DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2021

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on February 3 and 4, 2021. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2020 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2020 DoD P&T Committee meeting on January 27, 2021.

    a) **Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)-risdiplam (Evrysdi) PA criteria:** The Deputy Director requested the DoD P&T Committee review the age limit restrictions on the risdiplam (Evrysdi) prior authorization criteria (see pp. 14, 16, 37).

2. **Clarification of Previous Minutes**

    a) **February 2019 Meeting—Migraine Agents: CGRP Preventative: Expanded MTF/Mail Pharmacy Initiative (EMMPI)**: Erenumab (Aimovig) was recommended for removal from the EMMPI program, but this was inadvertently omitted from the meeting minutes. Aimovig will no longer remain on the EMMPI program.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/Not Covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for

fiscal year (FY) 2018. Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

NF medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

IV. UF DRUG CLASS REVIEWS

A. Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the CDK inhibitor subclass used for advanced or metastatic hormone receptor-positive (HR(+)), human epidermal growth factor receptor 2-negative (HER2(-)) breast cancer. The drugs include abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali). Ribociclib is also co-packaged with the aromatase inhibitor letrozole (Kisqali Femara Co-Pack), which is a convenience formulation.

The Committee comprehensively reviewed the evidence including what was analyzed when Verzenio, Kisqali, and Kisqali Femara were presented as innovators in November, May, and August of 2017, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Efficacy

- A comprehensive review of the evidence shows that each CDK inhibitor offers a statistically and clinically significant advantage in objective response rate (ORR) and progression free survival (PFS), relative to the respective controls used in the individual clinical trials.
- There is no clear efficacy superiority of any one CDK inhibitor over another, and no clear superiority of the sequencing of when to use the CDK inhibitors. Overall, efficacy considerations do not drive selection of one particular agents.
- There are no head-to-head trials available directly comparing one CDK inhibitor with another.
- Indirect comparison of the hazard ratios of various efficacy endpoints (including ORR and PFS) from systematic reviews and network meta-analyses show that no one particular CDK inhibitor exhibits superiority over any other.

Guidelines

- The National Comprehensive Cancer Network (NCCN) guidelines recommend abemaciclib, palbociclib, and ribociclib as preferred first-line,

second-line or subsequent therapy, supported by the highest level of evidence.

- Abemaciclib (Verzenio) is also recommended as monotherapy for disease that has progressed on chemotherapy, but this is supported by a lower level of evidence (e.g., useful in certain circumstances).
- Other guidelines (e.g., American Society of Clinical Oncology, European Society for Medical Oncology) are in agreement with one another and make no distinction in the choice of a particular agent. Each CDK inhibitor has the same preference and strength of recommendation.

Safety

- There is no one clearly superior CDK inhibitor in terms of safety or tolerability.
- The safety profiles of the CDK inhibitors overlap, however, there are unique adverse events associated with each agent. Hematologic adverse events (e.g. neutropenia, anemia, and thrombocytopenia) are considered class effects.
    - Palbociclib (Ibrance) has the highest absolute risk of neutropenia, and a unique warning for the risk of pulmonary embolism.
    - Abemaciclib's (Verzenio's) safety profile includes a lower relative risk of neutropenia, but higher relative risk for diarrhea and unique warnings (amongst these agents) for hepatotoxicity and venous thromboembolism (VTE).
    - Ribociclib (Kisqali) has a lower relative risk of anemia, thrombocytopenia, and VTE, but higher relative risk for QT-prolongation and a unique warning (amongst these agents) for hepatobiliary toxicity.

Overall Clinical Conclusion

- Choice of treatment in HR(+)/HER2(-) advanced or metastatic breast cancer depends on several factors, including the safety profile of the individual CDK inhibitor, patients' preference, comorbidities, and disease burden.

Relative Cost-Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that ribociclib (Kisqali), ribociclib/letrozole (Kisqali Femara Co-Pack) abemaciclib (Verzenio) and palbociclib (Ibrance) were all cost-effective.

- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating all CDK inhibitors as UF demonstrated significant cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:
    - UF
        - abemaciclib (Verzenio)
        - palbociclib (Ibrance)
        - ribociclib (Kisqali)
        - ribociclib/letrozole (Kisqali Femora Co-Pack)
    - NF – None
    - Tier 4 – None
    - Note that no CDK inhibitors were added to the BCF

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Manual PA currently apply to all four CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent), updating the PA criteria to follow the NCCN guidelines, with the additional indication for Verzenio noted, and including all four drugs on one PA form. The unique safety and monitoring factors will be outlined for each drug. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QLs***—QLs currently apply to the CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) applying a 28 day supply at all points of service for Ibrance, Verzenio, Kisqali, and Kisqali Femara Co-Pack. See Appendix D for the full criteria.

4. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—***The CDK inhibitors are not currently included on the EMMPI program, due to the likelihood of dosage reduction from adverse events. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 2 absent) maintaining the current status (do not include Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack on the EMMPI program).

5. ***COMMITTEE ACTION: UF, PA, QL, and EMMPI 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. Based on the P&T Committee's recommendation, the effective date is March 16, 2022.

***Addendum to the UF recommendation*:** After the P&T meeting, a review of the bids submitted by one manufacturer showed that a re-calculation of the cost analysis was required. The new cost model was presented to the DoD P&T Committee via electronic means. An electronic vote was taken to determine whether to maintain the UF recommendation originally determined at the February 2021 meeting.

COMMITTEE ACTION: ADDENDUM TO UF RECOMMENDATION: The P&T Committee reaffirmed (14 for, 0 opposed, 0 abstained, 2 absent) the recommendation made at the meeting, which maintains all four CDK inhibitors (Verzenio, Ibrance, Kisqali, and Kisqali Femora Co-Pack) on the UF.

B. Pulmonary 3 Agents: Combinations Subclass

Background—The Pulmonary 3 agents contain a fixed-dose triple combination of inhaled corticosteroid, long-acting muscarinic antagonist, and long-acting beta agonist (ICS/LAMA/LABA) in one inhaler. A triple combination regimen can also be achieved using a variety of multiple inhalers, including single ingredient inhalers used separately, or by using various fixed dose dual combination inhalers, such as, an ICS/LABA or LAMA/LABA.

The two drugs in the class are fluticasone/umeclidinium/vilanterol (Trelegy) and budesonide/glycopyrrolate/formoterol (Breztri). Triple combination therapy is used in severe chronic obstructive pulmonary disease (COPD) and severe asthma after failure with dual therapy ICS/LABA or LAMA/LABA. Both Trelegy and Breztri are approved for maintenance treatment of COPD, while Trelegy has an additional indication for maintenance treatment of asthma in adults.

Although this is the first time the Pulmonary 3 Agents have been reviewed as a class, both Trelegy and Breztri were originally reviewed as new drugs, in November 2017 and November 2020, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Asthma

- The National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) Expert Panel Working Group guidelines recommend adding a LAMA to ICS/LABA in patients with uncontrolled asthma to improve symptom control and quality of life. Triple combination therapy does not affect asthma exacerbations requiring corticosteroids or rescue medication use.
- Although Trelegy was shown to improve forced expiratory volume in one second (FEV1) Trelegy lacks an indication in the label to reduce asthma exacerbations.

COPD

- The Global Initiative for Chronic Obstructive Lung Disease (GOLD 2020), strategy recommends reserving triple therapy for highly symptomatic patients after failure of dual therapy with LAMA/LABA or ICS/LABA.
- In the individual clinical trials used to gain FDA approval, both Trelegy and Breztri demonstrated statistically significant improvements in trough FEV1, and in the Saint George Respiratory Questionnaire (SGRQ) quality of life instrument, however these results did not reach the minimally clinically important difference threshold.
- Although varying results were shown in the clinical trials with regard to a reduction in COPD exacerbations, neither Trelegy nor Breztri are indicated to reduce COPD exacerbations.
- For COPD, despite the lack of head-to-head trials, indirect comparisons suggest there is not a clinically relevant difference in the drugs' effects on improving FEV1.

Safety

- The GOLD strategy and American Thoracic Society guidelines recommend withdrawing ICS in patients receiving triple therapy (ICS/LAMA/LABA), if the patient has had no exacerbations in the preceding year, due to the risk of pneumonia.
- In studies with longer treatment durations, there was a higher rate of pneumonia with Trelegy, Breztri and ICS-containing regimens, compared to regimens lacking an ICS component.
- Overall drug discontinuation due to adverse events was low in the individual clinical trials with Trelegy and Breztri, versus respective comparators.

Clinical Considerations

- Breztri advantages include that it is less reliant on a patient's inspiratory flow rate to activate the inhaler; however, it is dosed twice daily, and is only indicated for COPD. The Breztri Aerosphere metered dose inhaler requires patient breath-hand coordination to activate. Clinical trials evaluating Breztri in adults with asthma are ongoing.
- Trelegy's advantages include FDA-approval for both asthma and COPD, and once daily dosing. The Ellipta inhaler device is breath-activated, requiring the patient to have a higher minimum inspiratory flow rate, however, it does not require patient breath-hand coordination.

Overall Clinical Conclusion

- The triple combination inhalers provide a convenience to patients by offering three drugs in one inhaler for one copay. However there is no data to show the triple combination inhalers result in improved outcomes compared to taking multiple inhalers to comprise a regimen of LABA/ICS/LAMA [ICS/LABA (e.g., Advair) plus LAMA (e.g., Spiriva)].
- In order to meet the needs of Military Health System (MHS) patients with COPD, at least one option for the triple ingredients of ICS/LAMA/LABA is required on the formulary; however, it does not have to be a three-ingredients-in-one inhaler.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that budesonide/glycopyrrolate/formoterol (Breztri) and fluticasone/umeclidinium/vilanterol (Trelegy) were both cost-effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating Breztri and Trelegy as UF demonstrated the greatest cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:

   - UF
     - fluticasone/umeclidinium/vilanterol (Trelegy)
     - budesonide/glycopyrrolate/formoterol (Breztri)
   - NF: None

- Tier 4/Not Covered: None
- Note that a pulmonary 3 agent will not be included on the Basic Core Formulary. Advair and Spiriva Respimat remain on the BCF.

2. ***COMMITTEE ACTION: QUANTITY LIMITS (QL)—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) standardizing the current Quantity Limits for Trelegy, and Breztri to allow for one inhaler per fill at Retail Network pharmacies, and three inhalers per fill at the MTF and TRICARE Mail Order pharmacy. See Appendix D for the full criteria.

3. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—*** The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining only Trelegy on the program. Breztri will not be included on the program. *(See the August 2021 P&T Committee meeting minutes where Breztri was added to the EMMPI program.)*

4. ***COMMITTEE ACTION: UF, QL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Based on the P&T Committee's recommendation, the effective date is March 2, 2022.

   (Note: See the August 2021 P&T Committee meeting minutes for the recommendation for the Tier 1 copay for Breztri.)

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed for group 1: (18 for, 0 opposed, 1 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 0 absent), with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2021 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended for group 1: (18 for, 0 opposed, 1 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 0 absent) the following:

- UF:
    - berotralstat (Orladeyo) – Corticosteroids-Immune-modulators; for hereditary angioedema (HAE)
    - hydrocortisone oral sprinkle capsules (Alkindi) – Adrenocortical insufficiency in children
    - lonafarnib (Zokinvy) – Miscellaneous metabolic agent for Hutchinson-Gilford Progeria Syndrome or processing-deficient Progeroid Laminopathies
    - pegfilgrastim-apgf syringe (Nyvepria) – White Blood Cell Stimulants. Note that as part of this recommendation, Nyvepria will be designated as step-preferred.
    - setmelanotide injection (Imcivree) – Weight loss agent for obesity due to deficiencies of proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR)
- NF:
    - clascoterone 1% cream (Winlevi) – Acne Agents: Topical acne and rosacea agents
    - loteprednol 0.25% ophthalmic solution (Eysuvis) - Ophthalmic: Corticosteroid for short term use in dry eye disease
    - relugolix (Orgovyx) – Luteinizing hormone-releasing hormone (LHRH) agonists-antagonists for advanced prostate cancer
    - sodium sulfate/magnesium sulfate/potassium chloride (Sutab) – Laxatives-Cathartics-Stool Softeners: Bowel Preparation for colonoscopy
    - tramadol oral solution (Qdolo) – Narcotic analgesics and combinations
- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
    - calcipotriene/betamethasone dipropionate 0.005%/0.064% topical cream (Wynzora) - Topical Psoriasis agent.
        - Wynzora was recommended for Tier 4 status as it is has little to no clinical benefit relative to other formulations of calcipotriene/betamethasone dipropionate formulations, and the needs of TRICARE beneficiaries are met by alternative agents.

        - Formulary alternatives to Wynzora include using a vitamin D analog (calcipotriene 0.005% cream, ointment or solution) with a high potency topical corticosteroid (clobetasol propionate 0.05% ointment, cream, solution and gel; fluocinonide 0.05% cream, gel and solution), or calcipotriene 0.005% and betamethasone 0.064% foam (Enstilar) [Nonformulary].
    - clobetasol propionate 0.05% lotion metered dose pump (Impeklo) – High Potency Topical Corticosteroid for steroid-responsive dermatoses.
        - Impeklo was recommended for Tier 4 status as it is has little to no clinical benefit relative to other formulations of clobetasol propionate, and the needs of TRICARE beneficiaries are met by alternative agents.
            - Formulary alternatives to Impeklo include betamethasone/propylene glycol 0.05% lotion; betamethasone dipropionate 0.05% gel; clobetasol propionate/emollient 0.05 % (emulsion) foam; clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo, and fluocinonide 0.05% solution and gel

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended group 1: (17 for, 0 opposed, 2 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 1 absent) MN criteria for Eysuvis, Orgovyx, Qdolo, Sutab, Winlevi. See Appendix B for the full criteria.

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

- Pegfilgrastim: No PA is required for Nyvepria, however, note that Nyvepria will be step-preferred, along with Udenyca and Fulphila (which were reviewed at the August 2020 meeting); new patients receiving a non-step-preferred Pegfilgrastim (Neulasta, Neulasta Onpro, and Ziextenzo) will be required to have a trial of Nyvepria, Udenyca and Fulphila first. The PA forms for the non-step-preferred products will be updated accordingly.
- LHRH agonists-antagonists for advanced prostate cancer: Applying manual PA criteria to new users of Orgovyx.
- HAE drugs: applying manual PA criteria to new users of Orladeyo. See the Utilization Management Section on pages 14 and 28 for updates to the PAs for all the HAE prophylaxis drugs.

- Applying manual PA criteria to new users of Alkindi Sprinkle, Imcivree, Qdolo, and Zokinvy.
- Applying manual PA criteria to new and current users of Eysuvis and Winlevi.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Tier 1 Co-Pay for pegfilgrastim (Nyvepria)

The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) lowering the current Tier 2 cost-share for Nyvepria to the generic Tier 1 cost-share, with an effective date of the fist Wednesday two weeks after signing of the minutes at all points of service.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes." Lowering the cost-share for Cutaquig will provide a greater incentive for beneficiaries to use the most cost-effective SCIG, in the purchased care points of service.

E. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended group 1: (17 for, 0 opposed, 2 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF or NF Status:** An effective date of the first Wednesday upon two weeks after signing of the minutes in all points of service, on March 2, 2022. Note that the updated PAs for the HAE drugs will also occur at this time.

- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date upon 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation, on June 15, 2022.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

a) **Skeletal Muscle Relaxants and Combinations – orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte)—**The non-opioid combination product containing orphenadrine 50 mg, aspirin 770 mg, and caffeine 60 mg is indicated for mild to moderate acute musculoskeletal pain. The fixed dose combination generic Norgesic and Orphengesic products are not cost effective relative to the individual components, which are all available in low-cost formulations. Several other cost-effective prescription and OTC non-opioid alternatives (i.e., baclofen, cyclobenzaprine, NSAIDs, acetaminophen) are also available.

COMMITTEE ACTION: NEW PA CRITERIA FOR NORGESIC, ORPHENGESIC FORTE —The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for orphenadrine-aspirin-caffeine Norgesic and Orphengesic Forte in new users, to ensure that other therapies for musculoskeletal pain are tried first. See Appendix C for the full criteria.

b. Narcotic Analgesics and Combinations-levorphanol tartrate tablets— Levorphanol tartrate is reserved for patients who require an opioid for severe pain where alternative options (i.e., non-opioid analgesics, opioid combination products) are ineffective, not tolerated, or otherwise inadequate. It is not a first line treatment for pain, due to safety concerns related to the long half-life. Provider feedback mentioned unfamiliarity with this product and supported PA criteria. Numerous other appropriate pain management options are available.

COMMITTEE ACTION: NEW PA CRITERIA FOR LEVORPHANOL TARTRATE TABS—The P&T Committee recommended (17 for, 0 opposed, 2 abstained, 0 absent) manual PA criteria for levorphanol tartrate tablets in new users, to ensure that other therapies for pain are tried first. See Appendix C for the full criteria.

2. Updated PA Criteria, Step Therapy, and MN Criteria

The P&T Committee recommended (17 for, 0 opposed, 2 abstained, 0 absent) updates to the PA criteria for several drugs, based on new clinical trial data, clinical practice guidelines, or MTF provider requests. The updated PA criteria discussed below apply to new users of an SGL2-inhibitor, Xhance, Symbicort/Dulera, and Evrysdi. See Appendices B and C for the full criteria.

a) **Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors-empagliflozin (Jardiance), dapagliflozin (Farxiga), canagliflozin (Invokana), ertugliflozin (Steglatro) and their combinations with metformin—**The SGLT2 inhibitors were originally approved for treating type 2 diabetes mellitus (T2DM) when the class was reviewed for formulary status in 2015. Empagliflozin (Jardiance) is currently the preferred SGLT2 inhibitor; canagliflozin (Invokana), dapagliflozin (Farxiga), and ertugliflozin (Steglatro) are nonformulary and non-

step-preferred, requiring a trial of empagliflozin first. The SGLT2 inhibitors are also available in fixed-dose combinations with metformin.

Recently published trials provide evidence for the SGLT2 inhibitors in patients with heart failure with reduced ejection fraction (HFrEF) or chronic kidney disease (CKD), regardless of DM status. Clinical practice guidelines from the American College of Cardiology (ACC) (2021 ACC Consensus Decision Pathway for HFrEF Optimization) and the American Heart Association (AHA) (2020 Scientific Statement on cardiorenal protection in patients with DM and CKD) support a class effect for the SGLT2 inhibitors for improving cardiovascular outcomes. At the time of the February 2021 meeting, some of the package inserts for the SGLT2 inhibitors had not yet been updated to reflect the new clinical trial data. *Note that Jardiance received FDA approval for treating HFrEF on August 18, 2021.*

Provider input from MHS cardiologists and nephrologists overwhelmingly supported maintaining empagliflozin as the preferred SGLT2 inhibitor for T2DM, HFrEF and CKD, based on professional guidelines and clinical trial data, regardless of diabetes status or formal FDA-approval.

COMMITTEE ACTION: SGLT2 INHIBITORS UPDATED PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) removing the current PA criteria for empagliflozin and empagliflozin/metformin. The PA criteria for canagliflozin, dapagliflozin, and ertugliflozin and their respective combinations with metformin were revised to require a trial of empagliflozin first for patients with T2DM, HFrEF and CKD. The nonformulary SGLT2 inhibitors will be allowed if the patient has a contraindication or has experienced adverse effects from empagliflozin. See Appendix C for the full criteria.

b) Nasal Allergy Agents: Corticosteroids - fluticasone propionate 93 mcg nasal spray (Xhance)—An MTF provider requested the Committee review the current PA and MN criteria for Xhance, which was designated NF at the February 2018 meeting. Xhance is the fourth fluticasone nasal product marketed, but it is only indicated for adults with nasal polyps and is not approved for allergic rhinitis.

A review of the evidence shows that Xhance may provide enhanced penetration of medication into the nasal cavity, but there is no evidence that this results in improved outcomes for the patient. Xhance provides no confirmed benefit in reducing nasal polyp size compared to alternative intranasal corticosteroids or steroid lavage. However, changes to the Xhance manual PA criteria were made to align with current rhinosinusitis guidelines for treating nasal polyps, and to follow DHA Specialist recommendations.

Additions to the criteria include a new requirement for nasal saline irrigation. The option of nasal corticosteroid lavage (e.g., irrigation/rinse) was added to list of treatments that are required prior to Xhance (patients must still try two nasal

steroids before Xhance). The MN criteria were also updated to require a trial of one formulary alternative prior to Xhance.

c) **Pulmonary-1 Agents: Combinations: budesonide/formoterol (Symbicort) and mometasone/formoterol (Dulera)**—Manual PA criteria for Symbicort and Dulera were originally recommended in February 2014, requiring a trial of fluticasone/salmeterol (Advair) first. The PA criteria were most recently revised in November 2019, allowing ICS-formoterol (e.g., budesonide/formoterol, or mometasone/formoterol) as a rescue inhaler, based on the 2019 Global Initiative for Asthma (GINA) evidence-based strategy.

   In 2020, the U.S. based National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) focused update to the Asthma Management Guidelines now prefers combination ICS-formoterol for daily (maintenance) and as needed use (PRN or quick-relief therapy) for moderate persistent asthma (Steps 3 and 4 in the algorithm) over other ICS and ICS/LABA combinations. The traditional regimens of ICS with PRN short-acting beta agonist (SABA) or ICS/long acting beta agonist (LABA) with PRN SABA are now considered alternate treatments. However, no changes are needed if a patient's current regimen of maintenance ICS/LABA with SABA as quick-relief therapy is providing adequate asthma control.

   This approach of using ICS-formoterol for maintenance and PRN use was based on 10 studies comparing ICS-formoterol dual combination inhalers with the same dose ICS or higher dose ICS single ingredient inhalers. A reduction in asthma exacerbations was noted with ICS-formoterol therapy. Limitations to the studies were the inclusion of ICS-formoterol and SABA inhalers that are not commercially available in the U.S. and significant industry funding. Also note that the current FDA labeling for Symbicort and Dulera does not include quick-relief use.

   Provider feedback was solicited regarding the NAEPPCC recommendations, and overall, providers supported increased access to ICS/formoterol combinations for DoD beneficiaries. Current contracting commitments preclude changing the formulary status for Symbicort and Dulera at this time. However, manual PA criteria and MN criteria for both drugs were updated in accordance with the 2020 NAEPPCC recommendations.

d) **Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA): risdiplam (Evrysdi) oral solution—**Manual PA criteria for Evrysdi were added when it was first reviewed as a new drug at the November 2020 meeting. The Director, DHA recommended that the P&T Committee re-review the criteria. The Committee re-evaluated the current age restriction, which limits use to patients younger than 25. After further review, despite a lack of clinical evidence supporting Evrysdi in patients older than 25 years of age, for humanistic reasons the age restriction was

removed from the PA. Patients meeting all the other criteria will be allowed to use Evrysdi, regardless of age. See Appendix C for revised criteria.

COMMITTEE ACTION: UPDATED PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 2 abstained, 0 absent) updated PA criteria for Xhance, Symbicort, Dulera, the HAE drugs, and Evrysdi, and the updated MN criteria for Symbicort and Dulera. See Appendix B for the full MN criteria and see Appendix C for the full PA criteria.

3. Updated PA Criteria, Step Therapy, and MN Criteria for New FDA-Approved Indications, NCCN Guideline Updates, or Age Ranges

The P&T Committee (17 for, 0 opposed, 2 abstained, 0 absent) recommended updates to the manual PA criteria and step therapy for several drugs due to expanded age indications, and new FDA-approved indications, or other reasons. The updated PAs, MN criteria and step therapy outlined below will apply to new users. See Appendix C for full criteria.

- **Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis: plasma-derived human Cl Esterase Inhibitor IV (Cinryze), plasma-derived human Cl Esterase Inhibitor SC (Haegarda), lanadelumab (Takhzyro) SC injection** –The prophylactic HAE drugs were evaluated for formulary status in August 2017, and new drug review for Orladeyo was presented previously at this meeting (see 10). The manual PA criteria for the HAE prophylactic drugs were updated to reflect the 2020 U.S. Hereditary Angioedema Association guidelines which do not recommend a trial of anabolic androgens prior to other available prophylactic agents.
- **Targeted Immunomodulatory Biologics (TIBs) - anakinra (Kineret)—**Manual PA criteria now allow for the new indication of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).
- **Immunosuppressives - belimumab (Benlysta)**—belimumab injection SQ and IV (Benlysta)—Manual PA criteria were updated to include the new indication of active lupus nephritis in adults who are receiving standard therapy.
- **Cystic Fibrosis Agents - ivacaftor (Kalydeco), elexacaftor/tezacaftor/ivacaftor (Trikafta), and tezacaftor/ivacaftor (Symdeko)**—The PA criteria for the cystic fibrosis drugs were revised to standardize the wording for all three drugs, and to reflect the new indications allowing for mutation types that are responsive to Kalydeco or Symdeko, based on clinical and/or *in vitro* assay data.
- **Weight Loss Agents - liraglutide 3 mg (Saxenda)**—Manual PA criteria now allow use in patients as young as 12 years for weight loss. Patients age 16 years and older must first try phentermine, consistent with the requirements for adults, however

patients between the ages of 12 to 15 years are allowed to use Saxenda without first trying phentermine.

- **Oncological Agents**
  - **Breast Cancer - neratinib (Nerlynx)**—Includes the new FDA-approved indications for advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer in adults, when used in combination with capecitabine, and when the patient has received two or more prior anti-HER2-based regimens in the metastatic setting. The previous lifetime duration of one year was removed, since the new indication of HER2+ breast cancer does not limit length of the treatment course.
  - **Multiple Myeloma - selinexor (Xpovio)**—Updated the manual PA criteria to allow for the new indication for multiple myeloma, when used in combination with bortezomib and dexamethasone, and when the patient has received at least one prior therapy.
  - **Multiple Myeloma - ixazomib (Ninlaro)**—Updated the manual PA for NCCN recommended (category 1) use as a single-agent maintenance therapy for multiple myeloma when patients will receive Ninlaro following primary therapy and hematopoietic cell transplant (HCT).
- **Sleep Disorders**
  - **Wakefulness Promoting Agents - pitolisant (Wakix)**—The new indication of cataplexy in adults with narcolepsy is now included in the criteria.
  - **Sleep Disorders: Insomnia Agents - tasimelteon capsule and liquid (Hetlioz, Hetlioz LQ)**—tasimelteon capsule and liquid (Hetlioz/Hetlioz LQ)—Updated the manual PA criteria to include the new indication of Smith-Magenis Syndrome (SMS) for the capsules in patients 16 years of age and older, and for the liquid in patients 3 to 15 years of age.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA— The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for the CF drugs, Kineret, Benlysta, Saxenda, Nerlynx, Xpovio, Ninlaro, Wakix, Hetlioz, and Hetlioz LQ. See Appendix C for the full PA criteria.

B. Quantity Limits

General QLs: QLs were reviewed for five newly approved drugs.

COMMITTEE ACTION: QLs—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) QLs for Alkindi Sprinkle, Zokinvy, Imcivree, Orladeyo, and Winlevi. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

COMMITTEE ACTION: PA AND QLs IMPLEMENTATION PERIOD—The P&T Committee recommended the following implementation periods:

- (18 for, 0 opposed, 1 abstained, 0 absent) The new PA for orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte); the updated SGLT2 inhibitor PA criteria; and the removal of the age restriction for Evrysdi will become effective in new users the first Wednesday 30 days after the signing of the minutes (March 16, 2022). *Note that due to the BAP meeting delay and subsequent delay of the signing of the February 2021 P&T Committee meeting minutes, the PA for Evrysdi was updated in June 2021, based on the direction of the Director, DHA from the November 2020 DoD P&T Committee minutes' signing. .*
- (17 for, 0 opposed, 2 abstained, 0 absent) Updates to the current PA criteria in new users for Xhance; the LAMA/LABA inhalers Symbicort and Dulera; Kineret; Benlysta; the CF drugs Kalydeco, Symdeko, and Trikafta; Saxenda; the oncology drugs Nerlynx, Xpovio, and Ninlaro, and the sleep disorder drugs Wakix, Hetlioz, and Hetlioz LQ, along with MN criteria updates for Xhance, Symbicort, and Dulera will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2022). *Note that due to the BAP meeting delay and subsequent delay of the signing of the February 2021 P&T Committee meeting minutes, and the fact that the PA updates expand the potential patient eligible to receive the drugs listed above, the PAs were updated in June 2021*.
- (17 for, 0 opposed, 2 abstained, 0 absent) The new PA for levorphanol tartrate tablets will become effective in new users the first Wednesday 90 days after the signing of the minutes (May 18, 2022).
- (18 for, 0 opposed, 1 abstained, 0 absent) QLs listed in Appendix D will become effective the first Wednesday 2 weeks after the signing of the minutes in all POS (March 2, 2022).
- Note that the implementation for the updated PAs for the HAE drugs Cinryze, Haegarda, Takhzyro and Orladeyo will occur at two weeks after signing of the minutes, as outlined in the new drug section on p 10.

VII. LINE EXTENSIONS

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

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION—***The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (March 2, 2022).

- **Hepatitis C Agents: Direct Acting Agents—**designating **sofosbuvir/velpatasvir tablets (Epclusa) 200 mg-50 mg tablet** as UF, with the same manual PA requirements, QLs, and specialty reporting requirements similar to Epclusa 400 mg-100 mg tablet.
- **Gastrointestinal-2 Agents: Miscellaneous—fidaxomicin granules for oral suspension (Dificid)—**designating Dificid granules for oral suspension as UF with similar QLs as currently applies to the Dificid oral tablet. See Appendix D for the QL.

VIII. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE MAIL ORDER PROGRAM

Newly Approved Drugs per 32 CFR 199.21(g)(5)
See Appendix F for the mail order status of medications designated UF or NF during the February 2021 P&T Committee meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement. The implementation date for all of the recommendations from the February 2021 meeting listed in Appendices E and F, including those for newly approved drugs, will be effective upon the first Wednesday two weeks after the signing of the minutes.

1. ***COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—*** The P&T Committee recommended (groups 1: 17 for, 0 opposed, 1 abstained, 1 absent; group 2: 18 for, 0 opposed, 1 abstained, 0 absent), adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMI List) for the reasons outlined in the table. See Appendix F.

IX. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFS: NASAL COLD AND ALLERGY PRODUCTS

Background—The DoD P&T Committee continued reviewing the OTC drugs on the MHS GENESIS OTC list. For a full description of the background and process details, refer to the May 2019 and August 2019 DoD P&T Committee meeting minutes, found at http://health.mil/PandT.

Factors influencing whether a particular OTC product is retained or removed from the MHS GENESIS OTC List include volume and utilization across multiple MTFs; feedback from MTF stakeholders to include primary care providers, pediatricians, and other providers, DHA Clinical Community advisory groups, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

A. OTC Nasal Cold and Allergy Products—OTC nasal cold and allergy products include nasal corticosteroids (budesonide, fluticasone furoate, fluticasone propionate, and triamcinolone), cromolyn sodium, nasal decongestants (oxymetazoline and phenylephrine), and saline nasal products.

Legend products in this category include nasal steroids (beclomethasone, ciclesonide, flunisolide, fluticasone propionate, and mometasone), nasal anticholinergics (ipratropium) and nasal antihistamines (azelastine and olopatadine). By far the most commonly used products across these categories are legend fluticasone propionate 50 mcg, OTC oxymetazoline 0.05% spray, and the four OTC saline products noted below. These products are also consistently lower in cost compared to alternative products. Clinicians at MHS GENESIS sites that dispensed less commonly used OTC products (e.g., budesonide, the OTC version of fluticasone propionate 50 mcg, cromolyn, or phenylephrine) did not express an overwhelming need to retain any of these OTC products on formulary.

1. ***COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 1 absent) the following:

   - Retaining oxymetazoline 0.05% spray, sodium chloride, bicarbonate/squeeze bottle (e.g., Ayr, Neilmed Sinus) pack w/dev; sodium chloride/sodium bicarbonate (Ayr, Neilmed Sinus Rinse) packet; sodium chloride (Ayr Saline, Baby Ayr Saline) 0.65% drops; and sodium chloride (Ayr Saline, Deep Sea, Ocean) 0.65% spray.
   - Removing budesonide 32 mcg spray, fluticasone propionate 50 mcg spray, cromolyn sodium 5.2 mg spray, and phenylephrine 0.125%, 0.25% and 0.5% sprays, which are rarely used by MTFs.
   - An implementation date of the first Wednesday 120 days following signing of the minutes for the products removed from the list. No patient letters are required due to the typically intermittent use of

the products. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

X. ITEMS FOR INFORMATION

A. Tier 4/Not Covered Re-Review: Proton Pump Inhibitor (PPI) — dexlansoprazole (Dexilant) and esomeprazole strontium:

The Committee was briefed on the Tier 4 PPIs (dexlansoprazole and esomeprazole strontium) selected at the May 2019 meeting, with implementation occurring November 28, 2019 (with some MTFs implementing in January 2020). For dexlansoprazole (Dexilant), there was no new clinical data to change the May 2019 conclusion that it does not have a significant clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other PPI drugs currently included on the UF. Dexlansoprazole remains significantly more costly than the remainder of the class. Esomeprazole strontium was discontinued from the market in 2020.

In the future, after a medication in any drug class has been recommended for Tier 4 placement by the DoD P&T Committee, the Committee will only review the drug again if significant clinical or cost-effectiveness updates or changes have occurred that may necessitate a change in Tier 4 status.

B. Annual Review of Newly Approved Drugs

The Committee was briefed on the utilization and cost trends for the newly approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. Since the start of the program, 351 drugs have been reviewed, including 77 in calendar year 2020 alone. Updates on the metrics for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

C. Post-Implementation Review: Migraine Agents: Calcitonin Gene-related Peptide (CGRP) Preventatives

The CGRP migraine prophylaxis drugs [erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality)] were evaluated for formulary status in February 2019. Overall trends in utilization and expenditures were reviewed since implementation in November 2019.

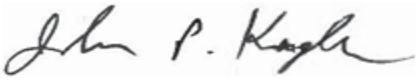
XI. ADJOURNMENT

The meeting adjourned at 1619 hours on February 4, 2021. The next meeting will be in May 2021.

Appendix A—Attendance: February 2021 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

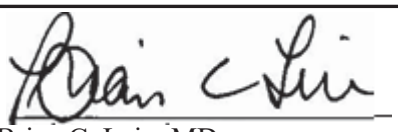
The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:



Brian C. Lein, MD
Assistant Director,
Healthcare Administration
for Ronald J. Place
LTG, MC, USA
Director

14 Feb 2022
Date

Appendix A—Attendance: February 2021 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Col Markus Gmehlin BSC	Chief, DHA Pharmacy Operations Division (POD)
CDR Scott Raisor, BCACP	DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
MAJ Wendra J Galfand, MC	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CDR Bradley Gotto for CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Jason Foote for CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Col Corey Munro, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Dr. Lara Au	Oncology Pharmacist
LTC Jason Burris	Army, Oncologist
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Beth Days, PharmD	Oncology Pharmacist
LCDR William Agbo CPT Hope Shen	DLA Troop Support

Elaine Furmaga (February 3rd) Mitchell Nazario (February 4th)	Department of Veterans Affairs

Guests	
Ms. Hilary Meckel	DHA Contracting Officer
Ms. Yvette Dluhos	DHA Contracting
Mr. Dwight Bonham	DHA Contracting
Mr. Hudson Tompkins	DHA Contracting
Ms. Grace Steier	DHA Contracting
Mr. Monroe Porter	DHA Contracting
Ms. Madison Northen	DHA Contracting
Others Present	
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch POD
CDR Heather Rovey, MSC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
MAJ Triet Nguyen, MSC	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
CDR Eric Parsons	DHA Purchased Care Branch
Mr. David Folmar	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Ebony Moore	DHA Formulary Management Branch Contractor
Ms. Rachel Lai	University of Texas PharmD Student

Drug / Drug Class	Medical Necessity Criteria
Newly Approved Drugs MN Criteria	
• clascoterone cream (Winlevi) **Acne Agents: Topical Acne and Rosacea**	• Use of formulary agents is contraindicated • Patient has tried AND failed or experienced significant adverse effects from at least 3 formulary agents, including 1 oral product and 1 clindamycin/benzoyl peroxide combination product. **Formulary alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel), spironolactone
• loteprednol 0.25% ophthalmic solution (Eysuvis) **Ophthalmic: Dry Eye**	• Patient has experienced significant adverse effects from formulary agents • A trial of two formulary agents has resulted in therapeutic failure (one of which must be loteprednol 0.5%) **Formulary alternatives:** loteprednol 0.5% gel, ointment, or suspension (Lotemax, generics); loteprednol 0.38% gel (Lotemax SM); loteprednol 1% suspension (Inveltys); loteprednol 0.2% suspension (Alrex, generics); fluorometholone (Flarex, FML)
• relugolix (Orgovyx) **Luteinizing Hormone-Releasing Hormone Agonists-Antagonists for Prostate Cancer**	• At least one formulary agent (Lupron Depot, Eligard, Firmagon) resulted in therapeutic failure. • No alternative formulary agent – Patient is not able to use a intramuscular injection, subcutaneous injection or implant **Alternatives**: leuprolide acetate IM (Lupron Depot), leuprolide acetate SQ (Eligard), degarelix SQ (Firmagon), goserelin SQ implant (Zoladex), histrelin SQ implant (Vantas), triptorelin IM (Trelstar Mixject)
• sodium sulfate/ magnesium sulfate/ potassium chloride (Sutab) **Laxatives-Cathartics-Stool Softeners: Bowel Preparations**	• No alternative formulary agent – the patient requires a bowel prep formulated as a tablet and cannot take OsmoPrep. **Formulary alternatives**: GoLytely, Suprep, MoviPrep
• tramadol oral solution (Qdolo) **Narcotic Analgesics & Combinations**	• No alternative formulary agent - Patient cannot swallow tablets **Formulary alternatives**: tramadol IR tablets, acetaminophen liquid, ibuprofen liquid

Drug / Drug Class	Medical Necessity Criteria
Utilization Management Updated MN Criteria	
• fluticasone propionate 93 mcg nasal spray (Xhance) **Nasal Allergy Agents: Corticosteroids**	**<u>Updates from the February 2021 meeting are in bold and strikethrough</u>.** • Use of at least ~~two~~ **one** formulary ~~and nonformulary~~ nasal allergy drugs has resulted in therapeutic failure **Formulary Alternatives**: ~~azelastine 137 mg nasal inhaler~~, flunisolide (generic Nasarel), fluticasone propionate 50 mcg nasal inhaler (generic Flonase), mometasone (generic Nasonex), beclomethasone (Beconase AQ), **budesonide (generic Rhinocort Aqua)**

• mometasone/formoterol (Dulera)
• budesonide/formoterol (Symbicort)
 	
Pulmonary I Agents – Combinations
	<u>Updates from the February 2021 meeting are in bold and strikethrough</u>.
	
	• Use of formulary agents (Advair Diskus and Advair HFA) is contraindicated
	• Patient has experienced significant adverse effects from Advair that is not expected to occur with the non-formulary ICS/LABA medication
	• Formulary agents (Advair Diskus and Advair HFA) result or are likely to result in therapeutic failure
	• Patient previously responded to the non-formulary agent and changing to a formulary agent (Advair Diskus and Advair HFA) would incur unacceptable risk
	• No alternative formulary agent:
	  • For Symbicort and Dulera: patient has asthma and requires rescue therapy **or intermittent and daily ICS-LABA** with an ICS-formoterol combination
	  • ~~Symbicort: Patient requires an MDI because they have decreased inspiratory effort and cannot use a DPI (Advair Diskus)~~
	  • ~~Breo Ellipta: patient has complicated drug regimen and requires once daily dosing~~
	
	Formulary Alternatives: Advair Diskus and Advair HFA

Drug / Drug Class	Prior Authorization Criteria
• Ibrance • Verzenio • Kisqali • Kisqali Femara Co-Pack **Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors**	**The PA criteria below replaces the current PA criteria for the CDK inhibitors.** Manual PA criteria apply to all new users of Ibrance, Verzenio, Kisqali, and Kisqali Femara Co-Pack. 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. ***(new indication from Oct 2021)*** • 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

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
• berotralstat (Orladeyo) • lanadelumab-flyo (Takhzyro) • C1-INH (Cinryze IV) • C1-INH (Haegarda SC) **Corticosteroids-Immune-modulators: Hereditary Angioedema Agents**	**The PA criteria below replace the current PA criteria for the drugs.** 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 o For Orladeyo, the patient is 12 years of age or older o For Takhzyro, the patient is 12 years of age or older o 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.
• clascoterone cream (Winlevi) **Acne Agents: Topical Acne and Rosacea**	Manual PA is required for all new and current users of clascoterone cream (Winlevi). Manual PA Criteria: Coverage is approved if all criteria are met: • The provider is aware and acknowledges that adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and spironolactone (tablets) are available to DoD beneficiaries without requiring prior authorization • Patient has a diagnosis of acne vulgaris • Patient is 12 years of age or older • The drug is prescribed by or in consultation with a dermatologist. • Provider acknowledges a potential increased risk of hypothalamic-pituitary-adrenal axis suppression in adolescents compared to adults • Patient has tried and failed or has contraindications to a topical retinoid product and to a combination of topical clindamycin and benzoyl peroxide product. The provider must fill in the dates of when the patient previously tried these agents or document the contraindication that exists. • Topical retinoid: Date_____Contraindication _____ • Combination topical clindamycin with benzoyl peroxide: Date _____ Contraindication _____ • Patient has tried and failed or has contraindications to at least one oral medication (i.e., spironolactone, a combined oral contraceptive, OR isotretinoin) for acne. The provider must fill in the dates of when the patient previously tried these agents or document the contraindication that exists • Oral medication:_____Date_____Contraindication _____ Non-FDA-approved uses are not approved, including for hair loss Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• hydrocortisone oral sprinkle (Alkindi Sprinkle) **Corticosteroids-Immune Modulators**	Manual PA criteria apply to all new users of Alkindi Sprinkle **PA is not required for patients 6 years of age and younger (age edit).** Manual PA criteria: Alkindi Sprinkle is approved if all criteria are met: • The provider is aware and acknowledges that 5 mg generic hydrocortisone tablets and prednisone Intensol oral syrup are available to DoD beneficiaries without requiring prior authorization • Patient is between the ages of 6 and 18 years of age. • Patient has a documented diagnosis of adrenocortical insufficiency • Provider acknowledges that the patient's dosing regimen requires small doses of hydrocortisone and cannot accurately split the dose using 5 mg hydrocortisone tablets or use the Intensol oral syrup Non-FDA-approved uses are not approved. Prior authorization does not expire.
• lonafarnib (Zokinvy) **Metabolic Agents: Miscellaneous**	Manual PA criteria apply to all new users of Zokinvy. Manual PA criteria: Zokinvy is approved if all criteria are met: • Patient is 12 months of age or older • Patient has a body surface area (BSA) of 0.39 m^2 and greater • Patient has a documented diagnosis of Hutchinson-Gilford Progeria Syndrome or the following processing deficient Progeroid Laminopathies: o Heterozygous LMNA mutation with progerin-like protein accumulation o Homozygous or compound heterozygous ZMPSTE24 mutations • Patient is not concomitantly receiving strong or moderate CYP3A inhibitors or inducers, midazolam, lovastatin, simvastatin, or atorvastatin • Patient's renal function, electrolytes, complete blood counts, and liver enzymes will be monitored at regular intervals • Female patients with reproductive potential have been advised of the risk to a fetus and effective contraception is used Non-FDA approved uses are NOT approved including for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• loteprednol 0.25% ophthalmic solution (Eysuvis) **Ophthalmic: Corticosteroid**	Manual PA criteria apply to all new and current users of Eysuvis Manual PA criteria—Coverage will be approved if all criteria are met: • The provider is aware and acknowledges that generic loteprednol 0.5%, and other loteprednol formulations, Lotemax SM, Lotemax FML and Inveltys, are available to DoD beneficiaries without requiring prior authorization • Eysuvis is prescribed by an optometrist or ophthalmologist • Patient has a diagnosis of dry eye disease as evidenced by at least one diagnostic test (e.g., Tear Film Break Up Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient has tried and failed or had an adverse event to a two week course of generic loteprednol 0.5% • Patient has tried and failed or had an adverse event to a two week course of at least one low-dose ophthalmic steroid formulation (e.g. Lotemax SM, Inveltys, Alrex, and FML) • Use of Eysuvis will not exceed 14 days per course of therapy for dry eye disease Non-FDA-approved uses are NOT approved, including allergic conjunctivitis and for post-operative use to decrease inflammation PA expires in 6 months. Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Eysuvis will be approved for an additional 6 months if the following is met • The patient has experienced improvement in dry eye signs and symptoms.
• relugolix (Orgovyx) **Luteinizing Hormone-Releasing Hormone Agonists-Antagonists**	Manual PA is required for all new users of relugolix (Orgovyx). Manual PA Criteria: Orgovyx is approved if all criteria are met: • The provider is aware and acknowledges that leuprolide acetate IM (Lupron Depot), leuprolide acetate SQ (Eligard), and degarelix SQ (Firmagon) are available to DoD beneficiaries without requiring prior authorization • Patient is 18 years of age or older • Orgovyx is prescribed by or in consultation with an oncologist or urologist • Patient has advanced prostate cancer • Patient has tried and failed OR is unable to use injectable leuprolide formulations (i.e., subcutaneous injection or implant, subcutaneous injection) Non-FDA-approved uses are not approved including cancers other than prostate cancer, and in women for endometrial thinning, endometriosis, and uterine leiomyomata (fibroids). Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• setmelanotide (Imcivree) **Weight Loss Agents**	Manual PA criteria apply to all new users of Imcivree. Manual PA criteria: Imcivree is approved if all criteria are met: • Patient is 6 yearsof age or older • Patient has a confirmed diagnosis (via genetic testing) of POMC-, PCSK1-, or LEPR-deficiency that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) • Patient and provider agree to evaluate weight loss after 12-16 weeks of treatment. Imcivree should be discontinued if a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential Initial prior authorization expires in 4 months. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Imcivree is approved for 1 year for continuation of therapy if all criteria are met: • The patient has a documented improvement (a decrease from baseline) in at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential. Non-FDA approved uses are NOT approved including Alström Syndrome, Bardet-Biedl Syndrome (BBS), POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity.
• tramadol oral solution (Qdolo) **Narcotic Analgesics & Combinations**	Manual PA criteria apply to all new users of tramadol oral solution (Qdolo). Manual PA Criteria: Qdolo will be approved if all criteria are met: • The provider is aware and acknowledges that several opioid analgesics are available to DoD beneficiaries without requiring prior authorization, including tramadol IR tablets, and codeine with acetaminophen tablets and solution. • Patient is 12 years of age or older • For patients less than 18 years of age, Qdolo will not be approved for pain following tonsillectomy or adenoidectomy • Patient has tried and failed or has a contraindication to liquid acetaminophen • Patient has tried and failed or has a contraindication to liquid ibuprofen • Patient has tried and failed or has a contraindication to tramadol IR tablets Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• pegfilgrastim (Neulasta) • pegfilgrastim (Neulasta Onpro) • pegfilgrastim-bmez (Ziextenzo) • **WBC Stimulants Class: Pegfilgrastim subclass**	**Note that the Manual PA criteria for the Pegfilgrastims was updated to include a trial of Nyvepria before the non-step-preferred products. Updates from the Feb 2021 meeting are in bold.** Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo) Note that Udenyca **and Nyvepria are** available at the Tier 1 copay at the Mail Order and Retail Network pharmacies. Manual PA Criteria: Coverage will be approved if all criteria are met: • Provider acknowledges that pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) **and pegfilgrastim-apgf (Nyvepria)** are the TRICARE preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist or oncologist • For Neulasta OnPro: Patient requires use of an on-body injector because the patient and/or 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) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) • **Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-apfg (Nyvepria) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo)** PA does not expire
New PAs	
• orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte) **Skeletal Muscle Relaxants and Combinations**	Manual PA criteria applies to all new users of orphenadrine-aspirin-caffeine 50 mg-770 mg-60 mg (Norgesic, Orphengesic Forte). Manual PA Criteria: Norgesic, Orphengesic Forte is approved if all criteria are met: • Provider is aware and acknowledges that orphenadrine ER, baclofen, cyclobenzaprine, acetaminophen, and numerous NSAIDs are available to DoD beneficiaries without requiring prior authorization • The provider must explain why the patient requires orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte) and cannot take the available alternatives. Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• levorphanol tartrate tablets **Narcotic Analgesics and Combinations**	Manual PA criteria applies to all new users of levorphanol tartrate tablets. Manual PA criteria: levorphanol tartrate is approved if all criteria are met: • Provider acknowledges that morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/ acetaminophen, and tapentadol IR are available to DoD beneficiaries without requiring prior authorization • Patient has tried and failed at least one of the following short acting opioids: morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, tapentadol IR Non-FDA approved uses are NOT approved. PA does not expire.
Updated PAs	
• fluticasone propionate 93 mcg nasal spray (Xhance) **Nasal Allergy Agents: Corticosteroids**	**<u>Updates from the February 2021 meeting are in bold and strikethrough.</u>** Manual PA criteria apply to all new users of fluticasone propionate 93 mcg nasal spray (Xhance). Manual PA Criteria: Xhance is approved if ALL criteria are met: • **Patient has chronic rhinosinusitis with nasal polyposis confirmed by imaging or direct visualization** • **Patient is 18 years of age or older** • The prescription is written by or in consultation with an allergist, immunologist, pulmonologist, or otolaryngologist • **The symptoms of chronic rhinosinusitis with nasal polyposis are inadequately controlled despite all of the following maximized treatments:** o **Nasal saline irrigation** o **Adequate duration of at least TWO of the following** ▪ **fluticasone propionate (generic Flonase)** ▪ **flunisolide (generic Nasarel)** ▪ **beclomethasone (Beconase AQ, QNASL)** ▪ **budesonide (Rhinocort Aqua, generic)** ▪ **mometasone (Nasonex, generics)** ▪ **nasal corticosteroid irrigation/rinse** ▪ ~~azelastine~~ ▪ ~~ipratropium nasal spray (Atrovent nasal spray)~~ o ~~Patient has tried and failed mometasone (Nasonex) OR beclomethasone (Beconase)~~ Non-FDA-approved uses are NOT approved, including allergic rhinitis Prior Authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• canagliflozin (Invokana) • canagliflozin/metformin (Invokamet, Invokamet XR) • dapagliflozin (Farxiga) • dapagliflozin/metformin (Xigduo XR) • ertugliflozin (Steglatro) **Diabetes Non-Insulin: Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor**	**The criteria below replaces the current SLGT2 inhibitor PA criteria and apply to new users** The previous automation requirements for the SGLT2 inhibitors no longer apply, and will be replaced with the manual PA criteria described below. Manual PA Criteria: Invokana, Invokamet, Farxiga, Xigduo XR, or Steglatro will be approved if all criteria are met: *For all indications :* • The patient is 18 years of age or older • Provider is aware and acknowledges that empagliflozin (Jardiance), empagliflozin/metformin (Synjardy, Synjardy XR) and empagliflozin/linagliptin (Glyxambi) are DoD's preferred SGLT2 inhibitor, and that PA is not required for empagliflozin *For Type 2 Diabetes Mellitus :* • Canagliflozin (Invokana, Invokamet), dapagliflozin (Farxiga, Xigduo XR), or ertugliflozin (Steglatro) are requested to improve glycemic control in patients with T2DM *OR* • Canagliflozin, (Invokana, Invokamet), dapagliflozin (Farxiga, Xigduo XR), or ertugliflozin (Steglatro) are requested to reduce the risk of cardiovascular death in patients with T2DM and established cardiovascular disease • Patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin • Patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, Synjardy XR) and had an inadequate response or experienced significant adverse reactions or have a contraindication. *For Heart Failure with reduced ejection fraction (HFrEF):* • Canagliflozin, (Invokana), dapagliflozin (Farxiga), or ertugliflozin (Steglatro) are requested for reduction in risk of heart failure hospitalization and/or cardiovascular death in patients with heart failure with reduced ejection fraction. • Patient has experienced significant adverse reactions has a contraindication to empagliflozin • Initial prescription is written by or in consultation with a cardiologist • Patient has a documented diagnosis of chronic HF (NYHA II-IV) with a left ventricular ejection fraction (LVEF) ≤ 40% and with continued heart failure symptoms • Patient is receiving appropriate guideline-directed medical therapy including the following: angiotensin-converting enzyme inhibitor (ACEI), angiotensin II receptor blocker (ARB), or angiotensin receptor neprilysin inhibitor(ARNI); beta blocker; and aldosterone antagonist, unless contraindicated or if the patient has experienced adverse effects or could not tolerate these therapies *For Chronic Kidney Disease (CKD):* • Canagliflozin, (Invokana, Invokamet), dapagliflozin (Farxiga, Xigduo XR), or ertugliflozin (Steglatro) are requested to reduce kidney disease progression and improve cardiovascular outcomes in patients with CKD. • Patient has experienced significant adverse reactions or has a contraindication to empagliflozin • Initial prescription is written by or in consultation with a nephrologist • Patient's estimated glomerular filtration rate (eGFR) is higher than 25 ml/min/1.73m2 AND the Urinary Albumin-to-Creatinine Ratio is greater than or equal to 200 mg/gram • Patient is receiving maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB), or is unable to use an ACEI or ARB Non-FDA-approved uses are not approved, including type 1 diabetes mellitus, heart failure with preserved ejection fraction, or acute decompensated heart failure Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• mometasone/formoterol (Dulera) • budesonide/formoterol (Symbicort) **Pulmonary I Agents – Combinations**	**Updates from the February 2021 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Symbicort and Dulera Note: fluticasone/salmeterol (Advair Diskus/Advair HFA) is DoD's preferred ICS/LABA and is available without a PA. Automated PA criteria: Symbicort or Dulera is approved if: • The patient has filled a prescription for Advair Diskus or Advair HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. OR • The patient is 12 years of age and younger (age edit) Manual PA criteria: Symbicort or Dulera is approved (i.e., trial of Advair Diskus or Advair HFA is NOT required) if one of the options below applies: • Use of formulary agents (Advair Diskus and Advair HFA) is contraindicated • Patient has experienced significant adverse effects from Advair that is not expected to occur with the non-formulary ICS/LABA medication • Formulary agents (Advair Diskus and Advair HFA) result or are like to result in therapeutic failure • Patient previously responded to non-formulary agent and changing to a formulary agent (Advair Diskus and Advair HFA) would incur unacceptable risk • The patient has asthma and requires rescue therapy **or intermittent and daily ICS-LABA therapy** with an ICS-formoterol combination ~~in accordance with GINA Strategy~~ o ~~Symbicort: patient requires an MDI because they have decreased~~ inspiratory effort and cannot use a DPI (Advair Diskus) o ~~Breo Ellipta: patient has complicated drug regimen and requires once daily dosing~~ Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• risdiplam (Evrysdi) **Neurological Agents Miscellaneous**	**Updates from the February 2021 meeting are in strikethrough.** Manual PA criteria applies to all new users of risdiplam (Evrysdi). Manual PA Criteria: Evrysdi is approved if all criteria are met: • ~~The patient is between the ages of 2 months to 25 years of age (Fill-in-the-blank)~~ • The drug is prescribed by a pediatric or adult neurologist • Patient has genetic confirmation of homozygous deletion or compound heterozygosity predictive of loss of function of the SMN1 gene (documentation required) • Patient has confirmation of at least two SMN2 gene copies (documentation required) • Patient has a confirmed diagnosis of Spinal Muscular Atrophy Types 1, 2, or 3 (Fill-in-the-blank) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients of childbearing potential have been counseled to use effective contraception during treatment and for at least 1 month after the cessation of therapy • Male patients of reproductive potential are counseled about the potential effects on fertility • Patient does not have evidence of hepatic impairment • Patient does not have permanent ventilator dependence • Patient does not have complete paralysis of all limbs • Evrysdi will not be used concurrently with Spinraza (nusinersen injection for intrathecal use) • Patient weight must be documented (Fill-in-the-blank) – (Any answer acceptable) • Patient dose in total mg/day and mg/kg per day must be documented (Fill-in-the blank) ▪ The dose must be 0.2 mg/kg if the patient is 2 months to < 2 years of age; OR 0.25 mg/kg for patients ≥ 2 years of age who weigh < 20 kg; OR 5 mg for patients ≥ 2 years of age who weigh ≥ 20 kg Non-FDA-approved uses are not approved. Prior authorization expires in 6 months. Renewal criteria: (Initial TRICARE PA approval is required for renewal) • According to the prescriber, the patient's level of disease has improved or stabilized to warrant continuation on Evrysdi as determined by an objective measurement and/or assessment tool and/or clinical assessment of benefit. (documentation required) Renewal criteria expires in 1 year.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• anakinra (Kineret)
 	
Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors
	Updates from the February 2021 meeting are in bold.
	
	Manual PA criteria applies to all new users of anakinra (Kineret).
	
	Manual PA Criteria: Kineret is approved if all criteria are met:
	• Patients ≥ 18 years with moderate to severe active rheumatoid arthritis OR
	• Pediatric patients (all ages) with:
	  • Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryopyrin Associated Period Syndrome (CAPS). (Trial of Humira not required).
	  • Systemic Juvenile Idiopathic Arthritis (sJIA) (Trial of Humira not required).
	  • **Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (Trial of Humira not required).**
	• Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications
	• The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent
	• The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])
	• The patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)
	• Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya)**, risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER)**
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• belimumab (Benlysta)
 	
Immunosuppressives
	Updates from the February 2021 meeting are in bold and strikethrough.
	
	Manual PA Criteria apply to all new users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta
	
	Manual PA criteria: Coverage is approved for Benlysta if all of the following are met:
	• Benlysta is prescribed by or in consultation with a specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist
	• **The patient is 18 years of age or older for active lupus nephritis** or the patient is 5 years of age or older for SLE
	• **Must of one of the following documented diagnoses**:
	  • Active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE
	  • **Class III, IV, or V active lupus nephritis**
	• For SLE, the patient is concurrently taking standard therapy (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)
	• **For active lupus nephritis, patient is concurrently receiving either mycophenolate mofetil or cyclophosphamide followed by azathioprine**
	• The patient does not have ~~severe active lupus nephritis~~ or severe active central nervous system lupus
	• The patient is not taking concomitant biologics (e.g., rituximab) ~~and/or intravenous cyclophosphamide~~
	
	Off-label uses are not approved
	
	Prior Authorization expires in **2 years**.
	
	Renewal PA Criteria: Benlysta will be approved on a yearly basis if all of the following are met:
	• For SLE, treatment with Benlysta has shown documented clinical benefit (i.e., improvement in number/frequency of flares, improvement in in Safety of Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.)
	• The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)
	• The patient does not have ~~severe active lupus nephritis or~~ severe active central nervous system lupus
	
	The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• elexacaftor/tezacaftor/ivacaftor (Trikafta) **Cystic Fibrosis Agents**	**Updates from the February 2021 meeting are in bold and apply to new patients.** Manual PA criteria applies to all new users of elexacaftor/tezacaftor/ivacaftor (Trikafta). Manual PA Criteria: Trikafta is approved if all criteria are met: • Prescribed for the treatment of cystic fibrosis (CF) for an FDA approved age • Prescribed by or in consultation with a pulmonologist • Patient has at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test **OR a mutation in the CFTR gene that is responsive based on *in vitro* data AND if the genotype is unknown, an FDA-approved test should be used to detect the presence of at least one *F508del* mutation or a mutation that is responsive based on *in vitro* data** • Not approved in combination therapy with Kalydeco, Symdeko, or Orkambi Non-FDA-approved uses are not approved. Prior authorization does not expire.
• ivacaftor (Kalydeco) **Cystic Fibrosis Agents**	**Updates from the February 2021 meeting are in bold and strikethrough and apply to new patients.** Manual PA Criteria: Kalydeco is approved if all criteria are met: • Prescribed for the treatment of cystic fibrosis (CF) for an FDA approved age • **Prescribed by or in consultation with a pulmonologist** • Patient ~~is not homozygous for the *F508del* mutation in the~~ **has one mutation in the** cystic fibrosis transmembrane conductance regulator (CFTR) gene **that is responsive to Kalydeco potentiation based on clinical and/or *in vitro* assay data** AND **if the genotype is unknown,** ~~patient has a specific CF-related gene mutation that has been detected by~~ an FDA-approved test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use • Not approved in combination therapy with Symdeko, Orkambi, or Trikafta • ~~What is the gene mutation? (fill in the blank)~~ Non-FDA-approved uses are not approved. Prior authorization does not expire.
• tezacaftor/ivacaftor (Symdeko) **Cystic Fibrosis Agents**	**Updates from the February 2021 meeting are in bold and strikethrough and apply to new users** Manual PA Criteria: Symdeko is approved if all criteria are met: • Prescribed for the treatment of cystic fibrosis (CF) for an FDA approved age • **Prescribed by or in consultation with a pulmonologist** • Patient is homozygous for the *F508del* mutation **OR have at least one mutation** in the cystic fibrosis transmembrane conductance regulator (CFTR) gene **that is responsive to Symdeko potentiation based on *in vitro* data and/or clinical evidence AND if the genotype is unknown, an FDA-approved test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use** • ~~Please enter the CF-related gene mutation based on FDA-approved testing (fill in blank)~~ • Not approved in combination therapy with Kalydeco, Orkambi, or Trikafta • ~~What is the gene mutation? (fill in the blank)~~ Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• ixazomib (Ninlaro)
 	
Oncological Agents: Multiple Myeloma
	Updates from the February 2021 meeting are in bold.
	
	Manual PA criteria applies to all new users of ixazomib (Ninlaro).
	
	Manual PA Criteria: Ninlaro is approved if all criteria are met:
	• Patient is greater than or equal to 18 years of age
	• Must be prescribed by or in consultation with a hematologist or oncologist
	• Patient is diagnosed with:
	  • Multiple myeloma AND patient must not have progressed on bortezomib NOR carfilzomib – containing regimen OR One or more of the following:
	  • Patient must have failed or not be a candidate for bortezomib AND carfilzomib
	  • Patient has failed or is not a candidate for carfilzomib and has high risk cytogenetics
	  • Patient will be starting ixazomib as third (or higher) line of therapy
	  • Must be used in combination with lenalidomide, pomalidomide, OR thalidomide
	  • Must be used in combination with dexamethasone
	OR
	  • **Multiple myeloma and has received hematopoietic cell transplant (HCT) AND patient will receive Ninlaro as maintenance therapy following primary therapy and HCT**
	• Must not be used concurrently with bortezomib NOR carfilzomib OR
	• The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____
	
	Other Non-FDA-approved uses are not approved, except as noted above
	Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• neratinib (Nerlynx) **Oncological Agents: Breast Cancer**	**Updates from the February 2021 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of neratinib (Nerlynx). Manual PA Criteria: Nerlynx is approved if all criteria are met: • Patient is greater than or equal to 18 years of age • Patient has early stage HER2-overexpressed/amplified breast cancer AND • Following adjuvant trastuzumab based therapy (preferably less than 1 year, but no more than 2 years after completion) OR • **Patient has advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer AND** • **Used in combination with capecitabine AND** • **Patient has received two or more prior anti-HER2-based regimens in the metastatic setting OR** • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis:_____AND • Counseled on significant adverse event profile AND • Co-prescribed antidiarrheal to mitigate for at a minimum 2 months AND • Counseled on possibility of unproven survival benefit gain • ~~Note: Place the following wording on the PA: This PA will expire in 18 months, NO renewal allowed, patient should not take more than 365 day lifetime supply~~ Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire ~~expires after 18 months; No renewal allowed~~.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• selinexor (Xpovio) **Oncological Agents: Multiple Myeloma**	**Updates from the February 2021 meeting are in bold.** Manual PA criteria applies to all new users of selinexor (Xpovio). Manual PA Criteria: Xpovio is approved if all criteria are met: • Patient is greater than or equal to 18 years of age • Prescribed by or in consultation with an oncologist • Patient has: ◦ relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody AND patient will use Xpovio in combination with dexamethasone OR ◦ relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy OR ◦ **Multiple myeloma who have received at least one prior therapy AND patient will use Xpovio in combination with bortezomib and dexamethasone OR** ◦ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ • Patient will be monitored for cytopenias including anemia, neutropenia, and thrombocytopenia • Patients will be monitored for electrolyte disturbances including hyponatremia and hypokalemia • Patients will be monitored for infection including upper respiratory infection and pneumonia • Patients will be monitored for dizziness and altered mental status • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • All patients (females AND males) of reproductive potential will use effective contraception during treatment and for at least 1 week after discontinuation Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	**Updates from the February 2021 meeting are in bold.** Manual PA criteria apply to all new and current users of Saxenda. Manual PA Criteria—Saxenda is approved if ALL of the following criteria are met: • **Patient is 12 years of age or older Or** • **Patient is 16 years of age or older and patient has tried and failed generic phentermine or has a contraindication to phentermine (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** • **Phentermine: Date_____Duration of therapy_____Or** • **Patient is 18 years of age or older and patient has tried and failed all of the following (generic phentermine, Qsymia, Xenical, and Contrave) or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** • Phentermine: Date_____Duration of therapy _____ • Qsymia: Date_____Duration of therapy _____ • Xenical: Date_____Duration of therapy _____ • Contrave: Date_____Duration of therapy _____ • If the patient is diabetic, they must have tried and failed metformin and the preferred GLP1-RAs (Bydureon and Trulicity) **All of the following criteria apply to patients 12 years of age and older** • Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy AND will remain engaged throughout course of therapy. • Patient is not pregnant. Non-FDA-approved uses are not approved, including Diabetes Mellitus. Prior authorization expires after 4 months and then annually. **Note: Renewal Criteria also applies to patients 12 years of age and older** Renewal PA Criteria: Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• tasimelteon (Hetlioz/Hetlioz LQ) **Sleep Disorders: Insomnia**	**Updates from the February 2021 meeting are in bold.** Manual PA criteria apply to all new users of Hetlioz and **Hetlioz LQ**. Manual PA criteria: Hetlioz or **Hetlioz LQ** is approved if ALL of the following criteria are met: • **For the capsule, the patient is 18 years of age or older and** is totally blind and has a documented diagnosis of non-24 sleep wake disorder **Or** • **For the liquid, the patient is 3 years of age up to 15 years of age and has a documented diagnosis of Smith-Magenis Syndrome (SMS)** • The patient has had a trial of melatonin and either failed or had an adverse event • The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) Non-FDA-approved uses are not approved including **jet lag disorder or other circadian rhythm disorders.** **Note: Hetlioz capsules are not approved for pediatrics or adolescents and is not approved for SMS. Hetlioz LQ is only approved for pediatrics with SMS and is not approved for Non-24 or for used in adults.** PA Criteria will expire after 6 months (if patient has not responded after 6 months, they will be deemed a non-responder)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• pitolisant (Wakix) **Sleep Disorders: Wakefulness-Promoting Agents**	**Updates from the February 2021 meeting are in bold.** Manual PA is required for all new users of Wakix. Manual PA Criteria: Wakix is approved if all criteria are met: • **Provider acknowledges that PA is not required for modafinil or armodafinil.** • Patient is 18 years of age of older • Wakix is not approved for use in children, adolescents, or pregnant patients. • Patient has a documented diagnosis of excessive daytime sleepiness associated with **one of the following**: ▪ narcolepsy and an Epworth Sleepiness Scale (ESS) score ≥ 14 and narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing ▪ **cataplexy and an Epworth Sleepiness Scale (ESS) score of ≥ 12 and at least 3 cataplexies per week** • Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Patient is not concurrently taking any of the following: ▪ Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • Patient must have tried and failed and had an inadequate response to modafinil • Patient must have tried and failed and had an inadequate response to armodafinil • Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient does not have a history of severe hepatic impairment • Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, cataplexy, obstructive sleep apnea, major depression, ADHD, or shift work disorder). PA expires in 1 year. Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.

Drug / Drug Class	Quantity Limits
• abemaciclib (Verzenio) • palbociclib (Ibrance) • ribociclib (Kisqali) • ribociclib/letrozole (Kisqali Femara Co-Pack) **Breast Cancer Agents: Cyclin-Dependent Kinase Inhibitors Subclass**	▪ Retail/Mail/MTF: 28 day supply Note that implementation will occur 30 days after signing of the minutes.
• budesonide/formoterol fumarate/ glycopyrrolate (Breztri Aerosphere) • fluticasone /umeclidinium/vilanterol (Trelegy Ellipta) **Pulmonary-3 Agents: Combinations Subclass**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill Note: no change to current status
• hydrocortisone oral sprinkle (Alkindi Sprinkle) **Corticosteroids-Immune Modulators**	▪ Retail/MTF/Mail: 30 day supply
• lonafarnib (Zokinvy) **Metabolic Agents-Miscellaneous**	▪ Retail/MTF/Mail: 30 day supply
• setmelanotide (Imcivree) **Weight Loss Agents**	▪ Retail/MTF/Mail: 30 day supply
• berotralstat (Orladeyo) **Corticosteroids-Immune Modulators: Hereditary Angioedema Agents**	▪ Retail: 28 tabs per fill ▪ MTF/Mail: 84 tabs per fill
• clascoterone 1% cream (Winlevi) **Acne Agents: Topical Acne and Rosacea**	▪ Retail: 1 tube/30 days ▪ MTF/Mail: 3 tubes/90 days
• sofosbuvir/velpatasvir (Epclusa) **Hepatitis C Agents: Direct Acting Agents**	▪ Retail/MTF/Mail: 28 day supply
• fidaxomicin oral suspension (Dificid) **Gastrointestinal-2 Agents: Miscellaneous**	▪ Retail/MTF/Mail: 1 bottle per fill ▪ Note if provider determines that there are circumstances that may qualify for patient to receive additional quantities, the provider may request coverage review through prior authorization

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
berotralstat (Orladeyo) Corticosteroids-Immune-modulators: Hereditary Angioedema Agents	• C1-INH, Pd (Cinryze) • C1-INH, Pd (Haegarda) lanadelumab-flyo (Takhzyro)	• 110 mg, 150 mg oral capsules • Once daily	To prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older	• Orladeyo is the 3rd kallikrein inhibitor for HAE and the first oral prophylaxis agent for treating HAE • Takhzyro and Orladeyo are both kallikrein inhibitors approved for prophylaxis, but are injections. Kalbitor is a medical benefit agent for treatment of acute HAE attacks. • Orladeyo showed a statistically significant and clinically relevant moderate benefit in reducing monthly HAE attack rates • Orladeyo offers a significant advantage for patient convenience as the first oral agent for HAE prophylaxis, however indirect comparison shows that the clinical efficacy is moderate compared to other prophylaxis agents	• UF • Do not add to EMMI list
calcipotriene/ betamethasone dipropionate 0.005%/0.064% topical cream (Wynzora) Psoriasis Agents	• Calcipotriene 0.005%-betamethasone DP 0.064% (Taclonex) ointment • Calcipotriene 0.005%-betamethasone DP 0.064% (Enstilar) foam • Any topical vitamin D analogue used with any topical high-potency corticosteroid	• Applied once daily for up to 8 weeks (maximum 100 g/week)	Topical treatment of plaque psoriasis in patients 18 years and older	• Wynzora is a topical combination of calcipotriene and betamethasone cream approved for plaque psoriasis • Wynzora offers no therapeutic advantages over individual calcipotriene and a high-potency topical corticosteroid used concurrently other than patient convenience • Of note, calcipotriene (Dovonex) 0.005% cream is BCF • Wynzora is 10th agent in class offering little to no therapeutic advantage over already-existing agents (which include 2 combination products)	• Tier 4/Not covered

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
clascoterone 1% cream (Winlevi) Acne Agents: Topical Acne and Rosacea	• spironolactone • tretinoin cream • clindamycin/ benzoyl peroxide gel	• 1% cream given as 1 application (1 gram) BID	Topical treatment of acne vulgaris in patients ≥ 12 years old	• Winlevi is the 1st topical antiandrogen indicated for the treatment of acne vulgaris and is also approved for use in males • Winlevi was compared to vehicle and showed statistically significant treatment benefit • No head to head studies with other therapies • No current guideline recommendations on topical antiandrogen therapy • Numerous topical agents available for acne • Providers recommend trying other topical acne drugs first • Winlevi is the first topical antiandrogen for the treatment of acne, but offers no additional benefit relative to existing formulary agents	• NF • Add to EMMI list
clobetasol propionate 0.05% lotion metered dose pump (Impeklo) Corticosteroids-Immune Modulators: High Potency	• Other high-potency topical corticosteroids	• Applied BID for up to 2 weeks; maximum dose 50 g/week	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years and older	• Impeklo is a new formulation of clobetasol propionate 0.05% lotion in a metered dose pump • No new clinical data, 24 alternative formulary agents available, and 11 scalp-friendly formulary options • Lotions already in category of efficient vehicles; i.e., metered dose pump offers little to no value • Impeklo provides no advantages in efficacy relative to existing topical high-potency topical corticosteroids and provides little to no clinical benefit relative to existing formulary agents	• Tier 4/Not covered
hydrocortisone oral sprinkle (Alkindi Sprinkle) Corticosteroids-Immune Modulators	• hydrocortisone tablets	• Oral granules contained in capsules • 50 caps/bottle • 0.5, 1, 2, 5 mg	Replacement therapy in pediatrics with adrenocortical insufficiency	• Alkindi Sprinkle is another formulation of hydrocortisone indicated for replacement therapy in pediatric patients with adrenocortical insufficiency • Alkindi Sprinkle was evaluated in 1 uncontrolled, open-label, single arm study in 18 pediatric patients • This drug offers no advantages in clinical efficacy relative to existing hydrocortisone formulations on the formulary • Other than availability of lower strengths, Alkindi provides little to no clinical benefit relative to existing formulary agents	• UF • Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
lonafarnib (Zokinvy) Metabolic Agents-Miscellaneous	• None	• Capsules: 50 mg, 75 mg • First 4 months: 115 mg/m^2 BID with morning and evening meals • After 4 months: 150 mg/m^2 BID with morning and evening meals	• Reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS) Treatment of processing-deficient Progeroid Laminopathies	• Zokinvy is the first approved treatment for Hutchinson-Gilford Progeria Syndrome and some Progeroid Laminopathies • Zokinvy was evaluated in two phase 2 trials • Mortality was statistically lower in treated patients vs untreated patients • Most common ADRs included nausea, vomiting, diarrhea, infection, decreased appetite and fatigue • Contraindications include use with strong or moderate CYP3A inhibitors or inducers, midazolam, lovastatin, simvastatin, and atorvastatin • Additional safety concerns include periodic monitoring of electrolytes, CBCs, liver function, renal function, and ophthalmological evaluations • Zokinvy provides the first treatment option for a rare disease	• UF • Do not add to EMMI list
loteprednol 0.25% ophthalmic solution (Eysuvis) Ophthalmic: Corticosteroids	• loteprednol 0.5% gel, ointment, or suspension (Lotemax, generics) • loteprednol 0.38% gel (Lotemax SM) • loteprednol 1% suspension (Inveltys) • loteprednol 0.2% suspension (Alrex, generics) • fluoromethalone (Flarex, FML)	• 0.25% ophth susp • 1gtt QID	Short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease	• 5th loteprednol product approved for treating inflammatory conditions • Eysuvis is the first ophthalmic steroid with an FDA approved indication for short-term treatment of dry eye • Guidelines recommend short courses of up to 2 weeks for treating dry eye disease • Loteprednol has evidence to show that it can be effective for treating dry eye disease for short durations but is not limited to Eysuvis • Providers agree that there are other available alternative low-dose ophthalmic steroids that can be used for dry eye • Eysuvis provides little to no clinical benefit over other ophthalmic steroid products	• NF • Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
pegfilgrastim-apgf (Nyvepria) White Blood Cell Stimulants	• Neulasta • Udenyca • Fulphila • Ziextenzo	• 6 mg/0.6 mL prefilled, syringe for subcutaneous use administered once per chemotherapy cycle	Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs	• Nyvepria is the 4th biosimilar to Neulasta and 9th agent in the white blood cell stimulant subclass • No new clinical data • Nyvepria provides no compelling clinical advantages over existing pegfilgrastim formulary agents	• UF, step preferred • Do not add to EMMI list • Tier 1 copay
relugoli (Orgovyx) Luteinizing Hormone-Releasing Hormone Agonists-Antagonists	• leuprolide acetate (Lupron Depot, Eligard) • degarelix SQ (Firmagon) Medical benefit: • goserelin SQ implant (Zoladex) • histrelin SQ implant (Vantas) • triptorelin IM (Trelstar Mixject)	• Available as 120 mg oral tablets • Dosed as 360 mg loading dose on the first day followed by 120 mg dose once a day	Treatment of adult patients with advanced prostate cancer	• Orgovyx is the 1st oral gonadotropin-releasing hormone (GnRH) drug approved for adult patients with advanced prostate cancer • Efficacy based on one open-label study comparing Orgovyx (GnRH antagonist) to leuprolide acetate (GnRH agonist) • Orgovyx met the primary endpoint of lowering testosterone levels to castration levels and maintaining for 48 weeks • No surge of testosterone levels with Orgovyx compared with leuprolide • Adverse events were similar to leuprolide • MACE = nonfatal MI, nonfatal stroke, and death from any cause were lower with Orgovyx (2.9%) vs leuprolide (6.2%) • Offers convenience of an oral tablet with once daily dosing, after a loading dose • Several alternative agents are available, but require injections • Place in therapy remains to be determined	• NF • Add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
setmelanotide injection (Imcivree) Weight Loss Agents	• None	• Multidose vial • 2 mg (0.2 mL) SubQ once daily x 2 weeks, then titrate up or down as tolerated • Max 3 mg SubQ daily • Start at 1 mg SubQ once daily for pediatrics •	Approved for rare forms of obesity • Proopiomelano-cortin (POMC) deficiency • Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency Leptin receptor (LEPR) deficiency	• Imcivree is a newly approved agent with a novel mechanism approved for rare forms of obesity in adults and peds 6 years and older • Genetic testing is required for diagnosis • FDA-Approved indications include ▪ proopiomelanocortin (POMC) deficiency ▪ proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency ▪ leptin receptor (LEPR) deficiency • Setmelanotide is a melanocortin 4 (MC4) receptor agonist • Imcivree is not approved for benign or likely-benign receptor variants • Imcivree is the first approved agent for rare forms of obesity	• UF • Do not add to EMMI list
sodium sulfate/ magnesium sulfate/ potassium chloride (Sutab) Laxatives-Cathartics-Stool Softeners: Bowel Preparations	• OsmoPrep • PEG based preps • Suprep • PrePopik • ClenPiq	• Oral tablets • Day 1 = 12 tabs + 48 ounces water • Day 2 = repeat	Cleansing of colon in preparation for colonoscopy in adults	• 2nd available tablet-based bowel prep • Similar ingredients to Suprep; same manufacturer • Non-inferior efficacy to MoviPrep and PrePopik for bowel cleansing • Sutab compared to OsmoPrep: 24 vs 32 tabs; 2.8 L vs 1.9 L total volume consumed • No compelling clinical advantage relative to existing bowel prep formulary agents	• NF • Do not add to EMMI list
tramadol oral solution (Qdolo) Narcotic Analgesics & Combinations	• acetaminophen solution • Ibuprofen solution • tramadol IR tablets • codeine/APAP solution • hydrocodone/ acetaminophen solution	• Oral solution • 5 mg/mL clear liquid, grape flavor • 473 mL bottle; • 50-100 mg q 4-6 hrs PRN	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	• Qdolo is another formulation of tramadol as an oral solution indicated for management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate • Qdolo was approved based on equivalence to tramadol IR tablets • There are other narcotic analgesics available in alternate dosage forms but have different mechanisms of action and potency • Other than being an alternate dosage form, Qdolo provides little to no compelling clinical advantage over existing agents	• NF • Do not add to EMMI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the February 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)
February 2021	**Pulmonary-3 Agents: Combinations UF (brand maintenance only)** *Maintain current status:* • fluticasone furoate /umeclidinium/vilanterol (Trelegy Ellipta) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending availability at mail:* • clascoterone 1% cream (Winlevi) • relugolix (Orgovyx)	**Breast Cancer Agents: Cyclin-Dependent Kinase Inhibitors UF** *Maintain current status and exempt from EMMPI Program:* • abemaciclib (Verzenio) • palbociclib (Ibrance) • ribociclib (Kisqali) • ribociclib/letrozole (Kisqali Femara Co-Pack) **Pulmonary-3 Agents: Combinations UF** *Maintain current status and exempt from EMMPI Program:* • budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere) *(Note see the August 2021 P&T Committee meeting minutes where Breztri was added to the EMMPI program)* **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Drugs in class not currently represented on EMMPI List (removed Aug 2020 subclass review) due to limited duration use/not maintenance medications*: • pegfilgrastim-apgf (Nyvepria) *Not yet clear if feasible to provide through mail order:* • berotralstat (Orladeyo) • hydrocortisone oral sprinkle (Alkindi Sprinkle) • lonafarnib (Zokinvy) • setmelanotide (Imcivree) **Designated NF:** *Exception due to acute use/limited duration of use and similar agents are not on the list:* • sodium sulfate/magnesium sulfate/potassium chloride (Sutab) • tramadol oral solution (Qdolo) *Exception due to acute use/limited duration of use and more cost advantageous to make exception:* • loteprednol 0.25% ophthalmic solution (Eysuvis) **Line Extensions** **Designated UF** *Drugs for limited duration use and similar agents are not on the list:* • fidaxomicin oral suspension (Dificid) *Similar agents are not on the list:* • sofosbuvir/velpatasvir (Epclusa)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2021	**Breast Cancer Agents – Cyclin-Dependent Kinases (CDK) Inhibitors Subclass**	UF Class Review	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ None			Pending signing of the minutes / 30 days The effective date is March 16, 2022	▪ Updated PA criteria. See Appendix C	
			▪ None Note: CDKI was not selected for the BCF.	▪ palbociclib (Ibrance) ▪ abemaciclib (Verzenio) ▪ ribociclib (Kisqali) ▪ ribociclib/letrozole combo pack (Kisqali Femara Co-Pack)	▪ None			
Feb 2021	**Pulmonary III Agents: Combinations**	UF Class Review	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** • None			Pending signing of the minutes/2 weeks The effective date is March 2, 2022	▪ QLs updated. See Appendix D	N/A
			▪ None	▪ fluticasone/umeclidinium/vilanterol (Trelegy Ellipta) ▪ budesonide/glycopyrrolate/formoterol (Breztri Aerosphere)	▪ None			

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives (Last 12 months)*†

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2021	Corticosteroids -Immune Modulators: High Potency	• clobetasol propionate 0.05% lotion metered dose pump (Impeklo)	• betamethasone/propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % (emulsion) foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• June 15, 2022
Feb 2021	Psoriasis Agents	• calcipotriene/ betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora)	• vitamin D analog (calcipotriene 0.005% cream, ointment or solution) with a high potency topical corticosteroid (clobetasol propionate 0.05% ointment, cream, solution and gel • fluocinonide 0.05% cream, gel, and solution • calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary]	• June 15, 2022
Nov 2020	Attention-Deficit/ Hyperactivity Disorder (ADHD) Agents: Stimulants	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	• budesonide ER 9 mg capsules (Ortikos)	• budesonide ER tablets (Entocort EC, generics) • other corticosteroids	• June 2 2021
Nov 2020	Corticosteroids	• dexamethasone 20 mg tables (Hemady)	• dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	• fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler)	• fluticasone (Flovent Diskus) • fluticasone (Flovent HFA) • fluticasone furoate (Arnuity Ellipta) [non formulary] • beclomethasone (QVAR) [non formulary] • budesonide (Pulmicort Flexhaler) [non formulary] • ciclesonide (Alvesco) [non formulary] • flunisolide (Aerospan) [non formulary] • mometasone (Asmanex Twisthaler [non formulary]	• June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	• fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler)	• fluticasone/salmeterol (Advair Diskus) • fluticasone/salmeterol (Advair HFA) • fluticasone/vilanterol (Breo Ellipta) [non formulary] • mometasone/formoterol (Dulera) [non formulary] • budesonide/formoterol (Symbicort) [non formulary] • fluticasone/salmeterol (AirDuo Respiclick) [non formulary]	• June 2 2021
Nov 2020	Calcium Channel Blockers	• levamlodipine (Conjupri)	• amlodipine • felodipine • nifedipine • diltiazem • verapamil	• June 2 2021
Nov 2020	GI-2 Agents	• metoclopramide nasal spray (Gimoti)	• metoclopramide oral tablet (Reglan generics) • metoclopramide oral solution (Reglan, generics) • metoclopramide orally disintegrating tablet (Reglan ODT)	• June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	• calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic)	*Scalp Psoriasis:* • calcipotriene 0.005% solution • clobetasol 0.05% solution, shampoo • fluocinonide 0.05% solution • calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] *Psoriasis involving areas other than the scalp:* • calcipotriene 0.005% ointment, cream, solution • clobetasol 0.05% ointment, cream • fluocinonide 0.05% cream, ointment	• February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	• halcinonide 0.1% topical solution (Halog)	• betamethasone propylene glycol 0.05% cream • clobetasol propionate 0.05% cream and ointment • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream and ointment • fluocinonide 0.05% cream and ointment • fluocinonide/emollient base 0.05% cream • halobetasol propionate 0.05% ointment	• February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	• tazarotene 0.045% lotion (Arazlo)	• adapalene 0.1% lotion, gel, cream • adapalene 0.3% gel • clindamycin phosphate 1% gel, cream, lotion, and solution • clindamycin/ benzoyl peroxide 1.2% - 5% gel • tazarotene 0.1% cream • tretinoin 0.025%, 0.05%, and 0.1% cream • tretinoin 0.01% and 0.025% gel	• February 24, 2021
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			

* 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, based on an interim final rule published on December 11, 2018. https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service**.**

† For a cumulative list of previous Tier 4 recommendations, refer to the November 2020 DoD P&T Committee minutes, found at health.mil/pandt

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
OTC Nasal Cold and Allergy Products		
February 2021	**Retain these GCNs:** • 34062 – oxymetazoline 0.05% spray (e.g., Afrin) • 36878 – sodium chloride, bicarbonate /squeeze bottlepack w/dev (e.g., Ayr, Neilmed Sinus) • 24904 – sodium chloride/sodium packet bicarb (e.g., Ayr, Neilmed Sinus Rinse) • 34300 – sodium chloride 0.65% drops (e.g., Ayr Saline, Baby Ayr Saline) • 34291 – sodium chloride 0.65% spray (e.g., Ayr Saline, Deep Sea, Ocean)	**Remove these GCNs:** • 40708 – budesonide 32 mcg spray(e.g., Rhinocort) • 37683 – fluticasone propionate 50 mcg spray susp (e.g., Flonase allergy) • 46790 – cromolyn sodium 5.2 mg spray (Nasalcrom) • 34182 – phenylephrine 0.125% drops (e.g., Little Noses) • 34122 – phenylephrine 0.25% spray (e.g., Neo-synephrine) • 34123 – phenylephrine 0.5% spray (e.g., Neo-synephrine)

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

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
ACC	American College of Cardiology	MHS	Military Health System
ADR	Adverse reaction	MN	Medical Necessity
AE	Adverse event	MTF	Military Treatment Facility
AHA	American Heart Association	NAEPP	National Asthma Education and Prevention Panel
BCF	Basic Core Formulary	NAEPPCC	National Asthma Education and Prevention Panel Coordinating Committee
BIA	Budget impact analysis	NCCN	National Comprehensive Cancer Network
BSA	Body surface area	NDAA	National Defense Authorization Act
CDK	Cyclin-Dependent Kinase	NDC	National Drug Codes
CFR	Code of Federal Regulations	NOMID	Neonatal-Onset Multisystem Inflammatory Disease
CMA	Cost minimization analysis	ODT	Orally Disintegrating Tablet
COPD	Chronic obstructive pulmonary disease	ORR	Objective response rate
CV	Cardiovascular	OTC	Over the counter
DHA	Defense Health Agency	PA	Prior authorization
DIRA	Deficiency of Interleukin-1 Receptor Antagonist	PCSK1	Proprotein convertase subtilisin/kexin type 1
DoD	Department of Defense	PFS	Progression free survival
DR	Delayed release	POD	Pharmacy Operations Division
ECF	Extended Core Formulary	POMC	proopiomelanocortin
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	POS	Point of service
ER	Extended release	PPI	Proton Pump Inhibitor
FDA	U.S. Food and Drug Administration	PRN	As needed
GINA	Global Initiative for Asthma	QL	Quantity limits
GOLD	Global Initiative for Chronic Obstructive Lung Disease	SC	Subcutaneous
HAE	Hereditary angioedema	SGLT2	Sodium-Glucose Co-Transporter 2
HCT	Hematopoietic cell transplant	SGRQ	Saint George Respiratory Questionnaire
HER2 (-)	Human epidermal growth factor receptor 2-negative breast cancer	SMA	Spinal muscular atrophy
HFrEF	Heart failure with reduced ejection fraction	SMS	Smith-Magenis Syndrome
HR(+)	Hormone receptor positive breast cancer	SMN2	Survival of motor neurons 2
ICS	Inhaled Corticosteroid	SLE	Systemic lupus erythematosus (SLE)
LABA	Long-acting beta agonist	T2DM	Type 2 diabetes mellitus
LAMA	Long-acting muscarinic antagonist	TIB	Targeted Immunomodulatory Biologics
LEPR	leptin receptor	VTE	Venous thromboembolism
LHRH	luteinizing hormone-releasing hormone		