DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE AUGUST 2021 MEETING

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) or their designee, 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 or their designee before making a final decision.

II. UF DRUG CLASS REVIEWS—Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass

P&T Comments

A. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass — Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the three agents in the BTK inhibitor subclass, comprised of ibrutinib (Imbruvica), acalabrutinib (Calquence), and zanubrutinib (Brukinsa). The Committee comprehensively reviewed the evidence including what was reviewed when Imbruvica, Calquence, and Brukinsa were presented as innovators in May 2018, February 2018, and February 2020, respectively.

The BTK inhibitors are indicated for use in chronic lymphocytic leukemia (CLL) and a variety of non-Hodgkin lymphoma subtypes including small lymphocytic lymphoma (SLL) and mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), non-germinal center B-Cell diffuse large B-Cell lymphoma (non-GCB-DLBCL), and Waldenström macroglobulinemia (WM).

The comprehensive evidence review included information from individual clinical trial data; guidelines from the National Cancer Comprehensive Network (NCCN), American Society of Clinical Oncology (ASCO), and European Society for Medical Oncology (ESMO); meta-analyses; FDA labeling; current Military Health System (MHS) patterns of use; and MHS provider comments.

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

- Ibrutinib (Imbruvica) has the greatest number of FDA-approved indications, guideline-recommended uses, and the most voluminous and validated evidence base. In the Military Health System, it is the most utilized and the de facto preferred agent by oncologists.

- Where data is available, by indirect comparison, via network meta-analysis, and in head-to-head trials, all three agents appear to be equally clinically effective.

- While their safety profiles largely overlap, each agent has unique features. Specialists will tailor their choice of agent based on patient comorbidities.

- Acalabrutinib (Calquence) and zanubrutinib (Brukinsa) have favorable safety profiles relative to ibrutinib (Imbruvica) among certain clinically significant adverse events. Some providers prefer acalabrutinib over ibrutinib, either for specific patient comorbidities or indications.

- Zanubrutinib (Brukinsa) is the newest of the three agents, and has an immature evidence base and generally lower rankings where guidelines recommend use, when compared to the other two drugs.

- The ibrutinib (Imbruvica) capsule formulation allows for more flexible dosage titration, either for increasing the dose or reducing the dose due to adverse events, compared to the ibrutinib tablets.

- Once a patient's disease becomes refractory to one BTK inhibitor, it tends to be refractory to all BTK inhibitors.

B. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass — Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that acalabrutinib (Calquence), ibrutinib (Imbruvica), and zanubrutinib (Brukinsa) were all cost effective, when compared to each other. For Imbruvica, the capsule formulations are more cost effective than the tablet formulations.

- 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 acalabrutinib (Calquence), ibrutinib (Imbruvica), and zanubrutinib (Brukinsa) as UF demonstrated the greatest cost avoidance for the MHS.

C. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
    - acalabrutinib (Calquence)
    - ibrutinib (Imbruvica)
    - zanubrutinib (Brukinsa)
- NF – None
- Tier 4/Not Covered – None

D. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass—Manual PA Criteria

Existing PA criteria currently apply to all three drugs. For the ibrutinib tablets, further justification is required on the PA to state why the capsules cannot be used, due to more flexible dosage titration with the capsules. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) minor updates to the ibrutinib PA criteria to reflect the clinical and cost differences of the capsules and tablets, and recommended maintaining the current PA criteria for acalabrutinib and zanubrutinib.

The PA criteria are as follows:

1. **ibrutinib (Imbruvica)**

    Updates from the August 2021 meeting are in bold

    Manual PA is required for new users of Imbruvica capsules and tablets, and is approved if all criteria are met.

    Imbruvica capsules are **more cost effective than Imbruvica tablets for DoD**.

    - The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for DoD
    - If the prescription is for Imbruvica tablets, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below
    - If the prescription is for the Imbruvica capsules, please continue with the PA criteria below.
    - Patient is 18 years of age or older
    - Imbruvica is prescribed by or in consultation with a hematologist/oncologist

- Imbruvica will be used in one of the following contexts:
    - Pretreatment to limit the number of cycles of RhyperCVAD/rituximab maintenance therapy for Mantle Cell Lymphoma
    - Second line (or subsequent therapy) for Mantle Cell Lymphoma
    - Second line (or subsequent therapy) for Marginal Zone Lymphoma
    - Second line (or subsequent therapy) for non-germinal center B cell-like Diffuse Large B Cell Lymphoma if unable to receive chemotherapy
    - Frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation
        - Patient fits one of the following categories:
            - Frail patient with significant comorbidity (not able to tolerate purine analogues)
            - Patient ≥ 65 years old with significant comorbidity
            - Patients < 65 years old
    - Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation
    - Waldenström macroglobulinemia
    - Chronic Graft versus Host Disease
    - The patient will be monitored for bleeding, infection, hypertension, cardiac arrhythmias, cytopenias, and Tumor Lysis Syndrome
    - If the patient is female, she is not pregnant or planning to become pregnant
    - Breastfeeding female patients will be advised that the potential harm to the infant is unknown
    - All patients (males and females) of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation
    - 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.

PA does not expire.

2. acalabrutinib (Calquence)

Note that no changes were made to the PA criteria at the August 2021

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

- Age 18 years of age or older
- Calquence is prescribed by or in consultation with a hematologist/oncologist
- Patient meets one of the following categories:
    - Patient must have pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 that had a short response duration to prior therapy (< median progression-free survival).
    - Patient will use acalabrutinib as relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation
        - Patient fits one of following categories:
            - Frail patient with significant comorbidity (not able to tolerate purine analogues)
            - Patient ≥ 65 years old with significant comorbidity
            - Patients < 65 years old
    - Patient will use acalabrutinib as relapsed refractory therapy for CLL/SLL with del(17p)/TP53 mutation
- If the patient has CLL, the patient's disease has no evidence of a BTK C481S mutation nor prior ibrutinib-refractory disease
- Patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec
- The patient will be monitored for bleeding, infection, cardiac arrhythmias, and cytopenias
- If the patient is female and of childbearing potential, advise the patient of the risk of significant fetal harm
- Female patients will not breastfeed during treatment and for at least 2 weeks following cessation of treatment
- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.

Other non-FDA-approved uses are not approved.

PA does not expire

3. zanubrutinib (Brukinsa)

Note that Brukinsa received new FDA indications following the August 2021 P&T Committee meeting, and prior to the BAP meeting and P&T Committee minutes' singing. The new indications are noted below in bold.

Manual PA Criteria applies to all new patients and Brukinsa is approved if all criteria are met:

- Patient is 18 years if age or older
- Brukinsa is prescribed by or in consultation with a hematologist/oncologist
- Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) or
- **Patient has Waldenström's macroglobulinemia (WM) or**
- **Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen**
- The patient will be monitored for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias
- Patient will use sun protection in sun-exposed areas
- Female patients of childbearing age and are not pregnant confirmed by (-) HCG.
- Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment
- Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment
- The diagnosis Is NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.

Other non-FDA-approved uses are not approved.

PA does not expire.

E. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass – UF, PA and Implementation Plan

The P&T Committee recommended (18 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.

III. UF DRUG CLASS REVIEWS- Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass

BAP Comments

A. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass—UF/Tier 4/Not-Covered Recommendations

The P&T Committee recommended the formulary status for the BTK inhibitors as discussed above.

- UF
  - Calquence
  - Imbruvica
  - Brukinsa
- NF
  - None
- Tier 4/Not Covered
  - None

BAP Comment: ☐ Concur ☐ Non-concur

B. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass— PA Criteria

The P&T Committee recommended updating the PA criteria as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

C. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass—UF, PA and Implementation Plan

The P&T Committee recommended the implementation plan of the first Wednesday two weeks after signing of the minutes in all points of service.

BAP Comment:	☐ Concur	☐ Non-concur

IV. UF DRUG CLASS REVIEWS—Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass

P&T Comments

A. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the bowel preparations indicated for colon cleansing in preparation for colonoscopy. Drugs in the class include generic preparations comprised of polyethylene glycol (PEG) 3350 with and without additional electrolytes. Six branded products are marketed, Osmoprep, Plenvu, Clenpiq, Suprep, Sutab, and Moviprep. The class has not been previously reviewed for formulary status, although Clenpiq, Plenvu and Sutab were evaluated as newly approved drugs at the February 2018, November 2018, and February 2021, respectively.

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

- Several different dosage formulations are available, including powders for reconstitution, oral solutions, and tablets. The bowel preparations vary in the amount of liquid that is required for consumption, ranging from 2 to 4 liters.
    - Full-volume (standard volume) preparations require consumption of 4 liters (L) of total volume and include Colyte, GoLYTELY, NuLYTELY, and TriLyte and their generics.
    - Low-volume preparations range from 2 to 3.5 liters of total volume consumed and include Osmoprep (2 L), Plenvu (2 L), Clenpiq (2.2 L), Suprep (3 L), Sutab (3 L), and Moviprep (3 L). Although the tablet

formulations (Osmoprep and Sutab) do not require mixing of solutions, significant additional water consumption is still required.

- There do not appear to be clinically relevant differences in efficacy, based on indirect evidence. Compared with standard-volume preparations, low volume products demonstrate superior bowel prep completion rate, improved adenoma detection rates, improved patient satisfaction for the prep and procedure, and increased likelihood that the patient will undergo future colonoscopy.

- Professional treatment guidelines recommend split-dose regimens over single dose traditional regimens (which are administered the day before the colonoscopy), due to improved cleansing. However, no one specific agent is recommended over another.

- Tolerability issues, including poor palatability and the requirement for large volumes of liquid may result in an inadequate bowel prep. Safety concerns vary by product and include gastrointestinal obstruction/perforation, gastric retention, and electrolyte disturbances, potentially exacerbating heart failure or renal dysfunction. PEG products are preferred in patients with heart failure, renal dysfunction or liver disease.

- Specific clinical considerations for the products are as follows:

    - **PEG 3350 with electrolytes powder for solution (Colyte, GoLYTELY, TriLyte, NULYTELY)** advantages include availability in generic formulations; approval for children as young as 6 months of age (TriLyte and NuLYTELY); additional indications for bowel cleansing prior to barium enema X-ray examinations (Colyte and GoLYTELY); and availability in sulfate-free formulations (TriLYTE and NULYTELY). Disadvantages include the large volumes required (4 L), poor taste, and tolerability issues.

    - **PEG 3350 with electrolytes powder for solution (MoviPrep**) is a low volume preparation (3 L) that has high MHS utilization, is well tolerated in elderly patients, and was frequently mentioned by providers as requiring inclusion on the formulary. MoviPrep should be used with caution in patients with phenylketonuria.

    - **PEG 3350 with electrolytes powder for solution (Plenvu)** is a low volume (2 L) preparation that is similar to MoviPrep.

- **Sodium picosulfate, magnesium oxide, anhydrous citric acid oral solution (Clenpiq)** is a low volume formulation (2.2 L) indicated for patients 9 years of age and older that is already constituted and well-tolerated. Electrolyte disturbances can occur.

- **Sodium sulfate, potassium sulfate, magnesium sulfate, concentrated oral solution (Suprep)** is a low volume (3 L) product indicated for patients 12 years of age and older. Safety concerns include a higher risk of nausea, vomiting and abdominal distension compared to other products. Overall Suprep offers no compelling clinical advantages relative to the other bowel prep agents.

- **Sodium sulfate, potassium chloride, magnesium sulfate tablets (Sutab):** Although Sutab provides the convenience of a tablet, it requires consumption of 28 tablets and 3 L of extra volume. Overall Sutab offers no compelling clinical advantages relative to the other bowel prep agents.

- **Sodium phosphate tablets (Osmoprep)** requires 32 tabs and 2 L of extra volume and has existing low utilization in the MHS. Significant safety concerns include the boxed warning for acute phosphate nephropathy. Overall Osmoprep offers no compelling clinical advantages relative to the other bowel prep agents.

- **Sodium picosulfate, magnesium oxide, anhydrous citric acid power packets (Prepopik)** is an older formulation that was voluntarily discontinued from the market.

- In order to meet the needs of MHS beneficiaries, at least one product approved in young children, and at least one low volume product is required.

B. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass — Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 1 abstained, 0 absent) the following:

- CMA results showed that the generic standard volume PEG formulations (Colyte, GoLYTELY, NULYTELY, TriLYTE) were the most cost effective bowel preparations, followed by the branded products (ranked

from most cost effective to least cost effective) MoviPrep, Plenvu, Clenpiq, Suprep, Sutab and Osmoprep.

- 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 the generic PEG formulations, MoviPrep, Plenvu, and Clenpiq as UF, and designating Suprep, Sutab, Osmoprep and Prepopik as NF, demonstrated significant cost avoidance for the MHS.

C. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass — UF/Tier 4/Not-Covered Recommendation

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) the following:

- UF
  - PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics)
  - PEG 3350, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (NuLYTELY, TriLyte, generics)
  - PEG 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for oral solution (Moviprep)
  - PEG 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for solution (Plenvu)
  - sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution (Clenpiq) *(moves from NF to UF)*
- NF
  - sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution (Suprep) *(moves from UF to NF)*
  - sodium sulfate, potassium chloride and magnesium sulfate tablets (Sutab)
  - sodium phosphate tablets (Osmoprep) *(moves from UF to NF)*
  - sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets (Prepopik) *(moves from UF to NF)*
- Tier 4/Not Covered: None

D. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass—UF and Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Note that letters won't be sent to patients who have received Suprep, Sutab, Osmoprep or Prepopik, due to the acute use of these drugs, and since the majority of prescriptions are for one-time use.

V. UF DRUG CLASS REVIEWS- Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass

BAP Comments

A. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass—UF/Tier 4/Not-Covered Recommendation

The P&T Committee recommended the formulary status for the Bowel Preparations as discussed above:

- UF
  - Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics
  - NuLYTELY, TriLyte, generics
  - Moviprep
  - Plenvu
  - Clenpiq *(moves from NF to UF)*
- NF
  - Suprep *(moves from UF to NF)s*
  - Sutab
  - Osmoprep *(moves from UF to NF)*
  - Prepopik *(moves from UF to NF)*
- Tier 4/Not Covered: None

BAP Comment: ☐ Concur ☐ Non-concur

B. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass—UF and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday two weeks after signing of the minutes in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

VI. 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 for group 1: (16 for, 0 opposed, 1 abstained, 1 absent); group 2: (14 for, 1 opposed, 1 abstained, 2 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 (for group 1: 16 for, 0 opposed, 1 abstained, 1 absent; group 2: 14 for, 1 opposed, 1 abstained, 2 absent; and for Accrufer 12 for, 4 opposed, 1 abstained, 1 absent) the following:

- UF:
    - dasiglucagon injection (Zegalogue) – Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents for severe hypoglycemia

- infigratinib (Truseltiq) – Oncological agent for cholangiocarcinoma
- omalizumab syringe (Xolair) – Respiratory Interleukin for asthma, nasal polyps, and chronic idiopathic urticaria (CIU)
- pegcetacoplan injection (Empaveli) – Hematological agent for paroxysmal nocturnal hemoglobinuria (PNH)
- relugolix/estradiol/norethindrone (Myfembree) – Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
- riluzole oral film (Exservan) – Miscellaneous neurological agent for amyotrophic lateral sclerosis (ALS)
- semaglutide injection (Wegovy) – Weight loss agent and a GLP-1 receptor antagonist for the treatment of obesity
- sotorasib (Lumakras) – Oncological agent for non-small cell lung cancer (NSCLC)

- NF:
  - drosperinone/estetrol (Nextstellis) – Contraceptive Agents: Monophasics with 20 mcg estrogen
  - ferric maltol (Accrufer) – Electrolyte-Mineral-Trace Element Replacement for iron deficiency
  - viloxazine extended release (Qelbree) – Non-Stimulant for Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17 years of age

- Tier 4/Not Covered:
  - rosuvastatin/ezetimibe (Roszet) – Antilipidemic 1
    - Roszet was recommended as Tier 4 as it has little to no additional clinical effectiveness relative to the statins that are combined with ezetimibe, and the needs of TRICARE beneficiaries are met by available alternative agents. Formulary alternatives include taking rosuvastatin and ezetimibe separately, atorvastatin with ezetimibe, simvastatin/ezetimibe (Vytorin), and the PCSK-9 inhibitors.

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

The P&T Committee recommended (for group 1: 16 for, 0 opposed, 1 abstained, 1 absent; group 2 14 for, 0 opposed, 2 abstained, 2 absent, and for Accrufer (12 for, 4 opposed, 1 abstained, 1 absent) the following:

- Weight loss drugs: Applying manual PA criteria to new users of Wegovy, consistent with the requirements for Saxenda and the other weight loss drugs. A trial of all the other weight loss drugs except Saxenda will be required before Wegovy.
- Oncologic drugs: Applying manual PA criteria to new users of Lumakras and Truseltiq, consistent with PA requirements in general for oncology drugs.
- Respiratory Interleukins: Applying manual PA criteria to new users of the Xolair syringe, consistent with the requirements for the other respiratory biologics intended for patient self-administration.
- LHRH Agonists-Antagonists: Applying manual PA criteria to new users of Myfembree, similar to the requirements for Oriahnn.
- ALS Drugs: Applying manual PA criteria to new users of Exservan oral film, consistent with the requirements for riluzole oral suspension (Tiglutik).
- Applying manual PA criteria to new users of Accrufer, Empaveli, Nextstellis, and Qelbree.

<u>Full PA Criteria for the Newly Approved Drugs per 32 CFR 199.21(g)(5) is as follows</u>

1. **drospirenone/estetrol (Nextstellis)**

   Manual PA criteria apply to all new users of Nextstellis and is approved if all criteria are met:

   - Provider acknowledges that ethinyl estradiol/drospirenone (Yaz, Yasmin) and numerous other contraceptives are available for TRICARE patients and do not require a PA. Providers are encouraged to consider changing the prescription to Yaz, Yasmin, or another formulary contraceptive
   - Patient has tried an ethinyl estradiol containing oral contraceptive and has had significant adverse effects attributed to the ethinyl estradiol component
   - Provider acknowledges that Nextstellis may be less effective in females with a body mass index (BMI) ≥ 30 kg/m^2 per the FDA label

   Non-FDA-approved uses are not approved.

   Prior authorization does not expire.

2. ferric maltol (Accrufer)

Manual PA criteria apply to all new users of Accrufer and is approved if all criteria are met:

- Patient has a documented diagnosis of iron deficiency
- Patient is 18 years of age or older
- Patient has tried and failed two oral iron products (must be different salts e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) for at least six weeks in duration for each product, unless contraindicated or clinically significant adverse effects are experienced.
  - The provider must provide the date of when the patient previously tried each medication, or the contraindication or clinically significant adverse effect that the patient experienced:
  - Oral iron product:_____ Date:_____ Contraindication or clinically significant adverse effect: _____
  - Oral iron product:_____ Date:_____ Contraindication or clinically significant adverse effect: _____
- Provider acknowledges there is insufficient data on drug interactions at this time.

Non-FDA-approved uses are not approved.

Prior authorization expires in 6 months.

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional 6 months for continuation of therapy if:

- Patient is still iron deficient
- Documentation of clinically significant improvement in patient's iron deficiency required.

3. infigratinib (Truseltiq)

Manual PA criteria apply to all new users of Truseltiq and is approved if all criteria are met:

- Patient is 18 years of age or older
- Patient has previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor

receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

- The patient will be monitored for retinal pigment epithelial detachment, hyperphosphatemia, and soft-tissue mineralization
- The drug is prescribed by or in consultation with a hematologist/oncologist
- Female patients of childbearing age are not pregnant confirmed by (-) HCG
- Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment
- Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 month after 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: _____.

Other non-FDA-approved uses are not approved.

Prior authorization does not expire.

4. pegcetacoplan injection (Empaveli)

Manual PA criteria apply to all new users of Empaveli and is approved if all criteria are met:

- Patient is 18 years of age or older
- Patient has a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Patient has been counseled on the appropriate administration of the drug via infusion pump
- Patient has been vaccinated against certain encapsulated bacteria (e.g., *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B)

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

5. riluzole oral film (Exservan)

Manual PA criteria apply to all new users of Exservan and is approved if all criteria are met:

- Patient is diagnosed with amyotrophic lateral sclerosis (ALS)
- Patient has dysphagia/swallowing dysfunction

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

6. relugolix/estradiol/ norethindrone (Myfembree)

Manual PA criteria apply to all new users of Myfembree and is approved if all criteria are met. Note that the PA criteria are similar to Oriahnn, with differences bolded below.

- Patient is 18 years of age or older
- Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD)
- Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist
- Patient is not pregnant. Pregnancy test required.
- Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment
- Patient does not have current or a history of thrombotic or thromboembolic disorders or an increased risk for these events
- Patient is not a smoker over the age of 35
- Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs or if the patient has a sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions
- Patient does not have uncontrolled hypertension
- Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly
- Patient does not have osteoporosis
- Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes
- Patient does not have a history of breast cancer or other hormonally-sensitive malignancies
- Patient does not have known liver impairment or disease

- Provider agrees to counsel patients on the signs and symptoms of liver injury
- Patient does not have undiagnosed abnormal uterine bleeding
- Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors
- **Patient is not using Myfembree with oral P-gp inhibitors (e.g., erythromycin) or combined P-gp and strong CYP3A inducers (e.g., rifampin)**

Non-FDA-approved uses are not approved including **contraception** or pain associated with endometriosis.

Prior authorization expires after 24 months (lifetime expiration). **Cumulative treatment with Oriahnn and Myfembree will not exceed 24 months during the patient's lifetime**

7. semaglutide injection (Wegovy)

Manual PA criteria apply to all new users of Wegovy and is approved if all criteria are met:

- Patient is 18 years of age or older
- Patient has a BMI ≥ to 30, or a BMI ≥ to 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)
- Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy
- Patient has tried and failed or has a contraindication to all of the following agents (generic phentermine, Qsymia, Xenical, and Contrave). (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 DoD's preferred GLP1RAs (Trulicity and Bydureon Bcise)
- If the patient is an Active Duty Service Member, the individual is enrolled in a Service-specific Health/Wellness Program AND will

adhere to Service policy, AND will remain engaged throughout course of therapy

- Patient is not pregnant
- Concomitant use of Wegovy with other GLP1RA drugs is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy)
- The patient does not have a history of or does not have a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2

Non-FDA approved uses are NOT approved including for diabetes mellitus and for those less than 18 years of age.

Initial prior authorization expires after 4 months and then annually.

Renewal PA Criteria: Wegovy will be approved for an additional 12 months if the following are met:

- The patient is currently engaged in behavioral modification and remains on a reduced calorie diet
- Wegovy 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.

8. sotorasib (Lumakras)

Manual PA criteria apply to all new users of Lumakras and is approved if all criteria are met:

- Patient is 18 years of age or older
- Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test
- The patient will be monitored for interstitial lung disease and hepatotoxicity
- The drug is prescribed by or in consultation with a hematologist/oncologist
- Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment

- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.

Other non-FDA-approved uses are not approved.

Prior authorization does not expire.

9. viloxazine (Qelbree)

Manual PA criteria apply to all new users of Qelbree and is approved if all criteria are met:

- Patient is 6 to 17 years of age
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient has tried and failed, had an inadequate response, OR contraindication to amphetamine salts XR (Adderall XR, generic) or other long acting amphetamine or derivative drug
- Patient has tried and failed, had an inadequate response, OR contraindication to methylphenidate OROS and other (Concerta, generic) or other long acting methylphenidate or derivative drug
- Patient has tried and failed, had an inadequate response, OR contraindication to at least one non-stimulant ADHD medication (generic formulations of Strattera, Kapvay, or Intuniv)

Non-FDA-approved uses are not approved (to include depression and anxiety).

Prior authorization does not expire.

10. omalizumab syringe (Xolair)

Manual PA criteria apply to all new users of Xolair syringe and is approved for initial therapy for 12 months if all criteria are met:

For all indications:

- Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc.
- Patient has received at least 3 doses of Xolair under the guidance of a healthcare provider without experiencing any hypersensitivity reactions
- Provider agrees to ensure that the patient or caregiver is able to recognize symptoms of anaphylaxis presenting as bronchospasm,

hypotension, syncope, urticaria, and/or angioedema of the throat or tongue. Provider agrees to counsel the patient that anaphylaxis has occurred up to 2 hours post administration and appropriate monitoring will occur.

- Provider agrees to ensure that the patient or caregiver is able to treat anaphylaxis appropriately and consider co-prescribing epinephrine.
- Provider agrees to ensure that the patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe with proper technique according to the prescribed dosing regimen
- For all indications the patient is not currently receiving another immunebiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or dupilumab [Dupixent])

For Asthma:

- The patient is 6 years of age or older
- The drug is prescribed by an allergist, immunologist, pulmonologist, or asthma specialist
- The patient has moderate to severe asthma with baseline IgE levels that are greater than 30 IU/ml
- The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid:
    - Long-acting beta agonist (LABA e.g., Serevent, Striverdi)
    - Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or
    - Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo)

For chronic rhinosinusitis with nasal polyposis:

- The patient is 18 years of age or older
- The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist
- The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following:
    - Presence of nasal polyposis is confirmed by imaging or direct visualization AND
    - At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain

- Xolair will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation
- The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments
    - Adequate duration of at least two different high-dose intranasal corticosteroids AND
    - Nasal saline irrigation AND
    - The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery

For chronic idiopathic urticaria (CIU):

- The patient is 12 years of age or older
- The drug is prescribed by an allergist, immunologist, or dermatologist
- Xolair is not indicated for any other form of urticaria
- Patient has symptoms lasting for greater than 6 weeks
- Patient remains symptomatic despite trial of at least 4 weeks with recommended urticarial dosing of a second generation H1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine)

Non-FDA-approved uses are not approved.

Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely.

Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND

- Asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations or improvements in forced expiratory volume in one second (FEV1)
- Chronic rhinosinusitis with nasal polyposis: There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score
- Chronic Idiopathic Urticaria: The patient has had a positive response to therapy and improvement in clinical symptoms to warrant maintenance of therapy

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, Tier 4/Not Covered, PA, and Implementation Plan

The P&T Committee recommended group 1 (16 for, 0 opposed, 1 abstained, 1 absent); group 2 (14 for, 0 opposed, 2 abstained, 2 absent) an effective date of the following:

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

- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date of the first Wednesday120 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.

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

BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4 Recommendation

The P&T Committee recommended the formulary status for the newly approved drugs as discussed above:

- **UF**
  - Zegalogue
  - Truseltiq
  - Xolair syringe
  - Empaveli
  - Myfembree
  - Exservan oral film
  - Wegovy injection
  - Lumakras

- NF:
  - Nextstellis
  - Accrufer
  - Qelbree

- Tier 4/Not Covered:

  Roszet

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, Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended the following implementation plans as described above.

BAP Comment: ☐ Concur ☐ Non-concur

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. New Manual PA Criteria

1.) Miscellaneous Insulin Devices—Omnipod and Omnipod DASH

The Omnipod and Omnipod DASH cartridge pods are wearable, tubeless insulin management systems that are controlled using a personal diabetes manager (PDM). These FDA-approved medical devices must be filled with insulin by the patient, and supply up to 3 days (72 hours) of insulin. Omnipod systems are meant for those who require multi-day injections of insulin (defined as at least three times daily). The smartphone-like PDM allows for remote management of basal and bolus insulin dosing.

The Omnipod and Omnipod DASH are covered under the TRICARE pharmacy benefit, but the starter kit is packaged with the actual device and is not a pharmacy benefit. Prior authorization was recommended to reflect current TRICARE Policy Manual coverage requirements for external infusion pumps (EIPs).

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for new and current users of Omnipod and Omnipod DASH cartridge pods to ensure appropriate use in the expected patient population, as well as to ensure continued monitoring of blood glucose levels and proper patient education on the device.

a) Omnipod and Omnipod DASH PA criteria: The manual PA criteria apply to all new and current users of Omnipod and Omnipod DASH, and these devices will be approved if all the following are met:

- The patient has diabetes mellitus and requires insulin therapy
- The patient is on an insulin regimen of 3 or more injections per day and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy
- The patient performs 4 or more blood glucose tests per day or is using a Continuous Glucose Monitoring (CGM) system
- The patient has completed a comprehensive diabetes education program
- The patient has demonstrated willingness and ability to play an active role in diabetes self-management

Initial prior authorization expires after 1 year.

Renewal criteria: Note that initial TRICARE PA approval is required for renewal.

- Omnipod or Omnipod DASH is approved for 1 year for continuation of therapy if all criteria are met:
- Patient has been successful with therapy

- Patient does not require changing the Omnipod DASH unit more frequently than every 72 hours (e.g., changing the unit every 48 hours is not allowed)

b) Omnipod and Omnipod DASH Manual PA Criteria—Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the new PA criteria will become effective the first Wednesday 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

2) Laxatives-Carthartics-Stool Softeners – Lactulose Packet (Kristalose, generics) PA criteria and implementation plan

Lactulose formulated in packets (Kristalose brand and generic) are not cost effective relative to other formulary lactulose products or other laxatives (i.e., glycerin, lactitol, polyethylene glycol 3350, sorbitol), which are all available in low-cost formulations.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for lactulose packets (Kristalose, generics) in new users, due to the significant cost differences compared with numerous available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes.

Lactulose packets (Kristalose packets) Manual PA criteria apply to new users and is approved if all criteria are met:

- Provider acknowledges that lactulose solution and other laxatives (i.e., glycerin, lactitol, polyethylene glycol 3350, sorbitol) are available to DoD beneficiaries without the need of prior authorization
- The provider must explain why patient requires Kristalose packets as opposed to available alternatives.

Non-FDA approved uses are not approved.

Prior Authorization does not expire

3) Vitamins Prenatal – Prenatal Vitamins (Neonatal-DHA, Neonatal FE) PA criteria and implementation plan

Neonatal-DHA and Neonatal FE are prenatal dietary supplements manufactured by a single company and require a prescription prior to dispensing. The primary ingredients of Neonatal-DHA and Neonatal FE are similar to that found in other prenatal vitamins (Azesco, Zalvit, Trinaz) which

require manual PA. Several prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for Neonatal-DHA and Neonatal FE (regardless of the woman's age) in new users, due to the significant cost differences compared with numerous available alternative agents. The new PA will become effective the first Wednesday 90 days after the signing of the minutes.

Neonatal-DHA or Neonatal-FE Manual PA criteria apply to new users and is approved if all criteria are met:

- Provider acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, and Prenatal Plus DHA are the preferred products and are covered without a prior authorization for women who are under the age of 45 years and planning to become pregnant or who are pregnant. The provider is encouraged to consider changing the prescription to one of these agents.
- The provider must explain why the patient requires Neonatal DHA or Neonatal FE and cannot take the available alternatives.

Non-FDA-approved uses are not approved.

PA does not expire.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. New Manual PA Criteria for Omnipod, Omnipod DASH, Kristalose packets, and Neonatal-DHA and Neonatal-FE prenatal vitamins:

The P&T Committee recommended manual PA criteria for Omnipod and Omnipod DASH in new and current users, for Kristalose packets in new users, and for Neonatal-DHA and Neonatal FE prenatal vitamins in new users, as outlined above.

BAP Comment: □ Concur □ Non-concur

B. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the new PA criteria for Omnipod and Omnipod DASH become effective at 90 days and that DHA will send letters; the new PA for Kristalose packets become effective at 60 days, and the new PA for the prenatal vitamins become effective at 90 days.

BAP Comment: □ Concur □ Non-concur

X. UTILIZATION MANAGEMENT—UPDATED PA AND STEP THERAPY CRITERIA

P&T Comments

A. Updated PA and Step Therapy Criteria:

Updates to the manual PA criteria and step therapy were recommended for the following products, due to availability of cost-effective alternative treatments, results from clinical trial data, clinical practice guideline updates, or provider recommendation. The updated PAs and step therapy outlined below will apply to new users.

1.) Multiple Sclerosis Agents—ozanimod (Zeposia) PA criteria and implementation plan

Zeposia is a sphingosine-1 phosphate receptor modulator originally approved for treating relapsing forms of multiple sclerosis. It recently gained approval for ulcerative colitis (UC), another type of immune-mediated inflammatory disorder. At the time of review the trial supporting Zeposia for UC was not published. Other treatments, including non-biologics (e.g., azathioprine, sulfasalazine) and the targeted immunomodulatory biologic (TIBs) adalimumab (Humira) are well-established therapies for UC, and are more

cost effective than Zeposia. The Zeposia PA was updated to allow for treatment of UC after a trial of non-biologic systemic therapy and trial of Humira.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updating the current PA criteria for Zeposia to require more clinically established and cost effective treatments first. Updates to the current PA criteria in new users for Zeposia will become effective the first Wednesday 30 days after the signing of the minutes.

Zeposia Manual PA criteria apply to all new users and will be approved if all criteria are met: (Note that the updates for UC are in bold)

- All recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes CBC, LFT, varicella zoster virus (VZV) antibody serology, ECG, and macular edema screening as indicated.
- **Patients of childbearing potential agree to use effective contraception during treatment and for 3 months after stopping therapy**
- Zeposia will not be used in patients with significant cardiac history, including:
    - Patients with a recent history (within the past 6 months) of class Ill/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization
    - Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker

For relapsing Multiple Sclerosis

- Zeposia is prescribed by a neurologist
- Patient has a documented diagnosis of relapsing forms of MS
- There is no concurrent use of other MS disease-modifying therapy
- Patient has not failed a course of another S1p receptor modulator (e.g., Gilenya, Mayzent)

For Ulcerative Colitis

- **The patient has a diagnosis of moderate to severe active Ulcerative Colitis**
- **The patient is 18 years of age or older**
- **The provider acknowledges that Humira is the Department of Defense's preferred targeted immunomodulatory biologic agent for ulcerative colitis.**
- **The patient must have tried Humira AND:**

- Had an inadequate response to Humira OR
- Experienced an adverse reaction to Humira that is not expected to occur with Zeposia OR
- Has a contraindication to Humira

- **The patient is not receiving oral immunomodulatory or biologic therapies concomitantly**
- **The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)**

Non-FDA-approved uses are not approved.

Prior authorization does not expire

2.) Migraine Agents—rimegepant (Nurtec ODT), ubrogepant (Ubrelvy), lasmiditan (Reyvow) PA criteria and implementation plan

These three oral drugs were originally approved for acute treatment of migraine headache, and were reviewed at the May 2020 P&T Committee meeting. PA criteria currently apply. Rimegepant orally disintegrating tablets (Nurtec ODT) is now FDA-approved for preventive treatment of episodic migraine in adults. Other migraine preventive medications (e.g., antiepileptics, beta blockers, antidepressants, and the injectable calcitonin gene-related peptide [CGRP] antagonists) are available that have shown greater reductions in monthly migraine days than Nurtec ODT, based on indirect comparison, and are more cost-effective.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updating the current PA criteria for Nurtec ODT, Ubrelvy, and Reyvow to require a trial of other preventive medications (oral agents, and injectable CGRPs) first. PAs for Nurtec ODT, Ubrelvy, and Reyvow were also updated to include renewal criteria, to assess for efficacy. Updates to the current PA criteria in new users for Nurtec ODT, Ubrelvy, and Reyvow will become effective the first Wednesday 60 days after the signing of the minutes.

a.) rimegepant (Nurtec ODT) Manual PA criteria apply to all new users and will be approved if all criteria are met: (Note that updates from the August 2021 meeting are in bold.)

- The patient is 18 years of age or older
- The medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., another gepant [Ubrelvy]) is not allowed
- Not approved for patients who have clinically significant or unstable cardiovascular disease

For Acute Treatment

- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
  - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)

For Prevention of Episodic Migraine

- **The patient has episodic migraine as defined by one of the following:**
  - **Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR**
  - **Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months**
- **Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:**
  - **Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate**
  - **Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol**
  - **Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine**
- **Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents**
  - **erenumab-aooe (Aimovig)**
  - **fremanezumab-vfrm (Ajovy)**
  - **galcanezumab-gnlm (Emgality)**

Non-FDA-approved uses are NOT approved.

PA expires after 6 months

Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if one of the following apply (Note that initial TRICARE PA approval is required for renewal):

Acute Treatment

- **Patient has a documented positive clinical response to therapy**

Preventive Treatment

- **The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR**
- **The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:**
  - **Migraine Disability Assessment (MIDAS)**
    - **Reduction of ≥ 5 points when baseline score is 11–20**
    - **Reduction of ≥ 30% when baseline score is > 20**
  - **Headache Impact Test (HIT-6)**
    - **Reduction of ≥ 5 points**
  - **Migraine Physical Functional Impact Diary (MPFID)**
    - **Reduction of ≥ 5 points**

b.) ubrogepant (Ubrelvy) Manual PA criteria apply to all new users and will be approved if all criteria are met: (Note that updates from the August 2021 meeting for the renewal criteria are in bold.)

- The patient is 18 years of age or older
- The medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., another gepant [Nurtec ODT]) is not allowed
- Not approved for patients who have clinically significant or unstable cardiovascular disease
- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
  - 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

Non-FDA-approved uses are NOT approved.

PA expires after 6 months

Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if one of the following apply (Note that initial TRICARE PA approval is required for renewal):

Acute Treatment

- **Patient has a documented positive clinical response to therapy**

c.) lasmiditan (Reyvow) Manual PA criteria apply to all new users and will be approved if all criteria are met: (Note that updates from the August 2021 meeting for the renewal criteria are in bold.)

- The patient is 18 years of age or older
- The medication is prescribed by or in consultation with neurologist
- Reyvow is not approved for patients with a history of hemorrhagic stroke
- Reyvow is not approved for patients with a history of epilepsy or any other condition with increased risk of seizure
- Not approved for patients who have clinically significant or unstable cardiovascular disease
- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
  - 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
- If Reyvow is used with a triptan, the 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 expires after 6 months

Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if one of the following apply (Note that initial TRICARE PA approval is required for renewal):

Acute Treatment

- **Patient has a documented positive clinical response to therapy**

XI. UTILIZATION MANAGEMENT—UPDATED PA AND STEP THERAPY CRITERIA

BAP Comments

A. Updated PA and Step Therapy Criteria:

The P&T Committee recommended the update PA criteria for Zeposia, Nurtec ODT, Ubrelvy, and Reyvow in new users, as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

B. Updated PA Criteria and Implementation Plan

The P&T Committee recommended the updated PA criteria for Zeposia become effective the first Wednesday 30 days after the signing of the minutes, and for the migraine drugs at 60 days after signing.

BAP Comment: ☐ Concur ☐ Non-concur

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS OR EXPANDED AGE RANGES

P&T Comments

A. Updated PA Criteria for Expanded Uses and implementation plan:

Updates to the PA criteria for several drugs were recommended due to new FDA-approved indications and expanded age ranges. The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updates to the manual PA criteria for Ayvakit, Cosentyx, Myrbetriq, Toviaz, Epclusa and authorized generic, Mavyret, Evekeo ODT, and Ocaliva, due to new FDA-approved indications and expanded age ranges. The updated PA criteria summarized below will apply to new users.

Note that since these types of updates expand the patient population eligible for the drug, only a summary of the PA criteria is provided here; the current full PA criteria can be found on the TRICARE Formulary Search Tool at https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/. The updated PA criteria will become effective the first Wednesday 60 days after the signing of the minutes.

1.) **Oncologic Agents Target –avapritinib (Ayvakit)**—Includes the new indication for adult patients with advanced systemic mastocytosis (comprises patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia)

2.) **Targeted Immunomodulatory Biologics —secukinumab (Cosentyx)**—Manual PA criteria now allow use in pediatric patients 6 years of age and older, as well as in adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

3.) **Overactive Bladder Agents**

- **mirabegron (Myrbetriq) tablets and granules**—The manual PA criteria were updated to allow for the new indication for treatment of neurogenic detrusor overactivity (NDO) in patients 3 years of age and older (for the granules) and weighing 35 kg or more (for the tablets) *(note that the granules were reviewed as an innovator at the November 2021 meeting)*

- **fesoterodine (Toviaz)**—Manual PA criteria were updated to allow for the new indication for treatment of neurogenic detrusor overactivity (NDO) in patients 6 years of age and older and weighing more than 25 kg.

4.) **Hepatitis C Agents: Direct Acting Agents— sofosbuvir/velpatasvir (Epclusa) and authorized generic; glecaprevir/pibrentasvir (Mavyret)**—The manual PA criteria now allow use in pediatric patients 3 years of age and older as well as adults for treatment of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6.

5.) **ADHD Agents: Stimulants – amphetamine sulfate ODT (Evekeo ODT)**—The manual PA criteria now allow use in pediatric patients between the ages of 3 to 17 years for treatment of ADHD.

6.) **Gastrointestinal-2 Agents – obeticholic acid (Ocaliva)** —The manual PA criteria was revised and updated for safety information to narrow the indication for the patient population with primary biliary cholangitis (PBC), based on information from the manufacturer.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS OR EXPANDED AGE RANGES

BAP Comments

A. Updated PA Criteria for expanded uses:

The P&T Committee recommended the updates to the current PA criteria in new users for the following drugs: Ayvakit, Cosentyx, Myrbetriq, Toviaz, Epclusa and authorized generic, Mavyret, Evekeo ODT, and Ocaliva as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

B. Updated PA Criteria for Expanded Uses Implementation Plan

The updated PA criteria will become effective the first Wednesday 60 days after the signing of the minutes.

BAP Comment: ☐ Concur ☐ Non-concur

XIV. COPAYMENT CHANGE – TIER 1 for the PULMONARY 3 AGENTS: COMBINATIONS SUBCLASS—BREZTRI INHALER COPAYMENT CHANGE

P&T Comments

A. Tier 1 Copayment and Implementation Plan:

The fixed-dose triple combination inhalers containing an inhaled corticosteroid, long-acting muscarinic antagonist, and long-acting beta agonist (ICS/LAMA/LABA) were reviewed for formulary status at the February 2021 Committee meeting. Both budesonide/glycopyrrolate/formoterol (Breztri) and fluticasone/umeclidinium/vilanterol (Trelegy) were recommended to remain on the UF.

Following the meeting, more favorable pricing for Breztri became available, making it the most cost effective triple combination inhaler. As a result the Tier 1 copay was recommended for Breztri at this (August 2021) meeting. (Note that Committee recommendations from February 2021 had not yet been implemented at the time of the August 2021 P&T Committee meeting, due to the BAP zero-based review.)

Applying the Tier 1 copay at both Retail and Mail will also encourage use of the most cost-effective triple fixed-dose combination inhaler. Additionally, lowering the copay for this agent is consistent with 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020, in that the P&T 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 P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) changing the copay for Breztri inhaler from Tier 2 (brand) to the Tier 1 (generic) copay at the purchased care points of service (Retail and Mail). Implementation will occur on signing of the minutes.

XV. TIER 1 COPAYMENT CHANGE for the PULMONARY 3 AGENTS: COMBINATIONS SUBCLASS— BUDESONIDE/GLYCOPYRROLATE/FORMOTEROL (BREZTRI INHALER) COPAYMENT CHANGE

BAP Comments

A. Breztri Inhaler Tier 1 Copayment and Implementation Plan

The Committee recommended the Tier 1 Copay change for Breztri inhaler, as outlined above, with implementation occurring upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur

XVI. BRAND OVER GENERIC AUTHORIZATION and TIER 1 (GENERIC) COPAYMENT PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS: AMBRISENTAN (LETAIRIS)

P&T Comments

A. Ambrisentan (Letairis) brand over generic authorization and Tier 1 Copayment and Implementation Plan

The PAH drugs including the endothelin receptor antagonist subclass were most recently reviewed for formulary placement in May 2019. The Committee originally recommended brand over generic authorization and Tier 1 status for branded ambrisentan (Letairis). However, multiple cost effective generic formulations were subsequently available prior to the implementation date of October 2019, so this requirement was removed at the August 2019 meeting.

At the August 2021 DoD P&T Committee meeting, the Committee reviewed overall trends in utilization and expenditures since implementation of the formulary recommendations in October 2019. The post-implementation review did reveal that supply of cost effective generic ambrisentan was unreliable. As a result, branded Letairis is currently more cost-effective than generic ambrisentan products. Due to these supply and cost issues, the Committee recommended implementing the brand over generic requirements for ambrisentan, requiring use of the branded Letairis formulation prior to a generic formulation, and applying the Tier 1(generic) copay to the branded Letairis product.

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) requiring brand Letairis over generic ambrisentan in all new and current users, based on cost effectiveness. The prescriber will provide patient-specific justification as to why branded Letairis cannot be used. The Tier 1 (generic) copayment will apply to brand Letairis. The effective date will be upon signing of the minutes in all points of service. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3): [W]hen a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

XVII. BRAND OVER GENERIC AUTHORIZATION and TIER 1 COPAYMENT PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS: — AMBRISENTAN (LETAIRIS)

BAP Comments

A. Brand over generic authorization for ambrisentan (Letairis) and Tier 1 Copayment and Implementation Plan

The P&T Committee recommended the Letairis brand over generic authorization, PA criteria, Tier 1 (generic) copay and implementation upon signing of the minutes, as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

XVIII. INFORMATION ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT (AUGUST 2021 DOD P&T COMMITTEE MEETING)

Table of implementation Status of UF Recommendations/Decisions Summary

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors	▪ acalabrutinib (Calquence) ▪ ibrutinib (Imbruvica) ▪ zanubrutinib (Brukinsa)	▪ None	▪ None	Pending signing of the minutes: 2 weeks	▪ Existing PAs in place for all 3 drugs ▪ Minor updates to the Ibrance tablets PA, requiring use of the capsules first ▪ UUs affected – not applicable; no NF drugs, no new PAs
Laxatives-Cathartics-Stool Softeners: Bowel Preparations	▪ PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution **(Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics**) ▪ PEG 3350 sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution **(NuLYTELY, TriLyte, generics)** ▪ PEG sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for oral solution **(Moviprep)** ▪ PEG sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for solution **(Plenvu)** ▪ sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution **(Clenpiq)**	▪ sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution **(Suprep)** ▪ sodium sulfate, potassium chloride and magnesium sulfate tablets **(Sutab)** ▪ sodium phosphate tablets **(Osmoprep)** ▪ sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets **(Prepopik)**	▪ None	Pending signing of the minutes: 2 weeks	▪ No PAs for any of the drugs ▪ UUs affected – not applicable – drugs are used acutely once for bowel prep ▪ Current utilization for the drugs moving to NF: ▪ Suprep: 83,000 patients in calendar year 2020 ▪ Osmoprep: 600 patients ▪ Prepopik: 0 patients

Table of Newly Approved New Drugs Designated Tier 4—Unique Utilizers Affected

Drug	Total
rosuvastatin/ezetimibe (Roszet)	3

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Miscellaneous Insulin Devices: Omnipod	1	95	64	160
Miscellaneous Insulin Devices: Omnipod DASH	80	4	2,284	2,368

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Miscellaneous Insulin Devices: Omnipod	1	95	64	160