeability.
- Clinical practice guidelines do not prefer one basal product over another for safety or efficacy. Basal insulin analogs are considered equally safe and efficacious when compared to one another.
- Differences between basal products are largely based on provider experience or patient preferences.
- MHS provider feedback was overwhelmingly positive for Lantus remaining on the formulary.
- In order to meet the needs of MHS patients, one basal insulin product is needed, but additional options should be considered to protect against shortage situations.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that insulin glargine yfgn (unbranded), Lantus, insulin glargine (unbranded) and Rezvoglar, were the most cost effective basal insulins, followed by Toujeo; Levemir, Basaglar and Tresiba were the least cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the basal insulins in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

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

    - UF step-preferred

    - insulin glargine (Lantus)
- UF non-step-preferred
    - insulin glargine U-300 (Toujeo SoloStar, Toujeo Max SoloStar)
    - insulin glargine U-300 (unbranded)
    - insulin glargine (Rezvoglar) *(moves from NF to UF non-step-preferred)*
    - insulin glargine-yfgn (unbranded) *(moves from NF to UF non-step-preferred)*
    - insulin glargine U-100 (unbranded by Winthrop) *(vials move from NF to UF non-step-preferred, pens remain UF non-step-preferred)*
- NF non-step-preferred
    - insulin detemir (Levemir), pens and vials *(pens move from UF to NF non-step-preferred, vials remain NF non-step-preferred); note market removal in 2024)*
    - insulin degludec (Tresiba)
    - insulin degludec (unbranded)
    - insulin glargine (Basaglar)
    - insulin glargine (Semglee); *note market removal in 2024*
    - insulin glargine-yfgn (Semglee)
- Completely Excluded - None
- Note that as part of this recommendation, a trial of Lantus is required in all new users for all non-step-preferred products. (See the PA criteria section for additional details.)
- Note that Lantus will remain on the Basic Core Formulary (BCF)

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA is not required for Lantus, however PA criteria have applied to the non-step-preferred products since the 2017 class review. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) changes to the PA criteria for the non-step-preferred products in all new users as outlined below. See Appendix C for the full criteria.
    - For new users of Basaglar, Semglee, Semglee-yfgn, Rezvoglar, insulin glargine-yfgn (unbranded), insulin glargine (unbranded), or insulin detemir (Levemir), a trial of Lantus is required first, unless the patient has had an inadequate response to Lantus.

- New users of insulin glargine U-300 (Toujeo, unbranded) must be currently using greater than 80 units of basal insulin per day and have experienced clinically significant hypoglycemia, or they must be using greater than 100 units of basal insulin per day (regardless of whether they have experienced hypoglycemia).
- Providers ordering insulin degludec (unbranded) for new users must explain why the patient cannot use Lantus and Toujeo.
- For insulin degludec (Tresiba) in new users, the provider must indicate why the patient cannot use Lantus, Toujeo, and insulin degludec (unbranded).

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for the NF, non-step-preferred products, (Levemir, Tresiba, unbranded insulin degludec, Basaglar, Semglee, Semglee-yfgn). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the basal insulins on the EMMPI program. See Appendix F).

5. ***COMMITTEE ACTION: TIER 1 COPAY FOR LANTUS—***Lantus currently has a Tier 1 copay, implemented in 2017. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the Tier 1 copay for Lantus.

6. ***COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding the basal insulins to the program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.

7. ***COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM, TIER 1 COPAY, RAPID RESPONSE PROGRAM and IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) 1) An effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) that DHA will send letters to beneficiaries receiving Levemir who will be affected by the NF recommendation and market removal. See Appendix G for the actual implementation date.

B. Weight Loss Agents

Background—Section 729 of the NDAA for FY 2017 authorized coverage under TRICARE Prime and TRICARE Select for medically necessary treatment of obesity even if it is the sole or major condition treated. The DoD P&T Committee initially reviewed the weight loss agents for formulary status in 2017.

The drugs in the class are comprised of older amphetamine derivatives (e.g., phentermine, benzphetamine), and branded products including fixed dose combinations of phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), a proprietary phentermine 8 mg formulation (Lomaira), the fat absorption inhibitor orlistat (Xenical) and the injectable glucagon-like peptide-1 receptor agonists (GLP1-RAs) liraglutide (Saxenda), semaglutide (Wegovy), and tirzepatide (Zepbound). Semaglutide, tirzepatide and liraglutide are also FDA-approved under distinct brand names for diabetes (Ozempic, Mounjaro, and Victoza, respectively). Notable changes since the last formulary review include clinical practice guideline updates and market removal of locaserin (Belviq) in 2020.

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

Clinical Practice Guidelines

- In overweight and obese individuals, particularly those with comorbidities, long-term weight loss greater than or equal to 5 percent of baseline body weight following diet, exercise, or drug treatment is associated with improvement in metabolic and cardiovascular risk factors.
- Although professional treatment guidelines differ with respect to weight loss recommendations, there is universal agreement that comprehensive lifestyle intervention is the foundation for obesity management. Pharmacotherapy may be considered for patients with a body mass index (BMI) greater than 30 and for those with a BMI greater than or equal to 27 with additional obesity-associated comorbidities (e.g., diabetes, impaired glucose tolerance, hypertension, dyslipidemia, sleep apnea).
- The 2024 ADA Standards of Care in Diabetes state obesity management can delay the development of T2DM. There is additional strong evidence that maintaining a 10% weight loss can lead to disease modifying effects and possible remission of T2DM. The guideline specifies that semaglutide and tirzepatide are very highly effective for weight loss compared to other available therapies, with dulaglutide (Trulicity) and liraglutide (Victoza), which are GLP-1RAs approved for diabetic patients listed as highly effective.
- The 2023 AACE consensus statement recommends the GLP-1RA agents (semaglutide, liraglutide, tirzepatide) or Qsymia for overweight or obese patients who are at risk of developing T2DM and who have failed lifestyle modification. Contrave, short-term phentermine, or orlistat can be used if the above medications are not tolerated or are inaccessible to patients.

- The 2022 American Gastroenterological Association (AGA) guideline recommends semaglutide over other approved anti-obesity medications for long term treatment in most patients with an inadequate response to lifestyle interventions. The AGA recommends against the use of orlistat (Xenical) for weight loss. Tirzepatide was not yet approved for weight loss at the time of the guideline publication.

Efficacy

- There are limited head-to-head comparative data for the weight loss drugs. Individual clinical trial data, package labeling and meta-analyses show greater weight loss with semaglutide and tirzepatide compared to phentermine, liraglutide, phentermine/topiramate and bupropion/naltrexone.
- A 2023 network meta-analysis comparing the efficacy of the GLP-1RAs for obesity management concluded the GLP-1RAs produce significant reductions in weight. Tirzepatide resulted in greater weight loss than semaglutide or liraglutide.
- A comparison of semaglutide with dulaglutide in the SUSTAIN-7 trial in diabetic patients showed the magnitude of weight loss achieved with semaglutide was double the amount achieved with dulaglutide.
- The SELECT trial evaluated major adverse cardiovascular events (MACE) between placebo and semaglutide in obese patients with pre-existing cardiovascular disease with no history of diabetes. After a mean follow-up of 40 months, semaglutide resulted in a 20% reduction in the risk of MACE (a composite of cardiovascular (CV) death, nonfatal myocardial infarction or non-fatal stroke), compared with placebo. The Wegovy package labeling was updated for this indication in March 2024.
    - The ongoing SURMOUNT-MMO trial is investigating cardiovascular outcomes with tirzepatide in obese patients without diabetes, with results expected in 2027.

Safety

- The products differ in their individual safety profiles, but common adverse reactions for most agents include increased heart rate, nausea, and diarrhea.
- Phentermine and the other amphetamine products are contraindicated in patients with a history of cardiovascular disease including coronary artery disease, stroke, arrhythmias, congestive heart failure, and uncontrolled hypertension.
- The GLP-1RAs share the same precautions, warnings, and adverse events. Gastrointestinal (GI) adverse events are most commonly reported and include nausea and vomiting. Patients receiving a GLP-1RA require

counseling regarding potential mental health side effects, need for contraception, and risk of GI paralysis.

- Contrave labeling includes a black box warning against use in major depression or psychiatric disorders and should be avoided in patients who have a history of seizures, uncontrolled hypertension, and in patients taking opioids.
- Qsymia requires a Risk Evaluation and Mitigation Strategy (REMS) program due to safety concerns in pregnant women and risk of congenital malformations, due to the topiramate component. Patients with hypertension, elevated heart rate, or renal dysfunction should use Qsymia with caution.
- Xenical should be avoided in patients with gallbladder disease or malabsorption syndromes.

Individual Product Characteristics

- **phentermine, phendimetrazine, benzphetamine and diethylpropion** have been approved for decades for short-term weight management. MHS provider feedback support phentermine as a first step for treating obese patients who do not have contraindications.
- **phentermine 8 mg (Lomaira)** is a low-dose phentermine formulation approved for short-term use that can be administered up to three times daily before meals. Package labeling contains the same cardiovascular warning as the other amphetamine products.
- **phentermine/topiramate (Qsymia)** is mentioned in the 2023 AACE guidelines and can produce weight loss ranging from 5% to 11% from baseline. Disadvantages include the REMS program requirement for teratogenicity, its controlled substance status (CIV), and unavailability from TMOP (due to the REMS program). Qsymia generic formulations are expected in late 2024. MHS providers mentioned they prescribe the individual generic components separately.
- **naltrexone SR/bupropion SR (Contrave)** treatment results in a weight loss average of 5% from baseline. Contrave is relegated to second-line status due to the black box warning for suicidal thoughts and reduced efficacy relative to the other drugs in the class.
- **orlistat (Xenical)** is approved for children however it results in minimal weight loss, causes significant adverse GI effects, and is no longer recommended in clinical practice guidelines.
- **liraglutide (Saxenda)** advantages include evidence for reduced major adverse cardiovascular outcomes with the Victoza branded product. It is the least effective of the injectable weight loss GLP-1RAs, resulting in an average 8% weight loss.

- **semaglutide (Wegovy)** treatment results in an average 15% weight loss from baseline. Semaglutide is mentioned in several guidelines as being highly effective for weight loss. It is the only GLP-1RA labeled to reduce the risk of adverse CV outcomes, based on the SELECT trial.
- **tirzepatide (Zepbound)** treatment can reduce baseline weight on average of 15% to 20%. MHS providers mentioned a potentially better tolerated GI side effect profile of tirzepatide over semaglutide.

Other Factors

- For adolescent patients, Wegovy, Qsymia and Xenical are approved for patients as young as 12 years, while phentermine is not recommended for those under 16 years of age.
- A comparison of DoD with other health care plans showed several commercial plans do not cover weight loss medications due to cost considerations.
- Shortages have notably affected this class as demand increases nationally and globally. Prescribers are encouraged to reserve use of GLP1-RAs specifically approved for diabetes [e.g., dulaglutide (Trulicity), liraglutide (Victoza), semaglutide (Ozempic) and tirzepatide (Mounjaro)], solely for patients with diabetes and not for treating non-diabetic obese patients.

Overall Clinical Conclusion

- There is a moderate degree of interchangeability within the weight loss class as a whole due to differences in efficacy and safety profiles. However, there is a high degree of interchangeability between Wegovy and Zepbound.
- Provider feedback showed support for a shared decision-making model for pharmacotherapy for weight management. There was strong agreement for formulary inclusion of at least one GLP-1RA.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- The committee reviewed the CMA results for benzphetamine, diethylpropion IR and ER, liraglutide (Saxenda), naltrexone SR/bupropion SR (Contrave), orlistat (Xenical, generics), phendimetrazine, phentermine, phentermine 8 mg (Lomaira, generics), phentermine/topiramate (Qsymia), semaglutide (Wegovy), and tirzepatide (Zepbound).
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely

excluded on the UF. BIA results showed that designating the weight loss agents in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

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

   - UF generics
     - phentermine (Adipex-P, generics)
     - benzphetamine (Didrex, generics)
     - diethylpropion immediate release (IR) and sustained release (SR) (Tenuate, Tandil, generics)
     - phendimetrazine IR and SR (Bontril, generics)
     - phentermine 8mg (Lomaira, generics)
   - UF step-preferred brands
     - naltrexone SR/bupropion SR (Contrave) – *moves from NF to UF step-preferred*
     - phentermine/topiramate (Qsymia) – *moves from NF to UF step-preferred*
     - semaglutide (Wegovy) – *moves from UF to UF step-preferred*
     - tirzepatide (Zepbound) – *moves from UF to UF step-preferred*
   - NF non-step-preferred brands
     - liraglutide (Saxenda)
     - orlistat (Xenical, generics)
   - Completely Excluded – None
   - Note that as part of this recommendation, a trial of generic phentermine or one of the older generic phentermine derivatives in addition to all of the step-preferred branded drugs is required first for the NF, non-step-preferred products in all new users, unless the patient has a contraindication, inadequate response, or has experienced adverse effects with the step-preferred products.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA has been in place since the original class review in 2017, with several updates made since then. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria as discussed below in new users. PA is required to ensure appropriate use of the weight loss drugs

and due to national supply shortages. Currently a sequential trial of phentermine, Qsymia, and Contrave is required before a GLP1-RA. The PA changes will apply to new patients, due to the varying mechanisms of action for the products and national supply shortages. See Appendix C.

- Lifestyle modification remains a requirement prior to use of pharmacotherapy, based on clinical practice guidelines.
- PA is removed for phentermine, benzphetamine, diethylpropion IR/SR, phendimetrazine IR/and Lomaira.
- For Contrave, Qsymia, Wegovy and Zepbound, only a trial of generic phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR is required, rather than sequential use of all the products, unless the patient has a contraindication, inadequate response, or has experienced adverse effects to the step-preferred products.
- For Wegovy and Zepbound, the requirement for a trial of dulaglutide (Trulicity) and metformin first in patients with diabetes is removed, as Trulicity is not as effective at weight loss compared to semaglutide and tirzepatide.
- For new adult users of Saxenda and Xenical, a trial of phentermine plus all the step-preferred branded drugs (Contrave, Qsymia, Wegovy, and Zepbound) is required first, unless the patient has a contraindication, inadequate response, or has experienced adverse effects to the step-preferred products.
- The initial four- or six- month renewal period was removed, and the PAs will now expire annually (yearly renewal required).
- FDA-approved ages for pediatric patients were considered in the step-therapy requirements for adolescents.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated MN criteria for Saxenda and Xenical. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) excluding all the weight loss products from the EMMPI program. See Appendix F.

5. ***COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM and IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date the first

Wednesday 30 days after signing of the minutes in all points of service. See Appendix G for the actual implementation date.

C. PULMONARY II AGENTS: INHALED CORTICOSTEROIDS (ICS) SUBCLASS

Background—The P&T Committee evaluated the relative clinical effectiveness of the Inhaled Corticosteroids (ICS) subclass. The class includes a variety of dry powder inhalers and hydrofluoroalkane (HFA) oral inhalers. This class was last reviewed for formulary status in May 2014, when fluticasone propionate (Flovent Diskus and Flovent HFA) was designated as the UF step-preferred products, and all other products were non-step-preferred.

The branded Flovent HFA and Diskus agents were discontinued from the market in late 2023 (see November 2023 DoD P&T Committee meeting minutes). Language in the PA criteria for the non-step-preferred inhaled corticosteroids was updated to require a trial of fluticasone propionate first, rather than Flovent HFA or Flovent Diskus. Additionally, the previous Tier 1 copay for brand Flovent HFA and Flovent Diskus were removed in November 2023.

Note that budesonide nebulized solution (Pulmicort Respule) remains UF but is not subject to the step-therapy structure for this subclass. All agents are FDA-approved for asthma management. The clinical review focused on available published trials, clinical practice guidelines, meta-analyses, and systematic reviews.

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

Clinical Practice Guidelines

- *Asthma*: Guidelines support monotherapy with ICS as part of a treatment plan for children and as an alternative treatment option for adolescents and adults. Preferred asthma treatment continues to support use of Maintenance and Reliever Therapy (MART) with combination formoterol and ICS. Society guidelines do not prefer one specific ICS product over another.
- *Off-label uses*:
    - *Eosinophilic Esophagitis (EoE)*: Topical corticosteroids may be used to treat EoE; however no single product is favored in guidelines.
    - *Chronic Obstructive Pulmonary Disease (COPD)*: Professional guidelines state monotherapy with ICS is not recommended.

Efficacy

- *Asthma*: There is limited head-to-head data between agents within the subclass. A network meta-analysis was reviewed for asthma treatment in children and concludes an improvement in asthma symptoms and exacerbations with ciclesonide versus budesonide and fluticasone could be neither demonstrated nor refuted. An additional network meta-analysis was reviewed which supported comparable treatment effect between

fluticasone furoate (Arnuity Ellipta) and fluticasone propionate (Flovent) in adolescents and adults with persistent asthma.

Safety

- In terms of safety, all agents carry similar warnings. Milk allergen concerns are unique to dry powder inhaler formulations. Budesonide remains the preferred ICS for use in pregnancy. MHS providers mentioned ciclesonide (Alvesco) may be preferred for use in rare cases of concern for patients with adrenal suppression.

Other Factors and Individual Product Characteristics

- **Budesonide** is the only drug in this subclass which is available in a nebulized solution (Pulmicort Respules) and dry powder inhaler (Pulmicort Flexhaler). **Mometasone** is available in a dry powder inhaler (Asmanex Twisthaler) and HFA (Asmanex HFA).
- **Fluticasone propionate** is available in multiple formulations, including dry powder inhaler (diskus) and HFA. The branded Flovent products were removed from the market by the manufacturer in late 2023, but authorized generic formulations are available for both the diskus and HFA. The completely excluded agent, fluticasone propionate digihaler (ArmonAir Digihaler), continues to offer no significant clinical benefit relative to other ICS agents and the needs of TRICARE beneficiaries are met by numerous alternative agents.
- **Fluticasone furoate (Arnuity Ellipta**) is available as a single product (dry powder inhaler) and offers no compelling clinical advantages compared to using fluticasone propionate.
- **Beclomethasone (Qvar Redihaler)** and **ciclesonide (Alvesco)** are only available in HFA formulations.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, at least two ICS products are required on the formulary.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results of the ICSs showed the following, ranked from most cost effective to least cost effective: ciclesonide (Alvesco HFA), mometasone furoate (Asmanex Twisthaler), fluticasone propionate diskus authorized generic, mometasone furoate (Asmanex HFA), fluticasone propionate HFA authorized generic, fluticasone propionate (Flovent Diskus brand - discontinued), fluticasone furoate (Arnuity Ellipta), budesonide (Pulmicort Flexhaler), beclomethasone (Qvar Redihaler), fluticasone propionate (Flovent

HFA brand - discontinued), budesonide (Pulmicort Respule) and fluticasone propionate digihaler (Armonair Digihaler).

- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the ICS agents in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

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

    - UF
        - ciclesonide (Alvesco) – *moves from NF to UF status*
        - fluticasone propionate diskus authorized generic
        - fluticasone propionate HFA authorized generic
        - mometasone (Asmanex Twisthaler) – *moves from NF to UF status*
        - mometasone (Asmanex HFA)
    - NF
        - beclomethasone (QVAR Redihaler)
        - budesonide (Pulmicort Flexhaler)
        - fluticasone furoate (Arnuity Ellipta) – *moves from UF to NF status*
    - Completed Excluded
        - fluticasone propionate digihaler (Armonair Digihaler)

    - Note that budesonide nebulized solution (Pulmicort Respules) remains UF
    - Note the brand fluticasone diskus and HFA (Flovent Diskus, Flovent HFA) are no longer marketed e

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA and step therapy have been required since the original class review in 2014. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria and step therapy for all the products in the class.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1

absent) updates for the MN criteria for Arnuity Ellipta, Pulmicort Flexhaler, and Qvar Redihaler. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent), maintaining the current QL for all the ICS products at all points of service. See Appendix D.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the ICS products on the EMMPI program. See Appendix F).

6. ***COMMITTEE ACTION: UF, MN, PA REMOVAL, QLs, EMMPI PROGRAM, and IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) DHA mail letters to patients affected by the copay change for Arnuity Ellipta. See Appendix G for the actual implementation date.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (17 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 May 2024 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from TMOP.

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

    - UF
        - birch triterpenes 10% (w/w) topical gel (Filsuvez) – Skin Preps for epidermolysis bullosa
        - budesonide 2 mg/10 mL oral suspension (Eohilia) – Gastrointestinal-1 Agent for eosinophilic esophagitis (EoE)
        - eflornithine tablets (Iwilfin) – Oncological Agent for neuroblastoma

        - eltrombopag 9 mg, 18 mg, 35 mg, 54 mg tablets (Alvaiz) – Hematological Agents: platelets, for chronic immune thrombocytopenia (ITP)
        - eplontersen injection (Wainua) – Miscellaneous Neurological Agent for hereditary transthyretin-mediated amyloidosis
        - infliximab-dyyb injection (Zymfentra) – Targeted Immunomodulatory Biologics (TIBs): tumor necrosis factor (TNF) inhibitor for ulcerative colitis and Crohn's disease.
        - nedosiran injection (Rivfloza) – Nephrology Agent for hyperoxaluria type 1 (PH1)
        - omalizumab autoinjector (Xolair) – Atopy Agents; new formulation and indication for reduction of allergic reactions (Type I) in patients with IgE-mediated food allergy
        - vamorolone oral suspension (Agamree) – Corticosteroids – Immune Modulator for Duchenne Muscular Dystrophy
        - zilucoplan injection (Zilbrysq) – Miscellaneous Neurological Agent for myasthenia gravis
    - NF
        - bosutinib capsules (Bosulif) – Oncological Agents for chronic myelogenous leukemia (CML)
        - cyclosporine 0.1% ophthalmic solution (Vevye) – Ophthalmic agent for dry eye disease
        - iptacopan (Fabhalta) – Hematological Agent for paroxysmal nocturnal hemoglobinuria (PNH)
        - roflumilast 0.3% topical foam (Zoryve) – Psoriasis Agent
        - sitagliptin free base (Zituvio) – Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitor for diabetes
        - sitagliptin free base (Zituvio authorized generic) – Diabetes Non-Insulin: (DPP-4) Inhibitor for diabetes
    - Completely Excluded – None

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Bosulif capsules, Vevye, Fabhalta, Zoryve foam, Zituvio and Zituvio authorized generic. See Appendix B for the full criteria.

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

- Applying manual PA criteria to new users of the oncology drugs Bosulif capsules and Iwilfin; and for new users of Filsuvez, Eohilia, Wainua, Fabhalta, Rivfloza, Agamree, Xolair and Zilbrysq.
- Applying manual PA criteria to new users of Zymfentra requiring a trial of Humira or intravenous infliximab, similar to what is in place for the other non-step-preferred TIBs approved for treating ulcerative colitis.
- Applying manual PA criteria to new users of Vevye, requiring a three-month trial of generic Restasis unit dose, Cequa, and Xiidra first, similar to the requirements for the other NF ophthalmic cyclosporine products.
- Applying manual PA criteria to new users of Zituvio and Zituvio authorized generic, requiring a trial of Januvia, similar to other NF, non-step-preferred DPP-4 inhibitor in the class.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Filsuvez, Bosulif, Vevye, Iwilfin, Wainua, Zymfentra, Fabhalta. Rivfloza, Xolair, Zoryve, Agamree, and Zilbrysq. See Appendix D for the QLs.

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

6. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.
    - **New Drugs Recommended for UF or NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

a) Anticonvulsants-Antimania Agents—brivaracetam (Briviact)— Briviact was reviewed as an innovator at the August 2016 P&T meeting and designated as NF. Briviact is an analog related to levetiracetam

(Keppra). Indirect comparison suggests there are no statistically significant differences between Briviact and Keppra with regard to efficacy and adverse effects.

Specialist feedback supported use of other anticonvulsants, including levetiracetam, before prescribing Briviact. MHS utilization data showed 50% of Briviact prescriptions were initiated by a neurologist, and nearly 50% of patients did not have a trial of levetiracetam first. Many commercial health plans require PA criteria for Briviact. PA criteria were recommended for Briviact tablets and oral solution in new patients requiring neurologist prescribing, limiting use to FDA-approved indications, and requiring a trial of levetiracetam first. An automated look back will apply, allowing coverage if the patient has received any formulation of levetiracetam in the past 180 days.

COMMITTEE ACTION: BRIVARACETAM (BRIVIACT) PA CRITERIA, RAPID RESPONSE PROGRAM ADDITION AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) PA criteria in new users of Briviact tablets and oral solution. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. Additionally, Briviact will be added to the rapid response ("safety net") program managed by the TRICARE pharmacy contractor. See Appendix C for the full PA criteria.

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

Manual PA criteria was recommended for one recently marketed drug produced by a sole manufacturer which contains an active ingredient that is widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, the product does not meet the criteria for innovators and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

a) Narcotic Analgesics and Combinations—tramadol 25 mg tablets— Numerous other tramadol formulations are available, including scored tramadol 50 mg tablets, that are more cost-effective than this 25 mg formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for tramadol 25 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective

the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

a) **Atopy—dupilumab (Dupixent)**—Dupixent was recently approved for use in younger patients with eosinophilic esophagitis. The manual PA criteria were updated to allow use in pediatric patients aged 1 year and older, weighing at least 15 kilograms.

b) **Oncological Agents: Breast Cancer—alpelisib (Piqray)**—The manual PA criteria for Piqray were updated to allow use in pre- and peri-menopausal women.

c) **Oncological Agents: Lung Cancer—alectinib (Alecensa)—**The manual PA criteria were updated to allow use in non-metastatic disease. Additionally, the FDA-approved age range was added to the PA, similar to what is in place for other oncology drugs.

d) **Oncological Agents—erdafitinib (Balversa)—**The manual PA criteria were updated due to two recent changes in the FDA labeling. The product labeling no longer requires a trial of platinum-containing chemotherapy, but rather requires only one line of prior systemic therapy. Additionally, the FDA indication was restricted and Balversa is no longer indicated for patients with FGFR2 genetic alterations.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Dupixent, Piqray, Alecensa, and Balversa in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

4. Updated PA Criteria for Reasons other than New Indications

a) **Oncological Agents: Lung Cancer—sotorasib (Lumakras)—**The manual PA criteria for Lumakras were updated to remove the preference for the 120 mg tablets over the 320 mg tablets as there is no longer a cost justification for the preference.

b) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis**

Factor Inhibitors (TNFs)—golimumab (Simponi)—Based on MTF provider feedback and clinical trial data, Simponi will be allowed for use as monotherapy for rheumatoid arthritis. The requirement to use Simponi in conjunction with methotrexate will be removed.

c) **TIBs—adalimumab (Humira), etanercept (Enbrel), ixekizumab (Taltz), ustekinumab (Stelara), and secukinumab (Cosentyx)—**PA criteria for pediatric indications for several TIBs were evaluated. Opportunities to modify the PAs for Humira, Enbrel, Taltz, Stelara, and Cosentyx were identified to improve consistency, clarity, and intent. These changes include allowing Humira for additional ages (for children as young as 2 years of age for all uses), and indications (including psoriatic arthritis and plaque psoriasis) based on clinical evidence and practice guidelines; updating the other TIBs corresponding to the changes made to Humira; standardizing PA flow for pyoderma gangrenosum and hidradenitis suppurativa based on treatment guidelines; updating the criteria for ankylosing spondylitis and non-radiographic ankylosing spondyloarthritis (nr-axSpA) to follow similar NSAID treatment pathways based on guidelines; and removing research-based scoring systems for nr-axSpA. For Enbrel, Taltz and Stelara, a trial of Humira will be required for all appropriate indications regardless of age.

d) **Growth Hormone Stimulating Agents—**The growth hormone stimulating agents were last reviewed at the February 2024 P&T Committee meeting. Currently annual renewal is required for both adult and pediatric indications. Provider feedback relayed the adult indications for growth hormone agents are usually permanent and occur as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy. Clinical and utilization data were reviewed which supported removing the annual renewal criteria for adults. Annual renewal is still required for pediatric patients.

e) **Corticosteroid Immune Modulators—deflazacort (Emflaza)—**Emflaza was reviewed as a new drug at the February 2020 P&T Committee meeting and is approved for treating patients 2 years of age and older with Duchenne Muscular Dystrophy (DMD), similar to the new drug Agamree. The Emflaza PA criteria were updated to reflect the criteria recommended for Agamree in the new drug section.

f) **Gastrointestinal-2 Agents—sacrosidase oral solution (Sucraid)—**At the May 2023 P&T meeting, PA criteria were originally added to Sucraid to ensure appropriate use of this medication. Sucraid utilization and prescribing trends were reviewed. Based on MTF provider feedback, the following edits were recommended in new and current users: gastroenterologist specialist prescribing, diagnostic confirmation of congenital sucrase-isomaltase deficiency (CSID) by biopsy or genetic testing with documentation submitted, dietary restriction of sucrose, and annual PA expiration.

***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, MEDICAL NECESSITY CRITERIA, AND IMPLEMENTATION PERIOD*—**The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Lumakras, Simponi, Humira, Enbrel, Taltz, Stelara, Cosentyx, growth hormone stimulating agents and Emflaza in new users, and updates to the Sucraid PA in new and current users. Implementation will be effective the first Wednesday 60 days after signing of the minutes. Patients affected by the Sucraid updated PA criteria will receive letters. See Appendix C for the full criteria.

5. Removal of PA

Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors—empagliflozin/linagliptin (Glyxambi) and empagliflozin/ linagliptin/metformin XR (Trijardy XR)—Currently, both Glyxambi and Trijardy XR are designated as UF requiring PA. Empagliflozin (Jardiance) is the step-preferred SGLT-2 inhibitor. At the February 2021 P&T meeting, the PA was removed from empagliflozin and empagliflozin/metformin combinations. A cost analysis showed that Glyxambi and Trijardy XR are now more cost-effective than the individual component agents taken separately.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for Glyxambi and Trijardy XR. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Line Extensions

The P&T Committee clarified the formulary status for one product line extension by the original manufacturer. Line extensions have the same FDA indications as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

Antihemophilic Factors—designating **emicizumab-kxwh (Hemlibra) 12 mg/0.4 mL and 300 mg/2 mL vials** with the same formulary status (UF), PA, QL, and Specialty status as the parent Hemlibra strengths.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, Specialty status and EMMPI program status for Hemlibra. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR LISDEXAMFETAMINE (VYVANSE)

Lisdexamfetamine (Vyvanse) capsules and chewable tablets are designated as UF and require a PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agents. Therefore, the branded Vyvanse capsules and chewable tablets will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization. The Tier 1 copay for brand Vyvanse is recommended.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) requiring brand Vyvanse capsules and chewable tablets over the generics in all new users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Vyvanse capsules and chewable tablets. The effective date will be no later than 60 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

VIII. RE-EVALUATION OF NF GENERICS: CALCIUM CHANNEL BLOCKERS, TOPICAL CORTICOSTEROIDS, PROTON PUMP INHIBITORS, AND SELECTIVE SEROTONIN REUPTAKE INHIBITORS

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF/Tier 3 drugs that are now available in generic formulations need to be readdressed. Refer to the May 2007, November 2012, and November 2022 P&T Committee minutes for additional information regarding established procedures for returning generic NF agents to formulary status.

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30 days, for the current NF calcium channel blockers, topical corticosteroids, proton pump inhibitors, and selective serotonin reuptake inhibitors (SSRI).

COMMITTEE ACTION: CALCIUM CHANNEL BLOCKERS, TOPICAL CORTICOSTEROIDS, PROTON PUMP INHIBITORS, AND SELECTIVE SEROTONIN REUPTAKE INHIBITORS FORMULARY STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) making the following changes to formulary status, step therapy status, and prior authorization criteria and medical necessity criteria, effective the first Wednesday 30 days after signing of the minutes. (See Appendix G for implementation dates).

a) Calcium Channel Blockers (CCBs)

- Return to UF status. The following CCBs are considerably more costly than the far more commonly used CCB amlodipine (Norvasc, generics), but are less costly than similar agents on the UF and utilization is very low
  - diltiazem 24h extended release (ER) tablets (Cardizem LA generics)
  - verapamil 24h sustained release pellet-filled capsules (Verelan generics)
  - nisoldipine 24h ER tablets, controlled release (Sular generics)
- Retain the following dihydropyridine CCBs as NF; even though both are available in generic formulations, they remain extremely costly
  - isradipine (Dynacirc generics)
  - nicardipine (Cardene generics)

b) High- and medium-potency "hair-friendly" topical corticosteroids (solutions, foams, shampoos)

- Return to UF status: betamethasone valerate 0.12% foam (Luxiq, generics; GCN 32052); generic formulations are now the least costly medium potency alternative
- Retain as NF with PA: clobetasol propionate/emollient 0.05% foam (Olux-E, generics); several alternatives (clobetasol propionate 0.05% solution, shampoo, and foam) are UF
- Retain as completely excluded
  - halobetasol propionate 0.05% foam (Lexette, generic)
  - clobetasol propionate 0.05% shampoo/cleanser kit (Clodan Kit)

c) High- and medium-potency topical corticosteroids (creams, gels)

- Return to UF status, based on comparable costs relative to other high-potency topical corticosteroids
  - fluocinonide 0.1% cream (Vanos, generics)
  - halobetasol propionate 0.05% cream (Ultravate, generics)

d) Proton Pump Inhibitors (PPIs)

- Move from UF, non-step-preferred to UF step-preferred status (i.e., the PA will be removed), to reduce administrative burden and due to relatively low use, as well as making necessary changes to PA requirements requiring the use of the step-preferred PPIs prior to non-preferred PPIs
  - rabeprazole tabs
  - esomeprazole caps
  - lansoprazole caps

- Retain as NF, non-step-preferred but exempt from the NF mandatory TMOP requirement based on cost effectiveness (they are substantially less costly at retail), thus removing them from the TRICARE Maintenance List:
  - omeprazole/bicarb caps (Zegerid, generics) – the PA will be updated to also include lansoprazole caps as one of the step preferred products
  - lansoprazole rapidly dissolving tabs (Prevacid, generics) – the PA will be updated to also include lansoprazole caps as a step-preferred product
- Making no changes to the status of the following except as noted:
  - omeprazole/bicarb packets (Zegerid, generics) [NF non-step-preferred and on the TRICARE Maintenance Drug List] – update the PA to include lansoprazole caps as
  - omeprazole/bicarb suspension (Konvomep) [UF with a PA]
  - vonoprazan (Voquezna) [NF with a PA and on the TRICARE Maintenance Drug List]
  - dexlansoprazole caps (Dexilant, generics) [completely excluded]

e) SSRIs—fluoxetine

- Return to UF status: fluoxetine 10 and 20 mg tablets; while they remain less cost effective than the far more commonly used 10, 20, and 40 mg caps, costs have dropped substantially, and utilization is relatively low.
- Retain as NF: Generic fluoxetine 90 mg DR tabs (Prozac Weekly generics)

IX. TRICARE MAINTENANCE DRUG LIST UPDATES

Nonformulary medications are generally restricted to TMOP pursuant to 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), added by Section 702(c)(2) of the NDAA for FY 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the TRICARE pharmacy contractor managed TMOP. Medications subject to either the nonformulary requirement or added to the EMMPI program are combined as the TRICARE Maintenance Drug List, formerly known as the Select Maintenance Drug List.

The P&T Committee reviewed the list of drugs added to the TRICARE Maintenance Drug List on a contingent basis that were implemented as of March 1, 2024. These agents are outlined in Appendix F, Table 2, along with a running list of medications added or recommended for addition to the TRICARE Maintenance Drug List on a contingent basis. The P&T Committee also reviewed additional individual medications and classes/subclasses of medications for potential addition to the TRICARE Maintenance Drug List.

COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) addition of the following agents to the TRICARE Maintenance Drug List, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing from TMOP):

- *By subclass*
    - Oncological agents: non-Brutons Tyrosine Kinase Inhibitors (non-BTKI) for Chronic Lymphocytic Leukemia (CLL)
- *By individual agent*
    - decitabine/cedazuridine (Inqovi)
    - larotrectinib sulfate (Vitrakvi)
    - nintedanib (Ofev)
- *Added to TRICARE Drug List but removed from TRICARE Specialty Drug List*
    - lotilaner 0.25% ophthalmic solution (Xdemvy)

Note: The TRICARE Specialty Drug List defines medications for which specialty care pharmacy services are provided at TMOP under the current TRICARE pharmacy contract (TPharm5).

The TRICARE Specialty Drug list is a comprehensive specialty drug list based on the definition of a specialty drug previously agreed upon by the P&T Committee at the Aug 2014 meeting and it supersedes the previous Specialty Agent Reporting list.

X. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

Annual Utilization Management Review: The Committee reviewed a summary of approximately 100 UM actions from the four P&T Committee meetings held in FY2023 (November 2022 to August 2023). A focused review of actions showed that while there were more PA additions than removals, more patients were affected by PA removals than PA additions. Additionally, several oncology drugs had indications removed by the FDA due to a lack of positive confirmatory trials. The Committee reviewed detailed analysis of the effects of PAs on MHS utilization and spend.

XI. ADJOURNMENT

The meeting adjourned at 1545 hours on May 2nd. The next meeting will be in August 2024.

Appendix A—Attendance: May 2024 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

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

[redacted]

Telita Crosland LTG, MC, USA
Director
29 July 2024
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
MAJ Megan Donahue, MC (Day #1)	Army, Physician at Large
MAJ Danielle Zsido, MSC, for COL Aatif Sheikh, MSC	Army, Pharmacy Consultant Alternate
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
CAPT Peter Cole, MC (Day #2)	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Capt Andrew Gaillardetz, MC	Air Force, Physician at Large
Lt Col Brooke van Eeghen, BSC, for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
LCDR Shira Paul, MC	Navy, Oncology Physician
Beth Days, RPh, BCOP	DHA, Oncology Pharmacist
CAPT Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA	TRICARE Health Plan Chief Medical Officer

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Ms. Marsha Peterson	DHA Contracting Officer
Eugene Moore, PharmD	Tpharm5 Clinical COR
CAPT Bill Kelly, MSC, USN	Defense Logistics Agency
Pete Glassman, MD	Department of Veteran's Affairs
Guests	
CDR Derek Larson, MC	Navy, Internal Medicine Physician Alternate
CDR Christopher McKnight, USCG	Coast Guard, Pharmacy Consultant Alternate
CAPT Chris Lamer	Indian Health Service
CAPT Marisol Martinez	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
CAPT Carl Olongo	Immigration and Customs Enforcement (ICE) Health Service Corps
Others Present	
CAPT Tiffany Cline	DHA POD Beneficiary Advisory Panel DFO
COL Aatif Sheikh, MSC	Army Pharmacy Consultant
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
CDR Giao Phung, MSC	DHA POD Formulary Management Branch
Heather Johnson, PharmD, BCPS	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
Mr. David Folmar	DHA POD Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA POD Formulary Management Branch Contractor

Appendix A—Attendance

Mr. Michael Lee	DHA POD Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA POD Formulary Management Branch Contractor
Fakhrudin Valibhai, PharmD	DHA POD Purchased Care Branch
Mr. Eric Parsons, R.Ph.	DHA POD Purchased Care Branch
Julia Trang, PharmD	DHA Contracting
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Juliane Canaley	DHA Contracting
Ms. Shiela Mirrielees	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• insulin detemir (Levemir) • insulin glargine (Basaglar) • insulin glargine (Semglee) • insulin glargine-yfgn (Semglee) **Insulins: Basal Insulin Analogs**	**Changes from May 2024 are in bold and ~~strikethrough~~** • Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure ~~• **Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control**~~ ~~• **For Levemir only: No formulary alternative: The patient is pregnant and not able to use insulin glargine (Lantus)**~~ **Formulary alternatives:** insulin glargine (Lantus), insulin glargine (Rezvoglar), insulin glargine-yfgn (unbranded), insulin glargine (unbranded)
• insulin degludec (unbranded) **Insulins: Basal Insulin Analogs**	**Changes from May 2024 are in bold and ~~strikethrough~~** • Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure • No formulary alternative: Patient is younger than 6 years of age and cannot take Lantus. ~~• **Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control**~~ **Formulary alternatives:** insulin glargine (Lantus), insulin glargine (Rezvoglar), insulin glargine-yfgn (unbranded), insulin glargine (unbranded), insulin glargine U-300 (Toujeo, and unbranded U-300)
• insulin degludec (Tresiba) **Insulins: Basal Insulin Analogs**	**Changes from May 2024 are in bold and ~~strikethrough~~** • Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure • No alternative formulary agent: Patient is younger than 6 years of age and cannot take Lantus. ~~• **Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control**~~ **Formulary and nonformulary alternatives:** insulin glargine (Lantus), insulin glargine (Rezvoglar), insulin glargine-yfgn (unbranded), insulin glargine (unbranded), insulin glargine U-300 (Toujeo, and unbranded U-300), insulin degludec (unbranded) – *note nonformulary*
• liraglutide (Saxenda) • orlistat (Xenical, generics) **Weight Loss Agents**	• Use of all formulary agents is contraindicated for patients 18 years of age or older • Use of Qsymia and Wegovy is contraindicated for patients 12 years of age or older and younger than 17 years of age • Use of all formulary agents resulted in therapeutic failure **Formulary alternatives:** phentermine products (phentermine, benzphetamine, diethylpropion IR/SR, phendimetrazine IR/SR) Qsymia, Contrave, Wegovy, and Zepbound.

Appendix B—Table of Medical Necessity Criteria

• beclomethasone (Qvar Redihaler) • budesonide (Pulmicort Flexhaler) • fluticasone furoate (Arnuity Ellipta) **Pulmonary Is: Inhaled Corticosteroids (ICS)**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure • Patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk • No alternative formulary agent: For Pulmicort Flexhaler only - the patient is pregnant and requires Pulmicort Flexhaler **Formulary alternatives:** ciclesonide (Alvesco), fluticasone propionate, mometasone (Asmanex HFA, Asmanex Twisthaler)
New Drugs MN Criteria	
• bosutinib capsules (Bosulif) **Oncological: Chronic Myelogenous Leukemia**	• Use of formulary agents is contraindicated **Formulary alternatives:** bosutinib tablets (Bosulif)
• cyclosporine 0.1% ophthalmic suspension (Vevye) **Ophthalmic: Dry Eye**	• Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis/Restasis Multidose), cyclosporine 0.09% (Cequa), lifitegrast (Xiidra)
• iptacopan injection (Fabhalta) **Hematological Agents**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** pegcetacoplan (Empaveli)
• roflumilast 0.3% topical foam (Zoryve) **Psoriasis Agents**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** generic ketoconazole 2% cream, foam, or shampoo; topical corticosteroid
• sitagliptin free base (Zituvio and Zituvio AG) **Diabetes Non-Insulin: DPP-4 Inhibitors**	• Patient has experienced significant adverse effects from formulary agents **Formulary alternatives:** sitagliptin phosphate (Januvia)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• insulin glargine U-300 (Toujeo SoloStar, Toujeo Max SoloStar, unbranded U-300) **Insulins: Basal Insulin Analogs**	**May 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new users of insulin glargine U-300 (Toujeo SoloStar, Toujeo Max SoloStar, unbranded insulin glargine U-300)** Manual PA Criteria: Coverage for Toujeo SoloStar, Toujeo Max SoloStar and unbranded insulin glargine U-300 are approved if: • **The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay** • The patient is 6 years of age or older • The patient has a diagnosis of diabetes and is using a minimum of 100 units of **basal** insulin ~~glargine (Lantus)~~ per day **(i.e., insulin glargine, insulin degludec)** OR • The patient **has diagnosis of diabetes and is using a minimum of 80 units of basal insulin** ~~requires a dosage increase with Lantus~~ and has experienced a clinically significant, severe hypoglycemia episode~~, despite splitting the Lantus dose~~ • The patient, parent, or caregiver has been counseled regarding the risk of dosing errors • The following are not acceptable reasons for receiving Toujeo: ▪ Nonadherence to previous insulin treatment OR ▪ Patient or prescriber preference for the use of Toujeo OR ▪ Patient or prescriber preference for a smaller injection volume • For patients older than 18 years of age, the prescription is written by or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist) Non-FDA-approved uses are not approved Prior authorization does not expire
• insulin glargine (Rezvoglar) • insulin glargine-yfgn (unbranded) • insulin glargine U-100 (unbranded by Winthrop) • insulin glargine (Basaglar) • insulin glargine (Semglee) • insulin glargine-yfgn (Semglee) **Insulins: Basal Insulin Analogs**	**May 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new users of Basaglar, Semglee, Semglee-yfgn, Rezvoglar, insulin glargine-yfgn (unbranded), or insulin glargine (unbranded Winthrop)** Manual PA Criteria: Coverage for Basaglar, Semglee, Semglee-yfgn, Rezvoglar, insulin glargine-yfgn (unbranded), or insulin glargine (unbranded by Winthrop) are approved if • **The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay** • The patient has tried and ~~**failed**~~ **had an inadequate response** to insulin glargine (Lantus) Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• insulin detemir (Levemir) **Insulins: Basal Insulin Analogs**	**May 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new users of Levemir** Manual PA Criteria: Coverage for Levemir is approved if • **The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay** • **The provider acknowledges that branded Levemir will be discontinued from the market in 2024** • The patient has tried and **~~failed~~ had an inadequate response** to insulin glargine (Lantus) • ~~The patient is pregnant and cannot use insulin glargine~~ Non-FDA-approved uses are not approved Prior authorization does not expire
• insulin degludec (unbranded) **Insulins: Basal Insulin Analogs**	**May 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new users of insulin degludec (unbranded)** Manual PA Criteria: Coverage for insulin degludec (unbranded) is approved if • **The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay** • The patient has tried and **~~failed~~ had an inadequate response** to insulin glargine (Lantus) • The patient is one year of age or older • The provider must explain why the patient cannot use Lantus (fill in the blank) AND • The provider must explain why the patient cannot use Toujeo (fill in the blank) ▪ **Acceptable responses include the following:** o **The patient has experienced clinically significant hypoglycemia with insulin glargine (Lantus) and insulin glargine U-300 (Toujeo) that is not expected to occur with insulin degludec OR** o **The patient works an alternating or inconsistent work shift schedule resulting in substantially varied meal times on a day-to-day bases resulting in an increased risk for level 2 or 3 hypoglycemia** – **Level 2 (moderate) hypoglycemia defined as glucose level less than 54 mg/dL** – **Level 3 (severe) hypoglycemia define a person is unable to function due to mental/physical changes from a low glucose level and requires assistance** ▪ **Note the following are not acceptable reasons for receiving insulin degludec** o **Non-adherence to previous insulin treatment OR** o **Patient or prescriber preference for the use of insulin degludec** Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• insulin degludec (Tresiba) **Insulins: Basal Insulin Analogs**	**May 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new users of insulin degludec (Tresiba)** Manual PA Criteria: Coverage for insulin degludec (Tresiba) is approved if • **The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay** • The patient has tried and **~~failed~~ had an inadequate response** to insulin glargine (Lantus) • The patient is one year of age or older • The provider must explain why the patient cannot use Lantus (fill in the blank) • The provider must explain why the patient cannot use Toujeo (fill in the blank) • **The provider must explain why the patient cannot use unbranded insulin degludec (fill in the blank)** ▪ **Acceptable responses include the following:** ○ **The patient has experienced clinically significant hypoglycemia with insulin glargine (Lantus), insulin glargine U-300 (Toujeo) and insulin degludec (unbranded) that is not expected to occur with insulin degludec ~~OR~~** ○ **~~The patient works an alternating or inconsistent work shift schedule resulting in substantially varied meal times on a day-to-day bases resulting in an increased risk for level 2 or 3 hypoglycemia~~** – **~~Level 2 (moderate) hypoglycemia defined as glucose level less than 54 mg/dL~~** – **~~Level 3 (severe) hypoglycemia define a person is unable to function due to mental/physical changes from a low glucose level and requires assistance~~** ▪ **Note the following are not acceptable reasons for receiving insulin degludec (Tresiba)** ○ **Non-adherence to previous insulin treatment OR** ○ **Patient or prescriber preference for the use of insulin degludec (Tresiba)** Non-FDA-approved uses are not approved Prior authorization does not expire
• bupropion/naltrexone (Contrave) **Weight Loss Agents**	**May 2024 changes are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of Contrave Manual PA Criteria: Coverage for Contrave is approved if: • The patient is 18 years of age or older • The patient has a BMI greater than or equal to 30, or a BMI greater than or equal to **27 in the presence of at least one weight-related comorbidity** ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • The patient must have tried and failed to achieve a 5 percent reduction in baseline weight after 12-week course of phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension, hyperthyroidism) OR

	• **The patient has experienced an adverse reaction to phentermine that is not expected to occur with Contrave ~~the requested agent~~** • The patient is not receiving concurrent opioid therapy, and does not have a seizure disorder • The patient is not currently on a monoamine oxidase inhibitor (e.g., Emsam, Marplan, Nardil), or another formulation of bupropion or naltrexone • Patient is not pregnant • ~~If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin~~ Non-FDA-approved uses are not approved PA expires **in 12 months** ~~after 4 months~~ for initial therapy, ~~renewal therapy approves for 12 months~~; **annual renewal required** **Renewal PA Criteria: Contrave will be approved for an additional 12 months if the following are met:** • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient lost greater than or equal to 5 percent of baseline body weight since starting medication • The patient is not pregnant
• phentermine/topiramate (Qsymia) **Weight Loss Agents**	**May 2024 changes are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of Qsymia Manual PA Criteria: Coverage for Qsymia is approved if: • Patient is 12 years of age or older and younger than 18 years of age with BMI greater than or equal to 95th percentile standardized for age and sex OR • Patient is 18 years of age or older with a BMI greater than or equal to 30, or a BMI greater than or equal to 27 **in the presence of at least one weight-related comorbidity** ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss and will remain engaged throughout course of therapy • The patient must have tried and failed to achieve a 5 percent reduction in baseline weight after 12-week course of phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension, hyperthyroidism) OR • **The patient has experienced an adverse reaction to phentermine that is not expected to occur with the requested agent** • ~~Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension, hyperthyroidism)~~ • ~~Patient has tried generic phentermine for 3 months and had an inadequate response if they are older than 18 years OR~~ • Patient is not pregnant. • Provider agrees to monitor the rate of weight loss in pediatric patients. If weight loss exceeds 2 pounds (0.9 kg)/week, consider dosage reduction

	• Prescriber will abide by and the patient has been informed of the Risk Evaluation and Mitigation Strategy (REMS) program and safety concerns associated with this agent: – Use in combination with other products intended for weight loss has not been established – Use in patients with increased cardiovascular risk has not been established – Qsymia is pregnancy category X and is associated with increased risk of teratogenicity • ~~If patient has impaired glucose tolerance or diabetes, must have tried metformin first or is concurrently taking metformin.~~ Non-FDA approved uses are not approved PA expires after ~~four~~ in **12 months** for initial therapy, ~~renewal therapy approves for 12 months~~, **annual renewal required** Renewal PA Criteria: Qsymia will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost greater than or equal to 5 percent of baseline body weight since starting medication • For patients initially receiving Qsymia 7.5 mg/46 mg: discontinue Qsymia or escalate to 15 mg/92 mg if a percent reduction in baseline body weight is not achieved **or a pediatric patient has not experienced a reduction of at least 3% of baseline BMI** at 12 weeks • For patients receiving Qsymia 15 mg/92 mg: discontinue if a 5 percent reduction in baseline body weight is not achieved **or a pediatric patient has not experienced a reduction of at least 5% of baseline BMI** at 12 weeks • The patient is not pregnant
• semaglutide (Wegovy) • tirzepatide (Zepbound) **Weight Loss Agents**	**May 2024 changes are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of Wegovy and Zepbound <u>Manual PA Criteria</u>: Coverage for Wegovy or Zepbound is approved if: For Wegovy and Zepbound for adults • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 i**n the presence of at least one weight-related comorbidity** ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried **3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response** ~~all of the following (generic phentermine, and Qsymia, and Contrave)~~ – Phentermine: Date_____ Duration of therapy _____ OR • The patient has a contraindication to **generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension) OR** ~~to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)~~

	~~• Qsymia: Date_____ Duration of therapy _____~~ ~~• Contrave: Date _____ Duration of therapy _____~~ ~~• If the patient is diabetic, must have tried and failed metformin and the DoD's preferred GLP1RAs (Trulicity)~~ • **The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound** For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) • Patient is 12 years of age or older and younger than 18 years of age • Patient has a BMI greater than or equal to 95th percentile standardized for age • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy For all patients • Concomitant use of this medication with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus ~~Initial prior authorization expires after 4 months and then annually.~~ **PA expires in 12 months for initial therapy; annual renewal required** **<u>Renewal PA Criteria</u>: Wegovy and Zepbound will be approved for an additional 12 months if the following are met:** • The patient is currently engaged in behavioral modification and on a reduced calorie diet • For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication ~~despite 16 weeks of therapy~~ **with full dosage titration** • For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5%of baseline body weight since starting medication • The patient is not pregnant

Appendix C—Table of Prior Authorization (PA) Criteria

• liraglutide (Saxenda) **Weight Loss Agents**	**May 2024 changes are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of Saxenda Manual PA Criteria: Coverage for Saxenda is approved if **Adults** • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 **in the presence of at least one weight-related comorbidity** ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried and failed all of the following (generic phentermine [or benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR], Qsymia, and Contrave) or has experienced an adverse reaction or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) – Phentermine, benzphetamine, diethylpropion (IR/SR), or phendimetrazine (IR/SR: Date_____ Duration of therapy _____ – Qsymia (or one of its individual generic components phentermine or topiramate): Date_____ Duration of therapy _____ – Contrave (or one of its individual generic components bupropion or naltrexone): Date _____ Duration of therapy _____ – **Wegovy: Date _____ Duration of therapy _____** – **Zepbound: Date _____ Duration of therapy _____** • ~~If the patient is diabetic, must have tried and failed metformin and the DoD's preferred GLP1RAs (Trulicity)~~ **Adolescents** • Patient is 12 years of age or older and younger than 18 years of age with BMI greater than or equal to 95th percentile standardized for age • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried and failed Qsymia or its individual generic components OR • Patient has a contraindication or has had an adverse reaction to Qsymia or its individual generic components (Note: provider must include the date of use and duration of therapy or contraindication to the drug) and Wegovy – Qsymia (or one of its individual generic components, phentermine or topiramate): Date_____ Duration of therapy _____ – **Wegovy: Date _____ Duration of therapy _____** **For all patients** • Concomitant use of Wegovy with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2

	• Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus ~~Initial prior authorization expires after 4 months and then annually.~~ **PA expires in 12 months for initial therapy, annual renewal required** Renewal PA Criteria: Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • **Patient is older than 12 years of age and younger than 18 years of age: the patient has lost greater than or equal to 4% of baseline body weight since starting medication despite 16 weeks of therapy with full dosage titration** • **Patient is older than 18 years of age: the patient has lost greater than or equal to 5% of baseline body weight since starting medication** • The patient is not pregnant
• orlistat (Xenical) **Weight Loss Agents**	**May 2024 changes are in bold and ~~strikethrough~~** Manual PA criteria apply to all new users of Xenical Manual PA Criteria: Coverage for Xenical is approved if For adults: • The patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 **in the presence of at least one weight-related comorbidity** ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and will remain engaged throughout course of therapy. • **Patient has tried and failed all of the following (generic phentermine, Qsymia, Contrave, Wegovy, and Zepbound) or has experienced an adverse reaction or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** – **Phentermine: Date_____ Duration of therapy _____** – **Qsymia** (or one of its individual generic components phentermine or topiramate)**: Date_____ Duration of therapy _____** – **Contrave** (or one of its individual generic components bupropion or naltrexone)**: Date _____ Duration of therapy _____** – **Wegovy: Date _____ Duration of therapy _____** – **Zepbound: Date _____ Duration of therapy _____** • Patient does not have chronic malabsorption syndrome, or cholestasis • Patient is not pregnant ~~• If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin~~ Non-FDA-approved uses are not approved **PA expires after 12 months** ~~4 months~~ for initial therapy,~~ renewal therapy approves for 12 months~~ **annual renewal required** Renewal Criteria

	• Patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant For adolescents: • The patient is 12 years if age or older and younger than 18 years of age • Patient currently has a BMI greater than or equal to 95th percentile for age and sex, or in greater than or equal to 85th percentile but less than 95th percentile for age and sex and has at least one severe co-morbidity (type 2 diabetes mellitus, premature cardiovascular disease) or has a strong family history of diabetes or premature cardiovascular disease (CVD) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss and will remain engaged throughout course of therapy • Must have tried and failed or have adverse reaction or have a contraindication to ~~generic phentermine~~ **Qsymia and Wegovy** (Note: provider must include the date of use and duration of therapy or contraindication to the drug) – **Qsymia** (or one of its individual generic components phentermine or topiramate)**: Date_____ Duration of therapy _____** – **Wegovy: Date_____ Duration of therapy _____** • Patient does not have chronic malabsorption syndrome, or cholestasis • Patient is not pregnant Non-FDA-approved uses are not approved PA expires after **12 months** ~~4 months~~ for initial therapy, ~~renewal therapy approves for 12 months;~~ **annual renewal required** Renewal Criteria • Patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient current BMI percentile decreased for age and weight (considering the patient is increasing in height and will have a different normative BMI from when Xenical was started) • The patient currently has a BMI greater than 85th percentile • The patient is not pregnant

Appendix C—Table of Prior Authorization (PA) Criteria

Newly Approved Drug PAs	
• birch triterpenes 10% topical gel (Filsuvez) **Skin Preps**	Manual PA criteria apply to all new users of Filsuvez Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 6 months of age or older • Prescribed by ~~or in consultation with~~ a dermatologist or wound care specialist • Patient has a diagnosis of dystrophic epidermolysis bullosa (DEB) **or junctional epidermolysis bullosa (JEB)** • Patient has one or more open wounds that will be treated • Patient's wound is clean in appearance and does not appear to be infected • ~~Patient's wound is 10 cm^2 to 50 cm^2~~ • ~~Patient's wound is at least 21 days old and less than 9 months old~~ • ~~Squamous cell and/or basal cell carcinoma have been ruled out~~ Non-FDA approved uses are NOT approved PA expires in ~~three~~ **6** months **Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met:** • The patient has had disease stabilization or improvement in disease on therapy • Renewal prescription is written by a dermatologist or wound care specialist
• bosutinib capsules (Bosulif) **Oncological Agents: CML**	Manual PA criteria apply to all new users of Bosulif capsules Manual PA criteria: Coverage is approved if all criteria are met: • Bosulif capsules are prescribed by or in consultation with a hematologist/oncologist • Patient is 1 years of age or older with chronic phase Ph+ chronic myelogenous leukemia, that is either newly diagnosed or resistant or intolerant to prior therapy OR • Patient is 18 years of age or older with accelerated or blast phase Ph+ chronic myeloid leukemia with resistance or intolerance to prior therapy • Patient cannot swallow tablets due to a documented medical condition (e.g., dysphagia) • The provider is aware of all warnings, screening, and monitoring precautions for Bosulif • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation Other non-FDA approved uses are NOT approved except as noted above PA does not expire
• budesonide 2 mg/10 mL oral suspension (Eohilia) **GI-1 Agent**	Manual PA criteria apply to all new users of Eohilia Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by a gastroenterologist or allergy/immunology specialist • Patient has a documented diagnosis of eosinophilic esophagitis (EoE) by endoscopic biopsy • Patient has tried and had an inadequate response, intolerance, or contraindication to a Proton Pump Inhibitor • ~~Patient has tried and had an inadequate response, intolerance, or contraindication to a formulary topical glucocorticoid (e.g., fluticasone HFA or budesonide respule)~~

Appendix C—Table of Prior Authorization (PA) Criteria

	~~that is not expected to occur with Eohilia; note: an intolerance does not include preferences for flavor or taste of medication for pediatric patients~~ Non-FDA approved uses are NOT approved PA does not expire
• cyclosporine 0.1% ophthalmic solution (Vevye) **Ophthalmic Dry Eye Disease**	Manual PA criteria apply to all new users of Vevye Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by an ophthalmologist or optometrist • Patient has a diagnosis of moderate to severe dry eye disease • Patient had positive symptomology screening for dry eye disease from an appropriate measure • Patient has at least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient has had at least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) • Patient has had at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • Patient has had at least a 3 month trial of cyclosporine (Restasis) cyclosporine 0.09% (Cequa) AND lifitegrast (Xiidra) Non-FDA approved uses are not approved PA does not expire
• eflornithine tablets (Iwilfin) **Oncological Agents**	Manual PA criteria apply to all new users of Iwilfin Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by or in consultation with an oncologist • Patient has high-risk neuroblastoma • Medication is being used to reduce the risk of relapse • Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy • The provider is aware of all warnings, screening, and monitoring precautions for Iwilfin • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation Other non-FDA approved uses are not approved except as noted above PA does not expire
• eplontersen injection (Wainua) **Miscellaneous Neurological Agents**	Manual PA criteria apply to all new users of Wainua Manual PA criteria: Coverage is approved if all criteria are met: • The patient is 18 years of age or older • Drug is prescribed by or in consultation with a specialist who manages hereditary transthyretin amyloidosis (hATTR), such as a neurologist, cardiologist, and/or medical geneticist • The patient has documented evidence of hATTR polyneuropathy as confirmed by the following: ▪ Genetically confirmed transthyretin mutation resulting in Coutinho stage 1 or 2 hereditary transthyretin-mediated amyloidosis (hATTR) ▪ The patient has polyneuropathy secondary to hereditary transthyretin-mediated amyloidosis

	▪ The patient has a Neuropathy Impairment Score between 10-130 • The patient is not receiving concurrent treatment with Tegsedi (inotersen), Onpattro (patisiran), Amvuttra (vutrisiran) or Vyndaqel/Vyndamax (tafamidis) • The provider acknowledges that the patient will receive an oral Vitamin A supplement at the recommended daily allowance while receiving the requested medication Non-FDA approved uses are not approved including hATTR cardiomyopathy PA expires in one year Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient has demonstrated improvement in neuropathy
• infliximab-dyyb injection (Zymfentra) **TIBs: TNF inhibitors**	Manual PA criteria apply to all new users of Zymfentra <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has moderate to severely active ulcerative colitis or moderate to severe Crohn's disease • The provider acknowledges Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis **and Crohn's disease** • **Patient has experienced one of the following:** ▪ Patient has had an inadequate response to Humira ▪ Patient has had an adverse reaction to Humira that is not expected to occur with the requested agent ▪ Patient has a contraindication to Humira ▪ **Patient is clinically stable on IV infliximab and changing to Humira would incur unacceptable risk** • **Patient has received infliximab product administered intravenously as induction therapy and has demonstrated positive response** • Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc. • Patient has negative TB test result in past 12 months (or TB is adequately managed) • Patient will not be receiving any other targeted immunomodulatory biologics with infliximab-dyyb (Zymfentra) including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), upadacitinib (Rinvoq ER), or vedolizumab (Entyvio) Non-FDA approved uses are not approved PA does not expire
• iptacopan (Fabhalta) **Hematological Agents**	Manual PA criteria apply to all new users of Fabhalta <u>Manual PA criteria:</u> Coverage is approved if all criteria are met • Patient is 18 years of age or older • Prescribed by a hematologist or oncologist • Patient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

	• Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements • Patient is not receiving C3 or C5 inhibitors with Fabhalta, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or pegcetacoplan (Empaveli) Non-FDA approved uses are NOT approved PA expires after 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient meets initial criteria, has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, or reductions in hemolysis
• nedosiran injection (Rivfloza) **Nephrology Agents**	Manual PA criteria apply to all new users of Rivfloza <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation • The medication is prescribed by or in consultation with a nephrologist or urologist • The medication is prescribed for an FDA-approved age • Patient has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2 • **Patient has trialed pyridoxine and has experienced an inadequate response or intolerance OR patient has a contraindication to pyridoxine** • Rivfloza will not be used in combination with lumasiran (Oxlumo) Non-FDA approved uses are NOT approved PA expires after one year; annual renewal required Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for continuation of therapy if all the criteria are met: • The patient has had disease stabilization or improvement in disease on therapy
• omalizumab autoinjector (Xolair) **Atopy Agents**	**Updates from the May 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Xolair autoinjector <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: There were no changes to the PA criteria for Xolair indications other than the new indication for food allergy. <u>For food allergy:</u> • Xolair is prescribed by an allergist or immunologist • The patient has a documented history of food allergy • **Provider acknowledges clinical trials excluded those with** ~~The patient does not have~~ a history of severe anaphylaxis, uncontrolled or severe asthma, uncontrolled atopic dermatitis, or eosinophilic gastrointestinal disease • ~~The patient does not have a history of severe anaphylaxis to the food allergen being treated~~ • The patient is not currently receiving oral, IM, or IV corticosteroids, tricyclic antidepressants, or beta-blockers (oral or topical) • The patient is not currently receiving or has not received in the last 6 months any immunotherapy [e.g., oral immunotherapy (OIT), sublingual immunotherapy (SLIT) or epicutaneous immunotherapy (EPIT)] to the food allergen being treated

	• The patient is not currently receiving or has not received in the last 6 months other immunomodulatory therapy • Provider acknowledges that the patient will be counseled on the following: ▪ **Xolair does NOT eliminate food allergy** and the patient must continue to avoid food allergen ▪ The need for access to an epinephrine injector ▪ Xolair is not intended to treat emergencies For all indications: ~~• For food allergy:~~ ~~• Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents (except foods), such as drugs, biologics, etc.~~ ~~• For asthma, chronic rhinosinusitis with nasal polyps, chronic idiopathic urticaria:~~ ~~▪ Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc.~~ • **Provider acknowledges Xolair carries a black box warning for anaphylaxis, should be initiated in a healthcare setting, and self-administration of Xolair should be based on criteria to mitigate risk from anaphylaxis.** • Patient has received **or will receive** at least 3 doses of Xolair under the guidance of a healthcare provider without experiencing any hypersensitivity reactions • Provider agrees to ensure that the patient or caregiver is able to recognize symptoms of anaphylaxis. ~~presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue. Provider agrees to counsel the patient that anaphylaxis has occurred up to 2 hours post administration and appropriate monitoring will occur.~~ • Provider agrees to ensure that the patient or caregiver is able to treat anaphylaxis appropriately ~~and consider~~ **with** co-prescribing epinephrine. • Provider agrees to ensure that the patient or caregiver is able to perform subcutaneous injections with **requested medication** with proper technique according to the prescribed dosing regimen • For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or dupilumab [Dupixent]) • For the Xolair prefilled syringe formulation, the provider acknowledges: ▪ Patients 1 to 11 years of age: must be administered by a caregiver. ▪ Patients older than 12 years: may be self-administered, or under adult supervision for pediatric patients • For the Xolair autoinjector formulation the provider acknowledges: ▪ Patients less than 12 years of age: not authorized ▪ Patients older than 12 years: may be self-administered, or under adult supervision for pediatric patients Non-FDA approves uses are not approved PA expires in one year Renewal criteria for food allergies **Note that initial TRICARE PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met:** • Food allergy: Provider acknowledges that the patient will continue to be counseled on the following: ▪ **Xolair does NOT eliminate** food allergy and patient must continue to avoid food allergen ▪ The need for access to an epinephrine injector ▪ Xolair is not intended to treat emergencies

Appendix C—Table of Prior Authorization (PA) Criteria

• roflumilast 0.3% topical foam (Zoryve) **Psoriasis Agents**	Manual PA criteria apply to all new users of Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 9 years of age or older • Prescribed by or in consultation with a dermatologist • Patient has diagnosis of moderate to severe seborrheic dermatitis • The patient must have tried for at least 2 weeks and failed, or have a contraindication to, or have had an adverse reaction to both of the following: ▪ at least one topical corticosteroid (e.g., mometasone furoate 0.1% solution) ▪ at least one topical antifungal (e.g., ketoconazole 2% shampoo) Non-FDA approves uses are not approved PA expires in one year; new PA must be submitted
• sitagliptin free base (Zituvio, Zituvio authorized generic) **DPP-4 inhibitors**	Manual PA criteria apply to all new users of Zituvio and Zituvio authorized generic Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Januvia is TRICARE's preferred dipeptidyl peptidase-4 inhibitor and are available to TRICARE beneficiaries without requiring prior authorization • Provider must document why the patient cannot use Januvia, Janumet or Janumet XR. (blank write-in) ▪ Acceptable responses include that the patient has had an adverse reaction to an excipient in brand sitagliptin phosphate (Januvia, Janumet or Janumet XR) that would not be likely to occur with Zituvio Non-FDA approved uses are NOT approved PA does not expire
• vamorolone oral suspension (Agamree) **Corticosteroids-Immune Modulators**	Manual PA criteria apply to all new users of Agamree Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 2 years of age or older • Prescribed by a neurologist • Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) that has been confirmed by genetic testing or muscle biopsy • Patient has a contraindication to, intolerability to, or has failed a trial for at least 3 months of at least one of the following: ▪ prednisone or ▪ deflazacort (Emflaza) • Provider acknowledges the FDA safety alerts, warnings, precautions, drug interactions, and monitoring recommendations for the requested medication Non-FDA approved uses are NOT approved PA does not expire
• zilucoplan injection (Zilbrysq) **Miscellaneous Neurological Agent**	Manual PA criteria apply to all new users of Zilbrysq Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by a neurologist • Patient has documented diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive • Patient is not known to be muscle-specific tyrosine kinase antibody-positive • Patient has had insufficient response or intolerance to pyridostigmine

	• Patient has had insufficient response or intolerance to glucocorticoid sparing therapy such as azathioprine, mycophenolate, cyclosporine, or tacrolimus • Patient has had insufficient response or intolerance to a neonatal Fc receptor antagonist such as efgartigimod alfa or rozanolixizumab (Rystiggo) • Patient has been vaccinated against certain encapsulated bacteria (for example, Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and *Haemophilus influenzae* type B) • Patient is not receiving neonatal Fc receptor antagonists or other C5 inhibitors with Zilbrysq, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), efgartigimod (Vyvgart), efgartigimod alfa and hyaluronidase (Vyvgart Hytrulo) Non-FDA approved uses are not approved PA expires in 6 months Renewal Criteria: Note that initial Tricare PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met: • Patient is continuing to derive benefit from Zilbrysq, according to the prescriber (Examples of derived benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function)
Utilization Management New PAs	
• brivaracetam (Briviact) **Anticonvulsants-Antimania Agents**	PA criteria apply to all new users of Briviact tablets and oral solution. Automated PA Criteria: The patient has filled a prescription for any formulation of levetiracetam at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage for Briviact is approved if all criteria are met: • The drug is prescribed by an adult or pediatric neurologist • The patient has a diagnosis of partial onset seizures • Patient has a contraindication to, intolerability to, or has had an inadequate response to a trial of levetiracetam Non-FDA-approved uses are not approved. Prior authorization does not expire.
• tramadol 25 mg tablets **Narcotic Analgesics and Combinations**	Manual PA criteria apply to all new and current users of tramadol 25 mg tablet. Manual PA criteria: tramadol 25 mg tablet is approved if all criteria are met: • Provider is aware and acknowledges that tramadol 50 mg tablets are available to DoD beneficiaries without the need of prior authorization. Providers are encouraged to consider changing the prescription to the preferred tramadol 50 mg. • Provider must explain why the patient requires tramadol 25 mg and cannot take the cost-effective generic tramadol 50 mg formulations (fill-in the blank) ▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg tablets Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management Updated PAs	
• dupilumab (Dupixent) **Atopy**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA apply to all **new users** of Dupixent. Note that there were no changes to the PA criteria for the indications of asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis, or prurigo nodularis. Manual PA criteria: Coverage for **Eosinophilic Esophagitis (EoE)** is approved if all criteria are met: • The patient is **one ~~12~~** year**~~s~~** of age or older and weighs at least **15 ~~40~~** kilograms (**~33 ~~88~~**lbs) • The drug is prescribed by or in consultation with a gastroenterologist or allergy/immunology specialist • Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy • For EoE, the patient has tried and failed an adequate course of both the following: ▪ Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND ▪ Topical glucocorticoids [e.g., fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, clinically significant adverse effects are experienced, or in children maximal doses cannot be reached due to concerns for growth suppression or adrenal insufficiency Non-FDA approved uses are not approved Prior authorization expires in 1 year. Renewal Criteria: (Initial TRICARE PA approval is required for renewal). Coverage will be approved indefinitely for continuation of therapy if the following criteria are met: • Eosinophilic Esophagitis (EoE): ▪ For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e): a) Reduced intraepithelial eosinophil count; OR b) Decreased dysphagia/pain upon swallowing; OR c) Reduced frequency/severity of food impaction; OR d) Reduced vomiting/regurgitation; OR e) Improvement in oral aversion/failure to thrive ▪ For relapse: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval
• alpelisib (Piqray) **Oncological Agents: Breast Cancer**	**Updates from the May 2024 meeting are in strikethrough.** Manual PA is required for all new users of Piqray. Manual PA Criteria: Piqray is approved if all criteria are met: • Patient must be ≥18 years. • Patient is diagnosed with advanced or metastatic HR positive, HER2 negative breast cancer with PIK3CA mutation as confirmed by an FDA-approved test. • Drug is prescribed by, or in consultation with, an oncologist/hematologist. • ~~Female patients are post-menopausal, or if pre-menopausal, they are receiving ovarian ablation/suppression.~~ • Female patients of reproductive potential will use effective contraception during therapy and for one week after the last dose.

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	• Patient has tried and failed, or is not a candidate for, adjuvant or neoadjuvant chemotherapy. • Patient has had disease progression while on or after endocrine-based therapy. • Patient will receive fulvestrant injection (Faslodex) therapy along with alpelisib (Piqray). • Patient has no history of Stevens Johnson Syndrome, Erythema Multiforme, or Toxic Epidermal Necrolysis. • Provider is aware and has informed patient of risk of serious, life-threatening skin reactions, including Stevens Johnson Syndrome; severe hyperglycemia; gastrointestinal toxicity, including severe diarrhea; kidney injury; lung injury including pneumonitis; pancreatitis; and severe hypersensitivity reactions. • Provider is aware and has informed patient that safety has not been established in type 1 or uncontrolled type 2 diabetic patients. • Male patients with female partners of reproductive potential should use condoms and effective contraception during therapy and for one week after last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• alectinib (Alecensa) **Oncological Agents: Lung Cancer**	**Updates from the May 2024 meeting are in bold.** Manual PA applies to **new users** of Alecensa, Alunbrig, and Zykadia. <u>Manual PA Criteria</u>: Alecensa, Alunbrig, or Zykadia is approved if all criteria are met: • **The patient is 18 years of age or older** • The patient has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an FDA-approved test **OR** • **Alecensa will be used as adjuvant treatment following tumor resection of ALK-positive NSCLC as detected by an FDA-approved test** • The drug is prescribed by or in consultation with a hematologist/oncologist OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• erdafitinib (Balversa) **Oncological Agents**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Balversa. <u>Manual PA Criteria</u>: Erdafitinib (Balversa) is approved if all criteria are met: • The patient is 18 years of age or older • Patient has locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR3 ~~or FGFR2~~ mutation confirmed with an FDA-approved test • The patient has progressed during or following at least one line of **prior systemic therapy** ~~platinum containing chemotherapy (including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy)~~ • Prescribed by or in consultation with an oncologist • The patient will be evaluated by an ophthalmologist before starting treatment and every month for the first 4 months; every 3 months thereafter

	• The patient will be advised to seek emergent evaluation for new ocular symptoms • The patient will be monitored for hyperphosphatemia. (Note that 33% of patients required a phosphate binder in the trial supporting FDA approval for erdafitinib) • If the patient is female, she is not pregnant or planning to become pregnant. • Female patients will not breastfeed. • All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• sotorasib (Lumakras) **Oncological Agents: Lung Cancer**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Lumakras. Manual PA criteria: Lumakras is approved if all criteria are met: • Patient is 18 years of age or older • Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test • ~~The provider acknowledges that sotorasib 120 mg tablets are significantly more cost effective than sotorasib 320 mg tablets~~ • ~~If the prescription is for sotorasib 320 mg, the patient cannot tolerate sotorasib (Lumakras) 120 mg tablets dispersed in water per manufacturer instructions and has documented swallowing dysfunction.~~ • The patient will be monitored for interstitial lung disease and hepatotoxicity • The drug is prescribed by or in consultation with a hematologist/oncologist • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• golimumab (Simponi) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all **new users** of golimumab (Simponi). Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, Simponi is approved if all criteria are met. • **Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent. and must be tried first for most indications.** • **The patient has had an inadequate response to Humira**

	• **The patient has experienced an adverse reaction to Humira that is not expected to occur with Simponi** • **The patient has a contraindication to Humira** • ~~The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira~~ Coverage approved for **adult** patients 18 years of age or older with ~~**one of the following diagnosis/indication:**~~ • Moderate to severe active rheumatoid arthritis (RA) ~~**in combination with methotrexate AND an active prescription for methotrexate**~~ • Active psoriatic arthritis (PsA) • Active ankylosing spondylitis (AS) • Moderately to severely active ulcerative colitis (UC) Below criteria applies to all patients unless noted: • Patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g., azathioprine], etc.) (Note: AS indication does not apply) • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS indication ONLY) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs **agents including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan)** Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• adalimumab (Humira) **TIBs: TNF Inhibitors**	**Updates from the May 2024 meeting are in bold and strikethrough.** <u>Automated PA Criteria</u>: If the provider is a Rheumatologist (Internal Medicine or Pediatric). PA is approved. <u>Manual PA Criteria</u>: If automated criteria are not met for Rheumatologist **specialist** prescribing, Humira is approved if all criteria are met: • Coverage is approved for adult patients 18 years of age or older with ~~one of the following diagnoses/indications:~~ ▪ Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) ▪ Moderate to severe chronic plaque psoriasis (Ps) in patients who are candidates for systemic therapy or phototherapy ▪ Moderate to severely active Crohn's disease (CD) ▪ Moderate to severely active ulcerative colitis (UC) ▪ Moderate to severe hidradenitis suppurativa (HS) ▪ Non-infectious intermediate, posterior, and panuveitis ▪ Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation

	▪ Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids OR ~~• Coverage approved for pediatric patients 12-17 years of age with diagnosis of:~~ ~~▪ Moderate to severe hidradenitis suppurativa (HS)~~ ~~• Coverage approved for pediatric patients 6-17 years of age with diagnosis of:~~ ~~▪ Moderate to severely active Crohn's disease (CD)~~ ~~• Coverage approved for pediatric patients 5-17 years of age with diagnosis of:~~ ~~▪ Moderately to severely active ulcerative colitis (UC)~~ ~~• Coverage approved for pediatric patients 4-17 years of age with diagnosis of:~~ ~~▪ Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate OR~~ • Coverage is approved for pediatric patients 2-17 years of age with ~~one of the following diagnosis/indication:~~ ▪ Moderate to severe active ~~**polyarticular**~~ juvenile idiopathic arthritis (~~**pJIA**~~ **JIA**), **including subtypes** ▪ Non-infectious intermediate, posterior, and panuveitis ▪ **Moderate to severe plaque psoriasis in patients who are candidates for systemic or phototherapy** ▪ **Moderate to severe hidradenitis suppurativa (HS)** ▪ **Moderately to severely active Crohn's disease (CD)** ▪ **Moderately to severely active ulcerative colitis (UC)** • Below criteria applies to AS **and nr-axSpA** indications only: ▪ Patient has had an inadequate response to at least two NSAIDs over a period of at least two months • Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease, ankylosing spondylitis (AS), **nr-axSpA,** ~~and pyoderma gangrenosum (PG)~~, psoriatic arthritis (PsA) and applies to pediatric patients with plaque psoriasis or Crohn's disease: ▪ Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]), **antibiotics or anti-androgens** • Below criteria applies to all patients (regardless of age): ▪ Providers acknowledge there have been cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. ▪ Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) ▪ Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER). • Coverage for non-FDA-approved uses not listed above: Please provide the diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• etanercept (Enbrel) **TIBs: TNF Inhibitors**	**Updates from the May 2024 meeting are in bold and strikethrough.** Step therapy and manual PA criteria apply to all new users. Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Enbrel if: contraindications exist to Humira OR inadequate response to Humira (need for different anti-TNF or non-TNF) OR adverse reactions to Humira not expected with requested non-step preferred TIB **Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent for adults and children** AND • Coverage approved for adult patients 18 years of age or older with: ▪ Moderate to severe active rheumatoid arthritis ▪ Moderate to severe active psoriatic arthritis, or active ankylosing spondylitis ▪ Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy • Coverage approved for pediatric patients 2–17 years of age with: ▪ Moderate to severe active polyarticular Juvenile Idiopathic Arthritis ▪ Juvenile Psoriatic Arthritis - Note that a trial of non-biologic systemic therapy and Humira is required • Coverage approved for pediatric patients 4-17 years of age of age with: ▪ Plaque psoriasis. Note that a trial of Stelara is required for pediatric patients 6 years of age or older, however for patients 4-5 years of age, a trial of Stelara is not required for this age group. • Provider is aware that worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Enbrel • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • Coverage is NOT provided for concomitant use with other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Prior authorization does not expire Non-FDA-approved uses are not approved
• ixekizumab (Taltz) **TIBs: Non-TNF Inhibitors**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of ixekizumab (Taltz). Manual PA Criteria: Taltz is approved if ALL criteria are met: • **Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent and must be tried first for most indications** • **The patient has had an inadequate response to Humira, Cosentyx, AND Stelara** • **The patient has experienced an adverse reaction to Humira, Cosentyx AND Stelara that is not expected to occur with Taltz** • **The patient has a contraindication to Humira, Cosentyx AND Stelara** • ~~Humira, Cosentyx, AND, Stelara Step:~~

	~~▪ Contraindication/inadequate response exists to Humira, Cosentyx, AND, Stelara~~ ~~▪ Adverse reactions to Humira, Cosentyx, AND, Stelara not expected with requested non-step-preferred TIB~~ • **Coverage is approved for adult p**atients 18 years of age or older with: ▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ▪ Active ankylosing spondylitis (AS): only Humira and Cosentyx step required ▪ Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation: only Humira and Cosentyx step required ~~• With evidence of elevated CRP and/or MRI evidence of sacroiliitis and ASDAS ≥ 2.1~~ • Coverage is approved for pediatric patients **6 years of age and older** with: ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ~~(6 years of age or older)~~ ~~• *Trial of Humira AND Cosentyx NOT required for age 6 to 17 years AND trial of Stelara NOT required for age 6 to 11 years~~ • Has the patient had an inadequate response to non-biologic systemic therapy? (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine], etc.)? • Negative TB test result in past 12 months (or TB adequately managed) Coverage is not provided for concomitant use with other TIBs including but not limited to adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Prior authorization does not expire Non-FDA-approved uses are not approved
• ustekinumab (Stelara) **TIBs: Non-TNF Inhibitors**	**Updates from the May 2024 meeting are in bold and strikethrough.** Note that Humira is the Department of Defense's preferred targeted biologic agent. Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Stelara if: • **Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent and must be tried first for most indications.** • **The patient has had an inadequate response to Humira** • **The patient has experienced an adverse reaction to Humira that is not expected to occur with Stelara** • **The patient has a contraindication to Humira** ~~• **Contraindications exist to Humira**~~ ~~• **Inadequate response to Humira (need for different anti-TNF or non-TNF)**~~

	• ~~**Adverse reactions to Humira not expected with requested non-step-preferred TIB**~~ AND • Coverage approved for patients 18 years of age or older with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ▪ Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids, or Humira. Alternatively, for moderate to severe ulcerative colitis (UC); infliximab may be used first in lieu of Humira • Coverage approved for patients 6-17 years of age ~~≤ 18 years~~ with: ▪ Active psoriatic arthritis ~~**(patients between the ages of 6 and 17 may receive Stelara for active psoriatic arthritis without the requirement to try Humira first)**~~ ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ~~**(patients between the ages of 6 and 17 may receive Stelara for plaque psoriasis without the requirement to try Humira first)**~~ • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade) Prior authorization does not expire Non-FDA-approved uses are not approved
• secukinumab (Cosentyx) **TIBs: Non-TNF Inhibitors**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of secukinumab (Cosentyx). Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, Cosentyx is approved if all criteria are met. • **Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent and must be tried first for most indications.** • **The patient has had an inadequate response to Humira** • **The patient has experienced an adverse reaction to Humira that is not expected to occur with Stelara** • **The patient has a contraindication to Humira** • ~~Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira~~ Coverage approved for patients 18 years of age or older with ~~one of the following diagnosis/indication:~~ • Active psoriatic arthritis (PsA)

	• Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy • Active ankylosing spondylitis (AS) • Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation **~~AND patient has evidence of elevated CRP and/or MRI evidence of sacroiilitis and ASDAS ≥ 2.1~~** • Moderate to severe hidradenitis suppurativa (HS) OR Coverage approved for pediatric patients 6-17 years of age with diagnosis of: • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy OR Coverage approved for pediatric patients 4-17 years of age with diagnosis of: • Active enthesitis-related arthritis (ERA) OR Coverage approved for pediatric patients 2-17 years of age with diagnosis of: • Active PsA Below criteria applies to all patients unless noted: • Patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g., azathioprine], etc.), **antibiotics, anti-androgens, etc.** (Note: AS, ERA, **~~and HS~~** indications do not apply) • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS indication ONLY) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade) Prior authorization does not expire Non-FDA-approved uses are not approved
• sacrosidase oral solution (Sucraid) **Gastrointestinal-2 Agents**	**Updates from the May 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all **new and current users** of sacrosidase (Sucraid) Manual PA criteria: Coverage is approved if all criteria are met: • Sucraid is prescribed by **~~or in consultation with~~** a gastroenterologist **~~or geneticist~~** • Patient has congenital sucrase-isomaltase deficiency (CSID) **as diagnosed by endoscopic biopsy or genetic testing** • **Submit documentation that confirms that the patient has CSID (i.e., can submit the progress note documenting that CSID was diagnosed via biopsy, and Sucraid recommended)** • Prior to starting therapy with Sucraid, patient had symptomatic CSID (e.g., diarrhea, bloating, abdominal cramping) **despite appropriate dietary modification** Non-FDA approved uses are NOT approved. PA expires **annually.** **Renewal Criteria: Initial TRICARE approval required for renewal. PA will be approved for an additional year if:** • **Patient continues to follow dietary modification and symptoms have improved with Sucraid therapy**

Appendix C—Table of Prior Authorization (PA) Criteria

• deflazacort (Emflaza) **Corticosteroids Immune Modulators**	**Changes from the May 2024 meeting are in BOLD and strikethrough.** Manual PA criteria applies to all new users of Emflaza. Manual PA Criteria: Emflaza is approved if all criteria are met: • Patient is 2 years of age or older • The drug is prescribed by a neurologist • The patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) **that has been confirmed by genetic testing or muscle biopsy** • **Patient has a contraindication to, intolerability to, or has had an inadequate response to a trial for at least 3 months of prednisone** • **Provider acknowledges the FDA safety alerts, warnings, precautions, drug interactions, and monitoring recommendations for the requested medication** • ~~Patient has tried prednisone for at least 6 months and has experienced at least 1 of the following adverse events:~~ • ~~Unmanageable weight gain OR~~ • ~~Experienced severe behavioral adverse events that requires a reduction in prednisone dose~~ Non-FDA-approved uses are not approved. Prior authorization does not expire
• generic lisdexamfetamine capsules and chewable tablets **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	Manual PA criteria applies **to new users** of lisdexamfetamine capsule and chewable tablet at all points of service Manual PA criteria: lisdexamfetamine generics are approved if all criteria are met: The following will be added to existing PA criteria • **Provider acknowledges that brand Vyvanse capsule and chewable tablet are the preferred products over generic lisdexamfetamine capsule and chewable tablet and are covered at the lowest copayment, which is the generic formulary copayment for non-Active-Duty patients, and at no cost share for Active-Duty patients. (Although Vyvanse is a branded product, it will be covered at the generic formulary copayment or cost share)** • **The prescriber must provider a patient-specific justification as to why brand Vyvanse cannot be used in this patient. _____ (fill-in the blank).** ▪ Acceptable responses include the patient has had an adverse reaction to an excipient in brand Vyvanse that would not be likely to occur with generic lisdexamfetamine

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• birch triterpenes 10% topical gel (Filsuvez) **Skin Preps**	▪ Retail/MTF/TMOP: 60-day supply
• bosutinib capsules (Bosulif) **Oncological Agents for CML**	▪ Retail/MTF/TMOP: 60-day supply
• cyclosporine 0.1% ophthalmic solution (Vevye) **Ophthalmic Dry Eye**	▪ Retail/MTF/TMOP: 30-day supply
• eflornithine (Iwilfin) **Oncological Agents**	▪ Retail/MTF/TMOP: 60-day supply ▪ Note: although Iwilfin dosage adjustments occur every 90 days, a 60-day supply is recommended as only one dosage strength is available
• eplontersen injection (Wainua) **Miscellaneous Neurological Agents**	▪ Retail/MTF/TMOP: 30-day supply
• infliximab-dyyb injection (Zymfentra) **TIBs TNF Inhibitors**	▪ Retail/MTF/TMOP: 60-day supply
• iptacopan (Fabhalta) **Hematological Agents**	▪ Retail/MTF/TMOP: 60-day supply
• nedosiran injection (Rivfloza) **Nephrology Agents**	▪ Retail/MTF/TMOP: 2 vials per month or 1 syringe per month
• omalizumab autoinjector (Xolair) **Atopy**	▪ MTF/TMOP: 60-day supply ▪ Retail: 60-day supply

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

Drug / Drug Class	Quantity Limits
• roflumilast 0.3% topical foam (Zoryve) **Psoriasis Agents**	▪ Retail/MTF/TMOP: 60-day supply
• vamorolone oral suspension **Corticosteroids-Immune Modulators for DMD**	▪ Retail/MTF/TMOP: 60-day supply
• zilucoplan injection (Zilbrysq) **Miscellaneous Neurological Agents**	▪ Retail/MTF/TMOP: 56-day supply
• beclomethasone (QVAR Redihaler) • fluticasone propionate diskus • fluticasone furoate (Arnuity Ellipta) • mometasone (Asmanex HFA, Asmanex Twisthaler) **Pulmonary Is: ICS**	quantity per dispensing event ▪ Retail: 1 inhaler per fill ▪ MTF/TMOP: 3 inhalers per fill
• budesonide dry powder inhaler (Pulmicort Flexhaler) • ciclesonide (Alvesco) • fluticasone propionate HFA **Pulmonary Is: ICS**	quantity per dispensing event ▪ Retail: 2 inhalers per fill ▪ MTF/TMOP: 6 inhalers per fill

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• birch triterpenes 10% w/w topical gel (Filsuvez) Skin Preps: Irritants/ Counter-irritants	• Vyjuvek	• Topical gel: 10 % • Dosing: Apply a 1 mm layer to affected wound surface and cover with wound dressing or apply directly to dressing	• Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatrics patients 6 months of age and older	ADRs (>2%): • application site reactions	• Filsuvez is the first agent approved for the treatment of wounds associated with JEB, and the second agent approved for wounds associated with DEB • Demonstrated marginal efficacy for complete wound healing; results mainly driven by efficacy in RDEB • Efficacy not demonstrated in DDEB or JEB compared to placebo; however, there were small numbers of patients in these groups • Filsuvez was well tolerated • The only other medication approved for this indication, Vyjuvek, would not be effective in patients with JEB and can only be given by a healthcare provider • Filsuvez is a drug for patients with a rare, serious disease that has limited available treatment options	• UF • PA • QL • Do not add to EMMPI list
• bosutinib capsules (Bosulif) Oncological: Chronic Myelogenous Leukemia	• Bosulif tab	• Oral capsule: 50 mg 100 mg • Dosing: varies based on indication	• Adult and pediatric patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia, newly-diagnosed or resistant or intolerant to prior therapy. Adult patients with accelerated phase, blast phase Ph+ CML with resistance or intolerance to prior therapy	ADRs (≥20%): • diarrhea • abdominal pain • vomiting • nausea • rash • fatigue • hepatic dysfunction • headache • pyrexia • decreased appetite • respiratory tract infection • constipation	• New capsule formulation of bosutinib for use in adults and pediatric patients 1 year of age or older that shares the same indications as the tablets • Phase 1/2 study demonstrated efficacy in pediatric patients as young as 1 year of age with tolerability profile consistent with data known in adults • Tablets must be swallowed whole while the capsules can be opened and mixed with applesauce or yogurt for patient who have difficulty swallowing • Provides another bosutinib formulation for patients with swallowing difficulties	• NF • PA • MN • QL • EMMPI
• budesonide 2 mg/10 mL oral suspension (Eohilia)	• budesonide ER capsule • budesonide neb • fluticasone HFA • Dupixent	• Oral suspension: 2 mg/10 ml • Dosing: 2mg twice	• 12 weeks of treatment in adult and pediatric 11 years of age and older with	ADRs (>2%): • respiratory tract infection	• First corticosteroid FDA-approved for the treatment of EoE • In two studies Eohilia demonstrated significant symptomatic and histologic improvements	• UF • PA • Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
Gastrointestinal-1 Agents: Gastrointestinal Steroids		daily x 12 weeks	eosinophilic esophagitis (EoE)	• gastrointestinal mucosal candidiasis • headache • gastroenteritis • throat irritation • adrenal suppression • erosive esophagitis	when compared with placebo following a 12-week treatment period • No data to address the time frame at which another 12-week course of Eohilia would be appropriate in patients who initially respond to treatment, but relapse following discontinuation • Budesonide inhalation suspension (compounded into a slurry and swallowed) and fluticasone propionate inhalation aerosol (actuated into the mouth and swallowed) have been used off-label for this condition • No data comparing Eohilia with off-label agents that are widely used in clinical practice and recommended in guidelines • Eohilia is a therapeutic alternative to budesonide and fluticasone oral inhalers for EoE	
• cyclosporine 0.1% ophthalmic solution (Vevye) Ophthalmic: Dry Eye	• cyclosporine ophthalmic soln 0.05 % • Cequa droperette 0.09% • Xiidra droperette 5 % • Verkazia droperette 0.1%	• Ophthalmic soln: 0.1 % • Dosing: 1 drop every 12 hours in each eye	• Treatment of the signs and symptoms of dry eye disease	ADRs (>8%) • instillation site reaction	• Vevye is 4th ophthalmic cyclosporine product; it is approved for dry eye disease • FDA approval included multiple clinical studies o Two studies demonstrated statistically significant evidence of superiority to vehicle in treating dry eye signs, but both studies failed with regards to symptom improvement of dry eye disease o The FDA approval is based on the post-hoc analysis of proportion of Schirmer's tear test responders • Vevye has a well-tolerated safety profile, consistent with other ophthalmic dry eye treatments • Provides an additional treatment option among an array of agents available for patients with dry eye disease, but has no compelling advantages over other products for dry eye disease	• NF • PA • MN • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• eflornithine tablets (Iwilfin) Oncological Agents: N/A	• n/a	• Tablet: 192 mg • Dosing: varies based on BSA	• Reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy	ADRs (≥5%): • hearing loss • otitis media • pyrexia • pneumonia • diarrhea	• Iwilfin is indicated to reduce the risk of relapse in patients with high-risk neuroblastoma • Efficacy was demonstrated in an externally controlled trial comparing outcomes of two separate studies; statistically significant improvements in event free survival (EFS) and overall survival were demonstrated in the Iwilfin group compared with the control group • Safety signals are difficult to interpret in the open label, single arm study design of Iwilfin; however most reported adverse events were mild in nature • FDA Oncologic Drug Advisory Committee voted 14 to 6 that sufficient evidence was provided to demonstrate EFS benefit of Iwilfin to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma • Provides a pharmacologic treatment option to reduce the risk of relapse for this high mortality disease state	• UF • PA • QL • EMMPI
• eltrombopag 9 mg, 18 mg, 35 mg and 54 mg tablets (Alvaiz) Hematological Agents: Platelets	• Promacta • Doptelet • Tavalisse • Mulpleta	• Oral tablets: 9 mg 18 mg 36 mg 54 mg • ITP and AA Dosing: 36 mg daily and adjust based on platelet count • Hep C Dosing: Dosing: 18 mg daily and adjust based on platelet count	• Thrombocytopenia in adults & children ≥6 yrs with persistent or chronic immune thrombocytopenia (ITP) with an insufficient response to steroids, immunoglobulins, or splenectomy • Thrombocytopenia (adults) with chronic hepatitis C for interferon-based tx (initiation & maintenance) • Severe aplastic anemia (adults) with an insufficient response to immunosuppressive therapy	ADRs (≥20%): • anemia • nausea • pyrexia • alanine aminotransferase increased • cough • fatigue • headache • diarrhea	• Another tablet formulation of eltrombopag that is not substitutable/interchangeable with other eltrombopag products on a mg per mg basis due to the observed bioavailability in studies conducted on Alvaiz • No new clinical studies; approved via 505(b)(2) • Promacta and Alvaiz have different strength tablets and max doses for each indication • Promacta has an additional indication for first line treatment of severe aplastic anemia and comes in an oral suspension • Promacta can be used in patient as young as 1 years old for ITP while Alvaiz in only indicated in patients as young as 6 years old for the same indication • Both agents have a boxed warning for hepatoxicity • Provides no compelling clinical advantage over existing agents	• UF • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• eplontersen injection (Wainua) Neurological Agents Misc: N/A	• inotersen (Tegsedi) • Onpattro (medical benefit) • Amvuttra (medical benefit)	• Autoinjector: 45 mg/0.8 ml • Dosing: 45 mg SC once monthly	• Treatment of polyneuropathy due to hereditary transthyretin-mediated amyloidosis (hTTRA) in adults	Serious ADRs: • atrioventricular block • complete AV block	• Second pharmacy benefit drug approved for treatment of polyneuropathy in adults with hTTRA; is administered SQ once monthly • The NEURO-TTRansform study used for FDA approval showed a statistically significant reduction in neuropathic impairment and improved quality of life scores compared to historical placebo which used data from inotersen (NEURO-TTR study) • Limitations include lack of published head-to-head trials, use of historical placebo and small active treatment group, plus question of clinical relevance of the results • Inotersen (Tegsedi) was the 1st pharmacy benefit drug for this condition, but is administered daily, and has a REMS program due to risk of thrombocytopenia and glomerulonephritis. Tegsedi voluntary market removal in Sept 2024. • FDA post-marketing studies are required to determine adverse effects, (thrombocytopenia, glomerulonephritis, vitamin A deficiency, ocular impairment, pregnancy/lactation) • Under investigation for hTTR-cardiomyopathy. If Wainua does obtain the cardiomyopathy indication, indirect comparisons with tafamidis (Vyndaqel/Vyndamax) would be warranted • The current place in therapy and long-term safety remain to be determined	• UF • PA • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• Infliximab-dyyb injection (Zymfentra) TIBS: TNF Inhibitors	• Renflexis IV • Humira • Rinvoq • Stelara • Entyvio	• Prefilled syringe: 120 mg/ml • Dosing: 120 mg SC every 2 weeks from week 10 and after	• Moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously • Moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously	ADRs ≥3%): • COVID-19 • anemia • arthralgia • injection site reactions • ↑ alanine aminotransferase • abdominal pain • diarrhea • URI • Headache • ↑ CPK • Hypertension • UTI • neutropenia • dizziness • leukopenia	• First infliximab product administered SC and appears to have similar efficacy as infliximab IV for the maintenance treatment of ulcerative colitis (UC) and Crohn's Disease (CD) in adults • Zymfentra demonstrated similar clinical remission rates and safety profiles as those of infliximab IV • Zymfentra can only be used in adults while IV infliximab can be used in patients as young as 6 years of age for CD and UC • Unlike the IV formulation, Zymfentra must be stored in the refrigerator • Zymfentra has a more limited place in therapy and is an alternative to infliximab IV for the maintenance treatment of CD or UC in adults	• UF non-step-preferred • PA • QL • EMMPI
• iptacopan (Fabhalta) Hematological Agents: N/A	• Ultomiris Vial • Empaveli Vial • Soliris Vial	• Capsule: 200 mg • Dosing: 200 mg PO Daily	• Treatment of adults with paroxysmal nocturnal hemoglobinuria	ADRs (≥10%) • headache • nasopharyngitis • diarrhea • abdominal pain • bacterial infection • viral infection • nausea • rash	• Oral complement Factor B inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) that controls both intravascular and extravascular hemolysis • Soliris, Ultomiris, Empaveli, and Fabhalta all control intravascular hemolysis and are available only via REMS programs • Fabhalta and Empaveli both additionally control extravascular hemolysis which improves hemoglobin and decreases transfusion requirements • Fabhalta is orally administered while Empaveli is administered via SC infusion • Phase 3 active comparator study demonstrated ↑ of Hb ≥ 2 g/dL from baseline in 82.3% of patients given Fabhalta vs. 0% for those who remained on Soliris/Ultomiris • Phase 3 single arm study demonstrated 77.5% of patients had a sustained increase in Hb ≥ 2 g/dL from baseline • No head-to-head study versus Empaveli • Provides an oral option for extravascular and intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)	• NF • PA • QL • MN • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• nedosiran injection (Rivfloza) Nephrology Agents: N/A	• Oxlumo	• Prefilled syringe: 128 mg 160 mg • SDV: 80 mg • Dosing: varies based on age and actual body weight once monthly	• Lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 and relatedly preserved kidney function	ADRs (≥20%) • injection site reactions	• Rivfloza is the second drug approved for treating primary hyperoxaluria type 1 (PH1) • Phase 2 study demonstrated change from baseline in 24-hour urinary oxalate excretion improvement for patients on Rivfloza vs. placebo • Additionally, normalization or near normalization of 24-hour urinary oxalate excretion on ≥ two consecutive visits was observed in 65% of patients given Rivfloza vs. 0% in the placebo arm ($p < 0.001$) • No head-to-head studies versus Oxlumo, a medical benefit drug for PH1; however, both agents decrease urinary oxalate concentrations to near normal levels compared with placebo • Provides a therapeutic alternative to Oxlumo for the treatment of PH1	• UF • PA • QL • EMMPI
• omalizumab autoinjector (Xolair) Atopy: NA	• Palforzia	• Autoinjector: 75 mg/0.5 ml; 150 mg/ml; 300 mg/ml • Dosing: varies based on serum total IgE level and body weight	• Mod-sev persistent asthma in pts ≥6 yr with a + skin test or in vitro reactivity to a peren aeroallergen & inadequately controlled with ICS. • CRSwNP in adults with inadequate response to nasal steroids, as add-on maintenance treatment. • IgE-mediated food allergy in pts≥1 yr for reduction of allergic reactions (Type I), to one or more foods. • Chronic spontaneous urticaria in ≥12 yr who remain symptomatic despite H1 antihistamine treatment	Common ADRs: • injection site reaction • pyrexia	• The autoinjector is another formulation with similar indications as the prefilled syringe • Xolair single-dose prefilled syringes are administered by a caregiver for patients 1-11 years of age; single dose Xolair autoinjectors are not intended for use in patients younger than 12 years old • Summary for the newly approved indication o Omalizumab is newly approved for patients 1 year of age and older for the reduction IgE-mediated food allergy and is to be used in conjunction with continued food allergen avoidance o Clinical data demonstrated omalizumab treatment for 16 weeks was superior to placebo in increasing the reaction threshold for peanut, cashew, egg, and milk; however, the sustained benefit is currently unknown o Provides an option for patients for the reduction of allergic reactions with IgE-mediated food allergy	• UF • PA • QL • Do not add to EMMPI List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• roflumilast 0.3% topical foam (Zoryve) Psoriasis: N/A	• ketoconazole shampoo • betamethasone foam • desonide lotion • Zoryve cream • Verdeso Foam	• Topical foam: 0.3 % • Dosing: Apply thin layer once daily to affected area	• Seborrheic dermatitis in adult and pediatric patients 9 years of age and older	ADRs (≥1%) • nasopharyngitis • nausea • headache	• Another topical formulation of Zoryve approved to treat seborrheic dermatitis • Two phase 2 studies demonstrated significantly more roflumilast-treated patients than vehicle-treated patients achieved the primary end point of IGA success at week 8 • Zoryve is well tolerated with a mild adverse event profile, to include nasopharyngitis, nausea and headache • Provides no compelling clinical advantage over existing agents	• NF • PA • MN • QL • EMMPI
• sitagliptin free base (Zituvio & Zituvio Authorized Generic) Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	• Januvia • Tradjenta • Nesina • Onglyza	• Oral tablet: 25 mg 50 mg 100 mg • Dosing: 100 mg daily	• Adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes Mellitus	ADRs (≥5%) • Upper respiratory tract infection • Nasopharyngitis • Headache	• Another formulation of sitagliptin approved via the 505(b)(2) pathway using data from Januvia. No clinical trial data available • Available in the same dosage strengths as sitagliptin phosphate (Januvia) • Prior to approval, Zituvio underwent quality testing to ensure it was not contaminated with nitrosamine impurities • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • MN • EMMPI
• vamorolone oral suspension (Agamree) Corticosteroids–Immune Modulators: N/A	• prednisone • Emflaza	• Oral suspension: 40 mg/ml • Dosing: 6 mg/kg once a day with meal	• Treatment of Duchenne Muscular Dystrophy (DMD) in patients 2 years of age and older	ADRs (≥10%) • cushingoid features • psychiatric disorders • vomiting • weight gain • vitamin D deficiency	• Second corticosteroid approved for the treatment of patients with DMD; deflazacort (Emflaza) was the first • A Phase 2b study demonstrated statistically significant improvement in TTSTAND velocity with Agamree compared with placebo at 24 weeks • No head-to-head studies comparing Emflaza or prednisone are available • Adverse events are mostly consistent with chronic corticosteroid administration • Provides an additional pharmacologic corticosteroid option for the treatment of patients with DMD	• UF • PA • QL • Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• zilucoplan injection (Zilbrysq) Neurological Agents Misc	• Rystiggo inj • Vyvgart Hytrulo inj	• Prefilled syringes: 16.6 mg/0.416 mL, 23 mg/0.574 mL, 32.4 mg/0.81 mL • Dosing: varies based on patient weight	• Treatment of generalized myasthenia gravis in adult patients who are antiacetylcholine receptor antibody positive	ADRs (≥10%) • injection site reaction • upper respiratory track infection • diarrhea	• Third complement C5 inhibitor and first self-administered SC formulation indicated for the treatment of generalized myasthenia gravis • Phase 3 study demonstrated significant and clinically meaningful improvement in MG-ADL • Guidelines do not address Zilbrysq, Ultomiris IV, or the neonatal Fc receptor blockers • Fc receptor blockers (Rystiggo, Vyvgart, Vyvgart Hytrulo) do not have a Boxed Warning and are generally viewed as having a more favorable safety profile compared with complement C5 inhibitors • Soliris, Ultomiris and Zilbrysq have a Boxed Warning regarding serious meningococcal infections and all three agents are only available through a REMS program • Zilbrysq has a unique warning about pancreatitis and other pancreatic conditions • No head-to-head studies with Soliris, Ultomiris or neonatal Fc receptor blockers, nor any guidance when to use one class over the other • Zilbrysq is an option for the treatment of anti-AChR antibody-positive generalized myasthenia gravis and is a therapeutic self-administered alternative to other complement C5 inhibitors and neonatal Fc receptor blockers	• UF • PA • QL • EMMPI

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes

DoD P&T Meeting	ADD to the TRICARE Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from TMOP Requirement)
May 2024	**Drug Class Reviews** **Insulin Class: Basal Insulin Subclass** ***Designated UF*** *Retain on the TRICARE Maintenance Drug List:* • insulin glargine (Lantus) • insulin glargine U-300 (Toujeo) • insulin glargine U-300 (unbranded) • insulin glargine (Rezvoglar) • insulin glargine-yfgn (unbranded) • insulin glargine U-100 (unbranded) ***Designated NF*** *Retain on the TRICARE Maintenance Drug List - no reason to exempt from NF requirement* • insulin detemir (Levemir – *impending market discontinuation*) • insulin degludec U-100, U-200 (Tresiba) • insulin degludec U-100, U-200 (unbranded) • insulin glargine (Basaglar) • insulin glargine (Semglee – *impending market discontinuation*) • insulin glargine-yfgn (Semglee) **Pulmonary -1s: Inhaled Corticosteroids** ***Designated UF*** *Retain all branded on the TRICARE Maintenance Drug List (included authorized generics)* • ciclesonide (Alvesco) • fluticasone propionate authorized generics (brand Flovent discontinued) • mometasone furoate (Asmanex HFA) • budesonide nebulization solution (brand Pulmicort Respules) ***Designated NF*** *Retain on the TRICARE Maintenance Drug List - no reason to exempt from NF requirement* • beclomethasone (QVAR Redihaler) • budesonide inhaler (Pulmicort Flexhaler) • fluticasone furoate (Arnuity Ellipta) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)**	**Drug Class Reviews** **Weight Loss Agents** ***Designated UF*** *Not cost advantageous to government* • bupropion/naltrexone (Contrave) • phentermine (Qsymia) • semaglutide injection (Wegovy) • tirzepatide injection (Zepbound) ***Designated NF*** *Exempt from NF requirement (not cost advantageous to government)* • orlistat (Xenical) • somatropin injection (Humatrope, Nutropin, liraglutide injection (Saxenda) **Utilization Management/Re-evaluation of NF Generics** **Calcium Channel Blockers** *Remove generic agents moving to UF status* • diltiazem 24 hr extended release (Cardizem LA, generics) • verapamil 24 hr sustained release pellet-filled capsules (Verelan, generics) • nisoldipine 24 hr ER tablets, controlled release (Sular, generics) **Proton Pump Inhibitors** *Exempt from NF requirement (not cost advantageous to the government)* • omeprazole/bicarbonate capsules (Zegerid, generics) • lansoprazole rapidly dissolving tabs (Prevacid, generics)

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary

DoD P&T Meeting	ADD to the TRICARE Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from TMOP Requirement)
	Designated NF *No reason to exempt from NF requirement* • cyclosporine 0.1% ophthalmic solution (Vevye) • roflumilast 0.3% topical foam (Zoryve) • sitagliptin free base (Zituvio, and authorized generics) **TRICARE Maintenance Drug List Updates** • lotilaner 0.25% ophthalmic solution (Xdemvy)	

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to EMMPI program requirements are listed on the TRICARE Maintenance Drug List.

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from TMOP Requirement)
May 2024	**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • eltrombopag 9-, 18-, 35, 54- mg tablets (Alvaiz) • eflornithine (Iwilfin) • nedosiran (Rivfloza) • eplontersen (Wainua) • zilucoplan (Zilbrysq) ***Designated NF*** *No reason to exempt from NF requirement; similar agents already on the list* • bosutinib capsules (Bosulif) • infliximab-dyyb (Zymfentra) • iptacopan (Fabhalta **Drugs or Drug Classes Designated by the P&T Committee as Generally Suitable for Inclusion** ***Designated UF*** ***Added as Individual Agents*** • decitabine/cedazuridine (Inqovi) • larotrectinib sulfate (Vitrakvi) • nintedanib (Ofev) ***Added by subclass*** • Oncological agents: non-Bruton Tyrosine Kinase Inhibitors (non-BTKI) for Chronic Lymphocytic Leukemia (CLL)	**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** *Acute or limited duration of use* • birch triterpenes topical gel (Filsuvez) *For future consideration* • vamorolone oral suspension (Agamree) • omalizumab autoinjector (Xolair) • budesonide 2 mg/10 mL oral suspension (Eohilia)
Medications previously on the contingent list that were added to the TRICARE Maintenance Drug List since the last P&T meeting, by class and subclass		
March 1, 2024	• Atopy (Adbry) • Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors (Ibrance, Kisqali, Kisqali Femara Co-Pack, Verzenio) • Corticosteroids-Immune Modulators: Hereditary Angioedema Agents (Takhzyro) • FSH-LH Fertility Agents (Follistim AQ, Gonal-F, Gonal-F RFF Redi-Jec. Menopur) • Growth Stimulating Agents (Voxzogo) • Hematological Agents: Platelets (Promacta) • Immunosuppressives (Benlysta) • Neurological Agents Misc: Movement Disorders (Austedo, Vyndamax, Vyndaqel) • Oncological Agents	

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary

	○ 2nd-Gen Antiandrogens (Erleada, Nubeqa, Xtandi) ○ Acute Myelogenous Leukemia (Daurismo, Idhifa, Onureg, Rydapt) ○ Breast Cancer (Piqray) ○ Chronic Myelogenous Leukemia (Bosulif, Scemblix) ○ Colorectal Cancer (Lonsurf) ○ Cyp-17 Inhibitors (Yonsa) ○ Epidermal Growth Factor Receptor (EGFR)+ Non-Small Cell Lung Cancer (NSCLC) (Gilotrif, Tagrisso) ○ Lung Cancer (Gavreto, Lumakras, Tabrecta, Tepmetko, Xalkori, Zykadia) ○ Melanoma (Cotellic, Mektovi, Zelboraf) ○ Myelofibrosis (Inrebic) ○ Poly Adenosine Diphosphate-Ribose Polymerase (Parp) Inhibitors (Lynparza, Talzenna) ○ Renal Cell Carcinoma (Inlyta, Votrient) ○ No Subclass (Hycamtin, Mekinist, Tafinlar, Odomzo, Zolinza) • Sphingosine 1 Phosphate (S1p) Receptor Modulators (Mayzent, Zeposia) • Targeted Immunomodulatory Biologics ○ Non-Tumor Necrosis Factor Inhibitors (Cosentyx Unoready Pen) ○ Tumor Necrosis Factor Inhibitors (Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimra
Medications placed on the contingent list at prior meetings but not yet implemented, by class and subclass	
May 2023 – Feb 2024	• Oncological Agents ○ Acute Myelogenous Leukemia (Xospata, Tibsovo, Rezlidhia, Vanflyta) ○ Breast Cancer (Truqap, Orserdu, Nerlynx, Tukysa) ○ Chronic Myelogenous Leukemia (Lytgobi, Turalio, Inclusig, Tasigna) ○ CYP-17 Inhibitors (Zytiga) ○ EGFR+ Non-Small Cell Lung Cancer (Vizimpro) ○ Lung Cancer (Krazati, Alunbrig, Rozlytrek, Lorbrena) ○ Melanoma (Braftovi) ○ Multiple Myeloma (Ninlaro, Revlimid, Pomalyst, Xpovio, Thalomid) ○ Myelofibrosis (Vonjo, Jakafi) ○ Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors (Zejula, Rubraca) ○ Renal Cell Carcinoma (Cabometyx, Cometriq, Afinitor, Afinitor Disperz, Lenvima, Nexavar, Fotivda) ○ No Subclass (Vijoice, Tafinlar, Fruzaqla, Ojjaara, Akeega, Stivarga, Erivedge) • Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitors (Bimzelx, Bimzelx Autoinjector, Siliq, Omvoh Pen, Arcalyst, Enspryng, Entyvio Pen)
Drug Classes or Subclasses Designated by the P&T Committee at prior meetings, as generally suitable for inclusion on the contingent list	
May 2023 – Feb 2024	• Atopy • Breast Cancer: Cyclin Dependent Kinase Inhibitors • LHRH agonists/antagonists • MS agents • Oncological agents ○ 2nd Generation Antiandrogens ○ Acute Myelogenous Leukemia ○ Breast Cancer ○ Chronic Myelogenous Leukemia ○ Colorectal Cancer ○ CYP-17 Inhibitors ○ EGFR+ Non-Small Cell Lung Cancer ○ Lung Cancer ○ Melanoma ○ Multiple Myeloma ○ Myelofibrosis ○ Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors ○ Renal Cell Carcinoma • Neurological Misc: Movement Disorders

	• Targeted Immunomodulatory Biologics

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: July 29, 2024

Two weeks after signing: August 14, 2024

30 days after Signing: August 28, 2024

60 days after signing: October 1, 2024

90 days after signing: October 30, 2024

120 days after signing: November 27, 2024

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

Appendix H—Completely Excluded Agents and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
May 2024	Pulmonary Is: Inhaled Corticosteroids	• fluticasone Armon Air Digihaler	• beclomethasone (QVAR Redihaler) [nonformulary] • budesonide dry powder inhaler (Pulmicort Flexhaler) [nonformulary] • ciclesonide (Alvesco) • fluticasone propionate diskus • fluticasone propionate HFA • fluticasone furoate (Arnuity Ellipta) [nonformulary] • mometasone (Asmanex Twisthaler)	• N/A previously Completely Excluded Nov 2020

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3).

Drugs recommended for complete exclusion will not be available at the MTFs or TMOP points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the complete exclusion agents at the Retail points of service.

For a cumulative listing of all completely excluded agents to date, refer to previous versions of the P&T Committee quarterly meeting minutes, found on the heatlh.mil website.