DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2020

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on May 6, 2020. 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 February 2020 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the February 2020 DoD P&T Committee meeting on April 27, 2020.

2. **Clarification of Previous Minutes**

   a) **May 2019 and November 2019 Meetings—Rapid Acting Insulins (RAI): Authorized generic insulin lispro PA criteria:** Prior authorization (PA) criteria for authorized generic insulin lispro requiring a trial of Humalog first were recommended at the May 2019 P&T Committee meeting. The PA was recommended for removal at the November 2019 meeting during the RAI class review, with an implementation date of July 1 2020. Due to significant price reductions in the authorized generic insulin lispro, the PA was removed on April 21, 2020.

   b) **November 2019 Meeting—Hematological Agents: Platelets: avatrombopag (Doptelet) Quantity Limits (QLs):** Avatrombopag was previously approved for pre-procedure use with a 5-day supply QL at all Points of Service (POS). It was subsequently approved for treating idiopathic thrombocytopenia (ITP) and the QLs were increased for this indication. However, QLs for avatrombopag will be set at a 30-day supply at all POS, since the QLs could not be operationalized by indication.

   c) **February 2020 Meeting—MHS GENESIS OTC Test List implementation:** Starting with the February 2020 meeting, the implementation for any added GCNs will occur on signing, with the deletions occurring at 120 days. This will help alleviate situations where existing MHS GENESIS sites need to change from one product to another quickly.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2020 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 (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
  - antihemophilic factor (recombinant) glycoPEGylated-exei (Esperoct) injection – Antihemophilic Factor; new recombinant pegylated formulation of factor VIII
  - avapritinib (Ayvakit) – Oncological agent for gastrointestinal stromal tumors (GIST)
  - cenobamate (Xcopri) – Anticonvulsants-Antimania Agents; for partial-onset seizures
  - diazepam nasal spray (Valtoco) – Anticonvulsants-Antimania Agents; new nasal spray formulation of diazepam for seizures
  - metformin ER suspension (Riomet ER) – Diabetes Non-Insulin Drugs, Biguanides; new extended-release oral suspension formulation of metformin
  - peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia) – Miscellaneous Immunologic Agent for peanut allergy
  - rimegepant orally disintegrating tablet (Nurtec ODT) – Migraine agent for acute treatment of migraine
  - tazemetostat (Tazverik) – Oncological agent for epithelioid sarcoma

- NF:
    - bempedoic acid (Nexletol) – Antilipidemic I (LIP-1) approved as an adjunct to a statin to reduce low density lipoprotein (LDL) cholesterol
    - cetirizine 0.24% ophthalmic solution (Zerviate) – Ophthalmic Allergy Drugs; new ophthalmic formulation of cetirizine
    - lasmiditan (Reyvow) – Migraine Agent for acute treatment of migraine
    - lumateperone (Caplyta) – Atypical Antipsychotic for schizophrenia
    - teriparatide (Bonsity) injection – Osteoporosis Agents: Parathyroid Hormone, a biosimilar of Forteo for osteoporosis
    - ubrogepant (Ubrelvy) – Migraine Agent for acute treatment of migraine

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Bonsity, Caplyta, Nexletol, Reyvow, Ubrelvy, and Zerviate. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Applying the same manual PA criteria to new and current users of Bonsity that currently applies to Forteo and Tymlos.
- Applying manual PA criteria to new and current users of Reyvow and Zerviate.
- Applying manual PA criteria to new users of Ayvakit, Caplyta, Nexletol, Nurtec ODT, Palforzia, Tazverik, and Ubrelvy.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service, on August 5th, 2020.

V. UTILIZATION MANAGEMENT

A. Quantity Limits

1. General QLs: QLs were reviewed for eight newly approved drugs from drug classes where there are existing QLs, including the anticonvulsants-antimania agents, immunological agents miscellaneous, migraine agents, oncological agents, and osteoporosis agents.

COMMITTEE ACTION: QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for Ayvakit, Bonsity, Nurtec ODT,

Palforzia, Reyvow, Tazverik, Ubrelvy, and Valtoco. See Appendix D for the QLs.

B. QLs Implementation Periods

1. ***COMMITTEE ACTION: QLs IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for the eight drugs listed above and in Appendix D become effective the first Wednesday 2 weeks after signing of the minutes in all POS.

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

A. 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 May 2020 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 May 2020 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 (16 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI List for the reasons outlined in the table. See Appendix F.

VII. ITEM FOR INFORMATION

Veteran's Administration Continuity of Care List

The P&T Committee was briefed on the updated DoD/VA Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715. Additions, deletions, and clarifications to the list were based on FY19 Active Duty prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The updated list will be posted on www.health.mil when finalized.

VIII. ADJOURNMENT

The meeting adjourned at 1400 hours on May 6, 2020. The next meeting will be in August 2020.

Appendix A—Attendance: May 2020 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 during the May 2020 DoD P&T Committee Meeting
Appendix G—Tier 4/Not Covered Drugs and Therapeutic Alternatives
Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

Mr. Guy Kiyokawa
Deputy Director, DHA
for Ronald J. Place
LTG, MC, USA
Director

24 July 20
Date

Appendix A—Attendance: May 2020 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	Chief, DHA Pharmacy Operations Division (POD)
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder) POD
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
CDR Peter Cole, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Christopher Janik 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 Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Eugene Moore, PharmD, BCPS, for CDR Eric Parsons, MSC	COR Tricare Pharmacy Program

Appendix A—Attendance (continued)

Guests	
LCDR William Agbo, MSC	DLA Troop Support
Ms. Kimberlymae Wood	DHA Contracting Officer
Ms. Yvette Dluhos	DHA Contracting
Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Dr. Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Dr. Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Dr. Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	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
MAJ Matthew Krull, MSC	DHA Formulary Management Branch
Dr. Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA MTF Management Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Ebony Moore	DHA Formulary Management Branch Contractor

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• teriparatide injection (Bonsity) **Osteoporosis Agents: PTH Analogs**	• No alternative formulary agent: Patient cannot use Forteo **Formulary alternatives**: teriparatide (Forteo)
• lumateperone (Caplyta) **Antipsychotics: Atypical**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure • Patient previously responded to the non-formulary agent and changing to a formulary agent would incur unacceptable risk **Formulary alternatives:** aripiprazole (tablets, ODT, and solution), quetiapine IR and XR tablets, risperidone (tablets and ODT), olanzapine (tablets & ODT), olanzapine/fluoxetine, paliperidone, ziprasidone, and lurasidone (Latuda)
• bempedoic acid (Nexletol) **Antilipidemics-1**	• Patient has experienced significant adverse events from the preferred formulary statins. • The preferred formulary statins have results in therapeutic failure **Formulary alternatives**: atorvastatin, simvastatin, pravastatin, rosuvastatin, fluvastatin, lovastatin, evolocumab, alirocumab, ezetimibe
• cetirizine 0.24% ophthalmic solution (Zerviate) **Ophthalmic: Allergy**	• Patient has experienced significant adverse effects from formulary agents **Formulary alternatives**: olopatadine 0.1%, azelastine 0.05%, epinastine 0.05%, olopatadine 0.7% (Pazeo)
• lasmiditan (Reyvow) **Migraine Agents**	• Use of formulary alternatives is contraindicated **Formulary alternatives**: rizatriptan (Maxalt, Maxalt MLT, generics), sumatriptan (Imitrex, generics), zolmitriptan (Zomig, Zomig ZMT, generics), eletriptan (Relpax), naratriptan (Amerge), rimegepant (Nurtec ODT)
• ubrogepant (Ubrelvy) **Migraine Agents**	• Use of formulary alternatives is contraindicated **Formulary alternatives**: rizatriptan (Maxalt, Maxalt MLT, generics), sumatriptan (Imitrex, generics), zolmitriptan (Zomig, Zomig ZMT, generics), eletriptan (Relpax), naratriptan (Amerge), rimegepant (Nurtec ODT)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
• teriparatide injection (Bonsity) **Osteoporosis Agents: PTH Analogs**	Manual PA is required for all new and current users of Bonsity. Manual PA Criteria: Bonsity is approved if all criteria are met: • The provider acknowledges that Forteo is the Department of Defense's preferred osteoporosis parathyroid hormone (PTH) analog; the patient must try and fail Forteo prior to use of Bonsity • The patient is ≥ 18 years old • The drug is prescribed for treatment of osteoporosis and not for prevention of osteoporosis. • The patient has one of the following diagnoses: o Patient is a postmenopausal female with osteoporosis; OR o Patient is a male with primary or hypogonadal osteoporosis; OR o Patient is a male or female with osteoporosis associated with sustained systemic glucocorticoid therapy (e.g., more than 6 months use of greater than 7.5 mg/day of prednisone or equivalent) AND • The patient has one of the following: o A high risk for fracture due to history of osteoporotic fracture, OR o Has multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) • Patient has a documented bone mineral density (BMD) with T-score of -2.5 or worse • Patient is able to take calcium and vitamin D supplements and will continue throughout therapy • Patient has tried and experienced an inadequate response to, has had therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) • Patient does not have an increased risk for osteosarcoma • Cumulative treatment with Bonsity, Tymlos, and/or Forteo must not exceed 24 months during the patient's lifetime Non-FDA-approved uses are not approved. PA expires in 24 months.
• lumateperone (Caplyta) **Antipsychotics: Atypical**	Manual PA is required for all new users of Caplyta. Manual PA Criteria: Caplyta is approved if all criteria are met: • Age ≥ 18 years • Patient has a diagnosis of schizophrenia • Patient has tried and failed at least TWO formulary atypical antipsychotics (e.g. risperidone, aripiprazole, lurasidone, quetiapine) • Drug is prescribed by or in consultation with a psychiatrist Non-FDA approved uses are NOT approved including sleep disorders, depression, and other neuropsychiatric and neurological disorders. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• bempedoic acid (Nexletol) **Antilipidemics-1**	Manual PA is required for all new users of Nexletol. Manual PA Criteria: Note that the automation for the LIP-I step therapy will not apply for Nexletol. Nexletol is approved if all criteria are met: • The drug is prescribed by a cardiologist, endocrinologist or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization) AND • The patient has tried a Department of Defense preferred statin with similar LDL lowering (moderate or low intensity; including atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin) at maximal doses and has not reached LDL goal OR • The patient has tried a Department of Defense preferred statin with similar LDL lowering (moderate or low intensity; including atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin or simvastatin) at maximal doses and has been unable to tolerate it due to adverse effects AND • The patient will continue on statin therapy, consistent with the package labeling. Non-FDA-approved uses are not approved. PA does not expire.
• cetirizine 0.24% ophthalmic solution (Zerviate) **Ophthalmic: Allergy**	Manual PA is required for all new and current users of Zerviate. Manual PA Criteria: Zerviate is approved if all criteria are met: • The patient has ocular symptoms of allergic conjunctivitis AND o The patient has tried and failed TWO of the following formulary alternatives in the last 90 days, olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine OR • The patient has experienced intolerable adverse effects to at least TWO of the following formulary alternatives, olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Peanut (*Arachis hypogaea)* Allergen Powder-dnfp (Palforzia) **Immunological agents miscellaneous**	Manual PA criteria apply to all new users of Palforzia. Manual PA Criteria: Palforzia is approved if all criteria are met: • Palforzia is prescribed by an allergist or immunologist , or in consultation with an allergist or immunologist, and the provider has satisfied the requirements of the REMS program • The patient is between the ages of 4 to 17 years • The patient has a documented history of peanut allergy • The patient has a history of diagnostic evidence of peanut allergy, including either serum IgE to peanut of ≥0.35 kUA/L (serum testing) and/or positive skin prick test (SPT) for peanut ≥ 3 mm greater than negative control • The patient does not have uncontrolled asthma; eosinophilic esophagitis or other eosinophilic gastrointestinal diseases • The patient has not had severe or life-threatening anaphylaxis within the previous 60 days prior to starting therapy • Provider acknowledges that the patient will be counseled on the following: o Avoiding peanut ingestion o The need for access to an epinephrine injector o Palforzia is not intended to treat emergencies Non-FDA-approved uses are not approved. PA does not expire.
• lasmiditan (Reyvow) **Migraine Agents**	Changes are in strikethrough below Manual PA is required for all new and current users of Reyvow. Manual PA Criteria: Reyvow is approved if all criteria are met: • Age ≥ 18 • Reyvow is prescribed by or in consultation with a neurologist • Reyvow is not approved for patients who have history of hemorrhagic stroke • Reyvow is not approved for patients with a history of epilepsy or any other condition with increased risk of seizure • The patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least TWO of the following medications o sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • The patient has had a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT • ~~Concurrent use with monoclonal CGRP antagonists are not allowed~~ • If Reyvow is used with a triptan, provider acknowledges Reyvow and the triptan should not be used within 24 hours of each other • Reyvow will be used with caution in patients with low heart rate and/or those using beta blockers, such as propranolol Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rimegepant orally disintegrating tablet (Nurtec ODT) **Migraine Agents**	Changes are in bold and strikethrough below Manual PA is required for all new users of Nurtec ODT. <u>Manual PA Criteria:</u> Nurtec ODT is approved if all criteria are met: • Age ≥ 18 • Nurtec ODT is prescribed by or in consultation with a neurologist • ~~Patient has had a diagnosis of migraine for at least 1 year with an onset before 50 years of age~~ • ~~Patient has fewer than 15 migraine headaches per month~~ • Nurtec ODT is not approved for patients who have clinically significant or unstable cardiovascular disease • The patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least TWO of the following medications – sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • ~~Concurrent use with monoclonal CGRP antagonists are not allowed~~ • **Concurrent use with any other small molecule CGRP targeted medication (i.e., including Ubrelvy or another "gepant") is not allowed** Non-FDA-approved uses are not approved. PA does not expire.
• ubrogepant (Ubrelvy) **Migraine Agents**	Changes are in bold and strikethrough below Manual PA is required for all new users of Ubrelvy. <u>Manual PA Criteria:</u> Ubrelvy is approved if all criteria are met: • Age ≥ 18 • Ubrelvy is prescribed by or in consultation with a neurologist • ~~Patient has had a diagnosis of migraine for at least 1 year with an onset before 50 years of age~~ • ~~Patient has fewer than 15 migraine headaches per month~~ • Ubrelvy is not approved for patients who have clinically significant or unstable cardiovascular disease • The patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least TWO of the following medications o sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • **Patient has had a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT** • ~~**Concurrent use with monoclonal CGRP antagonists are not allowed**~~ • **Concurrent use with any other small molecule CGRP targeted medication (i.e., including Nurtec ODT or another "gepant") is not allowed** Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• avapritinib (Ayvakit) **Oncological Agents**	Manual PA is required for all new users of Ayvakit. <u>Manual PA Criteria:</u> Ayvakit is approved if all criteria are met: • Patient must be ≥ 18 years • Ayvakit is prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation with or without the D842V mutation • Provider agrees to monitor for intracranial bleeding and other central nervous system (CNS) adverse effects • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 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 6 weeks after the cessation of therapy • 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: _____. Non-FDA-approved uses are not approved, except as noted above. PA does not expire.
• tazemetostat (Tazverik) **Oncological Agents**	Manual PA is required for all new users of Tazverik. <u>Manual PA Criteria:</u> Tazverik is approved if all criteria are met: • Patient must be ≥ 16 years • Tazverik is prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed metastatic or locally advanced epithelioid sarcoma not eligible for complete resection • Patient will be monitored for secondary malignancies (especially. T-cell lymphoblastic lymphoma, myelodysplastic syndrome, and acute myeloid leukemia) • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 months after cessation of therapy for males and 6 months for females • 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: _____. Non-FDA-approved uses are not approved except as noted above. PA does not expire.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• avapritinib (Ayvakit) **Oncological Agents**	• Retail/MTF/Mail: 30 day supply at all POS
• tazemetostat (Tazverik) **Oncological Agents**	• Retail/MTF/Mail: 30 day supply at all POS
• diazepam nasal spray (Valtoco) **Anticonvulsants-Antimania Agents**	• Retail: 5 cartons/30 days • MTF/Mail: 15 cartons/90 days Note that Valtoco is packaged in cartons of 2 nasal sprays per carton
• lasmiditan (Reyvow) **Migraine Agents**	• Retail: 8 tabs/30 days • MTF/Mail: 24 tabs/90 days
• rimegepant (Nurtec ODT) **Migraine Agents**	• Retail: 8 ODTs/30 days • MTF/Mail: 24 ODTs/90 days
• ubrogepant (Ubrelvy) **Migraine Agents**	• Retail: 10 tabs/30 days • MTF/Mail: 30 tabs/90 days Note that Ubrelvy is currently available only as cartons containing 10 tablets per carton
• peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia) **Immunological Agents Miscellaneous**	• Retail/MTF/Mail: 30 day supply at all POS
• teriparatide injection (Bonsity) **Osteoporosis Agents: PTH Analogs**	• Retail: 1 pen/28 days and 28 day supply • MTF/Mail: 3 pens/84 days and 84 day supply

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
antihemophilic factor (recombinant) glycoPEGylated-exei (Esperoct)	Antihemophilic Factors	• Recombinate • Hemofil M • Koate DVI • Kogenate FS • ReFacto • Advate • Afstyla • Obizur • Kovaltry • Novoeight • Nuwiq • Eloctate • Adynovate • Jivi	Hemophilia A	• Esperoct is the 15th antihemophilic factor indicated for the treatment of Hemophilia A • Esperoct is the 3rd pegylated formulation and is dosed every four days in adults and twice weekly in pediatrics • Esperoct was evaluated in five multinational open-label trials in patients with severe Hemophilia A and demonstrated efficacy in preventing and treating bleeding episodes consistent with other Factor VIII products • Esperoct's glycopegylated formulation and slightly longer half-life did not translate into a clinically relevant differences in dosing or effect compared to the other antihemophilic factors	• UF • Do not add to EMMPI list
avapritinib (Ayvakit)	Oncological Agents	• imatinib (Gleevac) • sunitinib (Sutent) • regorafenib (Stivarga)	GI stromal tumors (GIST)	• Ayvakit is the 4th option for metastatic unresectable GIST but the only option when patients carry the D842V mutation • Indicated only for GIST with PDGFRA exon 18 mutations (not for all GIST) • Highly effective as judged by depth and duration of response • Poorly tolerated with high rates of dose-reduction and discontinuation	• UF • Do not add to EMMPI list
bempedoic acid (Nexletol)	Antilipidemics-1	• simvastatin • atorvastatin • rosuvastatin • ezetimibe • PSC-K9 inhibitors	Treatment of established ASCVD or HeFH, as an adjunct to diet and maximally tolerated statin therapy in patients who require additional LDL lowering	• Antilipidemic with a new mechanism of action: adenosine triphosphate-citrate lyase (ACL) inhibitor • Reduces LDL an additional 18%-20% when added onto statins • Minimal impact on TG or HDL • Also available in a fixed dose combination with ezetimibe (Nexlizet); not launched yet • Long-term adverse event profile unknown • Potential place in therapy as an add-on option if patient has had an inadequate response on statin plus ezetimibe and an oral med is preferred over injectable PCSK-9 • Limited place in therapy due to lack of CV outcomes studies	• NF and non-step-preferred • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
cenobamate (Xcopri)	Anticonvulsants-Antimania agents	• brivaracetam (Briviact) • carbamazepine ER • eslicarbazepine • perampanel (Fycompa) • plus other formulary anticonvulsants	Partial-onset seizures	• Xcopri is the 18th antiepileptic drug approved for used in partial-onset seizures in adults • Efficacy is based on limited data, it is only indicated in adults, it is a controlled substance, and there are concerns with Xcopri use due to risk of drug rash with eosinophilia and systemic symptoms (DRESS) syndrome • No head-to-head studies with other anticonvulsants are available and professional treatment guidelines have not been updated to reflect its place in therapy • Most common ADRs included CNS effects (somnolence, dizziness, and fatigue) which occur at an increased incidence with increasing dose • Xcopri provides an additional option for adults with partial onset seizures, but provides no compelling advantage over existing anticonvulsants	• UF • Do not add to EMMPI list
cetirizine 0.24% ophthalmic solution (Zerviate)	Ophthalmic: Allergy	• olopatadine 0.1% (Patanol) • azelastine 0.05% (Optivar) • epinastine 0.05% (Elestat) • olopatadine 0.7% (Pazeo)	Ocular itching associated with allergic conjunctivitis in patients 2 years of age and older	• Zerviate is the first ophthalmic formulation of the antihistamine cetirizine • Zerviate was evaluated in three studies and demonstrated a statistically significant reduction in ocular itching and redness compared to vehicle at 15 minutes and 8 hours after treatment. ▪ Results at 15 minutes met the minimally clinically important difference (MCID), but not at 8 hours ▪ Redness scores did not meet MCID • Adverse events were relatively mild • There are no head-to-head trials with Zerviate and other ocular antihistamines • Indirect comparisons with other ocular antihistamines show that Zerviate is similar in efficacy in relieving ocular itching • Despite the advantage of a new mechanisms of action, Zerviate offers little to no clinical benefit relative to existing formulary agents and requires twice daily dosing	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
diazepam nasal spray (Valtoco)	Anticonvulsants-Antimania agents	• diazepam rectal (Diastat) • midazolam nasal spray (Nayzilam)	For the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older	• Valtoco is a nasal spray formulation of diazepam for acute intermittent seizures or seizure clusters • Valtoco was FDA approved through the 505(b)(2) pathway showing bioequivalence to diazepam (Diastat) for rectal administration • Both midazolam (Nayzilam) and diazepam (Valtoco) are nasal sprays for the same indication. Some differences include: ▪ Valtoco has a longer duration of action and requires fewer repeat doses ▪ Valtoco is approved in patients as young 6 years of age while Nayzilam is approved for 12 and older ▪ Valtoco has a range of available doses based on weight • Valtoco provides a clinically meaningful addition to the pharmacy benefit in the treatment of acute intermittent seizures or seizure clusters	• UF • Do not add to EMMPI list
lasmiditan (Reyvow)	Migraine Agents	• sumatriptan (Imitrex) • rizatriptan (Maxalt) • zolmitriptan (Zomig) • eletriptan (Relpax) • rimegepant (Nurtec ODT) • ubrogepant (Ubrelvy)	For the acute treatment of migraine with or without aura in adults Limitation: not indicated for the preventive treatment of migraine	• Reyvow is the first selective 5-HT1f agonist for acute migraine • Clinical trials show that Reyvow is superior to placebo for the endpoint of pain-free at 2 hours and relief of the most bothersome symptom at 2 hours • A 2020 ICER analysis evaluating acute migraine treatments concluded that Reyvow is incrementally better than or superior to placebo when patients cannot take triptans. If triptans are an option then Reyvow is comparable or inferior to triptans. • Unlike triptans, Reyvow is not contraindicated in patients with a history of cardiovascular disease. *In-vitro* data shows that Reyvow does not have vasoconstrictive effects, however, the patient population in the clinical trials excluded patients with clinically significant cardiovascular or cerebrovascular disease • Limitations to Reyvow include its C-V controlled substance status, and its warning regarding driving impairment. Patients should not drive for 8 hours after dosing. Studies showed that these patients are unaware of their impairment. • Reyvow provides an additional option for treating acute migraine for those unable to take triptans, but its place in therapy is limited due to the driving restriction and C-V status.	• NF and non-step-preferred • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lumateperone (Caplyta)	Antipsychotics: Atypical	• risperidone (tablets and ODT) • quetiapine IR and ER • aripiprazole • lurasidone (Latuda) • brexpiprazole (Rexulti)	Schizophrenia in adults	• Lumateperone is the 13th FDA-approved oral atypical antipsychotic and is approved for once daily use in adults • It was evaluated in 3 placebo-controlled trials with 2 studies using risperidone as an active-control • Conflicting results were seen in that only 2 of 3 the studies showed statistically significant results. Only the 42 mg dose showed statistical significance, and not 28 mg and 84 mg. • No study met the minimal clinically important difference (MCID) of at least a 20% reduction in positive and negative syndrome scale (PANSS) score from baseline • Caplyta is currently under investigation for other indications including bipolar depression, behavioral disorders associated with dementia in Alzheimer's, and other depressive disorders • Caplyta provides another treatment option in schizophrenia but has no compelling advantages over existing formulary atypical antipsychotics	• NF • Do not add to EMMPI list
metformin ER suspension (Riomet ER)	Diabetes non-insulin: Biguanides	• metformin 500 mg/5 mL liquid (Riomet, generics) • metformin IR 500, 850, 1000 mg tablets (generics) • metformin ER 500, 750 mg tablets (generics)	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years with T2DM	• New formulation of metformin liquid in an extended-release suspension • Glucophage IR and XR were used as the reference listed drugs • Performed bioequivalence study with Glucophage XR • No new clinical data to review • Generic formulations of the IR solution are available • Aside from reduced dosing of the IR solution from twice daily to once daily, Riomet ER offers little to no clinical benefit relative to existing formulary agents	• UF • Do not add to EMMPI list
peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia)	Immunological agents miscellaneous	• No formulary alternatives	Peanut allergy	• 1st FDA-approved oral agent for mitigation of allergic reactions that may occur with accidental exposure to peanuts in patients with a history of peanut allergy • Dosing consists of 11 titration levels followed by maintenance dosing. Initial: days 1-5 gradually increasing doses (0.5-6 mg); escalation: up-titration every 2 weeks and maintenance of 300 mg daily indefinitely • Requires patient monitoring for 1 hour after each dose for all 11 titration levels; administered in a healthcare setting • In the PALISADE trial, Palforzia was superior to placebo, with 67.2% vs 4.0% of patient's age 4-17 years able to tolerate 600 mg peanut protein during exit evaluation. Limitations include lack of statistical significance in pts 18-55 years old • Requires continuous treatment, EpiPen availability, and continued avoidance of peanuts • Is currently unknown how maintenance treatment with other peanut products or with exposure to actual peanuts would compare to Palforzia	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
rimegepant orally disintegrating tablet (Nurtec ODT) ubrogepant (Ubrelvy)	Migraine agents	• sumatriptan (Imitrex) • rizatriptan (Maxalt) • zolmitriptan (Zomig) • eletriptan (Relpax) • lasmiditan (Reyvow) • ubrogepant (Ubrelvy)	For the acute treatment of migraine with or without aura in adults Limitation: not indicated for the preventive treatment of migraine	• Ubrelvy is the first oral calcitonin gene-related peptide (CGRP) antagonist for acute migraine • Nurtec ODT is the 2nd oral CGRP antagonist, and the first in the class available as an alternate dosage form (ODT formulation) • Clinical trials show that Nurtec ODT and Ubrelvy are superior to placebo for the endpoint of pain-free at 2 hours and relief of the most bothersome symptom at 2 hours • A 2020 ICER analysis evaluating acute migraine treatments concluded that Nurtec ODT and Ubrelvy are incrementally better than or superior to placebo when patients cannot take triptans. If triptans are an option then Nurtec ODT and Ubrelvy are comparable or inferior to triptans • Unlike triptans, Nurtec ODT and Ubrelvy are not contraindicated in patients with a history of cardiovascular disease. *In-vitro* data shows that Nurtec ODT and Ubrelvy do not exhibit vasoconstrictive effects, however, they were not studied in patients with clinically significant cardiovascular or cerebrovascular disease • Nurtec ODT has mild side effects to include nausea, while Ubrelvy can cause mild nausea and somnolence. Both drugs have strong warnings regarding drug interactions with CYP3A4 inducers and inhibitors • Nurtec ODT is the only alternate dosage form within the newer migraine agents but the triptans are available in ODT and nasal spray formulations • Nurtec ODT is not approved for re-dosing, while Ubrelvy can have repeat dosing • Nurtec ODT and Ubrelvy provide additional option for treating acute migraine for those unable to take triptans, but head-to-head trials with other therapies are lacking	<u>*Nurtec ODT*</u> • UF • Do not add to EMMPI list <u>*Ubrelvy*</u> • NF and non-step-preferred • Do not add to EMMPI list
tazemetostat (Tazverik)	Oncological Agents	• None	Epithelioid sarcoma	• Tazverik is the only non-chemotherapeutic option for epithelioid sarcoma • Accelerated approval was based on a comparable response rate to chemotherapeutic options but for those in whom it is effective, significantly longer duration of response • Limited confidence in study results due to low power	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
teriparatide injection (Bonsity)	Osteoporosis Agents: PTH Analogs	• teriparatide (Forteo) • abaloparatide (Tymlos)	• Postmenopausal women with osteoporosis at high risk for fracture • Men with primary or hypogonadal osteoporosis at high risk for fracture to increase bone mass • Men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture	• Bonsity is a new formulation of teriparatide approved as a biosimilar via the 505(b)2 pathway to Forteo • It is a recombinant human parathyroid hormone analog (PTH 1-34) • Efficacy was established using Forteo's trials and Bonsity was evaluated in a comparative study, NCT03002428 • No new clinical data to review • Most common ADRs included arthralgia, pain, and nausea • Bonsity is available in an autoinjector pen, requiring storage in the refrigerator • Duration of treatment is not recommended for more than 2 years, similar to Forteo and Tymlos • Provides no compelling clinical advantage over existing formulary agents	• NF and non-step-preferred • Add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 during the May 2020 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)
May 2020	N**ewly Approved Drugs per 32 CFR 199.21 (g)(5)** **Designated UF:** *Similar agents are already on list* ▪ *None* **Designated NF:** *Similar agents are already on list:* ▪ bempedoic acid (Nexletol) ▪ teriparatide injection (Bonsity)	N**ewly Approved Drugs per 32 CFR 199.21 (g)(5)** **Designated UF:** *Comparable pricing at mail order vs MTFs or retail:* • cenobamate (Xcopri) • rimegepant (Nurtec ODT) *Not yet clear if feasible to provide through mail order:* • avapritinib (Ayvakit) • metformin ER suspension (Riomet ER) • peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia) • tazemetostat (Tazverik) *Drugs in classes not currently on the list:* • antihemophilic factor (recombinant) glycoPEGylated-exei (Esperoct) • diazepam nasal spray (Valtoco) **Designated NF:** *Antipsychotic exemption:* • lumateperone (Caplyta) *Comparable pricing at mail order vs MTFs or retail:* • lasmiditan (Reyvow) • ubrogepant (Ubrelvy) *Drugs for acute use or limited duration use:* • cetirizine 0.24% ophthalmic solution (Zerviate)

Appendix G—Tier 4/Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			
Feb 2020	Pain Agents Class; NSAIDs Subclass	• amlodipine/celecoxib (Consensi)	• Dihydropyridine calcium channel blockers: amlodipine, felodipine, nifedipine, isradipine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs)	• 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	• diclofenac potassium liquid-filled capsules (Zipsor) • diclofenac submicronized (Zorvolex) • fenoprofen capsules • indomethacin submicronized (Tivorbex) • meloxicam submicronized (Vivlodex)	• celecoxib • diclofenac • ibuprofen • meloxicam • naproxen • Also includes other NSAIDs	• 120 days after signing • August 26, 2020
Feb 2020	Pain Agents Class; NSAIDs Subclass	• ibuprofen and famotidine tablets (Duexis)	• H2 blockers: famotidine, ranitidine, cimetidine, nizatidine PLUS • NSAIDs: celecoxib, diclofenac, ibuprofen, meloxicam, naproxen, (also includes other NSAIDs)	• 120 days after signing • August 26, 2020
Feb 2020	Pain Agents – Combinations	• naproxen / esomeprazole (Vimovo)	• PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) 18669037258 • 75262416	• Aug 28, 2019 • Note that Vimovo reaffirmed as Tier 4 at the February 2020 NSAID subclass review
Feb 2020	Pain Agents Class; Pain Topical Subclass	• diclofenac 1.3% patch (Pennsaid) • diclofenac 2% solution (Pennsaid)	• oral NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs) • diclofenac 1.5% solution • diclofenac 1% gel	• 120 days after signing • August 26, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2020	Pain Agents Class; Pain Topical Subclass	• lidocaine 1.8% patch (ZTlido)	• lidocaine 5% patch	• 120 days after signing • August 26, 2020
Feb 2020	Acne Agents: Topical Acne and Rosacea	• benzoyl peroxide 9.8% foam (Enzoclear)	• clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) • clindamycin/benzoyl peroxide 1% - 5% gel (Benzaclin, generics) • clindamycin/benzoyl peroxide 1% - 5% gel kit (Duac CS Kit)	• 120 days after signing • August 26, 2020
Feb 2020	Anti-Infectives: Miscellaneous	• omeprazole magnesium, amoxicillin and rifabutin (Talicia)	• omeprazole PLUS amoxicillin PLUS rifabutin (given separately) • omeprazole PLUS clarithromycin PLUS amoxicillin • bismuth subsalicylate OTC PLUS metronidazole PLUS tetracycline PLUS PPI	• 120 days after signing • August 26, 2020
Feb 2020	Pulmonary-1: Short Acting Beta2 Agonists (SABA)	• albuterol dry powder inhaler (ProAir Digihaler)	• albuterol MDI (ProAir HFA) • albuterol DPI (ProAir Respiclick) • albuterol MDI (Proventil HFA) [Nonformulary] • albuterol MDI (Ventolin HFA) [Nonformulary] • levalbuterol MDI (Xopenex HFA) [Nonformulary]	• 120 days after signing • August 26, 2020
Nov 2019	PDE-5 inhibitor	• avanafil tablet (Stendra) • brand Viagra tablet • brand Cialis tablet • vardenafil tablet (Levitra and generics) • vardenafil oral disintegrating tablet (ODT) (Staxyn and generics)	• sildenafil tablet (generic Viagra only) • tadalafil tablet (generic Cialis only)	• June 3, 2020
Nov 2019	Rapid Acting Insulins	• insulin plus niacinamide (Fiasp)	• insulin aspart (Novolog) • insulin lispro (Humalog or authorized generic lispro) • insulin lispro (Admelog) [nonformulary] • insulin glulisine (Apidra) [nonformulary]	• July 1, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2019	Pulmonary-2 Agents: COPD	• formoterol/aclidinium (Duaklir Pressair)	• umeclidinium/vilanterol (Anoro Ellipta) • tiotropium/olodaterol (Stiolto Respimat) • glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary] • glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary]	• June 3, 2020
Nov 2019	Migraine Agents: Triptans	• sumatriptan nasal spray (Tosymra)	• sumatriptan nasal spray (Imitrex, generics) • sumatriptan nasal powder (Onzetra Xsail) [nonformulary] • zolmitriptan nasal spray (Zomig)	• June 3, 2020
Nov 2019	GI2 Agents: CIC and IBS-C	• tegaserod (Zelnorm)	• linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Amitiza) • prucalopride (Motegrity) [nonformulary]	June 3, 2020
Aug 2019	ADHD	• 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)	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.025% cream (Impoyz) • diflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog)	• betamethasone/propylene glycol 0.05% cream • clobetasol propionate 0.05% cream • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream • fluocinonide 0.05% cream • fluocinonide/emollient base 0.05% cream	• March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	• halcinonide 0.1% ointment (Halog)	• betamethasone dipropionate 0.05% ointment • betamethasone/propylene glycol 0.05% ointment • clobetasol propionate 0.05% ointment • desoximetasone 0.25% ointment • fluocinonide 0.05% ointment • halobetasol propionate 0.05% ointment	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.05% shampoo/ cleanser (kit) (Clodan kit) • halobetasol propionate 0.05% lotion (Ultravate) • halobetasol propionate 0.05% foam (authorized generic for Lexette) *(see Feb 2019 for brand Lexette recommendation)* • halobetasol propionate 0.01% lotion (Bryhali)	• 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	• March 4, 2020
May 2019	PPIs	• dexlansoprazole (Dexilant) • esomeprazole strontium	• esomeprazole • omeprazole • pantoprazole • rabeprazole	• Nov 28, 2019 MTF Tier 4 implementation for Dexilant delayed to Jan 31, 2020
Feb 2019	High-Potency Topical Corticosteroids	• halobetasol propionate 0.05% foam (Lexette brand)	• 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	• Aug 28, 2019
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	• metformin ER gastric retention 24 hours (Glumetza)	• metformin IR (Glucophage generic) • metformin ER (Glucophage XR generic)	• Aug 28, 2019

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2019	Pain Agents – Combinations	• naproxen / esomeprazole (Vimovo)	• PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs)	• Aug 28, 2019 • Note that Vimovo reaffirmed as Tier 4 at the February 2020 NSAID subclass review (see above)

*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 .

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**.**

Appendix H—Table of Abbreviations

Term	Definition	Term	Definition
ADR	Adverse reaction	MCID	Minimally Clinically Important Difference
AE	Adverse event	MIDAS	Migraine Disability Assessment
AHRQ	Agency for Healthcare Research and Quality	MHS	Military Health System
ASCVD	Atherosclerotic cardiovascular disease	MN	Medical Necessity
BCF	Basic Core Formulary	MTF	Military Treatment Facility
BIA	Budget impact analysis	NCCN	National Comprehensive Cancer Network
CFR	Code of Federal Regulations	NDAA	National Defense Authorization Act
CGRP	Calcitonin Gene-Related Peptide	NDC	National Drug Codes
CHCS	Composite Health Care System	NF	Non-Formulary
CMA	Cost minimization analysis	NICE	UK National Institutes for Health and Care Excellence
CV	Cardiovascular	ODT	Orally dissolving tablet
DHA	Defense Health Agency	OIT	Oral Immune Therapy
DoD	Department of Defense	OTC	Over the counter
DR	Delayed release	P&T	Pharmacy and Therapeutics
DRESS	drug rash with eosinophilia and systemic symptoms	PA	Prior authorization
ECF	Extended Core Formulary	PANSS	Positive and Negative Syndrome Scale
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	PDGFRA	Platelet-derived growth factor receptor alpha
ER	Extended release	POD	Pharmacy Operations Division
FDA	U.S. Food and Drug Administration	POS	Point of service
FMB	Formulary Management Branch	QL	Quantity limits
FY	Fiscal year	Rx	Medical Prescription
GCN	Generic code number	RAI	Rapid Acting Insulin drug class
GI	Gastrointestinal	SPT	Skin prick test
HCL	Hydrochloride	TIB	Targeted immunomodulatory biologic
HeFH	Heterozygous familial hypercholesterolemia	UF	Uniform Formulary
HFA	Hydroxyfluoroalkane	XR	Extended release
ICER	Institute for Clinical and Economic Review		
IR	Immediate release		
LDL	Low Density Lipoprotein		