

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL**

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA), on formulary or Tier 4/not covered status, prior authorization (PA), pre-authorizations, and the effective date for a drug's change from formulary to non-formulary (NF) or Tier 4 status are received from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision. Note Due to the COVID-19 pandemic, an abbreviated meeting was held via teleconference.

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

P&T Comments

A. 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).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered 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

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- 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.

Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5)

1. teriparatide injection (Bonsity)

Manual PA criteria apply to 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
- Patient is ≥ 18 years old
- The drug is prescribed for treatment of osteoporosis and not for prevention of osteoporosis.
- Patient has one of the following diagnoses:
 - Patient is a postmenopausal female with osteoporosis; OR
 - Patient is a male with primary or hypogonadal osteoporosis; OR
 - 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:
 - A high risk for fracture due to history of osteoporotic fracture, OR
 - 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.

2. lumateperone (Caplyta)

Manual PA is required for all new users of Caplyta.

Manual PA Criteria: Caplyta is approved if all criteria are met:

- Age \geq 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

3. bempedoic acid (Nexletol)

Manual PA is required for all new users of Nexletol.

Manual PA Criteria: 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.

4. Cetirizine 0.24% ophthalmic solution (Zerviate)

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
 - 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.

5. Peanut (*Arachis Hypogaea*) Allergen Powder-dnfp (Palforzia)

Manual PA is required for 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:
 - Avoiding peanut ingestion
 - The need for access to an epinephrine injector
 - Palforzia is not intended to treat emergencies

Non-FDA-approved uses are NOT approved

PA does not expire.

6. lasmiditan (Reyvow)

Manual PA is required for all new and current users of Reyvow.

Manual PA Criteria: Reyvow is approved if all criteria are met:

- Age \geq 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, intolerance to, or has failed a 2-month trial of at least TWO of the following medications
 - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)
- The patient has had a contraindication to, intolerance to, or has failed a 2-month trial of Nurtec ODT
- 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.

7. rimegepant orally disintegrating tablet (Nurtec ODT)

Manual PA criteria apply to all new users of Nurtec.

Manual PA Criteria: Nurtec is approved if all criteria are met:

- Age \geq 18
- Nurtec ODT is prescribed by or in consultation with a neurologist
- Nurtec ODT is not approved for patients who have clinically significant or unstable or recently diagnosed cardiovascular disease
- The patient has a contraindication to, intolerance 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 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.

8. ubrogepant (Ubrelvy)

Manual PA is required for all new users of Ubrelvy.

Manual PA Criteria: Ubrelvy is approved if all criteria are met:

- Age \geq 18
- Ubrelvy is prescribed by or in consultation with a neurologist
- Ubrelvy is not approved for patients who have clinically significant or unstable or recently diagnosed cardiovascular disease
- The patient has a contraindication to, intolerance to, or has failed a 2-month trial of at least TWO of the following medications
 - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)
- Patient has had a contraindication to, intolerance to, or has failed a 2-month trial of Nurtec ODT
- 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.

9. avapritinib (Ayvakit)

Manual PA applies to new users of Ayvakit.

Manual PA Criteria: Ayvakit is approved if all criteria are met:

- Patient must be \geq 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 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.

10. tazemetostat (Tazverik)

Manual PA criteria apply to all new users of Tazverik.

Manual PA Criteria: Tazverik will be 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.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- **New Drugs Recommended for UF or NF Status, and PA criteria:** An effective date upon the first Wednesday two weeks after signing of the minutes in all POS.

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

BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

- **UF**
 - Esperoct
 - Ayvakit
 - Xcopri
 - Valtoco
 - Riomet ER
 - Palforzia
 - Nurtec ODT
 - Tazverik
- **NF**
 - Nexletol
 - Zerviate

- Reyvow
- Caplyta
- Bonsity
- Ubrelvy

BAP Comment: Concur Non-concur

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria

The P&T Committee recommended the PA criteria for the new drugs as stated previously.

BAP Comment: Concur Non-concur

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF and PA Implementation Plan

- **New Drugs Recommended for UF or NF Status, and PA criteria:** An effective date upon the first Wednesday two weeks after signing of the minutes in all points of service.

BAP Comment: Concur Non-concur