DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE AUGUST 2025 MEETING

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING Day #2 AM - refer to the posted Agenda for meetings dates and times at https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with Section 1074g of Title 10, United States Code (USC), as implemented by Section 199.21 of Title 32, Code of Federal Regulations (CFR), 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 complete exclusion status, prior authorizations (PAs), pre-authorizations, and the effective date for a pharmaceutical agent's change from formulary to nonformulary (NF) or to complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEW—ATOPY AGENTS: INTERLEUKIN (IL)-13 AND IL-31 SUBCLASSES

P&T Comments

A. Atopy Agents: IL-13 and IL-31 Subclasses—Relative Clinical Effectiveness Conclusion

Background—The IL-13 and IL-31 subclasses include four biologic agents, dupilumab (Dupixent), lebrikizumab (Ebglyss), nemolizumab (Nemluvio) and tralokinumab (Adbry). All four agents are indicated for treatment of moderate to severe atopic dermatitis; additionally, Dupixent and Nemluvio are indicated for treatment of prurigo nodularis. Dupixent also has several additional indications.

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, meta-analyses and systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles for atopic dermatitis and prurigo nodularis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Atopic Dermatitis

- There are no head-to-head trials comparing Dupixent, Adbry, Ebglyss or Nemluvio.
- Guidelines from the American Academy of Dermatology (AAD) (2023) and the American Academy of Allergy, Asthma & Immunology (2023) support the use of multiple systemic and biologic treatments to treat moderate to severe atopic dermatitis refractory to topical treatments.

        - Both Dupixent and Adbry are recommended in the 2023 AAD guidelines with a high certainty for their evidence for efficacy and that they appear safe. Nemluvio and Ebglyss are not yet included in the guidelines due to their more recent FDA approval in November 2024.
        - Topical agents including corticosteroids and calcineurin inhibitors (i.e., tacrolimus and pimecrolimus) are recommended for mild to moderate atopic dermatitis. Topical agents can be used with phototherapy and systemic therapies for maintenance of response or treatment of flares.
    - A 2023 network meta-analysis evaluating the four agents along with the oral Janus kinase (JAK) inhibitors in 149 trials with over 28,000 patients concluded the following:
        - Dupixent, Ebglyss, and Adbry are of intermediate effectiveness and have favorable safety profiles.
        - For the Patient Oriented Eczema Measure, Pruritus Numeric Rating Scale, and Dermatology Life Quality Index all four agents were statistically significant when compared to placebo.
        - For the Eczema Area Severity Index, Dupixent, Ebglyss, and Adbry were all statistically significant in relieving symptoms, with Dupixent and Ebglyss also showing clinical significance.
        - In terms of safety, all four agents did not demonstrate a significant increase in frequency of any adverse event. However, Dupixent, Adbry and Ebglyss did show an increased frequency of conjunctivitis, compared with standard care. Dupixent demonstrated a reduced odds of serious adverse events and adverse events leading to discontinuation when compared to placebo.
    - Additional literature review included two placebo-controlled trials published in 2024 evaluating Nemluvio and reported statistically significant results for the four rating scales discussed above, with similar outcomes as reported in the 2023 NMA reviewed.

Prurigo Nodularis

- Dupixent and Nemluvio are also approved to treat prurigo nodularis in addition to atopic dermatitis. A 2021 U.S. expert consensus panel recommends Dupixent or Nemluvio for disease refractory to topical treatments, or for patients with more severe presentation. Topical corticosteroids and topical calcineurin inhibitors are recommended for mild disease. Other supported treatments include methotrexate, azathioprine, mycophenolate, and cyclophosphamide.
- An indirect efficacy analysis between Dupixent and Nemluvio is challenging due to varying inclusion criteria among the trials. The Dupixent data includes two randomized trials over 24 weeks allowing continuation of

stable topical treatments, while Nemluvio includes 2 randomized trials over 16 weeks excluding use of topicals.

- For the proportion of patients achieving Investigator Global Assessment scores of 0 to1 (clear to near clearance of lesions), the two Dupixent trials and a single Nemluvio trial achieved a statistically significant proportion of responders compared to placebo. For the endpoint of daily quality of life, all the studies showed that treatment with Dupixent and Nemluvio achieved a statistically significant, similar outcome.

- For the individual prurigo nodularis trials, treatment emergent adverse events occurred in over half of the patients across all trials. A higher proportion of patients had disease flare in the Nemluvio trials compared to those in the Dupixent trials.

Other Factors

- Dupixent carries the most FDA-approved indications (eight). The most recent label updates include bullous pemphigoid in adults and chronic spontaneous urticaria in children down to the age of 12 years. For atopic dermatitis, it is approved for children as young as 6 months of age. The package insert lists more warnings and adverse events compared to other agents in the subclass, including herpes simplex virus infection, conjunctivitis, eosinophilia and arthralgia. It is available in pre-filled syringes and pre-filled pens.

- Adbry and Ebglyss are only indicated for the treatment of atopic dermatitis for adults and children down to 12 years of age. Common adverse events for both include conjunctivitis and herpes simplex virus infection; Adbry can cause eosinophilia. Adbry is available in both an autoinjector and pre-filled syringe, while Ebglyss is supplied as prefilled pens and pre-filled syringes.

- Nemluvio is indicated for atopic dermatitis in adults and children as young as 12 years of age as well as prurigo nodularis for adults. Unique adverse events in the label include headache, urticaria and myalgia. It offers the longest dosing frequency of up to 8 weeks and is supplied as a pre-filled pen.

- In terms of therapeutic interchangeability, for efficacy for treating atopic dermatitis, Dupixent, Adbry, Ebglyss and Nemluvio have a high degree of therapeutic interchangeability; for safety, there is a moderate degree of therapeutic interchangeability. For prurigo nodularis, Dupixent and Nemluvio have a high degree of interchangeability for efficacy, and moderate degree of interchangeability for safety.

Overall Conclusion

- For clinical coverage, at least one agent is needed on the formulary to treat atopic dermatitis and prurigo nodularis in order to meet the needs of Military Health System (MHS) beneficiaries.

B. Atopy Agents: IL-13 and IL-31 Subclasses—Relative Cost Effectiveness Conclusion

The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) designating all four drugs as UF was cost-effective, based on the CMA and BIA.

C. Atopy Agents: IL-13 and IL-31 Subclasses—UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
  - dupilumab (Dupixent)
  - lebrikizumab (Ebglyss)
  - nemolizumab (Nemluvio)
  - tralokinumab (Adbry) - *moves from NF to UF*
- NF: None
- Complete Exclusion: None

D. Atopy Agents: IL-13 and IL-31 Subclasses—Manual PA Criteria

Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updated manual PA criteria for new users.

- In general, specialist prescribing is required, and renewal is recommended after one year, documenting improvement in symptoms.
- Guideline-recommend therapies are required first, including topical treatments and phototherapy for atopic dermatitis, and other therapies, depending on indication (e.g., pulmonary inhalers for asthma and chronic obstructive pulmonary disease for Dupixent; nasal saline irrigation and nasal steroids for nasal polyps).
- The new indications for Dupixent for bullous pemphigoid and chronic spontaneous urticaria were added to the PA.
- For Ebglyss, automated specialist bypass for patients 12 years of age and older when prescribed by a dermatologist, allergist or immunologist was added to bypass the PA. Additionally, an automated drug look back was added for Ebglyss, to allow continuation of coverage by any other prescriber if the patient has received a prescription for Ebglyss in the past 720 days.

The Manual PA criteria are as follows.

1. dupilumab (Dupixent)

Updates from the August 2025 meeting are in bold

Manual PA criteria apply to all new users of Dupixent

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

For all indications

- Non-FDA-approved uses are not approved
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])

Atopic Dermatitis indication

- The patient is at least 6 months of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe or uncontrolled atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 6 months to 17 years of age: any topical corticosteroid
  - For patients 2 years of age and older: topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient's disease severity has improved and stabilized to warrant continued therapy

Asthma indication

- The patient is 6 years of age or older
- The drug is prescribed by an allergist, immunologist **or** pulmonologist, ~~**or asthma specialist**~~
- The patient has one of the following
  - Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/microliter OR
  - Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months
- For eosinophilic asthma, the patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following;
  - Hospitalization for asthma in past year OR
  - Two courses oral corticosteroids in past year OR
  - Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids
- For eosinophilic asthma, 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)

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for asthma: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- **Patient's disease severity has improved and stabilized to warrant continued therapy** ~~the patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second(FEV1) or decrease in oral corticosteroid use~~

Chronic rhinosinusitis with nasal polyposis indication

- The patient is 12 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
- Dupixent 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
- Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic rhinosinusitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- **Patient's disease severity has improved and stabilized to warrant continued therapy**
- ~~There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score~~

Eosinophilic Esophagitis (EoE) indication

- The patient is one year of age or older and weighs at least 15 kilograms (approximately 33 lbs)
- The drug is prescribed by or in consultation with a gastroenterologist ~~or allergy/immunology specialist allergist or immunologist~~
- Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy

- For EoE, the patient has tried and failed an adequate course of both the following:
  - Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND
  - Topical glucocorticoids [e.g., fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, or clinically significant adverse effects are experienced, ~~or in children maximal doses cannot be reached due to concerns for growth suppression or adrenal insufficiency~~

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for EoE: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- **Patient's disease severity has improved and stabilized to warrant continued therapy**
- ~~For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e):~~
  - ~~Reduced intraepithelial eosinophil count; OR~~
  - ~~Decreased dysphagia/pain upon swallowing; OR~~
  - ~~Reduced frequency/severity of food impaction; OR~~
  - ~~Reduced vomiting/regurgitation; OR~~
  - ~~Improvement in oral aversion/failure to thrive~~
  - ~~For relapse: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval~~

Prurigo Nodularis Indication

- Patient is 18 years of age or older
- The drug is prescribed by an allergist, immunologist, or dermatologist
- Patient has a diagnosis of prurigo nodularis
- Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk
- Patient has experienced pruritus for 6 weeks or longer
- Patient’s prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR

- The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed
- The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy
- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])**

Non-FDA approved uses are not approved

~~Prior authorization does not expire for prurigo nodularis~~ **Prior authorization expires after 12 months**

Renewal criteria for prurigo nodularis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met:

- ~~Prurigo nodularis:~~ **The patient's disease severity has improved and stabilized to warrant continued therapy**

Chronic Obstructive Pulmonary Disease (COPD) indication

- Patient is 18 years of age or older
- Prescribed by a pulmonologist
- Patient has moderate to severe chronic obstructive pulmonary disease (COPD) with both chronic bronchitis and an eosinophilic phenotype (greater than 300 cells/microliter)
- Patient has uncontrolled COPD symptoms despite the use of all of the following: long-acting muscarinic antagonists (e.g., tiotropium bromide); long-acting-beta agonists (e.g., formoterol); inhaled corticosteroid (e.g., budesonide)
- Medication is being requested for add-on maintenance therapy for management of COPD
- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])**

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for COPD: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient's disease severity has improved and stabilized to warrant continued therapy

Chronic Spontaneous Urticaria indication

- **Patient is 12 years of age or older**
- **Prescribed by an allergist, immunologist or dermatologist**
- **Patient has a diagnosis of chronic spontaneous urticaria with symptoms lasting longer than 6 weeks**
- **Patient remains symptomatic despite a trial of at least 4 weeks up to 4 times the standard dosing of a second-generation histamine H-1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine)**
- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])**

Non-FDA approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for chronic spontaneous urticaria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- **Patient's disease severity has improved and stabilized to warrant continued therapy**

Bullous Pemphigoid indication

- **Patient is 18 years of age or older**
- **Prescribed by a dermatologist, allergist, or immunologist**
- **Patient has a confirmed diagnosis of bullous pemphigoid**
- **Patient has an initial bullous pemphigoid disease area index (BPDAI) score greater than or equal to 24**
- **Patient has an initial Peak Pruritus Numeric Rating Scale score of greater than or equal to 4**
- **The patient has a contraindication to, intolerability to, or has failed treatment with all the following:**
  - **One high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream)**
  - **One oral corticosteroid (e.g., prednisone, prednisolone)**
  - **Two additional adjuncts (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide, doxycycline)**

Non-FDA approved uses are not approved

Prior authorization expires after 12 months

<u>Renewal criteria for bullous pemphigoid:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- **Patient's disease severity has improved and stabilized to warrant continued therapy**

2. lebrikizumab (Ebglyss)

Updates from the August 2025 meeting are in bold and strikethrough

<u>Automated PA criteria:</u> When the patient is 12 years of age and older AND when prescribed by a dermatologist, allergist or immunologist, prior authorization is not required. Once therapy is initiated by a dermatologist, allergist or immunologist, an automated drug lookback will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days OR

Manual PA criteria apply to all new users of Ebglyss if automated criteria are not met

<u>Manual PA Criteria:</u> Ebglyss is approved if all criteria are met:

<u>Atopic Dermatitis indication</u>

- The patient is at least 12 years of age or older
- The patient's weight is 40 kg or greater
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 12 to 17 years of age: any topical corticosteroid
  - topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- The patient is not currently receiving another immunobiologic **(e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])**

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient's disease severity has improved and stabilized to warrant continued therapy

3. tralokinumab (Adbry)

Manual PA criteria apply to all new users of Adbry

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

Atopic Dermatitis indication

- The patient is 12 years of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 12 to 17 years of age: any topical corticosteroid
  - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient's disease severity has improved and stabilized to warrant continued therapy

4. nemolizumab (Nemluvio)

Updates from the August 2025 meeting are in bold

Manual PA criteria apply to all new users of Adbry

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

Atopic Dermatitis indication

- The patient is 12 years of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids
    - For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 12 to 17 years of age: any topical corticosteroid
  - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy
- **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair])**

Non-FDA-approved uses are not approved

Prior authorization expires after 12 months

Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

- Patient's disease severity has improved and stabilized to warrant continued therapy

Prurigo Nodularis Indication

- Patient is 18 years of age or older
- The drug is prescribed by an allergist, immunologist, or dermatologist
- Patient has a diagnosis of prurigo nodularis
- Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk
- Patient has experienced pruritus for 6 weeks or longer

- Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR
- The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed
- The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy
- The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])

Non-FDA approved uses are not approved

~~Prior authorization does not expire for prurigo nodularis~~ **Prior authorization expires in 12 months**

Renewal criteria for prurigo nodularis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met:

- ~~Prurigo nodularis:~~ **The patient's disease severity has improved and stabilized to warrant continued therapy**

E. Atopy Agents: IL-13 and IL-31 Subclasses —UF Recommendation, PA Criteria and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes.

III. UF DRUG CLASS REVIEW—ATOPY AGENTS: IL-13 AND IL-31 SUBCLASSES

UF BAP Comments

A. Atopy Agents: IL-13 and IL-31 Subclasses s—UF Recommendation

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

- UF
  - dupilumab (Dupixent)
  - lebrikizumab (Ebglyss)
  - nemolizumab (Nemluvio)
  - tralokinumab (Adbry) - *moves from NF to UF*
- NF: None

- Complete Exclusion: None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Atopy Agents: IL-13 and IL-31 Subclasses —Manual PA Criteria

The P&T Committee recommended PA criteria in new users of Dupixent, Ebglyss, Adbry and Nemluvio, as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Atopy Agents: IL-13 and IL-31 Subclasses —UF recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 30 days after signing of the minutes in all points of service.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—DIURETICS MINERALOCORTICOID RECEPTOR ANTAGONISTS SUBCLASS

P&T Comments

A. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the mineralocorticoid receptor antagonists (MRAs). The subclass is comprised of two generic medications, eplerenone and spironolactone (available in tablets and oral suspension), and branded finerenone (Kerendia). Kerendia was previously reviewed as a new drug in November 2021 and is designated as NF.

In terms of FDA-approved indications, eplerenone and spironolactone are both indicated for treating hypertension, and all three drugs are approved for heart failure. Finerenone is also approved for treating type 2 diabetic chronic kidney disease (CKD). Spironolactone has several additional indications including edema due to nephrotic syndrome or cirrhosis, and primary hyperaldosteronism. The clinical review focused on the place in therapy for type 2 diabetic CKD and heart failure.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

Efficacy for Type 2 diabetics CKD

- In patients with type 2 diabetes receiving therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), finerenone is approved to reduce the composite endpoint of decline in estimated glomerular filtration rate (eGFR) end-stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction and heart failure hospitalization, based on the FIDELIO and FIGARO studies.
    - Limitations to the results include the low use (4%) of current guideline-accepted background therapy with sodium-glucose transportor-2 (SGLT-2) inhibitors. Additionally, in the FIDELIO study, the results were driven by the reduction in eGFR; no difference was noted in progression to end-stage kidney disease or the other individual components of the composite endpoint.

- Studies with eplerenone and spironolactone report that both drugs reduce proteinuria, but do not reduce adverse renal outcomes (e.g., progression to end-stage kidney disease). There was a significantly increased risk of hyperkalemia. Overall, the long-term effects of eplerenone and spironolactone on renal outcomes, mortality and safety for type 2 diabetic CKD remain to be established.

- Finerenone is included in several clinical practice guidelines to slow the progression of CKD in patients with Type 2 diabetes. However, ACE inhibitors or ARBs remain the mainstay of therapy as first-line treatment. Guidelines also state the SGLT-2 inhibitors are preferred and more-established therapies, before adding finerenone. Guidelines reviewed included, but were not limited to, the following: 2024 American Diabetes Association, 2024 Kidney Disease Improving Global Outcomes, 2025 VA/DoD, and the 2023 United Kingdom National Institute for Clinical Effectiveness.

Efficacy for heart failure

- In July 2025, finerenone received approval for patients with heart failure and preserved ejection fraction (HFpEF) based on the FINEARTS trial. Treatment with finerenone resulted in a 16% risk reduction in the composite of worsening

heart failure event and CV death. No significant difference was noted for the individual endpoints of mortality or kidney outcomes. The results were driven by a reduction in heart failure events. As with CKD, the study is limited by low background use of SGLT-2 inhibitors.

- Spironolactone showed a 30% reduction in all-cause death in patients with heart failure and reduced ejection fraction (HFrEF) in the landmark RALES study. Reduced mortality (20% risk reduction) was seen for HFpEF in the TOPCAT study, when the results were limited to North America.
- Eplerenone showed a 15% reduction in all-cause death in patients with heart failure after myocardial infarction (EPHESUS).
- For HFpEF, SGLT-2 inhibitors remain the mainstay of therapy, based on results from several large trials. Other drug classes, including diuretics, eplerenone or spironolactone, sacubitril/valsartan or ARBs are added, based on individual patient clinical presentation (2023 American College of Cardiology.) Finerenone is not specifically mentioned in the guidelines.
- For HFrEF, spironolactone and eplerenone hold a Class I recommendation (strong evidence) for patients with New York Heart Association (NYHA) class II-IV heart failure (2023 American College of Cardiology.)

Safety

- Adverse events associated with all three MRAs include hyperkalemia, hypotension, and hyponatremia.
- Finerenone has different receptor affinity than spironolactone, which may account for some differences in the adverse event profile. Lack of head-to-head trials and study design run-in criteria complicates ability to determine if the hyperkalemia risk with finerenone is favorable or unfavorable compared to eplerenone or spironolactone.
- Gynecomastia does not appear to be an issue with eplerenone or finerenone.

Other Factors

- MHS providers requested UF placement of finerenone, due to inclusion in national guidelines for T2DM and CKD but acknowledged other guideline-recommended therapies should be used first.

Clinical Coverage

- In order to meet the needs of MHS patients, finerenone should be included on the formulary, despite limitations in clinical trial data.
- Spironolactone oral suspension is required for the pediatric population for edema and heart failure.

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) that designating finerenone as UF rather than NF would be cost effective.

C. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—UF Recommendation

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following.

- UF
  - eplerenone (Inspra, generics)
  - finerenone (Kerendia) - *moves from NF to UF*
  - spironolactone (Aldactone, generics)
  - spironolactone/hydrochlorothiazide (Aldactazide, generics)
  - spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*
- NF – None
- Complete Exclusion – None

D. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—Manual PA Criteria

PA criteria currently apply to Kerendia and for spironolactone oral suspension. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) revising the PA criteria for Kerendia in new users to incorporate feedback from MHS providers for the CKD indication, to modify the safety questions, and to add the new indication for HFpEF based on the inclusion and exclusion criteria from the FINEARTS trial. Other guideline-directed therapies are required first, based on clinical practice guidelines. No changes were recommended for the PA for spironolactone suspension.

The Manual PA criteria are as follows:

1. finerenone (Kerendia)

Updates from the August 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of Kerendia

Manual PA Criteria: Kerendia is approved if all of the following criteria are met:

- The patient is 18 years of age and older

For Type 2 Diabetes Mellitus and Chronic Kidney Disease

- Kerendia is prescribed by or in consultation with a nephrologist
- The patient has a diagnosis of type 2 diabetes mellitus (T2DM)
- The patient has documented diabetic kidney disease with albuminuria, defined as ~~one of the following~~
  - An estimated glomerular filtration rate (eGFR) of 25-75 AND urinary albumin-to-creatinine ratio of ≥ 30 mg/g OR
  - ~~eGFR 25-60 with albuminuria > 30mg/g plus diabetic retinopathy~~
- Patient has been taking max-dose ACE inhibitor or ARB ~~for at least 4 weeks~~ **or has a contraindication to ACE inhibitor or ARB or is unable to tolerate ACE or ARB**
- Patient **is maintained on a** ~~has tried DoDs preferred~~ sodium-glucose-co-transporter 2 (SGLT-2) inhibitor [**e.g., empagliflozin (Jardiance) note that-empagliflozin is DoD's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor**
- The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease
- **Patient's potassium is less than 5 mEq/mL at initiation of therapy**
- **Provider agrees to discontinue Kerendia if the patient begins renal replacement therapy**
- ~~Patient does not have uncontrolled hypertension (>170/110 mmHg) at initiation of Kerendia therapy~~
- ~~Patient does not have renal artery stenosis~~
- ~~Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc)~~
- ~~Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception~~

For Heart Failure with Preserved Ejection Fraction (HFpEF)

- **Prescribed by or in consultation with a cardiologist**
- **Patient has a documented diagnosis of chronic heart failure (New York Heart Association (NYHA) class II-IV) with a left ventricular ejection fraction (LVEF) greater than 40% and with continued heart failure symptoms**
- **Patient is maintained on an SGLT2 inhibitor [e.g., empagliflozin (Jardiance) note that-empagliflozin is DoD's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor**

- **Patient is maintained on other guideline-directed therapy for heart failure**
- **Patient's potassium is less than 5 mEq/mL at initiation of therapy**

Non-FDA approved uses are not approved, including in patients undergoing renal transplant

Prior authorization does not expire

2. spironolactone oral suspension (Carospir, generic)

Manual PA criteria apply to all new users

Manual PA Criteria: spironolactone oral suspension is approved if all of the following criteria are met:

Age Edit: PA does not apply to children 12 year of age and younger

Manual PA criteria—Coverage is approved if all criteria are met:

- The patient has heart failure, hypertension or edema from cirrhosis
- The provider must write in why the patient requires CaroSpir and cannot take an aldosterone blocker / potassium-sparing diuretic in a tablet formulation
  - Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience

Non-FDA approved uses are not approved

Prior Authorization does not expire

E. Diuretics: Mineralocorticoid Receptor Antagonists Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—DIURETICS MINERALOCORTICOID RECEPTOR ANTAGONISTS SUBCLASS

UF BAP Comments

A. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —UF Recommendation

The P&T Committee recommended formulary status as discussed above.

- UF

- eplerenone (Inspra, generics)
- finerenone (Kerendia) - *moves from NF to UF*
- spironolactone (Aldactone, generics)
- spironolactone/hydrochlorothiazide (Aldactazide, generics)
- spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*

- NF – None
- Complete Exclusion – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —Manual PA Criteria

The P&T Committee recommended updated manual PA criteria for Kerendia, as detailed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Diuretics: Mineralocorticoid Receptor Antagonists Subclass —UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended an effective date the first Wednesday 60 days after signing of the minutes in all points of service.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions— The P&T Committee agreed (19 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 Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
  - acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent
  - atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
  - avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
  - berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
  - efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)
  - ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
  - fitusiran (Qfitlia) – Antihemophilic Agent
  - insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
  - nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
  - taletrectinib (Ibtrozi) – Oncological Agent for (NSCLC)
  - treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension (PAH) Agent
- NF
  - chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
  - garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
  - hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
  - losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
  - terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent: Note the manufacturer discontinued Tezruly in February

2026. If Tezruly is returned to the market, the NF status will apply, along with the MN and PA criteria.

- ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara
- ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara

- Completely Excluded
  - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent
    - Combogesic was recommended for complete exclusion status as it has little to no clinical benefit relative to administering acetaminophen and ibuprofen separately, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include acetaminophen 325 mg and ibuprofen 200 mg.
  - meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent
    - Symbravo was recommended for complete exclusion status as it has little to no clinical benefit relative to administering meloxicam and rizatriptan separately, and the needs of TRICARE beneficiaries are met by alternative agents. Alternatives include meloxicam, rizatriptan and sumatriptan/naproxen (Treximet).

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria:

- Applying manual PA criteria to new users of the NF ustekinumab products ustekinumab (unbranded Stelara by Janssen) and ustekinumab-slrf (Imuldosa), similar to what is required for all non-step-preferred Interleukin-23 inhibitors, where a trial of adalimumab (Humira) will be required first. These products are non-step-preferred.
- Applying manual PA criteria to new users of Qfitlia, similar to the PA requirements for other hemophilia agents.
- Applying manual PA criteria to new users of Andembry, Arbli, Avmapki Fakzynja, Ensacove, Ibtrozi, Khindivi, nilotinib d-tartrate 50, 150, 200 mg capsules, Tezruly, Tryptyr, Vanrafia, Vyvgart Hytrulo, Yutrepia, and Zelsuvmi.
- Applying manual PA criteria to new and current users of Combogesic and Symbravo, until implementation of complete exclusion status.

The Manual PA criteria are as follows:

1. **acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic)**

   Manual PA criteria apply to all new users of Combogesic

   Manual PA criteria**:** Coverage is approved if all criteria are met:

   - Provider acknowledges that Combogesic will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T Committee meeting minutes by the Director, DHA
   - Provider acknowledges that other formulations of acetaminophen and ibuprofen are available to TRICARE beneficiaries and do not require prior authorization
   - The patient is 18 years of age or older
   - The patient is being treated for short-term mild to moderate acute pain
   - Provider must document why the patient cannot take formulary alternatives or OTC products
     - Acceptable responses include the patient has tried all the listed agents including acetaminophen 325 mg tablet, acetaminophen 500 mg tablet, acetaminophen 160 mg/5ml solution/suspension, ibuprofen 200 mg tablet, ibuprofen 800 mg tablet, ibuprofen 100mg/5ml solution/suspension

   Non FDA-approved uses are not approved

   PA does not expire until implementation of Complete Exclusion status

2. **acoltremon 0.003% ophthalmic solution (Tryptyr)**

   Manual PA criteria apply to all new users of Tryptyr

   Manual PA criteria: Coverage is approved if all criteria are met:

   - The patient is 18 years of age or older
   - The drug is prescribed by an ophthalmologist or optometrist
   - The patient has signs and symptoms of dry eye disease as supported by both of the criteria below:
     - Positive symptomology screening for dry eye disease from an appropriate measure
     - At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
   - Patient must have tried and failed the following:
     - At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera

Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube])

- Followed by at least 1 month of a different ocular lubricant that is nonpreserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol)
- 3-month trial of cyclosporine 0.05% (Restasis, generics)

Non-FDA approved uses are not approved

PA does not expire

3. atrasentan (Vanrafia)

Manual PA criteria apply to all new users of Vanrafia

Manual PA criteria: Coverage is approved if all criteria are met:

- The patient is 18 years of age or older
- The drug is prescribed by a nephrologist
- The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli
- Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/gram
- Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2
- Patient is not currently receiving dialysis or has not undergone kidney transplant
- Patient has not received immunosuppressants, including corticosteroids, in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months
- Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and is at high risk for disease progression
- The patient's baseline liver aminotransferase (AST and ALT) levels are not elevated to greater than 3 times the upper limit of normal
- If patient is a female of child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation
- If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation

Non-FDA approved uses are not approved, including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS)

PA expires in 9 months

Renewal criteria: Coverage will be approved indefinitely if all the following apply

- Patient has had a response to Vanrafia defined by:
  - reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR
  - reduction in proteinuria from baseline AND
- Patient's eGFR rate ≥ 30 mL/min/1.73 m2

4. avutometinib / defactinib (Avmapki Fakzynja Co-pack)

Manual PA criteria apply to all new users of Avmapki Fakzynja Co-pack

Manual PA criteria: Coverage is approved if all criteria are met:

- The patient is 18 years of age or older
- The drug is prescribed by a hematologist or oncologist
- Patient has recurrent low-grade serous ovarian cancer
- The cancer has a KRAS mutation
- Patient has tried at least one systemic 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: to facilitate approval, please list the diagnosis, guideline version, and page number _____.

Other non-FDA approved uses are not approved except as noted above

PA does not expire

5. berdazimer 10.3% topical gel (Zelsuvmi)

Manual PA criteria apply to all new users of Zelsuvmi

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 2 years of age or older
- Prescribed by a dermatologist
- Patient has a diagnosis of molluscum contagiosum which fulfills all the following criteria:
  - Treatment is not solely due to cosmetic concern
  - The lesions must be symptomatic (e.g. painful, itchy)
- A single lesion will be treated with Zelsuvmi for no more than 12 weeks

- Provider must explain why this agent is required and cannot be treated with ALL the following: cryotherapy, AND curettage, AND two additional topical agents
    - Acceptable responses include the following: Patient has contraindication to, intolerability to, or has failed treatment with cryotherapy, AND curettage, AND two additional topical treatments (e.g. salicylic acid, cantharidin (Ycanth))

Non-FDA approved uses are not approved

Initial PA expires in 3 months

Renewal Criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA

6. chlorthalidone 12.5 mg tabs (Hemiclor)

Manual PA criteria apply to all new users of chlorthalidone 12.5 mg tablets (Hemiclor)

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges that generic chlorthalidone 25 mg and 50 mg tablets can be split or crushed and are available to TRICARE beneficiaries and do not require prior authorization
- The patient is 18 years of age or older
- Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease
- Provider must write in why the patient requires Hemiclor and cannot take a loop diuretic and a thiazide diuretic in a tablet formulation
    - Acceptable responses: patient has tried and failed chlorthalidone 25 mg and 50 mg tablets or hydrochlorothiazide 25 mg tablets

Non-FDA approved uses are not approved

PA does not expire

7. efgartigimod alfa-fcab injection (Vyvgart Hytrulo)

Manual PA criteria apply to all new users of Vyvgart Hytrulo

Manual PA criteria: Coverage is approved if all criteria are met:

- The patient is 18 years of age or older
- Patient is 18 years of age or older
- Prescribed by a neurologist

- Patient is being treated for chronic inflammatory demyelinating polyneuropathy OR
- Patient is being treated for generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AchR) antibody positive
- For patients being treated for generalized myasthenia gravis:
  - Patient had insufficient response or intolerance to pyridostigmine AND
  - Patient had insufficient response or intolerance to glucocorticoid sparing therapy such as azathioprine, mycophenolate, cyclosporine, or tacrolimus
- Patient is not receiving concomitant neonatal Fc receptor antagonists or other C5 inhibitors with Vyvgart Hytrulo including but not limited to the following: efgartigimod injection for intravenous use (Vyvgart), eculizumab (Soliris), ravulizumab (Ultomiris), rozanolixizumab or (Rystiggo), zilucoplan (Zilbrysq)

Non-FDA approved uses are not approved

PA expires in 6 months

Renewal criteria: Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:

- The patient's disease severity has improved and stabilized to warrant continued therapy

8. ensartinib (Ensacove)

Manual PA criteria apply to all new users of Ensacove

Manual PA criteria: Coverage is approved if all criteria are met:

- The patient is 18 years of age or older
- The drug is prescribed by a hematologist or oncologist
- Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC)
- Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved test
- 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: to facilitate approval, please list the diagnosis, guideline version, and page number _____.

Other non-FDA approved uses are not approved except as noted above

PA does not expire

9. fitusiran injection (Qfitlia)

Manual PA criteria apply to all new users of Qfitlia

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 12 years of age or older
- Prescribed by or in consultation with a hematologist
- Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors
- Patient is not concurrently receiving factor VIII or factor IX therapy after initial transition period unless for the treatment of breakthrough bleeding
- For patients with hemophilia A, patient has had an inadequate response, intolerance, or contraindication to emicizumab-kxwh (Hemlibra)

Non-FDA approved uses are not approved

PA does not expire

10. garadacimab injection (Andembry)

Manual PA criteria apply to all new users of Andembry

Manual PA criteria: Coverage is approved if all criteria are met:

- Patient is 12 years of age or older
- Andembry is prescribed for prophylaxis to prevent attacks of hereditary angioedema (HAE)
- Prescribed by an allergist, immunologist, rheumatologist, or HAE specialist
- The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., two or more HAE attacks/month, or laryngeal attacks, etc.)
- The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly)
- The patient has had an inadequate response, adverse reaction, or contraindication to all of the following:
  - One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest)
  - One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo)

Non-FDA approved uses are not approved

PA does not expire

11. hydrocortisone 1mg/mL oral solution (Khindivi)

Manual PA criteria apply to all new users of Khindivi

Manual PA criteria: Coverage is approved if all criteria are met:

- Patients is at least 5 years of age
- Patient is not older than 18 years of age
- Provider acknowledges that the following products are available without a prior authorization: 5 mg generic hydrocortisone tablets, hydrocortisone 100 mg act-O-vials, and prednisone intensol oral solution. Please consider changing the prescription to one of these agents
- Patient is using Khindivi as replacement therapy for adrenocortical insufficiency
- Provider acknowledges that the patient's dosing regimen requires small doses of hydrocortisone and cannot accurately split the dose using 5 mg hydrocortisone tablets
- Provider must explain why this agent is required and patient cannot take generic hydrocortisone tablets, Alkindi Sprinkle, hydrocortisone 100 mg act-O-vials, and prednisone intensol oral solution. Blank write in _____
  - Acceptable response: patient requires a g-tube

Non-FDA approved uses are not approved

PA does not expire

12. losartan 10 mg/mL oral suspension (Arbli)

Manual PA criteria apply to all new users of Arbli

Automated PA Criteria: Age edit – PA not required if patient is 12 years of age and younger

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider must write in why the patient requires Arbli oral suspension and cannot take losartan tablets
  - Acceptable responses: Patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

13. meloxicam 20 mg/rizatriptan10 mg tabs (Symbravo)

Manual PA criteria apply to all new users of Symbravo

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges that Symbravo will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T Committee meeting minutes by the Director, DHA
- Provider acknowledges that other formulations of triptans are available to TRICARE beneficiaries and do not require prior authorization including eletriptan, sumatriptan, rizatriptan
- Patient is 18 years of age or older
- Patient is being treated for acute treatment of migraine with or without aura
- Provider must document why the patient cannot use rizatriptan tablet and meloxicam tablet.
    - Acceptable responses include the patient has had an adverse reaction to an excipient in rizatriptan tablet and/or meloxicam tablet that would not be likely to occur with Symbravo

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

14. nilotinib d-tartrate 50 mg, 150 mg and 200 mg caps (no brand name)

Manual PA criteria apply to all new users of nilotinib

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider acknowledges Prior Authorization is not required for Tasigna capsules. Please consider changing the prescription to Tasigna.
- Prescribed by or in consultation with a hematologist or oncologist
- Patient is 18 years of age or older
- Patient has a diagnosis of either:
    - Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR
    - Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib
- The patient has tried nilotinib tartrate tablet (Danziten) and had an adverse reaction to an excipient that would not be likely to occur with nilotinib tartrate capsule

- 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. To facilitate approval please list the diagnosis, guidelines version and page number:_____

Other non-FDA approved uses are not approved except as noted above

PA does not expire

15. taletrectinib (Ibtrozi)

Manual PA criteria apply to all new users of Ibtrozi

Manual PA criteria: Coverage is approved if all criteria are met:

- The patient is 18 years of age or older
- The drug is prescribed by a hematologist or oncologist
- Patient has locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)
- 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: to facilitate approval, please list the diagnosis, guideline version, and page number _____.

Other non-FDA approved uses are not approved except as noted above

PA does not expire

16. terazosin 1 mg/mL oral solution (Tezruly)

Manual PA criteria apply to all new users of Tezruly

Manual PA criteria: Coverage is approved if all criteria are met:

- Provider must explain why the patient requires Tezruly and cannot take terazosin tablets
  - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia) and not due to convenience

Other non-FDA approved uses are NOT approved except as noted above

PA does not expire

17. treprostinil inhalation powder (Yutrepia)

Manual PA criteria apply to all new users of vimseltinib (Yutrepia)

Manual PA criteria: Coverage is approved if all criteria are met:

- Prescribed by or in consultation with a cardiologist or pulmonologist
- Patient has WHO Group 1 pulmonary arterial hypertension (PAH) OR WHO Group 3 pulmonary hypertension with interstitial lung disease (PH-ILD)
- Patients with WHO Group 1 PAH have had a right heart catheterization
- Documentation was provided to confirm that patient had the procedure and confirmed diagnosis of WHO Group 1 PAH

Non-FDA approved uses are not approved

PA does not expire

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF and 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 Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service; and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion status at 30 days and 60 days prior to implementation.

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

UF BAP Comments

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

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

- UF
  - acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent
  - atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
  - avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
  - berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
  - efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)

- ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
- fitusiran (Qfitlia) – Antihemophilic Agent
- insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
- nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
- taletrectinib (Ibtrozi) – Oncological Agent for (NSCLC)
- treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension Agent

- NF
  - chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
  - garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
  - hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
  - losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
  - terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent
  - ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara
  - ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara
- Completely Excluded
  - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent
  - meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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.

UF BAP Comments

Concur: *Non-Concur:* *Abstain:* *Absent:*

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended implementation periods as noted above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

P&T Comments

A. Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for six recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablets (no brand name)—There are other bisoprolol formulations available, including bisoprolol 5 mg tablets (scored), that are more cost-effective than this 2.5 mg strength.

Antianxiety Agents—buspirone capsules (Bucapsol)—These buspirone capsules are less cost-effective than currently available buspirone tablets. Buspirone tablets are available in the same strengths or can be split to achieve the same strengths as these buspirone capsules

Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tablets (Clemasz)—This clemastine tablet is less cost-effective than other clemastine tablets that are available in the same strength.

Pain Agents: NSAIDs—diflunisal 375 mg tablet (Dolobid)—Numerous other more cost-effective generic NSAIDs are available.

Pain Agents: NSAIDs—flurbiprofen (Lurbipr)—There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

Diabetes Non-Insulin: Biguanides—metformin 625 mg immediate release (IR) tablet—Numerous other more cost-effective generic metformin IR and extended release (ER) tablets are available.

The Manual PA criteria are as follows:

1. **bisoprolol 2.5 mg tablets**

   The PA criteria are as follows:

   Manual PA criteria apply to all new users of bisoprolol 2.5 mg tabs

   Manual PA criteria: bisoprolol 2.5 mg tablets are approved if all criteria are met:

   - Provider acknowledges other formulations of bisoprolol tablets are available without prior authorization.
   - Provider must explain why the patient requires bisoprolol 2.5 mg tablet and cannot take the cost-effective generic bisoprolol 5 mg formulations
     - Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available bisoprolol formulations

   Non-FDA approved uses are not approved

   PA does not expire

2. **buspirone capsules (Bucapsol)**

   Manual PA criteria apply to all new users of Bucapsol

   Manual PA criteria: Bucapsol is approved if all criteria are met:

   - Provider acknowledges other formulations of buspirone tablets are available without prior authorization.
   - Provider must explain why the patient requires Bucapsol capsules and cannot take the cost-effective buspirone tablets formulations
     - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available buspirone formulations

   Non-FDA approved uses are not approved

   PA does not expire

3. **clemastine 2.68 mg tablets (Clemasz)**

   Manual PA criteria apply to all new users of Clemasz

   Manual PA criteria: Clemasz is approved if all criteria are met:

   - Provider acknowledges other formulations of clemastine are available without prior authorization.

- Provider must explain why the patient requires Clemasz and cannot take the cost-effective clemastine formulations
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available clemastine formulations

Non-FDA approved uses are not approved

PA does not expire

4. diflunisal 375 mg tablets (Dolobid)

Manual PA criteria apply to all new users of Dolobid

Manual PA criteria: Dolobid is approved if all criteria are met:

- Provider acknowledges other formulations of diflunisal are available without prior authorization.
- Provider must explain why the patient requires diflunisal 375 mg tablets and cannot take the cost-effective generic diflunisal 250 mg or 500 mg formulations
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available buspirone formulations

Non-FDA approved uses are not approved

PA does not expire

5. flurbiprofen (Lurbipr)

Manual PA criteria apply to all new users of Lurbipr

Manual PA criteria: Lurbipr is approved if all criteria are met:

- Provider acknowledges other formulations of flurbiprofen are available without prior authorization.
- Provider must explain why the patient requires Lurbipr and cannot take the cost-effective flurbiprofen formulations
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available buspirone formulations

Non-FDA approved uses are not approved

PA does not expire

6. metformin 625 mg IR tablet

Manual PA criteria apply to all new and current users of metformin 625 mg IR tablet

Manual PA criteria: metformin 625 mg IR Tablet is approved if all criteria are met:

- Provider acknowledges other formulations of metformin are available without prior authorization.
- Provider must explain why the patient requires metformin 625 mg IR tablet and cannot take the cost-effective generic metformin formulations
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin formulations

Non-FDA approved uses are not approved

Prior authorization does not expire

B. New PA Criteria for Drugs Not Subject to 32 CFR 199.21(G)(5) and Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for bisoprolol 2.5 mg tablets, buspirone capsules (Bucapsol), clemastine (Clemasz), diflunisal (Dolobid) 375 mg tablets, flurbiprofen (Lurbipr), and metformin 625 mg IR tabs in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

UF BAP Comments

The P&T Committee recommended manual PA for bisoprolol 2.5 mg tabs, Clemasz, Dolobid 375 mg tablets, Lurbipr and metformin 625 mg IR tabs and tramadol 100 mg tablets as stated above; and an effective date the first Wednesday 60 days after signing of the minutes and DHA will send letters to the affected beneficiaries.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Atopy—mepolizumab (Nucala)—**Nucala is now indicated for the treatment of COPD. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the COPD criteria for other biologics, requiring use of traditional oral inhalers first.

b) **Atopy: Oral JAK-1—upadacitinib (Rinvoq)—**The manual PA criteria were updated to allow for the new giant cell arteritis indication. Specialists supported requiring a trial of glucocorticoids and tocilizumab first, for this indication.

c) **Endocrine Agents Miscellaneous—osilodrostat (Isturisa)**—The manual PA criteria were updated to reflect minor changes in the FDA label and to remove the warnings and precautions language as this drug is restricted to specialists.

d) **Hematological Agents—iptacopan (Fabhalta)—**The manual PA was updated to include the new indication of Complement 3 Glomerulopathy (C3G). In addition, the PA for IgAN was updated to require a trial of Vanrafia or Filspari.

e) **Immunosuppressives—belimumab (Benlysta)—**Benlysta is now indicated in children as young as 5 years old with lupus nephritis. The PA criteria were updated accordingly.

f) **Oncological Agents—belzutifan (Welireg)**—Welireg received a new indication for locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma. Additionally, the FDA revised the renal cell carcinoma indication to clarify use for a clear cell component. The manual PA was updated to reflect these changes.

g) **Psoriasis Agents—roflumilast 0.3% foam (Zoryve)—**The manual PA criteria were updated to include the new indication for plaque psoriasis with the PA mirroring standard plaque psoriasis criteria.

B. Updated PA Criteria for New FDA Approved Indications Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) implementation for the new PA criteria for Nucala, Rinvoq, Isturisa, Fabhalta, Benlysta,

Welireg, and Zoryve in new users will be effective the first Wednesday 60 days after the signing of the minutes.

XI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

A. Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria due for Nucala, Rinvoq, Isturisa, Fabhalta, Benlysta, Welireg, and Zoryve due to FDA-approved indications and expanded age ranges. Implementation of the new PA criteria will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

A. Updated PA Criteria for Reasons other than New FDA Approved Indications

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs. The updated PA criteria outlined below will apply to new users.

a) **GI-1 Agent—budesonide oral suspension (Eohilia)**—The Eohilia PA was modified to allow use by general surgeons due to MTF provider feedback.

b) **Hematological Agents: Platelets—avatrombopag (Doptelet)**—The manual PA criteria were updated based on MTF provider feedback, expanding the specialists to allow hematologist and oncologist prescribing in addition to gastroenterologists, regardless of indication.

c) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists- Antagonists—leuprolide acetate (Lutrate Depot) 22.5 mg**—Lutrate Depot is a new formulation similar to other leuprolide products (Lupron Depot, Eligard). It is less cost-effective than the preferred leuprolide (Eligard), so new PA criteria will apply, requiring a trial of Eligard first, similar to Lupron Depot.

d) **Overactive Bladder (OAB) Agents): Beta-3 Adrenergic Agonists—mirabegron tablets (Myrbetriq) and vibegron (Gemtesa)—**Myrbetriq and Gemtesa are beta-3 agonists used to treat OAB. Currently, both drugs are UF with a PA requiring a

trial of generic anticholinergics. Efficacy is similar between anticholinergics and beta-3 agonists. PA automation was added to both PAs, to include specialist bypass for Myrbetriq tablets and an automated lookback for anticholinergics for both Myrbetriq and Gemtesa.

e) **White Blood Cell Stimulants: Filgrastims—filgrastim-sndz (Zarxio)—**Zarxio was moved from step-preferred to non-step-preferred status on the filgrastim PA. This change was due to Zarxio no longer being cost-effective and due to a high degree of therapeutic interchangeability in this biosimilar class.

f) **Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound)—**The definition of uncontrolled hypertension was clarified on the Wegovy and Zepbound PAs, based on provider feedback and hypertension professional treatment guidelines. Patients are considered to have uncontrolled hypertension if they do not meet individual blood pressure goal on two or more antihypertensive drugs.

B. Updated Manual PA Criteria and Implementation Period for Reasons other than New FDA Approved Indications

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Doptelet, Eohilia, Lutrate, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR REASONS OTHER THAN NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Doptelet, Eohilia, Lutrate, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—REMOVAL OF PA AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) removing the PA for one drug with implementation effective the first Wednesday 2 weeks after signing of the minutes.

a) **Cardiovascular Agents Miscellaneous—ivabradine (Corlanor)—**Currently, ivabradine (Corlanor) tablets are UF, with cost effective generic formulations now available. There is stable utilization of the drug and a low risk of inappropriate use. The PA will be removed for ivabradine (Corlanor) tablets

XV. UTILIZATION MANAGEMENT—REMOVAL OF PA and IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended removing the manual PA criteria for Corlanor tablets as outlined above, with implementation effective two weeks after signing of the minutes.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

XVI. UTILIZATION MANAGEMENT—PROSTATE CANCER AGENTS: CYP-17 INHIBITORS ZYTIGA and YOSA AND IMPLEMENTATION PLAN

P&T Comments

Abiraterone acetate 250 mg and 500 mg tablets (Zytiga) are available in generic formulations and require administration on an empty stomach. Abiraterone acetate micronized (Yonsa) is only available as a branded agent and is taken without regard to meals. Provider feedback and prostate cancer guidelines suggest that there is a high degree of therapeutic interchangeability between these two products. Yonsa has a tier 1 copay from when the class was last reviewed in February 2019. PA criteria apply to all three abiraterone formulations. At the August 2024 meeting, the PA for Zytiga and generic formulations were given automated PA specialist bypass and drug lookback criteria to allow PA approval if the prescriber is an oncologist, hematologist or urologist and continuation by a non-specialist.

Generic Zytiga 250 mg is now the most cost effective abiraterone formulation, compared with the generic Zytiga 500 mg strength and Yonsa. The following changes were recommended (18 for, 0 opposed, 0 abstained, 1 absent):

- abiraterone acetate 250 mg (Zytiga and generic)
    - Remove PA
    - Effective date of the first Wednesday 2 weeks after signing of the minutes
- abiraterone acetate 500 mg Zytiga and generic)

- Remove automated specialist bypass and the automated drug lookback
- Require a trial of abiraterone acetate 250 mg in new and current users
- Send letters to current users
- Effective date of the first Wednesday 120 days after signing of the minutes

- abiraterone acetate micronized (Yonsa)
  - Remove Tier 1 copay
  - Require a trial of generic abiraterone 250 mg in new and current users
  - Send letters to current users
  - Effective date of the first Wednesday 120 days after signing of the minutes

XVII. UTILIZATION MANAGEMENT—PROSTATE CANCER AGENTS: CYP-17 INHIBITORS ZYTIGA and YOSA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended the changes to the abiraterone products as outlined above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

XVIII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA) AND IMPLEMENTATION

P&T Comments

Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease—Umeclidinium /vilanterol (Anoro Ellipta) inhaler is designated as UF without a PA. An authorized generic has entered the market; however, this product is less cost-effective compared to the branded agent. Therefore, the branded Anoro Ellipta inhaler will continue to be dispensed at all three points of service, and the authorized generic will only be available with prior authorization. The brand Anoro Ellipta will continue to have the Tier 2 copay, as the authorized generic umeclidinium/vilanterol has a Tier 2 copay.

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) requiring brand Anoro Ellipta inhalers over the authorized generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The effective date will be the first

Wednesday 60 days after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XIX. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA) AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended brand over authorized generic criteria for Anora Ellipta as outlined above.

UF BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***