DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2023

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 3rd and 4th, 2023.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February 2023 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the February 2023 DoD P&T Committee meeting on May 1, 2023.

B. Clarification of previous meeting minutes

1. February 2023

- **Weight Loss Drugs PA updates: Prescribing weight loss drugs for Active-Duty Service Members (ADSM)—**Several updates were made to the prior authorization (PA) criteria for the weight loss drugs. A memo from Dr. Lein has clarified when prescribing weight loss medications for ADSM that providers must continue to follow Military Department-specific policies that set the requirements for participation in weight loss programs. The memo also clarifies that the service-specific policies have not been removed by these PA changes. See Appendix J.
- **Luteinizing Hormone Releasing-Hormone (LHRH) Agents—**The quantity limit (QL) for leuprolide acetate depot injection (unbranded) was clarified as 1 kit per fill, similar to the other LHRH agents.
- **Rapid Acting Insulin Agents—**A PA was included on the Humalog Tempo Pen requiring a trial of the Humalog Kwikpen.
- **Androgens-Anabolic Steroids: Testosterone Replacement Therapies—**It was clarified that the PA criteria for the renewal include both the patient who has had a positive response to therapy AND the risks of continued therapy do not outweigh the benefits. Previously it was listed as OR. Additionally, the implementation for the Testosterone Replacement Therapies was moved from July 5th to July 12th due to the holiday.

2. August 2022

- **Atopy Agents—dupilumab (Dupixent)—**The requirement for a trial of phototherapy or topical calcineurin inhibitors in children will be removed from the PA, because these treatments are not FDA-approved for this age range.

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 (Tier 4 (complete exclusion)) 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 mail order program pursuant to 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 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

IV. UF DRUG CLASS REVIEWS

A. Antilipidemics-1—Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

Background—The P&T Committee evaluated the relative clinical effectiveness of the PCSK9 inhibitors, which reduce low density lipoprotein cholesterol (LDL-C). The two drugs in the class include alirocumab (Praluent) and evolocumab (Repatha). The PCSK9 inhibitors were previously reviewed for formulary status in November 2016 based on trials demonstrating reduction in LDL-C. Since then, two large cardiovascular outcomes studies have been published.

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

Efficacy

- Both alirocumab (Praluent) and evolocumab (Repatha) are injectable nonstatin therapies that provide significant reductions in LDL-C, ranging from 45% to 65%.
- In addition to lowering LDL-C, both PCSK9 inhibitors reduce major adverse cardiovascular events when used as secondary prevention, based on data from the ODYSSEY OUTCOMES trial with alirocumab, and the FOURIER trial with evolocumab.
- The drugs are FDA-approved for patients with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction (MI), stroke and

coronary revascularization (for Repatha) or to reduce the risk of MI, stroke and unstable angina requiring hospitalization (for Praluent).

- There is conflicting data between the FOURIER and ODYSSEY OUTCOMES trials with regard to effects on risk of cardiovascular (CV) death and all-cause death.
- The full mortality benefits of PCSK9s inhibitors are unknown due to early study termination.

Guidelines

- Recent updated guidance for nonstatins from the 2022 American College of Cardiology Expert Consensus Decision Pathway continue to support use of high intensity statins first-line for adults with atherosclerotic cardiovascular disease (ASCVD). The high intensity statins include atorvastatin 40 mg and 80 mg, and rosuvastatin 20 mg and 40 mg.
- PCSK9 inhibitors either alone or with ezetimibe can be considered in patients receiving maximally tolerated statin therapy who require a greater than 50% reduction in LDL-C.
- PCSK9 inhibitors may be considered for patients with clinical ASCVD at very high risk for future ASCVD events and who require a greater than 25% additional LDL lowering. Patients at very high risk for future ASCVD events include those with a history of major ASCVD events (i.e., recent acute coronary syndrome within the past 12 months, prior MI, prior ischemic stroke or symptomatic peripheral arterial disease), or those with one major ASCVD event and who have multiple high-risk conditions (e.g., age older than 65 years, heterozygous familial hypercholesterolemia, prior coronary revascularization, diabetes mellitus, hypertension, chronic kidney disease, current smoking, LDL-C > 100 mg/dL despite maximal statin therapy and history of chronic heart failure).
- The decision pathway now recommends lower LDL-C thresholds for starting nonstatin therapy, based on clinical status.
    - For patients with ASCVD at very high risk of future ASCVD events, the threshold for starting a nonstatin is an LDL-C > 55 mg/dL.
    - For patients with ASCVD not at very high risk of future ASCVD events, the threshold for starting a nonstatin is an LDL-C of > 70 mg/dL.

Safety

- Overall, the PCSK9 inhibitors are well tolerated, with injection site reactions reported most commonly. Alirocumab is associated with significantly more injection site reactions than evolocumab, based on systematic review and network meta-analysis.

- No major differences are seen between the PCSK9 inhibitors with regard to discontinuations due to adverse effects.

Other Factors

- *Other nonstatins:* The results of a CV outcomes trial (CLEAR OUTCOMES) with bempedoic acid (Nexletol, Nexlizet) were recently published. CV outcomes trials are currently ongoing with inclisiran (Leqvio injection), which is available under the TRICARE medical benefit.
- Both PCSK9 inhibitors are indicated for treating homozygous familial hypercholesterolemia (HoFH) and heterozygous familiar hypercholesterolemia (HeFH), which are rare genetic conditions causing highly elevated LDL-C levels. Repatha is indicated for patients as young as 10 years of age with HoFH or HeFH, while Praluent is only labeled for use in adults.
- Repatha is available in a prefilled syringe, autoinjector, and an on-body infusor (Pushtronex), while Praluent is solely available in an autoinjector.

Overall Clinical Effectiveness Conclusion

- Although head-to-head trials are not available, the two PCSK9 inhibitors are highly therapeutically interchangeable, systematic reviews and network meta-analyses.
- At least one PCSK9 inhibitor is required on the formulary to meet the needs of MHS beneficiaries.

Relative Cost Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that evolocumab (Repatha) is more cost effective than alirocumab (Praluent).
- BIA was performed to evaluate the potential impact of designating the PCSK9 inhibitors as UF, NF, or completely excluded from the formulary. BIA results showed that designating evolocumab (Repatha) as UF and step-preferred and alirocumab (Praluent) as UF and non-step-preferred demonstrated significant cost avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the current formulary status for the PCSK9 inhibitors.

- UF and step-preferred
  - evolocumab (Repatha)
- UF and non-step-preferred
  - alirocumab (Praluent)
  - Note that as part of the formulary recommendation for Praluent, a trial of Repatha is required first.
- NF
  - None
- Complete exclusion
  - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria have been in place for the PCSK9 inhibitors since market entrance in 2015. In general, the following are currently required: specialist prescribing by a cardiologist; a trial of both high intensity atorvastatin and rosuvastatin, or if the patient is not on a high-intensity statin, they must be on ezetimibe plus a lower intensity statin, unless statin intolerance is documented; and renewal criteria are required after one year. Additionally, a trial of Repatha is required before Praluent.

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following changes to the criteria for new users. Reducing the requirement to try both high intensity atorvastatin and rosuvastatin to a trial of one high intensity statin and removing the requirement for specialist prescribing. Updates to the threshold LDL-C for patients with ASCVD were made, based on the ACC Expert Consensus Decision Pathway. Lastly, the requirement for renewal criteria was removed, and the PA will not expire. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for the PCSK9 inhibitors. See Appendix D.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining Repatha and Praluent on the EMMPI program.

5. ***COMMITTEE ACTION: UF, PA, QL, EMMPI and IMPLEMENTATION PERIOD—*** The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first

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

B. Ophthalmic—Dry Eye Agents

Background—The P&T Committee evaluated the relative clinical effectiveness of the Ophthalmic Dry Eye Agents, which are used to treat keratoconjunctivitis sicca (dry eye disease) and vernal keratoconjunctivitis (VKC). The class is comprised of 4 formulations containing differing concentrations of cyclosporine [0.05% ophthalmic emulsion unit dose and multidose (Restasis, Restasis Multidose), 0.09% ophthalmic solution (Cequa), and 0.1% ophthalmic emulsion (Verkazia)], lifitegrast 5% ophthalmic solution (Xiidra), loteprednol 0.25% ophthalmic suspension (Eysuvis), and varenicline nasal solution (Tyrvaya). Restasis and Xiidra were previously reviewed for formulary status in February 2018, while the remaining drugs were reviewed individually as new drugs.

All the drugs are indicated for dry eye disease, except for Verkazia, which is only indicated for VKC.

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

Clinical Practice Guidelines

Dry Eye Disease

- The 2018 American Academy of Ophthalmology Preferred Practice Pattern (AAO PPP), and the 2017 Tear Film and Ocular Surface Society International Dry Eye Workshop II (TFOS DEWS II) recommend a stepwise treatment approach based on disease severity, and do not favor one product over another.
    - Ocular lubricants (e.g., artificial tears) are recommended as first-line (Step 1) treatments for dry eye disease, along with education, environmental changes, and eyelid hygiene.
    - Second-line (Step 2) treatments include cyclosporine, lifitegrast, or short course low-dose ophthalmic steroids (e.g., prednisolone, loteprednol).
    - The guidelines have not yet been updated to include the newer agents Cequa, Tyrvaya, or Eysuvis.

Vernal Keratoconjunctivitis (VKC)

- VKC is a rare disease causing severe ocular inflammation which can lead to corneal scarring and vision loss. It most commonly occurs in pediatric males living in warm, dry subtropical climates.
- The 2018 AAO PPP guidelines for VKC recommend a stepwise treatment approach based on disease severity, along with cool compresses and ocular lubricants.
    - Mild disease can be treated with ocular mast cell stabilizers (e.g., azelastine, olopatadine) and antihistamines, followed by topical corticosteroids for moderate disease severity, with severe disease requiring

treatment with the immunomodulatory therapies (cyclosporine and tacrolimus).

Efficacy

- There are no direct comparative studies between Restasis, Xiidra, Cequa, Tyrvaya, and Eysuvis for treatment of dry eye disease.
- *Dry Eye Disease:* A 2022 abstract from the Association for the Research in Vision and Ophthalmology (ARVO) Annual Meeting indirectly compared Cequa, Restasis, and Xiidra. There were no significant differences between the products with regard to patient subjective improvement, objective tests (Schirmer's tear test and tear osmolarity) and side effects. Limitations to this analysis include the retrospective study design and small sample size.
- *VKC*: No direct comparative data is available between Verkazia and lower dose cyclosporine agents for VKC treatment; however, the 2018 AAO PPP guidelines state that cyclosporine 0.05% is an appropriate option for treatment and has been effective in preventing seasonal recurrences.

Safety

- Ocular stinging and burning are common adverse effects with all the products. Unique safety features include the following:
  - Xiidra can cause dysgeusia.
  - Eysuvis carries warnings of delayed healing, intraocular pressure increase, cataracts, and risk of bacterial, viral, and fungal infections
  - Tyrvaya as a nasal spray has unique nasal symptoms including nasal irritation, coughing, and sneezing.

Individual Product Characteristics

- **cyclosporine 0.05% (Restasis)** has a well-established efficacy and safety profile. Full clinical response may take 3 to 6 months to occur. The unit-dose formulation is now available as a generic product, while the multi-dose formulation is still branded. Ocular burning and stinging are the most commonly reported adverse effects. MHS providers agreed that generic Restasis can be trialed before other dry eye agents.
- **cyclosporine 0.09% (Cequa)** provides a higher strength of cyclosporine but does not show compelling clinical benefits over Restasis or Xiidra.
- **cyclosporine 0.1% (Verkazia)** is a higher strength cyclosporine formulation specifically indicated to treat VKC.
  - Clinical trial data and guidelines (2018 AAO PPP) support efficacy of lower-strength cyclosporine formulations for treatment of severe VKC.
  - MHS providers agreed that a trial with other cyclosporine strengths is appropriate, and Verkazia should be reserved for severe VKC cases.

- **lifitegrast (Xiidra)** offers a different mechanism of action and potentially a faster onset of action compared to Restasis (as early as 2 weeks, with peak effect at 12 weeks vs. 6 months with cyclosporine), but there are no significantly compelling clinical benefits of Xiidra over Restasis.
- **loteprednol 0.25% (Eysuvis)** is currently the only loteprednol formulation to carry the FDA indication for short-term treatment of dry eye disease. However, guidelines (2018 AAO PPP and 2017 TFOS DEWS II) and MHS providers support the use of alternative loteprednol formulations, as well as other low-dose steroids for effective treatment. Ophthalmic steroids should only be used for short-term periods due to the risk of corneal perforation and increased ocular pressure. Eysuvis provides little-to-no clinical benefit over other ophthalmic steroid products. Note that loteprednol 0.2% (Alrex) and loteprednol 0.5% (Lotemax) and several other ophthalmic steroids are on the UF.
- **varenicline nasal spray (Tyrvaya)** has a unique mechanism of action using the parasympathetic pathway to increase tear production and does not cause ocular burning. However, Tyrvaya does not correct the underlying ocular inflammation. Sneezing, coughing and throat irritation can occur. MHS providers recommend a trial OTC artificial tears and generic cyclosporine or Xiidra first, before Tyrvaya. Its place in therapy remains unclear, and long-term benefit has not been determined.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, at least one ophthalmic immunomodulatory agent is needed to treat the majority of patients with dry eye disease and VKC.

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

- CMA results showed that cyclosporine 0.05% (Restasis and Restasis MultiDose), lifitegrast 5% (Xiidra), cyclosporine 0.09% (Cequa), varenicline nasal spray (Tyrvaya), and cyclosporine 0.1% (Verkazia) were cost effective, and that loteprednol 0.25% (Eysuvis) was not 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 cyclosporine 0.05% (Restasis and Restasis MultiDose), lifitegrast 5% (Xiidra), and cyclosporine 0.09% (Cequa) as UF, with varenicline nasal spray (Tyrvaya) and cyclosporine 0.1% (Verkazia) as NF, and loteprednol 0.25% (Eysuvis) as completely excluded, demonstrated the greatest 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
     - cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generics)
       - Note that as part of the formulary recommendation the current Tier 1 copay for brand Restasis unit dose was removed; the Tier 2 copay will now apply to branded Restasis.
     - cyclosporine 0.05% ophthalmic emulsion multidose (Restasis Multidose)
     - cyclosporine 0.09% ophthalmic solution (Cequa) – *moves from NF to UF*
     - lifitegrast 5% ophthalmic solution (Xiidra)
   - NF
     - cyclosporine 0.1% ophthalmic emulsion (Verkazia)
     - varenicline nasal solution (Tyrvaya)
   - Complete exclusion
     - loteprednol etabonate 0.25% ophthalmic solution (Eysuvis) – *moves from NF to complete exclusion*

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria has applied to all the products in the class since they were first reviewed individually for formulary status. In general, the following are required: specialist prescribing, a trial of two OTC lubricants (including preservative-free products), objective testing to confirm the diagnosis of dry eye disease or VKC, and renewal criteria, as the PAs expire in one year. Off-label use of Restasis is allowed for several conditions, including VKC.

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following changes to the PAs for new patients. For generic Restasis unit dose, Restasis Multidose, Cequa and Xiidra, the current 18 year age restriction and renewal criteria will be removed. For Restasis Multidose, Cequa and Xiidra, a 3-month trial of generic Restasis unitdose will now be required for dry eye disease. Cequa will also be authorized for patients with VKC without requiring a trial of Restasis first. For Verkazia, a trial of Restasis or Cequa is required.

   There were no changes to the current PA criteria for Tyrvaya, which requires trial of Restasis or Xiidra first. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the MN criteria currently in place for Tyrvaya and

updating the MN criteria for Verkazia to require a trial of Cequa in addition to Restasis. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MTF/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining branded Restasis, Tyrvaya, and Verkazia on the EMMPI program and removing Xiidra and Cequa from the EMMPI program.

5. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) excluding Restasis, Cequa, Xiidra, Verkazia and Tryvaya from the Auto-Refill program at the TRICARE Mail Order Pharmacy.

6. ***COMMITTEE ACTION: UF, MN, PA, EMMPI and AUTO-REFILL PROGRAM IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service for Restasis, Cequa, Xiidra, Verkazia, and Tryvaya, and an effective date of the first Wednesday 120 days after signing of the minutes in all points of service for Eysuvis. DHA will send letters to patients affected by the complete exclusion status of Eysuvis. See Appendix G for the actual implementation date.

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

The products were divided into two groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Krazati, Atorvaliq, Orserdu, Rezvoglar, Konvomep, Stimufend, and Jaypirca; Group 2 was comprised of Amjevita, Altuviiio, Filspari, Pradaxa, Daybue, and Tezspire.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (for both group 1 and group 2: 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 2023 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

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

    - UF

- adagrasib (Krazati) – Oncological agent for advanced or metastatic non-small cell lung cancer
- antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl vial (Altuviiio) – Antihemophilic Factors
- elacestrant (Orserdu) – Oncological agent for breast cancer
- omeprazole and sodium bicarbonate 2 mg/mL oral suspension (Konvomep) – Proton Pump Inhibitors
- pegfilgrastim-fpgk injection (Stimufend) – White Blood Cell Stimulants: pegfilgrastims
- pirtobrutinib (Jaypirca) – Oncological agent for relapsed or refractory mantle cell lymphoma
- sparsentan (Filspari) – Nephrology Miscellaneous Agent for immunoglobulin A nephropathy
- tezepelumab-ekko autoinjector (Tezspire) – Atopy Agent for add on maintenance severe asthma treatment
- trofinetide 200 mg/mL oral solution (Daybue) – Neurological Miscellaneous Agent for treatment of Rett syndrome

- NF
  - adalimumab-atto injection (Amjevita) – Targeted Immunomodulatory Biologics (TIBS); Humira biosimilar
  - atorvastatin 20 mg/5 mL oral suspension (Atorvaliq) – Antilipidemics-1 agents
  - dabigatran oral pellet packets (Pradaxa pellets) – Direct Acting Oral Anticoagulant for treatment of venous thromboembolism (VTE) in pediatric patients aged 3 months to less than 12 years
  - insulin glargine KwikPen (Rezvoglar) – Basal Insulins; Lantus biosimilar

- Tier 4 (complete exclusion) - None

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (for group 1 and group 2: 17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Amjevita, Atorvaliq, Pradaxa and Rezvoglar. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (for both group 1 and group 2: 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 Amjevita (the biosimilar to Humira), similar to what is required for all non-step-preferred TIBs. A trial of brand Humira is required first before the biosimilar in new users.
- Oncologic drugs: Applying manual PA criteria to new users of Krazati, Jaypirca, and Orserdu.
- Applying manual PA criteria to new users of Atorvaliq oral suspension, Pradaxa oral pellets, Filspari, Rezvoglar, Konvomep oral suspension, Daybue oral solution, and Tezspire injection.
- Applying manual PA criteria to Stimufend, similar to what is in place for the other non-step-preferred pegfilgrastims. New patients receiving Stimufend or one of the other non-step-preferred pegfilgrastims (Neulasta, Neulasta Onpro, and Ziextenzo) will be required to have a trial of Nyvepria, Udenyca or Fulphila first.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (for group 1: 16 for, 1 opposed, 0 abstained, 1 absent; and for group 2: 17 for, 0 opposed, 0 abstained, 1 absent) QLs for Krazati, Orserdu, Jaypirca, Amjevita, Altuviiio, Daybue, and Tezspire. See Appendix D for the QLs.

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

6. ***COMMITTEE ACTION: UF, MN, PA, QL, and EMMPI IMPLEMENTATION PERIOD***—The P&T Committee recommended (for group 1 and group 2: 17 for, 0 opposed, 0 abstain, 1 absent) an effective date of the following:
   - **New Drugs Recommended for UF or NF Status**: An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

a) Gastrointestinal-2 Agents—sacrosidase oral solution (Sucraid)—Sucraid is approved to treat patients with Congenital Sucrase-Isomaltase Deficiency (CSID).

Sucraid was identified as a high-cost, specialty medication with increasing utilization. Many commercial health plans require PA for Sucraid, and MTF providers support the addition of a prior authorization restricting it to its FDA-approved indication.

COMMITTEE ACTION: SACROSIDASE ORAL SOLUTION (SUCRAID)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria in new and current users of Sucraid, limiting use to patients who have a CSID diagnosis and symptoms. 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.

b) Thyroid Agents—levothyroxine sodium capsule (Tirosint)—Tirosint is a formulation that does not contain some common excipients (e.g., dyes, gluten, etc.) found in other levothyroxine formulations. However, Tirosint is not cost-effective relative to generic levothyroxine tablets or Synthroid. MTF providers support the addition of a prior authorization, to encourage use of more cost-effective levothyroxine formulations.

COMMITTEE ACTION: LEVOTHYROXINE SODIUM CAPSULES (TIROSINT)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria in new users of Tirosint capsules requiring a trial or contraindication to generic levothyroxine tablets or Synthroid first. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

2. Updated PA Criteria for New FDA-Approved Indications

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

a) Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)—abrocitinib (Cibinqo)— The manual PA criteria were updated to include the new expanded age indication for adolescents with refractory, moderate-to-severe atopic dermatitis. Cibinqo is now approved for patients 12 years of age and older. In addition, the new PA criteria were edited to allow for pediatric patients to try and fail, have a contraindication to, or intolerability to any topical corticosteroid (as opposed to a high potency topical corticosteroid).

b) **Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors—** abemaciclib (Verzenio)—The manual PA criteria were updated to remove the requirement for patients to have a high Ki-67 score.

c) **Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis—lanadelumab (Takhzyro)—**Expands the HAE prophylaxis indication to include patients 2 years of age and older.

d) **Immunological Agents Miscellaneous: Oral Agents—**house dust mite allergen extract (Odactra)—Manual PA criteria were updated to reflect the expanded pediatric age indication. Odactra is now approved for patients ranging from 12 to 65 years of age.

e) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors—zanubrutinib (Brukinsa)—**A new indication was added for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adults.

f) **Oncological Agents—tucatinib (Tukysa)—**The manual PA criteria were updated for Tukysa to allow for use in combination with trastuzumab for the treatment of RAS wild-type, HER2-positive, unresectable, or metastatic colorectal cancer in adults that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

g) **Therapeutic Continuous Glucose Monitoring Systems (CGMS)—Freestyle Libre 2 and 3**—The Freestyle Libre 2 and 3 systems are now approved for use in pregnant patients. The manual PA criteria were updated to change the requirement that patient had a diagnosis of "type 1 or type 2 diabetes" to a requirement that patients just have a diagnosis of "diabetes". Patients will still need to meet all additional PA requirements as last specified at the November 2022 meeting.

> ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for Brukinsa, Odactra, Takhzyro, Tukysa, Cibinqo, Verzenio and Freestyle Libre 2 and 3 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.

3. **Updated PA Criteria and/or Medical Necessity Criteria for Reasons other than New Indications**

a) **Antipsychotic Agents: Atypical—olanzapine/samidorphan (Lybalvi)—**Lybalvi was reviewed as an innovator at the November 2021 meeting and designated non-formulary with a PA. Although Lybalvi was associated with approximately 5 pounds less weight gain than olanzapine alone, several other options are available to mitigate antipsychotic-induced weight gain, including choosing a different antipsychotic (e.g., aripiprazole and ziprasidone) or adding on metformin. The

P&T Committee recommended clarifying the PA criteria to include these other options. In addition, the medical necessity criteria were changed to require a trial of four formulary agents including one olanzapine containing product (i.e., olanzapine or olanzapine/fluoxetine) and aripiprazole, ziprasidone, and lurasidone.

b) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—liraglutide (Victoza) and exenatide once weekly (Bydureon BCise)—**Dulaglutide (Trulicity) is the DoD's preferred GLP1RA, and it was previously only indicated for adults. Victoza and Bydureon BCise are indicated for patients as young as 10 years of age. The Victoza and Bydureon BCise PAs currently bypass the requirement to try Trulicity first in pediatric patients. The Trulicity package label was recently updated to allow for use in children 10 years of age and older, based on the results of a clinical trial. The P&T Committee recommended removing both the PA and MN criteria that allow the bypass of a trial of Trulicity first for pediatric patients with prescriptions for Victoza and Bydureon BCise.

c) **Oncological Agents: Lung Cancer—sotorasib (Lumakras)—**Previously, Lumakras had only been available as a 120 mg tablet. In order to get the recommended dose of 960 mg, a patient needed to take eight tablets. A new 320 mg tablet is now available which only requires a patient to take three tablets, but it is significantly less cost-effective than the 120 mg formulation. Both the 120 mg and 320 mg tablets can be dispersed in 4 ounces of water for patients who have swallowing difficulties. MTF provider feedback supports the addition of prior authorization criteria preferring the Lumakras 120 mg tablets over the 320 mg tablets.

> ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, MEDICAL NECESSITY CRITERIA, AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria and medical necessity criteria for olanzapine/samidorphan (Lybalvi), liraglutide (Victoza), and exenatide (Bydureon BCISE) in new users, and updates to the manual PA criteria for new users of sotorasib (Lumakras) 320 mg tablets. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix B and Appendix C for the full criteria.

d) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors Agents—adalimumab (Humira)—**The PA criteria for Humira were updated to allow for approval if the prescriber specialty is Rheumatology. Humira is a high value medication, and the inclusion of this new PA criteria enables rheumatologists, who possess advanced training and certification, to prescribe Humira without having to complete a PA. This change will also encourage appropriate use of this preferred product.

> ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—***The P&T Committee

recommended (16 for, 0 opposed, 0 abstained, 2 absent) updated manual PA criteria in new users of Humira allowing for PA approval if the prescriber is a rheumatologist. The new PA will become effective the first Wednesday 30 days after the signing of the minutes. See Appendix C for the full criteria.

5. Removal of PA

a) Diabetes Non-Insulin: Thiazolidinediones (TZDs) and Dipeptidyl Peptidase-4 inhibitors (DPP-4s)— Several diabetes drug classes are available on the formulary, and new products are now recommended first-line in addition to metformin, including the GLP1RAs (e.g., Trulicity) and SGLT-2 inhibitors (e.g., Jardiance). However, older classes still play a role in lowering glucose levels. The American Diabetes Association 2023 guidelines includes guidance for using the TZDs and DPP-4 inhibitors before metformin.

The UF preferred TZD pioglitazone and UF preferred DPP-4 inhibitor sitagliptin and their combination products are cost-effective, with high PA approval rates. Additionally, the TZDs and DPP-4 inhibitors have a low likelihood for off-label use (in contrast to the GLP1RAs.) The P&T Committee recommended removing the PA requirements for the UF TZD and DDP-4 inhibitors. PA will still remain for the NF, non-step-preferred TZD (e.g., rosiglitazone) and DPP-4 inhibitors (e.g., linagliptin, saxagliptin).

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for pioglitazone (Actos), pioglitazone/metformin (Actoplus Met), pioglitazone/glimepiride (Duetact), sitagliptin (Januvia), and sitagliptin/metformin (Janumet, Janumet 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 seven product line extensions by the original manufacturer. Line extensions have the same FDA indications as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

a) Atopy Agents—designating mepolizumab (Nucala) 40 mg prefilled syringe with the same formulary status (UF), PA, QL, Specialty program, and EMMPI status as the parent Nucala 100 mg syringe.

b) Hematological Agents: Sickle Cell Anemia Agents—designating voxelotor (Oxbryta) 300 mg tablets with the same formulary status (UF), PA and Specialty status as the parent Oxbryta 300 mg tablets for oral suspension.

c) Laxatives-Cathartics-Stool Softeners: Bowel Preparations—designating Na picosulfate, MgO, anhydrous citric acid (Clenpiq) 10 mg-3.5 g-12 g/175 mL with the same formulary status (UF) as the parent Clenpiq 10 mg-3.5 g-12 g/160 mL.

d) **Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors—** designating ibrutinib (Imbruvica) oral suspension with the same formulary status (UF), PA, QL, and Specialty status as the parent Imbruvica capsules.

e) **Oncological Agents**—designating pexidartinib (Turalio) 125 mg capsule with the same formulary status (UF), PA, QL, and Specialty program status as the parent Turalio 200 mg capsules.

f) **Oncological Agents: Second-Generation Antiandrogens—**designating apalutamide (Erleada) 240 mg tablet with the same formulary status (UF, non-step preferred), PA, QL, and Specialty program status as the parent Erleada 60 mg tablets.

g) **Pulmonary Arterial Hypertension (PAH) Agents: Prostacyclins—**designating treprostinil extended-release (Orenitram ER) 1, 2, and 3 month titration packs with the same formulary status (UF), PA and Specialty program status as the parent Orenitram ER tablets.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD— The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, Specialty program, and EMMPI status of the line extension products, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR FLUTICASONE/SALMETEROL (ADVAIR HFA), LENALIDOMIDE (REVLIMID) AND TOPIRAMATE ER (TROKENDI XR)

The Committee evaluated drugs from 3 classes that are currently UF:

- Pulmonary Is: Inhaled Corticosteroid/Long-Acting Beta Agonist Inhalers—fluticasone/salmeterol HFA inhaler (Advair HFA)
- Oncological Agents: Multiple Myeloma—lenalidomide (Revlimid)
- Anticonvulsant-Anti Mania Agents—topiramate ER (Trokendi XR)

AB-rated generic versions of all three drugs have entered the market; however, the generic products are less cost-effective compared to the branded agents. Therefore, the branded Advair HFA, Revlimid, and Trokendi XR will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 copay for brand Advair HFA, Revlimid, and Trokendi XR dose is recommended.

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) requiring brand Advair HFA, Revlimid and Trokendi XR over their respective generic formulations in all new and current users at all points of service, based on cost effectiveness. The

prescriber will provide patient-specific justifications as to why the branded product cannot be used. The Tier 1 (generic) copay will apply to the brand Advair HFA, Revlimid and Trokendi XR. Advair HFA will also remain on the EMMI list. The effective date will be the first Wednesday 60-days after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to AB-rated generics.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) requiring brand Advair HFA, Revlimid, and Trokendi XR over their respective generic formulations in all new and current 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 Advair HFA, Revlimid, and Trokendi XR. The effective date will be 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. OVER-THE-COUNTER (OTC) DRUG BENEFIT—NALOXONE NASAL SPRAY (OTC NARCAN NASAL)

Background: Pursuant to 32 CFR 199.21(h)(5)(i), an OTC drug may be included on the UF upon the recommendation of the P&T Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. OTC drugs placed on the UF, in general, will be treated the same as generic drugs on the UF for purposes of availability in the MTF pharmacies, retail pharmacies, and the Mail Order pharmacy program and other requirements. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the requirement for the prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under 32 CFR 199.21 (i)(2)(xii) for OTC drugs specifically used in certain emergency care treatment situations.

OTC Naloxone Nasal: The P&T Committee evaluated the clinical and cost-effectiveness for the addition of OTC nasal naloxone 4 mg/0.1mL (OTC Narcan Nasal Spray) to the UF. Other prescription naloxone formulations are available on the UF (Kloxxado, Zimhi), with prescription Narcan nasal designated with BCF status. The OTC naloxone nasal spray is the same as the prescription product.

Multiple references, including guidance from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, and the 2022 DoD/VA Guideline for the Use of Opioids in Management of Chronic Pain, as well as input from DoD pain management specialists, support the use of intranasal naloxone for the emergency treatment of known or suspected opioid overdose. Based on clinical effectiveness and ease of access, OTC naloxone nasal (4 mg/0.1mL) was recommended for addition to the UF, when the product is launched

commercially (expected in summer 2023). QLs currently exist for the class and were recommended for the OTC product.

COMMITTEE ACTION: UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT, QUANTITY LIMITS, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- adding OTC naloxone 4 mg/0.1 mL nasal spray to the UF
- waiving the copay requirement
- waiving the prescription requirement
- applying the current quantity limit of 2 cartons per fill at all POS (Retail/MTF/Mail) (note each carton contains 2 devices)
- implementation plan of two weeks after signing of the minutes and market launch of OTC Narcan nasal in all points of service

The P&T Committee voted to waive the prescription and copay requirements. While the P&T Committee voted to waive the requirement for a prescription at all points of service, there may be state or operational limitations that require some provider input for processing. As an example, some states allow pharmacists who have National Provider Identifier (NPI) numbers to prescribe but the pharmacy claims adjudication systems may require a valid prescription. According to National Council for Prescription Drug Programs (NCPDP) rules, a provider NPI is required for claims to process.

Regarding copay, 32 CFR 199.21(i)(2)(xii) states as a general rule, OTC drugs placed on the UF will have copayments equal to those for generic drugs on the UF. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the copayment may be established at $0.00 for any particular OTC drug in the retail pharmacy network. The P&T Committee recommended the copay for OTC naloxone be zero at retail and the Tier 1 generic copay at mail.

Note that additional considerations of dispensing OTC naloxone (e.g., distribution to first responders) fall outside the scope of P&T Committee.

IX. EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST AND NF (TIER 3) MEDICATIONS AVAILABLE UNDER THE TRICARE MAIL ORDER PHARMACY PROGRAM

NF medications are generally restricted to the Mail Order program pursuant to 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 (9), added by Section 702(c)(2) of the NDAA 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the ESI-managed TRICARE mail order program.

The P&T Committee reviewed several classes of medications for potential addition to the EMMPI program and agreed that branded maintenance medications in the following classes are generally suitable for inclusion on the EMMPI program.

- Atopy agents
- LHRH agonists-antagonists
- Multiple sclerosis agents
- Oncological Agents: 2nd Generation Antiandrogens (oral)
- Oncological Agents: Melanoma agents (oral)
- Targeted Immunomodulatory Biologics (TIBs)

COMMITTEE ACTION: EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) addition of appropriate agents in these six classes/subclasses to the EMMPI program or clarification of their status with regard to the NF to mail requirement, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing at mail order). The specific medications are outlined in Appendix F. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

X. ITEMS FOR INFORMATION

A. Commercial Trends

The DoD P&T Committee was updated on MHS prescribing patterns, including overall trends and spends, utilization by point of service, comparative costs across points of service, and comparison of DoD to commercial trends, including percent spend on specialty medications, drug classes experiencing the greatest growth, and the top 20 individual medications by total cost. Other information included the near-term forecast for biosimilar and generic introduction and a comparison of DoD and average commercial copays.

B. DoD/VA Continuity of Care List Annual Review

The DoD/VA Continuity of Care Drug List is a joint list of medications for pain, sleep disorders, psychiatric conditions, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by Section 715 of the NDAA 2016. Additions, deletions, and clarifications to the list are based on ADSM prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The P&T Committee was notified that no new additions or deletions were identified for the list during this year's review. The list is posted on www.health.mil.

C. Ruxolitinib (Opzelura) and coverage for Nonsegmental Vitiligo

The P&T Committee reviewed use of ruxolitinib (Opzelura) to treat nonsegmental vitiligo. Although Opzelura treats the depigmentation caused by vitiligo, it has no other known

functional impacts. Medication intended to treat depigmentation is excluded by federal regulation [32 CFR 199.4(e)(8)] and Tricare Policy Manual [Chapter 4, Section 2.1], therefore, no update to coverage for this indication was recommended. Opzelura remains covered for treatment of atopic dermatitis.

D. Specialty Medications

The P&T Committee was updated on potential changes regarding procurement and dispensing of specialty pharmaceuticals through the TRICARE Mail Order Program under the 5th Generation TRICARE Pharmacy Service (TPharm5) contract.

XI. ADJOURNMENT

The meeting adjourned at 1630 hours on May 4th. The next meeting will be in August 2023.

Appendix A—Attendance: May 2023 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the February 2023 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Completely Excluded Agents (Tier 4) and Therapeutic Alternatives
Appendix I—Table of Administrative Authorities
Appendix J—Prescribing Weight Loss Medications to Active-Duty Service Members memo

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

//sign

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

//sign

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

26 Jul 2023
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Paul Carby, MSC for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, COL (Ret.) MC, USA	Army, Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Consultant
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Col Larissa Weir, MC	Air Force, OB/GYN Physician
Capt Courtney Clutter, MC	Air Force, Internal Medicine Physician
Col Soo Sohn, BSC, for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	Physician at Large, DHA
Maj Blair Destefano, MC	Oncology Physician, Air Force
Beth Days, RPh, BCOP	Oncology Pharmacist
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
COL Yang Xia, MC	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Chartered Members	
Ms. Megan Gemunder	Attorney Advisor, Contract Law
Eric Parsons, RPh	TPharm5 Clinical COR, Purchased Care Branch
Eugene Moore, PharmD	TPharm4 Clinical COR, Purchased Care Branch
Dean Valibhai, PharmD	TPharm5 Clinical COR, Purchased Care Branch
CAPT Bill Kelly, MSC	DLA
Richard Ruck, MD	TRICARE Health Plan Chief Medical Officer
Pete Glassman, MD	Department of Veteran's Affairs
Ms. Marsha Peterson	DHA Contracting Officer
Guests	
CDR Phung Thien Nguyen, USPHS	Senior Executive Officer, DHA Pharmacy Operations Division
Major Greg Palmrose, BSC	DHA Direct Care Branch
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Sheila Mirrieles	DHA Contracting
Others Present	
CDR Scott Raisor, BCACP, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
Ellen Roska, PharmD, PhD	DHA Formulary Management Branch,
Mr. David Folmar	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor

Appendix A—Attendance

Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA Formulary Management Branch Contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• cyclosporine 0.1% ophthalmic emulsion (Verkazia) **Ophthalmic: Dry Eye**	**Changes from May 2023 meeting are in BOLD** • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis) **AND** cyclosporine 0.09% (Cequa)
• varenicline nasal solution (Tyrvaya) **Ophthalmic: Dry Eye**	**Changes from May 2023 meeting are in BOLD** • Formulary agents have resulted in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis/Multidose), lifitegrast 5% (Xiidra), **cyclosporine 0.09% (Cequa)**
New Drugs MN Criteria	
• atorvastatin oral suspension (Atorvaliq) **Antilipidemics-1**	• No alternative formulary agent: Patient requires simvastatin, atorvastatin, or rosuvastatin and cannot swallow all formulary alternatives **Formulary alternatives:** rosuvastatin tablets and sprinkles, simvastatin tablets, atorvastatin tablets
• insulin glargine KwikPen (Rezvoglar) **Insulins: Basal**	• Patient has experienced significant adverse effects from formulary agents **Formulary alternatives:** insulin glargine (Lantus), insulin glargine U-300 (Toujeo)
• adalimumab-atto injection (Amjevita) **TIBs: Tumor Necrosis Factor Inhibitors**	• Patient has experienced significant adverse effects from all formulary agents **Formulary alternatives:** adalimumab (Humira), certolizumab (Cimzia), ustekinumab (Stelara)
• dabigatran oral pellets (Pradaxa) **Anticoagulants: Oral anticoagulants**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • All formulary agents resulted in therapeutic failure • Patient previously responded to all non-formulary agents and changing to a formulary agent would incur unacceptable risk **Formulary alternatives:** enoxaparin (Lovenox), rivaroxaban (Xarelto), dabigatran capsules (Pradaxa)

Appendix B—Table of Medical Necessity Criteria

Utilization Management Updated MN Criteria	
• olanzapine/samidorphan (Lybalvi) **Atypical Antipsychotic Agents**	**Updates from the May 2023 meeting are in bold and strikethrough** • Patient has experienced significant adverse effects from ~~**two**~~ **four** formulary agents **including one olanzapine containing product (olanzapine or olanzapine/fluoxetine) AND aripiprazole, ziprasidone, and lurasidone** **Formulary alternatives:** olanzapine/fluoxetine, olanzapine, aripiprazole, ziprasidone, and lurasidone
• liraglutide (Victoza) • exenatide once weekly (Bydureon BCise) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	**Updates from the May 2023 meeting are in bold and strikethrough** • Patient has experienced significant adverse effects from dulaglutide (Trulicity) and semaglutide (Ozempic) which is not expected with the non-preferred products. • ~~**No alternative formulary agent - for Victoza and Bydureon BCise only: patient is between the ages of 10 to less than 18 years**~~ Formulary and non-formulary alternatives: dulaglutide (Trulicity) semaglutide (Ozempic), and **tirzepatide (Mounjaro)**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	

• evolocumab (Repatha)
 	
PCSK9 Inhibitor
	Changes from May 2023 meeting are in BOLD and strikethrough
	
	PA applies to new patients
	
	Manual PA Criteria: evolocumab (Repatha) is approved if all criteria are met
	
	• ~~The initial prescription is written by a cardiologist, lipidologist, or endocrinologist.~~
	
	For HoFH and HeFH
	
	• For heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH), the patient is 10 years of age or older.
	
	• The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol.
	
	• The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.
	
	For ASCVD
	
	• The patient is at least 18 years of age for clinical atherosclerotic cardiovascular disease (ASCVD).
	
	• ~~The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >70 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below:~~
	
	• **The patient has established ASCVD with the following LDLs, despite maximally tolerated statin doses:**
	
	  • **Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high risk conditions. *Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information*) OR**
	
	  • **Not at very high risk of events: LDL > 70 mg/dL**
	
	  AND
	
	  • The patient must have tried **either** ~~both~~ atorvastatin 40-80 mg **or** ~~and~~ rosuvastatin 20-40 mg, OR
	
	  • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR
	
	  • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy ~~with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants)~~, AND
	
	  • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.
	
	• For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:
	
	  • Intolerance
	
	  ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND
	
	  ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. • Contraindication to statin ▪ The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) *For all FDA-approved indications* • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: • 140 mg every 2 weeks, or • 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. **PA does not expire** ~~PA expires in one year.~~ ~~• PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, and lipidologist. Continued use of Repatha will be approved for the following:~~ ~~• The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND~~ ~~The patient has documented adherence~~
• alirocumab (Praluent) **PCSK9 Inhibitor**	**Changes from May 2023 meeting are in BOLD and strikethrough** Manual PA criteria apply to all new users of alirocumab (Praluent). ~~All new users of alirocumab (Praluent) are required to try evolocumab (Repatha) first~~. <u>Manual PA criteria:</u> Praluent is approved if: *For HoFH and HeFH* ~~• The initial prescription is written by a cardiologist, lipidologist, or endocrinologist.~~ • For HeFH and HoFH, patient is at least 18 years of age and older. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. *For ASCVD* • The patient is at least 18 years of age for clinical ASCVD. ~~• The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below:~~ • **The patient has established atherosclerotic cardiovascular disease (ASCVD) with the following LDLs, despite maximally tolerated statin doses:** • **Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high risk conditions. *Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information*) OR**

	• **Not at very high risk of events: LDL > 70 mg/dL** **AND** • The patient must have tried **either** ~~both~~ atorvastatin 40-80 mg **or** ~~and~~ rosuvastatin 20-40 mg, OR • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy ~~with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants)~~, AND • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: • Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatin kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. • Contraindication to statin ▪ The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) *For all FDA-approved indications* • Praluent is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • **The patient has tried and failed therapy with evolocumab (Repatha) OR** • **The patient has experienced a significant adverse reaction to evolocumab (Repatha) that is not expected to occur with alirocumab (Praluent)** • Praluent is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: • 75 mg every 2 weeks, or • 150 mg every 2 weeks. **PA does not expire** ~~PA expires in one year.~~ ~~• PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, and lipidologist. Continued use of Repatha will be approved for the following:~~ ~~• The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND~~ ~~The patient has documented adherence~~

Appendix C—Table of Prior Authorization (PA) Criteria

• cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose) **Ophthalmic Dry Eye**	**Updates from the May 2023 meeting are in Bold and strikethrough** ~~**Patients younger than 18 years of age do not require a PA**~~ **Manual PA criteria apply to all new users of cyclosporine 0.05% ophthalmic emulsion unit-dose (Restasis unit-dose, generic)** ~~Automated PA: If there is no Restasis, Cequa, or Xiidra prescription in the past 120 days, a manual PA is required.~~ Manual PA criteria: Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • ~~The patient is 18 years of age or older~~ • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: ▪ Positive symptomology screening for moderate to severe dry eye disease from an appropriate measure ▪ At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systame, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. • Restasis unit-dose is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) **Other** Non-FDA-approved uses are not approved. ~~PA expires in one year.~~ **PA does not expire** ~~Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all criteria are met:~~ ~~• The drug is prescribed by an ophthalmologist or optometrist.~~ ~~• The patient must have documented improvement in ocular discomfort.~~ ~~The patient must have documented improvement in signs of dry eye disease.~~

Appendix C—Table of Prior Authorization (PA) Criteria

• cyclosporine 0.05% ophthalmic multi dose (Restasis Multidose) • cyclosporine 0.09% ophthalmic (Cequa) • lifitegrast 5% ophthalmic solution (Xiidra) **Ophthalmic Dry Eye**	**Updates from May 2023 are in BOLD and strikethrough** **Manual PA criteria apply to all new users of Restasis Multidose, Cequa and Xiidra** ~~PA criteria apply to all new and current users~~. ~~A new user is defined as a patient who has not filled a prescription for Cequa in the past 120 days.~~ • ~~If there is no Restasis, Cequa, or Xiidra prescription in the past 120 days, a manual PA is required.~~ Manual PA Criteria: Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • ~~For Cequa: the patient is 18 years of age or older~~ • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: ▪ Positive symptomatology screening for moderate to severe dry eye disease from an appropriate measure ▪ At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) ▪ **3-month trial of cyclosporine 0.05% unit dose** • Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. • **Cequa is approved if the patient has a diagnosis of Vernal Keratoconjunctivitis (VKC)** **Other** Non-FDA-approved uses are NOT approved. ~~PA expires in one year.~~ **PA does not expire** ~~Renewal Criteria: Coverage will be approved indefinitely if all criteria are met:~~ • ~~The drug is prescribed by an ophthalmologist or optometrist.~~ • ~~The patient must have documented improvement in ocular discomfort.~~ ~~The patient must have documented improvement in signs of dry eye disease~~
• cyclosporine 0.1% ophthalmic emulsion (Verkazia) **Ophthalmic Dry Eye**	**Updates from May 2023 are in BOLD and strikethrough** Note that an age edit and automated look back apply. • Patients who are younger than 21 years of age who have a history of Restasis **or Cequa** do not require a PA; Verkazia is approved • Patients who are younger than 21 years of age who do not have a history of Restasis **or Cequa** require manual PA • Manual PA is required in all new patients 21 years of age and older Automated PA criteria: The patient is younger than age 21 years AND has filled a prescription for cyclosporine 0.05% ophthalmic solution (Restasis) **or cyclosporine 0.09% (Cequa)** at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days.

Appendix C—Table of Prior Authorization (PA) Criteria

	Manual PA Criteria: If automated criteria are not met, coverage is approved for Verkazia if all criteria are met: • Verkazia is prescribed by or in consultation with an optometrist or ophthalmologist • Patient has a diagnosis of moderate to severe vernal keratoconjunctivitis (VKC) • Patient has tried and failed an adequate course of at least one mast cell stabilizer/antihistamine (i.e., olopatadine, azelastine, epinastine, lodoxamide, cromolyn) • Patient has tried and failed, or has a contraindication to an adequate course of cyclosporine 0.05% ophthalmic emulsion (Restasis) **or the patient has tried and failed, or has a contraindication to an adequate course of cyclosporine 0.09% (Cequa)** Non-FDA-approved uses are NOT approved including dry eye disease, graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC), and LASIK associated dry eye PA does not expire

• varenicline nasal solution (Tyrvaya)
 	
Ophthalmic Dry Eye
	Note – there were no changes to the current PA criteria
	
	Manual PA criteria apply to all new users of Tyrvaya.
	
	Manual PA criteria: Tyrvaya is approved if all criteria are met:
	• The patient is 18 years of age or older
	• Tyrvaya is prescribed by an ophthalmologist or optometrist
	• Patient has a diagnosis of dry eye disease as supported by both of the criteria below:
	  • Positive symptomology screening for dry eye disease from an appropriate measure
	  • At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
	• Patient must try and fail the following:
	  • At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube])
	  • Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol)
	• If the patient has moderate to severe dry eye dissease:
	  • Patient has tried and failed an adequate course (at least 6 weeks) of treatment of lifitegrast or cyclosporine treatment
	
	Non-FDA-approved uses are not approved.
	Prior Authorization expires after 1 year
	
	Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely if all criteria are met:
	• The drug is prescribed by an ophthalmologist or optometrist.
	• The patient must have documented improvement in ocular discomfort.
	• The patient must have documented improvement in signs of dry eye disease.

Appendix C—Table of Prior Authorization (PA) Criteria

Newly Approved Drug PAs	
• adagrasib (Krazati) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of adagrasib (Krazati) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a hematologist or oncologist The patient has a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test • The patient will be monitored for QTC prolongation, gastrointestinal adverse reactions, hepatotoxicity, and interstitial lung disease • If patient is a female, the patient will avoid breastfeeding during treatment and for at least 1 week after 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 Other non-FDA approved uses are NOT approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• adalimumab-atto injection (Amjevita)
 	
TIBS: Tumor Necrosis Factor Inhibitors
	Manual PA criteria apply to all new and current users of adalimumab-atto (Amjevita)
	
	Manual PA criteria: Coverage is approved if all criteria are met:
	• Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations
	• Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient
	  ○ Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Amjevita biosimilar.
	• If patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease
	  ○ If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older
	  ○ If indication is moderate to severe Crohn's disease patient must be 6 years of age or older AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease
	• If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa
	  ○ If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease
	  ○ If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months
	• Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira
	• Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed)
	• Patient is not receiving other targeted immunomodulatory biologics with Humira, 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)
	
	Non-FDA approved uses are NOT approved
	PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• atorvastatin oral suspension (Atorvaliq) **Antilipidemics-1**	Manual PA criteria apply to all new users of atorvastatin oral suspension (Atorvaliq) Age edit: PA does not apply to patients younger than 12 years of age (Age edit) PA criteria apply to all new users of Atorvaliq 12 years of age and older Manual PA criteria: Coverage is approved if all criteria are met: • Provider must explain why patient requires atorvastatin oral suspension and cannot take simvastatin, atorvastatin or rosuvastatin tablets or sprinkles ○ Acceptable responses include that the patient requires a high intensity statin and cannot swallow the statin tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience, and cannot take Ezallor sprinkles Non-FDA approved uses are NOT approved PA does not expire
• dabigatran oral pellet (Pradaxa) **Anticoagulant: Oral Anticoagulant**	Manual PA criteria apply to all new users of dabigatran oral pellets (Pradaxa) Age edit: PA does not apply to patients less than 8 years of age (age edit) AND who have tried Xarelto Suspension OR Lovenox Injection within the past 180 days Manual PA criteria: Coverage is approved if all criteria are met: • Patient is between the ages of 3 months to 12 years • The drug is prescribed by or in consultation with a pediatric hematologist/oncologist or pediatric cardiologist • Patient is being treated for venous thromboembolic events AND has been treated with parenteral anticoagulant for at least 5 days • Patient has tried and failed or has a contraindication to Xarelto Suspension AND Lovenox Injection • Patient is between the ages of 8 and 12 years and cannot take the Pradaxa capsule Non-FDA approved uses are NOT approved PA does not expire
• elacestrant (Orserdu) **Oncological Agents: Breast Cancer**	Manual PA criteria apply to all new users of elacestrant (Orserdu) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient is a male or a postmenopausal female • The medication is prescribed by or in consultation with a hematologist or oncologist • The patient has a diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer • Patient had disease progression following at least one line of endocrine therapy, which must include a CDK4/6 inhibitor • Patient does not have severe hepatic impairment (Child-Pugh C) • 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

Appendix C—Table of Prior Authorization (PA) Criteria

• insulin glargine KwikPen (Rezvoglar) **Basal Insulin**	Manual PA criteria apply to all new and current users of Rezvoglar Kwikpen Manual PA criteria: Coverage is approved if all criteria are met: • Patient must have tried and failed insulin glargine (Lantus) first. Non-FDA approved uses are NOT approved PA does not expire
• omeprazole and sodium bicarbonate 2 mg/mL oral suspension (Konvomep) **Proton Pump Inhibitors**	Manual PA criteria apply to all new users of omeprazole and sodium bicarbonate oral suspension (Konvomep) Age edit: PA does not apply to patients younger than 12 years of age (Age edit) PA criteria apply to all new users of Konvomep 12 years of age and older Manual PA criteria: Coverage is approved if all criteria are met: Manual PA criteria: Coverage is approved if all criteria are met: • The provider must provide patient-specific clinical rationale as to why the patient cannot take omeprazole capsules, pantoprazole tablets, or esomeprazole capsules • Acceptable response: Patient has a G-tube or patient cannot swallow other PPI capsules or tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience Non-FDA approved uses are NOT approved PA does not expire
• pegfilgrastim-fpgk injection (Stimufend) **White Blood Cell Stimulants: Pegfilgrastims**	Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta OnPro), pegfilgrastim-bmez (Ziextenzo) **and pegfilgrastim-fpgk (Stimufend)** Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) and pegfilgrastim-apgf (Nyvepria) are the preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist/oncologist • For Neulasta OnPro only: Patient requires use of an on-body injector (Neulasta OnPro) because the patient/caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration **OR** • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) or pegfilgrastim-apgf (Nyvepria) and is expected to respond to pegfilgrastim (Neulasta), pegfilgrastim-bmez (Ziextenzo), or **pegfilgrastim-fpgk (Stimufend)** Non-FDA approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• pirtobrutinib (Jaypirca) **Oncological Agents**	Manual PA criteria apply to all new users of pirtobrutinib (Jaypirca) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a hematologist or oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after 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, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• sparsentan (Filspari) **Nephrology Agents Miscellaneous**	Manual PA criteria apply to all new users of sparsentan (Filspari) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Filspari is only available through a Risk Evaluation and Mitigation Strategies (REMS) program due to the risk of hepatotoxicity and embryo-fetal toxicity, and will follow the monitoring requirements • Patient is 18 years of age or older • Filspari is prescribed by a nephrologist • The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli • Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/gram • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m^2 • Patient is not currently receiving dialysis or has not undergone kidney transplant • Patient has not received immunosuppressants, including corticosteroids, in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months • Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and is at high risk for disease progression • The patient is not receiving concomitant renin-angiotensin-aldosterone system inhibitors (for example ACE-inhibitors or ARBs such as irbesartan, telmisartan, losartan; or spironolactone), endothelin receptors antagonists (for example ambrisentan or bosentan) or aliskiren). • The patient's baseline liver aminotransferase (AST and ALT) levels are not elevated to greater than 3 times the upper limit of normal • If patient is a female of child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation • If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation Non-FDA approved uses are NOT approved, including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires in 9 months Renewal criteria: coverage will be approved indefinitely if all the following apply • Patient has had a response to Filspari defined by: o reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR o reduction in proteinuria from baseline • Patient's eGFR rate ≥ 30 mL/min/1.73 m2 • Filspari is not being used in combination with any RAAS blocker (e.g., ACE-Is, ARB), endothelin receptor antagonists, or aliskiren

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• tezepelumab-ekko autoinjector (Tezspire) **Atopy**	Manual PA is required for all new users of tezepelumab (Tezspire) <u>Manual PA Criteria</u>: Tezspire coverage will be approved if all criteria are met: • The patient is 12 years of age and older • The patient has a diagnosis of severe persistent asthma • The drug is prescribed by an allergist, immunologist, or pulmonologist • Provider acknowledges the FDA warnings and precautions associated with Tezspire • The patient's asthma must be uncontrolled, despite adherence to optimized medication therapy regimen, defined as requiring ONE of the following: o Hospitalization for asthma in past year OR o Two courses of corticosteroids for asthma exacerbation in past year OR o Daily high-dose inhaled corticosteroids with inability to taper off the inhaled corticosteroids • The patient has tried and failed an adequate course (3 months) of TWO of the following while using a high-dose inhaled corticosteroid: o Long-acting beta agonist (LABA e.g., Serevent, Striverdi), OR o Long-acting muscarinic antagonist (LAMA e.g., Spiriva, Incruse), OR o Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) Non-FDA-approved uses are not approved Prior authorization expires after 12 months <u>Renewal Criteria</u>: Note initial Tricare PA approval is required for renewal. Renewal PA criteria will be approved indefinitely if all the following apply • The patient has had a positive response to therapy, as defined by one of the following: o a decrease in asthma exacerbations o improvements in forced expiratory volume in one second (FEV1) o decrease in oral corticosteroid use
• trofinetide oral solution (Daybue) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of trofinetide (Daybue) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 2 years of age and older • The medication is prescribed by a geneticist, neurologist, or a developmental pediatrician • The patient has a diagnosis of Rett Syndrome with documented MECP2 gene mutation. Non-FDA approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management New PAs	
• levothyroxine sodium capsule (Tirosint) **Thyroid Agents**	Manual PA criteria apply to all new users of levothyroxine capsules (Tirosint) Manual PA criteria: Tirosint is approved if all criteria are met: • Tirosint is prescribed by or in consultation with an endocrinologist • Patient is 6 years of age or older • Patient must have tried and failed or have a contraindication to levothyroxine tablets that is not expected to occur with levothyroxine capsules Non-FDA approved uses are NOT approved PA does not expire
• sacrosidase oral solution (Sucraid) **Gastrointestinal-2 Agents**	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 a diagnosis of congenital sucrase-isomaltase deficiency (CSID) • Prior to starting therapy with Sucraid, patient had symptomatic CSID (e.g., diarrhea, bloating, abdominal cramping) Non-FDA approved uses are NOT approved PA does not expire
Utilization Management Updated PAs	
• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the May 2023 meeting are in bold.** **Automated PA Criteria: If the provider is a Rheumatologist (Internal Medicine or Pediatric). PA is approved.** Manual PA Criteria: **If automated criteria are not met for Rheumatologist prescribing,** Humira is approved if all criteria are met: Coverage is approved for 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) 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 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) • Non-infectious intermediate, posterior, and panuveitis Below criteria applies to AS indication 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), 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]) Below criteria applies to all patients (regardless of age): • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) Coverage for 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. 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).

Appendix C—Table of Prior Authorization (PA) Criteria

• abrocitinib (Cibinqo) **Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of abrocitinib (Cibinqo). Manual PA criteria: abrocitinib (Cibinqo) is approved if all criteria are met: • Patient is **12 ~~18~~** years of age or older • Medication is prescribed by an allergist, dermatologist, or immunologist • Drug is used to treat moderate to severe atopic dermatitis • Provider acknowledges that the requested medication is to be used for disease that is not adequately controlled with other systemic drug products including biologic, or when use of those therapies is inadvisable. • Patient failed, has a contraindication, or intolerability to one medication in each of the following four categories: 1. Topical Corticosteroids: ▪ **For patients 18 years of age or older:** high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream). ▪ **For patients 12 to 17 years of age: any topical corticosteroid.** 2. Topical calcineurin inhibitor (e.g.,pimecrolimus, tacrolimus). 3. Injectable interleukin antagonist: dupilumab (Dupixent). 4. Oral JAK: upadacitinib (Rinvoq). • Provider is aware of the boxed FDA warnings. • Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy. • Patient has had a negative TB test in the last 12 months (or is adequately managed). • Patient has no history of venous thromboembolism (VTE). • Patient does not have neutropenia (ANC < 1000). • Patient does not have lymphocytopenia (ALC < 500). • Patient does not have anemia (Hgb < 8 mg/dL). • Patient is not taking a concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulatory agents. Non-FDA-approved uses are not approved. PA expires in 1 year. Renewal PA criteria will be approved indefinitely. Renewal criteria: (initial TRICARE PA approval is required for renewal) The patient's disease severity has improved and stabilized to warrant continued therapy.

Appendix C—Table of Prior Authorization (PA) Criteria

• abemaciclib (Verzenio)
 	
Breast Cancer Agents: CDK Inhibitors
	Updates from the May 2023 meeting are in bold and strikethrough.
	
	Manual PA criteria apply to all new users of Verzenio.
	
	Manual PA Criteria: Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack is approved if all of the following criteria are met:
	
	• Drug is prescribed by or in consultation with an oncologist
	• The patient is not currently taking another cyclin-dependent kinase inhibitor
	• For Verzenio only: The patient has hormone receptor HR(+)/HER2(-), node(+) early breast cancer at high risk of recurrence **~~and a Ki67 score ≥ 20%~~** as determined by an FDA approved test.
	• The patient has advanced or metastatic hormone receptor (HR(+))/HER2(-) breast cancer
	• If the patient is female, the patient meets one of the following criteria:
	  • Ibrance, Verzenio, Kisqali, or Kisqali Femara Co-Pack will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR
	  • Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR
	  • For Verzenio only: Will be used as monotherapy following metastatic progression on chemotherapy
	• If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.
	• Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease
	• For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism
	• For Verzenio only: provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity
	• For Kisqali and Kisqali Femara Co-Pack only: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity
	• Female patients of childbearing age are not pregnant confirmed by (-) HCG
	• Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment
	• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only
	• Male patients have been informed of the risk of infertility
	• For Kisqali Femara Co-Pack only, female patients have been informed of the risk of infertility from letrozole
	• The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis:_____.
	
	Non-FDA approved uses are not approved, except as noted above
	
	Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• Freestyle Libre 2 and 3 **CGM: Therapeutic ontinuous Glucose Monitoring Systems**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Abbott FreeStyle Libre 3 Manual PA criteria: Coverage is approved if all criteria are met: • *Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria* • Patient has a diagnosis of ~~**type 1 or type 2**~~ diabetes • Patient is using basal and prandial insulin injections; OR patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR patient is ~~**a Type 2 diabetes mellitus**~~ on insulin therapy with a history of severe hypoglycemia episodes requiring medical intervention (grade 2 or higher) • Device is prescribed by an endocrinologist or diabetes management expert ▪ Diabetes management expert is defined as: licensed independent practitioner experienced in the management of insulin dependent diabetics requiring basal and bolus dosing or a pump and familiar with the operation and reports necessary for proper management of continuous glucose monitoring systems. This is a self-certification. • Documentation is required of all the following: ▪ Diagnosis ▪ Medication history ▪ Completion of a comprehensive diabetes education program ▪ Patient agrees to wear CGM as directed ▪ Patient agrees to share device readings with managing healthcare professional for overall diabetes management • Patient meets the age requirement (≥ 2 years if Dexcom G6, ≥ 4 years if FreeStyle Libre 2, 3) • Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips with the goal of minimizing/discontinuing use Initial PA Expiration: annual Renewal expiration: annual Annual renewal criteria: • Confirm patient has seen endocrinologist or diabetes specialist within past year • Patient has utilized CGM daily • Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) at every visit with the goal of minimizing/discontinuing use • Patients with T2DM continue to require basal and prandial insulin injections daily • Patient continues to share data with managing healthcare professional for the purposes of clinical decision making

Appendix C—Table of Prior Authorization (PA) Criteria

• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Odactra. Manual PA criteria: Coverage will be approved if all criteria are met: • Odactra is prescribed by an allergist/immunologist AND • The patient is between the ages of ~~18~~ **12** and 65 years AND • The patient has a diagnosis of house dust mite (HDM) allergic rhinitis confirmed with either a positive skin test or an in vitro test for pollen-specific for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites AND • The patient's symptoms of allergic rhinitis have not been controlled with a nasal corticosteroid (e.g., fluticasone) AND at least one of the following: oral antihistamine, nasal antihistamines, or a leukotriene receptor antagonist (montelukast) OR • The patient has a diagnosis of HDM-related allergic rhinitis and allergic asthma that has not responded to an adequate trial of inhaled steroids, and the patient's FEV1 >70% AND • The patient has received the first dose in the office setting and was observed for 30 minutes with no allergic reactions noted AND • The patient has a prescription for self-administered SC epinephrine AND • The patient does not have a history of severe local allergic reaction to sublingual immunotherapy AND • Patient is not receiving co-administered SC immunotherapy AND • Patient does not have severe, uncontrolled, unstable asthma Other off-label uses other than allergic asthma are not approved. PA expires in 6 months. Renewal Criteria: Coverage will be continued indefinitely if the patient has responded positively to treatment and is not receiving co-administered SC immunotherapy and does not have sever, uncontrolled unstable asthma.
• lanadelumab (Takhzyro) **Corticosteroid-Immune Modulators for Hereditary Angioedema Prophylaxis (HAE)**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Orladeyo, Takhzyro, Cinryze, and Haegarda. Manual PA criteria: Orladeyo, Takhzyro, Cinryze, or Haegarda is approved if all apply: • Patient Age ▪ For Orladeyo, the patient is 12 years of age or older ▪ For Takhzyro, the patient is ~~12~~ **2** years of age or older ▪ For Cinryze, the patient is 13 years of age or older • The patient has a diagnosis of hereditary angioedema (HAE) • Orladeyo, Takhzyro, Cinryze or Haegarda is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist • The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., ≥2 HAE attacks/month, laryngeal attacks, etc.) • The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly) Non-FDA-approved uses NOT approved. Prior Authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• liraglutide (Victoza) • exenatide (Bydureon BCISE) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	**Changes from the May 2023 meeting are in bold and strikethrough.** All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first. New users of Bydureon BCise, Byetta, Victoza, or Adlyxin, must try Trulicity and Ozempic first. Manual PA criteria—Bydureon BCise, Byetta, Victoza, or Adlyxin is approved (i.e., a trial of metformin is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus. • The patient has experienced any of the following issues on metformin: ▪ impaired renal function precluding treatment with metformin ▪ history of lactic acidosis • The patient has had inadequate response to metformin • The patient has a contraindication to metformin AND In addition to the above criteria regarding metformin the following PA criteria would apply specifically to new users of Bydureon BCise, Byetta, Victoza, and Adlyxin: • The patient has had an inadequate response to Trulicity and Bydureon BCise Ozempic • ~~**For Victoza and Bydureon BCise, patient is age 10 years to < 18 years.**~~ Non-FDA-approved uses are not approved. Prior Authorization does not expire
• olanzapine/samidorphan (Lybalvi) **Antipsychotic Agents: Atypical**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Lybalvi. Manual PA criteria: Lybalvi is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a documented diagnosis of schizophrenia or bipolar 1 disorder • **Patient has tried either olanzapine alone or olanzapine/fluoxetine combination (Symbyax generic) and experienced significant weight gain or other metabolic complications (i.e., worsening diabetes, new sleep apnea, development of NASH or obesity hypoventilation syndrome)** • **Patient has tried and failed either aripiprazole or ziprasidone** • ~~**Patient has tried and had an adverse event to at least 2 antipsychotic agents**~~ • ~~**Provider must indicate the drug, date of initiation, duration of therapy, and whether the patient had an adverse reaction or failure to therapy of other therapies tried**~~ ▪ ~~**Drug: Date_____ Duration of therapy _____Adverse Reaction _____ Therapeutic Failure _____**~~ ▪ ~~**Drug: Date_____ Duration of therapy _____Adverse Reaction _____ Therapeutic Failure _____**~~ Non-FDA-approved uses are not approved including major depressive disorder, fibromyalgia, or other mood disorders. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• sotorasib (Lumakras) **Oncological Agents: Lung Cancer**	**Updates from the May 2023 meeting are in bold.** 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.
• tucatinib (Tukysa) **Oncological Agents**	**Updates from the May 2023 meeting are in bold.** Manual PA is required for all new users of Tukysa. Manual PA Criteria: Tukysa is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by or consultation with a hematologist or oncologist • The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting AND Tucatinib will be used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda) **OR** • **The patient has a confirmed diagnosis of RAS wild-type, HER2-positive, unresectable, or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy AND tucatinib will be used in combination with trastuzumab** • Provider agrees to monitor for hepatotoxicity • Patient has been counseled on risk of diarrhea • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. Non-FDA approved uses are not approved except as noted above. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• zanubrutinib (Brukinsa) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors**	**Updates from the May 2023 meeting are in bold.** Manual PA apply to all new users of Brukinsa. Manual PA Criteria: Brukinsa is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) OR • Patient has Waldenström's macroglobulinemia (WM), a rare non-Hodgkin lymphoma OR • Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen OR • **Patient has chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)** • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception 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.

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• alirocumab (Praluent) **PCSK9 Inhibitors**	▪ Retail: 2 syringes/30 days ▪ MTF and Mail Order: 6 syringes/90 days
• evolocumab (Repatha) **PCSK9 Inhibitors**	▪ Retail: 2 x 140 mg syringes/30 days (prefilled syringe or autoinjector) ▪ MTF and Mail Order: 6 x 140 mg syringes/90 days (prefilled syringe or autoinjector) ▪ Repatha Pushtronex o Retail: 1 infusor device o MTF and Mail Order: 3 infusor devices
• adagrasib (Krazati) **Oncological Agents: Lung Cancer**	▪ Retail/MTF/Mail: 60-day supply
• elacestrant (Orserdu) **Oncological Agents**	▪ Retail/MTF/Mail: 60-day supply
• pirtobrutinib (Jaypirca) **Oncological Agents**	▪ Retail/MTF/Mail: 60-day supply
• adalimumab-atto (Amjevita) **Oncological Agents**	▪ Retail/MTF/Mail: 60-day supply
• antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl (Altuviiio) **Antihemophilic Factors**	▪ Retail/MTF/Mail: 30-day supply
• trofinetide (Daybue) **Neurological Agents, Miscellaneous.**	▪ Retail/MTF/Mail: 30-day supply
• tezepelumab-ekko (Tezspire) **Atopy**	▪ Retail: 1 device ▪ MTF/Mail: 2 devices
• OTC naloxone 4mg/0.1 mL nasal spray	▪ Retail/MTF/Mail: 2 cartons per fill; note each carton contains 2 devices

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

Generic (Trade) Name UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
adagrasib (Krazati) **Oncological Agents: Lung Cancer**	• sotorasib (Lumakras)	Formulation: • 200 mg film-coated tablets Dosing: • 600 mg PO BID until disease progression or unacceptable toxicity • Dose reduction/ interruption for adverse events	• For adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by FDA approved test, who have received at least one prior systemic therapy	ADRs (≥25%) • nausea, diarrhea, vomiting • fatigue • musculoskeletal pain • hepatotoxicity • renal impairment • edema • dyspnea • ↓ appetite (≥2%) Grade 3/4 lab abnormalities: • ↓lymphocytes • ↓hemoglobin • ↑AST/ALT • ↑alkaline phosphatase • ↓ K; ↓ NA • ↑lipase • ↓leukocytes • ↓neutrophils	• Second oral inhibitor of KRAS G12C (Lumakras was first) • Phase 2 study demonstrated an overall response rate (ORR) of 42.9% • Approved under accelerated approval based objective response rate and duration of response; continued approval may be contingent upon confirmatory trials • High incidence of GI side effects; can cause QTc prolongation, hepatotoxicity or worsening of interstitial lung disease • No direct comparisons to Lumakras which was also approved via accelerated approval with a single-arm phase 2 study • NCCN guidelines make the same recommendation for Krazati and Lumakras as subsequent therapy options after at least one prior systemic treatment • Patients who progressed on one of the agents should not attempt to switch to the other • Provides no compelling clinical advantage over existing agents	• UF • Do not add to EMMI List

adalimumab-atto injection (Amjevita) **TIBS**	• adalimumab (Humira)	Formulations: • 40 mg/0.8 mL single-use prefilled autoinjector, and prefilled syringe 20 mg/0.4 mL single-use prefilled glass syringe; citrate free • Dosing: Varies based on indication	• Rheumatoid Arthritis • Juvenile Idiopathic Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Adult Crohn's Disease • Ulcerative Colitis • Plaque Psoriasis • Hidradenitis Suppurativa	ADRs (> 10%): • infections (e.g., upper respiratory, sinusitis) • injection site reactions • headache • rash	• First Humira biosimilar to launch out of eight FDA approved Humira biosimilar products • Label does not have all the FDA-indications found in the Humira label • Two phase 3 studies demonstrated similar clinical efficacy, safety, and immunogenicity to the reference product • One of the phase 3 studies demonstrated similar clinical efficacy, safety, and immunogenicity after a single transition from reference product to Amjevita • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • Add to EMMI List
Antihemophilic factor recombinant, (Altuviiio) **Antihemophilic Factors**	• emicizumab-KXWH (Hemlibra) • Anti-hemophilic Factor - Recombinant, Fc Fusion Protein (Eloctate)	Formulation: • In kits with single-dose vials containing 250, 500, 750, 1000, 2000, 3000, or 4000 IU of Factor VIII potency, Dosing: • <u>Routine prophylaxis</u>: 50 IU/kg IV injection every week • <u>Treatment/ Control</u>: 30 or 50 IU/kg IV PRN bleeding every 2 to 3 days • <u>Perioperative dose</u>: 50 IU/kg once then 30-50 IU/kg IV PRN q2-3 days	• Indicated for use in adults and children with hemophilia A for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment & control of bleeding episodes • Perioperative management of bleeding	ADRs (>10%) • headache • arthralgia	• New once weekly antihemophilic factor VIII injection indicated for hemophilia A • Provides near-normal factor activity (>40%) for most of the week • Altuviiio was evaluated in two studies: XTEND-1 and XTEND-Kids – Results were significant for week-long efficacy (no comparators) – XTEND-Kids has not been published yet – While not reported, FVIII antibody development may still occur with use • May provide some clinical benefit relative to existing formulary agents • Altuviiio offers an additional option for the treatment of hemophilia A, although alternative formulary agents are available and there is no comparative efficacy data	• UF • Do not add to EMMI List

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

atorvastatin oral suspension (Atorvaliq) **LIP-1s**	• atorvastatin tabs • simvastatin suspension (FloLipid) • rosuvastatin sprinkles (Ezallor)	Formulation: • 150 mL bottles of 20 mg/5 mL • Orange flavoring Dosing: • Adults: 10 to 80 mg QD. • Pediatrics HeF): 10 to 20 mg QD. • Pediatrics with HoFH: 10 to 80 mg QD.	• same as Lipitor • ↓ risk of MI, stroke, RV procedures, angina with multiple risk factors for CHD • ↓LDL in adults with primary hyperlipidemia and • ≥ 10 y.o. with HeFH • ≥ 10 y.o. with HoFH • primary dys-betalipoproteinemia or ↑TG	Incidence ≥ 5%): • nasopharyngitis • arthralgia • diarrhea • pain in extremity • UTI • Same warnings as Lipitor re: hepatotoxicity and rhabdomyolysis	• 3rd statin approved in an alternate dosage form (simvastatin oral susp – FloLipid; rosuvastatin sprinkles – Ezallor) • Approved via 505b2 pathway using data from Lipitor; no clinical trials; only pharmacokinetic data available • FDA review mentioned some issues with the bioavailability data and significant deficiencies were identified in the manufacturing process and facility inspection • Other than a convenience formulation, provides no compelling clinical advantages over other statins	• NF • Add to EMMI List
dabigatran oral pellets (Pradaxa) **Anticoagulants**	• dalteparin inj. (Fragmin) • enoxaparin inj. • rivaroxaban oral suspension (Xarelto)	Formulation: • 20, 30, 40, 50, 110 and 150 mg packets Dosing: Varies based on weight	• patients from 3 months to < 12 years of age for VTE treatment • to reduce the risk of recurrent VTE	Incidence >15% • GI adverse events • bleeding	• Alternative Pradaxa formulation for pediatrics. • Not substitutable on a milligram-to-milligram basis with other dabigatran dosage forms • Phase 2/3 study demonstrated that Pradaxa pellets were non-inferior to standard of care • Phase 3 safety study demonstrated 99% overall probability of freedom from recurrence of VTE • Provides an oral option for patients 3 months to < 12 years old	• NF • Add to EMMI List
elacestrant (Orserdu) **Oncological Agents: Breast Cancer**	• fulvestrant • anastrozole • letrozole • exemestane	Formulation: • 86 mg oral tab • 345mg oral tab Dosing: • 345mg QD	• ER+/HER2- ESR1 mutated advanced or metastatic breast cancer after at least one line of endocrine therapy	• nausea • vomiting • increased AST • fatigue • decreased appetite • arthralgia • diarrhea • back pain	• First oral selective estrogen receptor degrader (SERD) for treatment of ER+/HER2- ESR1 mutation advanced or metastatic breast cancer • Phase 3 study demonstrated increased mean progression-free survival (PFS) compared with standard of care in patients with ESR1 mutation • Provides alternative and oral option after disease progression on established therapies	• UF • Do not add to EMMI List

insulin glargine injection (Rezvoglar Kwikpen) Insulins: Basal	• Lantus Solostar • Basaglar Kwikpen • Semglee Pen	Formulation: • 3ml single-patient-use prefilled pen Dosing: • Individualize dose	• T1DM and T2DM	Same as Lantus	• Second biosimilar of insulin glargine (Lantus) that is interchangeable with Lantus and unbranded Lantus • No new clinical studies; approved via 351(k) • Provides no compelling clinical advantage over existing agents	• NF NSP • Add to EMMI List
omeprazole and sodium bicarbonate oral suspension (Konvomep) **Proton Pump Inhibitors**	• Zegerid Cap/Susp • Protonix Susp	Formulation: • Suspension: 2mg/ml Dosing: • 40 mg QD	• Active benign ulcer • Decrease GI bleed risk	Same as Zegerid	• Another formulation of omeprazole and sodium bicarbonate oral suspension for the treatment of active benign gastric ulcer and for the reduction of risk of upper GI bleeding in critically ill patients • No new clinical studies; approved via 505(b)(2) • Zegerid packets for oral suspension is available OTC and in generics – Rx formulation is designated NF • Provides no compelling clinical advantage over existing agents	• UF • Do not add to EMMI List
pegfilgrastim-fpgk injection (Stimufend) **White Blood Cell Stimulants: Peg-filgrastims**	• pegfilgrastim (Neulasta) • pegfilgrastim-jmdb (Fulphila) • pegfilgrastim-cbqv (Udenyca) • pegfilgrastim-bmez (Ziextenzo) • pegfilgrastim-apgf (Nyvepria) • pegfilgrastim-pbbk (Fylnetra)	• Formulation: 6 mg/0.6 mL solution in a single-dose prefilled syringe. 27-gauge, ½-inch needle (needle cap is made with natural rubber latex) • Dosing: 6 mg SC once per chemotherapy cycle. Weight based dosing for pediatrics.	• Decrease incidence of infection, as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelo-suppressive anti-cancer drugs	ADRs (≥ 5% difference in incidence compared to placebo) • Bone pain • Pain in extremity	• Stimufend is the 6th biosimilar to Neulasta and 13th agent in the white blood cell stimulant class • No new clinical data • Stimufend provides little to no compelling clinical advantage over existing pegfilgrastim agents	• UF NSP • Do not add to EMMI List

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

pirtobrutinib tablet (Jaypirca) **Oncological Agents**	• acalabrutinib (Calquence) • zanubrutinib (Brukinsa) • ibrutinib (Imbruvica)	Formulation: • 50 mg, 100 mg tablet Dosing: • 200 mg PO QD	• Treatment of adults with relapsed or refractory mantle cell lymphoma after >2 lines of systemic therapy, including a Bruton Tyrosine Kinase inhibitor	ADR (≥15%) • fatigue • musculoskeletal pain • diarrhea • edema • dyspnea • pneumonia • bruising	• Non-covalent BTK inhibitor approved for the treatment of adults with relapsed or refractory mantle cell lymphoma • NCCN guidelines recommends the use of Jaypirca after 2nd line therapy with a covalent BTKi • Received FDA accelerated approval based on an overall response rate and a favorable benefit/risk profile • No direct comparisons to Brukinsa, Calquence or Imbruvica • Provides an alternative treatment option for this generally incurable disease state	• UF • Do not add to EMMI List
sparsentan tablet (Filspari) **Nephrology Agents Miscellaneous**	• budesonide delayed-release caps (Tarpeyo) • ARBs (irbesartan) • prednisone • methylprednisolone	Formulation: • 200mg and 400mg tablet Dosing: • 200 mg daily for 2 weeks, then 400 mg daily thereafter	• To reduce proteinuria in adults with primary immune-globulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g	• Same teratogenicity concerns as with other endothelin receptor agonists used for PAH (ambrisentan, etc.) • increased LFTs • hepatotoxicity • hypotension • acute kidney injury • fluid retention	• 2nd drug formally approved for IgA (after Tarpeyo) • New mechanism of action - dual-acting angiotensin II and endothelin type A receptor antagonist; (not a steroid like Tarpeyo, prednisone; not an immunosuppressant) • Unpublished Phase 3 PROTECT study in 400 pts vs. irbesartan 300 mg showed ↓ proteinuria (UPCR) from baseline at 36 weeks: 49.8% sparsentan vs. 15.1% irbesartan; p <0.001 • REMS program for teratogenicity and hepatotoxicity concerns • Approved using a surrogate endpoint; confirmatory studies are underway using eGFR • Indirect comparison vs Tarpeyo showed greater reduction in proteinuria with sparsentan • Initial results remain to be confirmed	• UF • Do not add to EMMI List
tezepelumab-ekko injection (Tezspire) **Atopy**	• mepolizumab (Nucala) • benralizumab (Fasenra) • dupilumab (Dupixent) • reslizumab (Cinqair)	Formulation: • 210 mg/1.91 mL in a single-dose prefilled pen Dosing: • 210 mg subcutaneously once every 4 weeks	• Add-on maintenance treatment of severe asthma, aged 12 years and older	(≥3%) • pharyngitis • arthralgia • back pain	• Adjunct treatment with a new mechanism of action for severe asthma • Clinical trials showed statistically significant relative reduction in asthma exacerbation vs. placebo • Adverse events are generally mild and include pharyngitis, arthralgia, back pain • Provides another treatment option in the management of severe asthma	• UF • Add to EMMI list

trofinetide oral solution (Daybue) **Neurological Agents, Miscellaneous**	• none	Formulation: • Solution, 450 mL (200 mg/mL) in a multi-dose, child-resistant bottle Dosing: • Orally or g-tube BID with or without food; weight based	• Treatment of Rett syndrome in patients 2 years of age and older	(≥10%) • Diarrhea • Vomiting	• Specialty orphan drug approved for the treatment of Rett Syndrome • Single phase 3 study demonstrated statistically significant improvement vs. placebo on Rett Behavior Questionnaire and Clinical Global Impression-Improvement Scale • GI adverse events are most common, diarrhea and vomiting • Daybue provides a pharmacologic treatment option outside of supportive care for this rare condition	• UF • Do not add to EMMI list

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

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
May 2023	**Drug Class Reviews** **Dry Eye Disease** **Designated UF:** *Remain on EMMPI program* • cyclosporine 0.05% (Restasis) – brand only **Designated NF:** *No reason to exempt from NF-2-Mail requirement (remain on list):* • varenicline nasal solution (Tryvaya) • cyclosporine 0.1% ophthalmic solution (Verkazia) **PCSK9 inhibitors** **Designated UF** *Remain on EMMPI program* • evolocumab (Repatha) • alirocumab (Praluent) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF** *Add to EMMPI program (implementation date is the first Wednesday 2 weeks after signing of the minutes)* • atorvastatin oral suspension (Atorvaliq) • dabigatran oral pellet (Pradaxa) *Add to EMMPI program (implementation date contingent on cost effectiveness and operational considerations)* • tezepelumab-ekko (Tezspire) *Note that after the meeting it was discovered that Tezspire could not operationally be added to the EMMPI program.* **Designated NF** *No reason to exempt from NF-2-Mail requirement (implementation date is the first Wednesday 2 weeks after signing of the minutes)* • insulin glargine (Rezvoglar) • adalimumab-atto (Amjevita)	**Drug Class Reviews** **Dry Eye Disease** **Designated UF** *Remove from EMMPI program (implementation date is the first Wednesday 2 weeks after signing of the minutes)* • cyclosporine 0.09% ophthalmic solution (Cequa) • lifitegrast 5% ophthalmic solution (Xiidra) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF:** *Limited duration of use* • pegfilgrastim-fpgk (Stimufend) *Not yet clear if feasible to provide through Mail* • adagrasib (Krazati) • elacestrant (Orserdu) • pirtobrutinib (Jaypirca) • sparsentan (Filspari) • trofinetide (Daybue) *Comparable pricing across points of service* • omeprazole/sodium bicarbonate oral suspension (Konvomep) *Consistent with others in the class* • antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl (Altuviiio)

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the November 2021 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
	Products in Classes Designated by the P&T Committee as Generally Suitable for Inclusion *(implementation date contingent on cost effectiveness and operational considerations)* **Designated UF** • degarelix acetate (Firmagon) - Luteinizing Hormone-Releasing Hormone Agonists-Antagonists for Prostate Cancer • ozanimod HCl (Zeposia) - MS • siponimod (Mayzent) - MS • apalutamide (Erleada – Oncological Agents: 2nd-Generation Antiandrogens • darolutamide (Nubeqa) – Oncological Agents: 2nd-Generation Antiandrogens • enzalutamide (Xtandi) – Oncological Agents: 2nd-Generation Antiandrogens • binimetinib (Mektovi) – Oncological Agents: Melanoma • cobimetinib (Cotellic) – Oncological Agents: Melanoma • encorafenib (Braftovi) – Oncological Agents: Melanoma • vemurafenib (Zelboraf) – Oncological Agents: Melanoma • TIBs – The Committee agreed that the TIBS are generally suitable for inclusion on the EMMPI program **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar agents already on list:* • tralokinumab-ldrm (Adbry) – Atopy • TIBs – The Committee agreed that the TIBS are generally suitable for inclusion on the EMMPI program	

* 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 the national mail order pharmacy.

Implementation Dates for UF Recommendations/Decisions*

Upon signing: July 26, 2023

Two weeks after signing: August 9, 2023

30 days after Signing: August 30, 2023

60 days after signing: September 27, 2023

90 days after signing: October 25, 2023

120 days after signing: November 22, 2023

*** 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 (Tier 4) and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4 (complete exclusion) Products	Formulary Alternatives	Implementation
May 2023	Ophthalmic Dry Eye Agents	• loteprednol etabonate 0.25% ophthalmic suspension (Eysuvis)	• cyclosporine 0.05% ophthalmic emulsion unit-dose (generic Restasis) • cyclosporine 0.05% ophthalmic emulsion multi-dose (Restasis Multidose) • cyclosporine 0.09% ophthalmic solution (Cequa) • lifitegrast 5% ophthalmic solution (Xiidra) • loteprednol 0.2% ophthalmic suspension (Alrex, generic) • loteprednol 0.5% ophthalmic suspension (Lotemax, generic)	• 120 days

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

Drugs recommended for Tier 4 (complete exclusion) will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4(complete exclusion) agents at the Retail points of service.

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

DoD P&T Committee Updates to Approval Authorities

Note that updates are in **bold** font.

Table 1. Processes and Recommendation/Approval Authorities For May 2023 DoD P&T Committee Meeting

Process	Function
Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; **P&T Committee Chair and others as needed**	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non step preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to prior authorization forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ **Implementing temporary prior authorization (PA) requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting).**

	▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as "innovator" drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be "grandfathered" when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative. ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing "brand over generic" authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. The branded product will adjudicate at the Tier 1 co-pay at the Retail Pharmacy Network and Mail Order Pharmacy. The "brand over generic" authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating "line extension" products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug, and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties

	of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA "health.mil" website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying manual PA criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QLs implemented in these situations will removed when the situation has resolved. ▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA approved devices or supplies and determination as to whether a new FDA approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination made to consider for coverage, timeline for review by DoD P&T Committee. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit.

Appendix I—Table of Administrative Authorities

	▪ Designating "line extension" devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments	▪ Classification of a medication as non-formulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication as Tier 4 (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and implementation plan (including effective date). ▪ Establishment of prior authorization requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing prior authorization (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of prior authorization requirements for a drug. ▪ Clarification of a medication as non-formulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as non-formulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as non-formulary (Tier 3 co-pay). ▪ The Director may approve devices or supplies as recommended by the P&T Committee and the BAP; however approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. ▪ Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with prior authorization criteria and implementation plans as recommended by the DoD P&T Committee and BAP.
Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)	▪ Establishment of quantity limits for a medication, **device or supply** or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for non-formulary drugs, devices or supplies. ▪ Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes, devices or supplies on the Expanded MFT/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program.

Appendix I—Table of Administrative Authorities

	▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.

Appendix J—Prescribing Weight Loss Medications to Active-Duty Service Members memo

DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

Healthcare Administration

MEMORANDUM FOR: ALL DEFENSE HEALTH AGENCY (DHA) MARKETS AND MILITARY MEDICAL TREATMENT FACILITIES

Subject: Prescribing Weight Loss Medications to Active-Duty Service Members

This memorandum is meant to clarify a recent action made by the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee members at the February 2023 DoD P&T Committee meeting. While a Prior Authorization (PA) continues to be required when prescribing weight loss medications, during the February 2023 meeting P&T Committee members made a recommendation, which DHA leadership approved, to remove two questions from the required PA process when military Medical Treatment Facility (MTF) providers prescribe weight loss medications. The following questions will be removed from the PA form in early August 2023:

- Is the patient an Active-Duty Service Member?
- Does the individual continue to be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy AND will remain engaged throughout the course of therapy?

For clarification, providers must continue to follow Military Department-specific policies that set the requirements for participation in weight loss programs for Active-Duty Service Members.

The PA form still requires answers to the following questions:

- Patient has a Body Mass Index (BMI) ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) OR patient is a pediatric patient 12 years of age or older with BMI ≥ 95th percentile standardized for age and sex, AND
- 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.

While there may be a need for the Military Departments to update their policies to incorporate recent additions to, or modifications of, weight loss medications available on the uniform formulary, **the Military Departments (not DHA) will continue to determine and direct the appropriate use of these medications in their health/weight loss and fitness programs for Active-Duty Service Members.**

My point of contact for this memorandum is Dr. Paul R. Cordts at //email or 703-681-8003. Please ensure widest dissemination in your Markets and MTFs.

//sign
Brian C. Lein, MD
Assistant Director
Health Care Administration