DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. UF CLASS REVIEWS—Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass

P&T Comments

A. ADHD: Stimulants Subclass Relative Clinical Effectiveness Analysis and Conclusion

Background—The ADHD Stimulants were most recently reviewed for formulary status in November 2015. There are currently 32 products in the subclass. The ten newest entrants include several methylphenidate formulations (Adhansia XR, Jornay PM, Quillichew ER, Cotempla XR-ODT); several amphetamine products (Adzenys XR-ODT, Adzenys ER OS, Dyanavel XR, Evekeo ODT); one mixed amphetamine salt (Mydayis); and a new lisdexamfetamine (Vyvanse) chewable tablet formulation. The new entrants do not contain new chemical entities; FDA approval was based on data from previously approved ADHD drugs, and there are no head-to-head studies available. The active ingredients for the new entrants are already available in generic formulations that are designated as UF, with the exception of lisdexamfetamine, which is still a branded agent and is currently NF.

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

Guidelines and Systematic Reviews

- The published literature is limited by several methodological problems, low quality evidence, and general inadequacy of clinical ADHD research. Longer-term studies are needed. Many guidelines recommend medications only after behavioral or environmental

modification have failed, particularly for children (e.g., American Academy of Pediatrics).

- The United Kingdom National Institute for Health and Care Excellence (NICE) 2018 guidelines recommend the following, in descending order of preference:
    - Adults – Methylphenidate or lisdexamfetamine (or dexamphetamine if there is an unacceptable side effect profile with lisdexamfetamine) should be used only after environmental modification and if ADHD symptoms persist in at least one area of functioning.
    - Children older than 5 years of age and young people – The same medication preferences apply as with adults, except that medications should be used along with ADHD-focused support (e.g., education and information on the causes and effects of ADHD, advice on parenting strategies, and liaison with school). Medications should be used only after environmental modification and if ADHD symptoms persist in at least one area of functioning.
    - Children younger than 5 years of age – ADHD-focused group training for parents is recommended as first-line. Medication is recommended second-line only after a second specialist opinion; no specific medications are cited in the guideline.
- A 2018 systematic review and network meta-analysis published in Lancet Psychiatry concurred with the NICE guidelines for methylphenidate as first choice of drug in children, and methylphenidate or lisdexamfetamine as first choice in adults when considering efficacy alone. However when both efficacy and safety or tolerability were considered for adults, the authors could not recommend lisdexamfetamine over other amphetamines, due to the limited number of studies available, and inability to draw firm conclusions.

Safety

- The ADHD stimulants are controlled substances (C-II) and contain a boxed warning for potential abuse and dependency. All the ADHD stimulants also now carry a label warning and precaution regarding the risk of cardiovascular events and sudden death.

Special Populations

- There are many alternative dosage forms for patients with swallowing difficulties. The contents of Vyvanse capsules are dissolvable in water and the chewable tablet is now available. Adderall XR, Focalin XR, Metadate CD, and Ritalin LA are formulated in capsules that can be opened and sprinkled on food. Aptensio XR sprinkle capsule, Evekeo ODT, Methylin oral solution, ProCentra oral solution, and

Quillivant XR oral suspension are currently available on the UF for patients with swallowing difficulties.

- Multiple ADHD stimulants are currently on the formulary that are approved for children ranging in age from the 6 to 17 years.

Clinical Considerations

- The P&T Committee specifically evaluated the 13 branded products that do not have generic equivalents available; one additional product with recent generic entrants (Aptensio XR) was also reviewed in detail. Factors discussed included duration of action, efficacy and safety, data from FDA summary reviews, published primary literature, formulary status from commercial health plans, and Military Health System (MHS) provider feedback.
    - lisdexamfetamine (Vyvanse) has been designated NF since November 2007. It is a prodrug that is converted to the stimulant amphetamine and the amino acid lysine. The duration of action ranges between 8 to 14 hours, and it is approved for children as young as 6 years. Generic formulations are expected in 2023.
        - Vyvanse is the only ADHD stimulant with an additional indication. Approval for Binge Eating Disorder was granted in 2015, based on two 12-week, placebo controlled trials enrolling approximately 350 patients. However, pharmacotherapy is generally regarded as less efficacious than psychotherapy (e.g., cognitive-behavioral therapy) for binge eating. Other treatments, including the SSRIs, topiramate, and zonisamide are used to treat binge eating disorder.
        - There was no new data to change the original conclusion that there is insufficient evidence to suggest there are clinically relevant differences between Vyvanse and other ADHD stimulant products in terms of efficacy or safety.
        - A survey of MHS providers found that Vyvanse was commonly requested for formulary addition. Providers mentioned the longer duration of action than Adderall XR, and that Vyvanse may be useful after patients have failed mixed amphetamine salts (Adderall XR) and methylphenidate ER formulations (e.g., Concerta).
    - methylphenidate ER sprinkle capsule (Adhansia XR) was designated Tier 4 in August 2019. Currently it is the only Tier 4/Not Covered ADHD Stimulant agent. Its stimulating effects can last up to 16 hours.

        - Several long-acting methylphenidate products are on the UF, including three products that are formulary alternatives for those who have difficulty swallowing (Focalin XR, Quillivant XR, and Aptensio XR). Other methylphenidate ER formulations have 12-hour durations of action (e.g., Concerta, Focalin XR, Quillivant XR, and Jornay PM) and one has a similar duration of 16 hours (Aptensio XR).
        - The new data reviewed by the P&T Committee did not change the previous conclusion and provider feedback strongly reaffirmed that Adhansia XR has little to no additional clinical effectiveness relative to similar drugs in the class, and the needs of TRICARE beneficiaries are met by alternative agents.
    - methylphenidate ER sprinkle capsule nighttime dosing (Jornay PM) was the 12th methylphenidate product marketed, and is approved for patients as young as 6. Jornay is administered at night before bedtime, and has a delayed onset of action so that therapeutic effects occur 8 hours after administration, in the morning. Stimulating effects may last 10 to14 hours.
        - Overall, Jornay PM shows no clinical advantage when compared to current formulary alternatives and had a higher rate of insomnia (up to 33%) when indirectly compared to other methylphenidate formulations, where insomnia occurred at a rate up to 13%.
        - MHS providers commented Jornay PM should remain UF, since it is helpful for children with developmental delays because of the bedtime dosing.
    - methylphenidate ER orally disintegrating tablets (Cotempla XR-ODT) is only approved for children between the ages of 6 to 17 years of age and is not approved for adults. The effects can last 12 hours, similar to other methylphenidate ER formulations. Providers commented that a young child would not need an ODT with such a long duration of action. Cotempla XR ODT offers no compelling advantages over the existing UF ADHD drugs.
    - methylphenidate ER sprinkle capsules (Aptensio XR) are approved for children as young as 6 years. The contents can be opened up and sprinkled on food and the long duration of action can last up to 16 hours. Generic formulations are now available.
    - methylphenidate ER oral suspension (Quillivant XR) is the only long-acting methylphenidate oral suspension marketed.

Immediate release methylphenidate (Methylin) and dextroamphetamine (ProCentra) oral solutions are therapeutic alternatives to Quillivant XR, but must be dosed twice daily.

- methylphenidate ER chewable tablet (Quillichew ER chew tab) is the first 8-hour duration chewable tablet; however, an additional short-acting agent will be required for children after school to complete homework. While Quillichew ER tablets provide an alternative ADHD dosage form, there are several UF products available for patients with swallowing difficulties.
- methylphenidate transdermal system patch (Daytrana) remains the only patch available for ADHD, but is associated with dermatologic adverse reactions. It has been designated as NF since 2006.
- amphetamine ER oral suspensions (Dyanavel XR OS and Adzenys ER OS) provide ER alternative amphetamine dosage formulations; however, they do not offer any additional clinical effectiveness, safety, or tolerability benefit over other amphetamine ER products.
- amphetamine ER orally disintegrating tablet (Adzenys XR-ODT) is the first and currently only amphetamine ER product available in an ODT formulation, however, amphetamine is not a first-line drug for ADHD treatment in children, and other amphetamine alternative dosage products are available.
- amphetamine IR orally disintegrating tablet (Evekeo ODT) is the only short acting ODT in the amphetamine category, with effects lasting 4 to 6 hours, similar to other short-acting stimulants in the class. It has been designated as UF since 2019. Evekeo IR tablets, the original product, are available in generic formulations.
- amphetamine mixed salts ER capsule triphasic release (Mydayis) was designated NF in August 2017. It is approved for children down to 13 years of age, but not for younger children as the effects can last up to 16 hours, including insomnia and appetite suppression. Multiple alternative products are available in generic formulations, including Adderall XR caps. Mydayis offers no compelling advantage over existing formulary agents.
- dextroamphetamine IR tablet (Zenzedi) is currently designated UF. It is available in additional strengths (2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg, along with 5 mg and 10 mg) compared to the original dextroamphetamine IR product Dextrostat, which is only available in generic formulations of 5 mg and 10 mg.

Therapeutics Interchangeability

- There is insufficient evidence to suggest that one stimulant is more effective or associated with fewer adverse events than another. The stimulants may vary in terms of duration of action but are highly therapeutically interchangeable.

Overall Clinical Conclusion

- The Committee agreed that in order to treat the needs of MHS beneficiaries, a variety of ADHD drugs are required on the formulary, including amphetamine type products and methylphenidates, and both long-acting and short-acting formulations in each of these categories. Additionally, alternative dosage formulations in each category are needed in order to treat special populations, including young children or patients with developmental delays.

B. ADHD: Stimulants Subclass—Relative Cost-Effectiveness Analysis and Conclusion

A cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- CMA results showed that the products with generic formulations are generally significantly more cost-effective than brand-only products.
- CMA results for certain branded products that have generic formulations available showed that dextroamphetamine ER capsule was the most cost-effective ADHD stimulant, followed by Adderall XR, Methylphenidate CD, and Evekeo IR tablet.
- CMA results for the brand-only agents showed that the cost-effectiveness for several of the agents varied depending on formulary status, and that Evekeo ODT was the least costly agent, followed by Quillivant XR, Jornay PM, Zenzedi, Vyvanse, Quillichew ER, Dyanavel XR, Mydayis, Adzenys XR-ODT, Adhansia XR, Adzenys, Daytrana and Cotempla XR-ODT, which was the most costly agent.
- BIA results for all branded products with generic formulations showed that maintaining the existing formulary status was the most cost-effective.
- BIA was performed to evaluate the potential impact of designating selected brand –only agents as UF, NF or Tier 4. BIA results showed that maintaining the existing formulary status of all current UF, NF and Tier 4 products, with the exception of moving Vyvanse capsule and chewable tablet from NF to UF status, resulted in significant cost avoidance.

C. ADHD: Stimulants Subclass—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF
  - amphetamine sulfate IR tabs (Evekeo, generics)
  - amphetamine sulfate orally dissolving tablet (ODT) (Evekeo ODT)
  - dextroamphetamine ER (Dexedrine Spansule, generics; Dextrostat tabs)
  - dextroamphetamine IR tablets (Zenzedi)
  - dextroamphetamine oral solution (ProCentra, generics)
  - lisdexamfetamine capsules and chewable tablets (Vyvanse) *(moves from NF to UF)*
  - methamphetamine HCl (Desoxyn, generics)
  - mixed amphetamine salts IR tablets (Adderall, generics)
  - mixed amphetamine salts XR capsules (Adderall XR, generics)
  - dexmethylphenidate IR (Focalin, generics)
  - dexmethylphenidate ER (Focalin XR, generics)
  - methylphenidate CD (Metadate CD, generics)
  - methylphenidate chewable tablets and oral solution (Methylin, generics)
  - methylphenidate ER (Methylin ER, generics)
  - methylphenidate ER sprinkle caps (Aptensio XR, generics)
  - methylphenidate ER sprinkle capsules nighttime dosing (Jornay PM)
  - methylphenidate ER oral suspension (Quillivant XR)
  - methylphenidate IR (Ritalin, generics)
  - methylphenidate long-acting (LA) (Ritalin LA, generics)
  - methylphenidate osmotic controlled release oral delivery system (OROS) tablets and other (Concerta, generics)

  - Note: methylphenidate SR (Ritalin-SR, generic), Metadate ER tablet, and Dextrostat tablet will remain UF but are no longer marketed

- NF
    - amphetamine ER orally dissolving tablets (ODT) (Adzenys XR-ODT)
    - amphetamine ER oral suspension (Adzenys ER)
    - amphetamine ER oral suspension (Dyanavel XR)
    - mixed amphetamine salts ER capsules triphasic release (Mydayis)
    - methylphenidate transdermal system (Daytrana)
    - methylphenidate ER chew tab (Quillichew ER)
    - methylphenidate XR-ODT (Cotempla XR-ODT)

- Tier 4/Not Covered
    - methylphenidate ER sprinkle caps (Adhansia XR)

D. ADHD: Stimulants Subclass—Manual PA Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current manual PA criteria for Evekeo ODT, Mydayis, Cotempla XR-ODT, and Jornay PM. The P&T Committee also recommended PA criteria for Vyvanse in new users to encourage use of cost-effective generic agents first, standardize the clinical criteria across all points of service, and allow for binge eating disorder (BED) when certain criteria are met.

The PA criteria are as follows:

1. **lisdexamfetamine capsule and chewable tablet (Vyvanse)**
   Manual PA criteria apply to all new users of Vyvanse

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

   ADHD

   - Patient is 6 years of age or older
   - Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
   - Patient has tried and failed mixed amphetamine salts ER (Adderall XR, generics) or other long acting amphetamine or amphetamine derivative type drug
   - Patient has tried and failed methylphenidate OROS and other (Concerta, generics) or other long acting methylphenidate or methylphenidate derivative type drug

OR

Binge Eating Disorder

- Note: If patient is an Active Duty Service Member (ADSM), the provider acknowledges the need to consult service specific policy for Binge Eating Disorder (BED) (*For ADSM, if the above is acknowledged,, continue following remaining criteria; for non-ADSM may by-pass this note and go directly to the criteria below)*
- Patient is 18 years of age or older
- Patient has a diagnosis of moderate to severe Binge Eating Disorder
- Prescribed by or in consultation with a psychiatrist or other behavioral specialist
- Patient has failed, does not have access to, or has had an inadequate response to cognitive behavioral therapy or other psychotherapy
- Patient has tried and failed OR has a contraindication to an SSRI (e.g., citalopram, fluoxetine, sertraline)
- Patient has tried and failed OR has a contraindication to topiramate or zonisamide
- Provider acknowledges that Vyvanse will be discontinued if the patient does not respond by having a positive clinical response of meaningful decrease of binge eating episodes or binge days per week from baseline or improvement in signs and symptoms of binge eating disorder after taking Vyvanse

Non-FDA approved uses are not approved, including weight loss/obesity

PA does not expire

2. amphetamine sulfate orally disintegrating IR tablet (Evekeo ODT)

Note that there were no changes to the current PA criteria

Manual PA Criteria: Evekeo ODT 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) that has been appropriately documented in the medical record

- Patient has tried, for at least two months, and failed OR has difficulty swallowing Adderall tablets (generic)
- Patient has tried, for at least two months, and failed OR the patient has a contraindication to methylphenidate IR tablets or solution

Non-FDA approved uses are not approved

PA does not expire

3. methylphenidate orally disintegrating XR tablet (Cotempla XR-ODT)

Note that there were no changes to the current PA criteria.

Manual PA Criteria: Cotempla XR-ODT 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 OR has a contraindication to generic Adderall XR
- Patient has tried and failed OR has a contraindication to generic Concerta
- Patient has tried and failed OR has a contraindication to Quillivant XR (methylphenidate ER oral suspension), or Aptensio XR (methylphenidate ER cap)

Non-FDA approved uses are not approved

PA does not expire

4. methylphenidate XR sprinkle capsules nighttime dosing (Jornay PM)

Note that there were no changes to the current PA criteria

Manual PA Criteria: Jornay PM is approved if all criteria are met:

- Patient is 6 years of age or older
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record
- Patient has had at least a 2 month trial and failure of generic Concerta, OR have difficulty swallowing pills

- Patient has had at least a 2 month trial and failure of another long-acting methylphenidate (Methylphenidate ER/CD/LA, Quillivant XR, Aptensio XR)
- Patient has had at least a 2 month trial and failure of Adderall XR (generic) OR has a contraindication to Adderall XR
- Patient has tried, for at least two months, an immediate release formulation methylphenidate product in conjunction with generic Concerta or another long-acting methylphenidate
- The provider must explain why the patient needs Jornay PM: *(fill-in blank question)*

Non-FDA approved uses are not approved

PA does not expire

5. mixed amphetamine salts ER capsules triphasic release (Mydayis)
Note that there were no changes to the current PA criteria

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

- Patient is 13 years of age or older
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient has tried and failed generic mixed amphetamine salts ER capsules (Adderall XR)
- Patient has tried and failed generic methylphenidate ER tablets (Concerta)

Non-FDA approved uses are not approved

PA does not expire

E. ADHD: Stimulants Subclass—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent): an effective date of the first Wednesday 30 days after signing of the P&T minutes at all points of service.

III. UF CLASS REVIEWS—ADHD: Stimulants Subclass

BAP Comments

A. ADHD: Stimulants Subclass—UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended the formulary status for the Stimulants Subclass as discussed above:

- UF
    - Evekeo, generics
    - Evekeo ODT
    - Dexedrine Spansule, generics; Dextrostat tabs
    - Zenzedi
    - ProCentra, generics
    - Vyvanse *(moves from NF to UF)*
    - Desoxyn, generics
    - Adderall, generics
    - Adderall XR, generics
    - Focalin, generics
    - Focalin XR, generics
    - Metadate CD, generics
    - Methylin, generics
    - Methylin ER, generics
    - Aptensio XR, generics
    - Jornay PM
    - Quillivant XR
    - Ritalin, generics
    - Ritalin LA, generics
    - Concerta, generics

- NF
    - Adzenys XR-ODT
    - Adzenys ER
    - Dyanavel XR
    - Mydayis
    - Daytrana
    - Quillichew ER
    - Cotempla XR-ODT

- Tier 4/Not Covered
    - Adhansia XR

BAP Comment: ☐ Concur ☐ Non-concur

B. ADHD: Stimulants Subclass—Manual PA Criteria

The P&T Committee recommended maintaining the current manual PA criteria for Evekeo ODT, Mydayis, Cotempla XR-ODT, and Jornay PM, and new PA criteria for Vyvanse, as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

C. ADHD: Stimulants Subclass—UF/Tier 4/Not Covered and PA Implementation Plan

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

BAP Comment: ☐ Concur ☐ Non-concur

IV. UF CLASS REVIEWS—Respiratory Interleukins

P&T Comments

A. Respiratory Interleukins Relative Clinical Effectiveness Analysis and Conclusion

Background—The Respiratory Interleukins is a newly created drug class, although the three products have been reviewed individually as innovators. The TRICARE pharmacy benefit medications are benralizumab (Fasenra), dupilumab (Dupixent), and mepolizumab (Nucala). Both benralizumab (Fasenra) and mepolizumab (Nucala) were formerly available under the TRICARE medical benefit before receiving FDA approval for self-administration. A new pen

formulation of Dupixent was recently launched and is included in the class. The respiratory biologics differ in their FDA-approved indications, although all three products are approved for treating asthma with eosinophilic phenotype. Loading dose requirements and administration frequency vary depending on the indication.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

Pathophysiology

- The respiratory interleukins act on Type 2 inflammatory pathways, which are associated with eosinophilic or allergic inflammation. These medications target interleukin 4 (Dupixent) and interleukin 5 (Nucala and Fasenra [5 alpha- receptor]). It is unclear if these differences in biologic target result in clinically relevant differences in efficacy or safety.
- Type 2 inflammatory pathway-related diseases include asthma with an eosinophilic phenotype, atopic dermatitis, and chronic rhinosinusitis with nasal polyposis, among others. There is significant overlap with Type 2 diseases, and patients often have multiple Type 2 conditions.

Asthma with an Eosinophilic Phenotype and Oral Corticosteroid Dependent Asthma

- Guidelines from the Global Initiative for Asthma (GINA 2019) recommend adding-on mepolizumab (Nucala) or benralizumab (Fasenra) for patients with uncontrolled severe eosinophilic asthma, and adding-on dupilumab (Dupixent) for patients with severe Type 2 asthma or those requiring treatment with maintenance oral corticosteroids. It was also noted there is urgent need for head-to head comparisons of the biologics.
- The European Academy of Allergy and Clinical Immunology (EAACI 2020) guidelines concluded there is high certainty that Fasenra, Dupixent, and Nucala reduce both the rate of severe asthma exacerbations and the need for oral corticosteroids. The biologics probably improve asthma control, quality of life measures and forced expiratory flow in one second (FEV1), without reaching the minimal important difference.
- A 2017 Cochrane review concluded that Fasenra and Nucala roughly halved the rate of asthma exacerbations requiring systemic steroids or hospitalization.
- A 2018 Institute for Clinical and Economic Research (ICER) review concluded the biologics are all safe and effective. Overall, the net health benefit of the respiratory interleukins is at best incremental, but ICER did not recommend one agent over the others.

Severe Atopic Dermatitis

- Dupilumab (Dupixent is currently the only respiratory biologic with an indication for atopic dermatitis.
- Treatment guidelines differ in their recommendations for Dupixent's place in therapy. The 2017 Consensus-Based US recommendations list it as first-line therapy in adults after failure of topical therapies (e.g., emollients, topical corticosteroids). In contrast, the 2018 Consensus-Based European Guidelines recommend Dupixent as second-line therapy after topical treatments, or if other systemic treatments (e.g., azathioprine, cyclosporine, methotrexate) are inadvisable. The 2017 International Eczema Council states phototherapy should be considered first, before dupilumab.
- The 2017 ICER review concluded there was high certainty that Dupixent provides at least a small net health benefit relative to treatment with topical therapies.
- Mepolizumab (Nucala) is an option in selected cases unresponsive to standard therapy (2018 Consensus-Based European Guidelines), but this use is currently off-label in the US.
- Both benralizumab (Fasenra) and Nucala are currently undergoing studies for treating atopic dermatitis.

Chronic Rhinosinusitis with Nasal Polyposis

- Dupixent is the only biologic indicated for treating adults with chronic rhinosinusitis with nasal polyposis (CRSwNP), although both Fasenra and Nucala have been evaluated in clinical trials for this condition.
- FDA-approval for Dupixent was based on a pooled analysis of two trials where 63% of the enrolled patients had previous sinus surgery, with an average of two prior surgeries. While a prespecified analysis showed a reduction in patients requiring systemic corticosteroids or nasal polyp surgery, the proportion of surgically naïve patients who benefited from dupilumab was not reported. *(Bachert C, Lancet 2019 and JAMA 2016)*
- A joint 2014 US practice parameter from several professional organizations state that although biologic treatments other than dupilumab lack FDA-approval for treating nasal polyps, they have demonstrated benefit.
- There is one large sufficiently powered study with Nucala given intravenously at a higher dose that showed a statistically significant reduction in the proportion of patients requiring surgery and improvement in symptoms of nasal obstruction and nasal polyp size. *(Bachert C, J Allergy Clin Immunol 2017)*
- The 2020 European Position Paper on Rhinosinusitis and Nasal Polyposis (EPOS) lists both Dupixent and Nucala for patients meeting certain criteria,

including presence of bilateral nasal polyps in a patient with prior endoscopic sinus surgery, and three of the following factors: high eosinophil count, continued use of corticosteroids, impaired quality of life, loss of the sense of smell (anosmia), and comorbid asthma.

- Provider feedback from MHS Otolaryngologists concurred that Dupixent should be reserved as a last resort when nasal polyp disease is recalcitrant despite traditional surgical therapy and maintenance therapy with intranasal steroids.

Other Type-2 Inflammatory Pathway Conditions

- *Eosinophilic granulomatosis with polyangiitis (EGPA)* (also known as Churg-Strauss syndrome) is a rare vascular disease that can cause asthma symptoms, along with chest pain, muscle aches, and rashes. Nucala is the only biologic approved for EGPA. Studies are currently evaluating Fasenra for this condition.
- *Hypereosinophilic Syndrome (HES)* is another rare disorder that causes patients to have extremely high eosinophil counts resulting in inflammation affecting the skin, lungs, heart, and nervous system. Nucala recently received FDA approval for HES, based on one clinical trial where a reduction in disease flare was noted.

Safety

- The three respiratory interleukins are associated with relatively mild adverse effects; injection site reactions and hypersensitivity can occur.
- Dupixent is distinct in that conjunctivitis was noted in the atopic dermatitis clinical trials. However, the incidence of conjunctivitis associated with Dupixent in the clinical trials for asthma was not significantly different from placebo.
- Increased systemic eosinophilia is a possible adverse event associated with Dupixent and providers should use caution when initiating therapy in patients with elevated eosinophil counts.
- The EAACI 2020 asthma guidelines state there is low to very low certainty of evidence that drug-related serious adverse events may increase with the use of Dupixent. For Fasenra and Nucala, the results are inconclusive.

Clinical Considerations

- Fasenra is only approved for one indication, severe eosinophilic asthma in patients at least 12 years of age, and requires a loading dose. However, advantages include the long frequency of dosing (every 8 weeks). It is only

available in one formulation as part of the TRICARE pharmacy benefit, a pen device.

- Dupixent advantages include multiple FDA approvals (moderate to severe eosinophilic asthma in children down to the age of 12; atopic dermatitis in children as young as 6 years; and CRSwNP in adults) and availability in multiple devices (prefilled syringe and the newly marketed pen device). MHS prescription data shows relatively good persistence, as about 50% of patients remain on therapy after one year. Disadvantages include the requirement for a loading dose for treating asthma and atopic dermatitis, the need for every 2-week dosing for all indications, and potential dosing errors due to availability in several dosage strengths.
- Nucala advantages include multiple indications (severe asthma in patients as young as 6 years; EGPA in adults; and HES in patients down to the age of 12). A loading dose is not required, but the dosing frequency is every 4 weeks for all indications. It is available in an autoinjector (reserved for patients 12 years and older) and prefilled syringe. The dosing for EGPA and HES will require three separate injections given simultaneously to achieve the recommended 300 mg dose.

Therapeutic Interchangeability

- For eosinophilic asthma, there is a moderate degree of therapeutic interchangeability for the products. However, for the other indications, there is a low degree of therapeutic interchangeability.

Overall Clinical Conclusion

- Based on MHS provider feedback, all three products are required on the formulary due to differences in biologic target, individual patient variation in response (e.g., for asthma due to genetic differences, environment and asthma type), and differences in current FDA approved indications and age ranges.

B. Respiratory Interleukins—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the topical pain agents. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that benralizumab (Fasenra), dupilumab (Dupixent), and mepolizumab (Nucala) were all cost-effective respiratory interleukin products.
- 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 benralizumab (Fasenra), dupilumab (Dupixent), and mepolizumab (Nucala) as UF demonstrated the greatest cost avoidance for the Military Health System (MHS).

C. Respiratory Interleukins—UF Recommendation

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

- UF
  - benralizumab (Fasenra)
  - dupilumab (Dupixent)
  - mepolizumab (Nucala)
- NF – None
- Tier 4/Not Covered – None

D. Respiratory Interleukins—Manual PA Criteria

Manual PA criteria currently apply to the class. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent for Fasenra and Nucala, and 15 for, 0 opposed 0 abstained, 2 absent for Dupixent) updated PA criteria for the Respiratory Interleukins, including prohibiting concomitant treatment with multiple biologics and standardizing renewal criteria based on indication. The new indication of HES was added to the Nucala criteria. For the Dupixent indication for atopic dermatitis, provider feedback resulted in removal of the current requirement for previous use of immunosuppressant therapy. The PAs take into account package insert labeling and lab data for eosinophils for the asthma indication. Updated PA criteria will apply to new users.

Updates are in bold and strikethrough. The PA criteria are as follows:

1. **benralizumab (Fasenra)**

   Manual PA criteria apply to all new users of Fasenra Pen.

   Manual PA Criteria: Fasenra Pen **coverage will be approved for initial therapy for 12 months** if all criteria are met:

   - The patient has a diagnosis of severe persistent eosinophilic asthma
   - The patient is 12 years of age or older

- The drug is prescribed by an allergist, immunologist, or pulmonologist
- The patient must have an eosinophilic phenotype asthma as defined as either
    - Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR
    - Eosinophils ≥ 300 cells/mcL
- 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
- 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)
- **The patient is not currently receiving another immunobiologic (e.g., mepolizumab [Nucala], dupilumab [Dupixent] or omalizumab [Xolair])**

Non-FDA-approved uses are not approved.

Prior authorization ~~**does not expire**~~ **expires after 12 months. Renewal PA criteria will be approved indefinitely**

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

- **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.**

2. dupilumab (Dupixent)

Manual PA criteria apply to all new users of Dupixent.

Manual PA Criteria: Dupixent **coverage will be approved for initial therapy for 12 months** if all criteria are met:

For Asthma:

- The patient is 12 years of age or older
- The drug is prescribed by an allergist, immunologist, pulmonologist, or asthma specialist,
- The patient has one of the following
    - Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils $\geq$ 150 cells/mcL OR
    - Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months.

- ~~**The patient's symptoms are not adequately controlled on stable high dose inhaled corticosteroid AND either a Long-Acting Beta Agonist or a Leukotriene Receptor Antagonist for at least 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

- ~~**Will not be used for relief of acute bronchospasm or status asthmaticus**~~
- ~~**Dupixent will be used only as add-on therapy to other asthma controller medications**~~
- 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)

For Atopic Dermatitis:

- The patient is 6 years of age or older
- The drug is prescribed by a dermatologist, immunologist, or pulmonologist
- 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 to 17 year of age: any topical corticosteroid**

AND

  - **Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)**
  - ~~**At least one systemic immunosuppressant (i.e., cyclosporine, methotrexate, azathioprine, mycophenolate)**~~
- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy

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**

- ~~**Nasal polyposis is confirmed by imaging or direct visualization**~~

- ~~**Patient has chronic rhinosinusitis with nasal polyps and is refractory to treatment with other therapies**~~

- 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 failed a trial of two courses of oral corticosteroids in the past year or has a contraindication to oral corticosteroids 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

AND

- **For all indications 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**~~ **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, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use.

- Atopic Dermatitis: ~~**The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear.**~~ The patient's disease severity has improved and stabilized to warrant continued therapy
- Chronic rhinosinusitis with nasal polyposis : There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score

3. mepolizumab (Nucala)

Manual PA is required for all new users of Nucala.

Manual PA Criteria: Nucala **coverage will be approved for initial therapy for 12 months** if all criteria are met:

For eosinophilic asthma:

- The patient has a diagnosis of severe persistent eosinophilic asthma
- The drug is prescribed by an allergist, immunologist, or pulmonologist
- The patient must have an eosinophilic phenotype asthma as defined as either
  - Eosinophils $\geq$ 150 cells/mcL within past month while on oral corticosteroids OR
  - Eosinophils $\geq$ 300 cells/mcL
- 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 of oral corticosteroids in past year OR
  - Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids
- 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 eosinophilic granulomatosis with polyangiitis (EGPA):

- The patient has a diagnosis of EGPA
- The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist
- The patient is 18 years of age or older
- ~~**The patient has had an adequate trial of at least 3 months of one of the following, with either an inadequate response to therapy or significant side effects/toxicity or the patient as a contraindication to therapy with**~~
  - ~~**Corticosteroids, cyclophosphamide, azathioprine, or methotrexate**~~
- A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication

For Hypereosinophilic Syndrome (HES):

- **The patient has a diagnosis of HES**
- **The patient has had eosinophil levels > 1,000 cells/mcL in the past year**
- **The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist**
- **The patient is 12 years of age or older**
- **A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the HES indication**

AND

- **For all indications, the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], dupilumab [Dupixent] or omalizumab [Xolair])**

Non-FDA-approved uses are not approved.

Prior authorization ~~**does not expire**~~ **expires after 12 months. Renewal PA criteria will be approved indefinitely**

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

- **Eosinophilic asthma: 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.**
- **EGPA and HES: The patient's disease severity has improved and stabilized to warrant continued therapy**

E. Respiratory Interleukins —UF and PA Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service.

V. UF CLASS REVIEWS—Respiratory Interleukins

BAP Comments

A. Respiratory Interleukins—UF Recommendation

The P&T Committee recommended the formulary status for the Respiratory Interleukins as discussed above:

- UF
  - Fasenra
  - Dupixent
  - Nucala
- NF – None
- Tier 4/Not Covered – None

BAP Comment: □ Concur □ Non-concur

B. Respiratory Interleukins—Manual PA Criteria

The P&T Committee recommended updates to the PA criteria for Fasenra, Dupixent, and Nucala, as outlined above. Updated PA criteria will apply to new users.

BAP Comment: ☐ Concur ☐ Non-concur

C. Respiratory Interleukins—UF and Implementation Period

The P&T Committee recommended an effective date of the first Wednesday 30 days 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: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent), and group 3: (16 for, 0 opposed, 0 abstained, 1 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: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
    - azacitidine (Onureg) – Oral oncologic agent for acute myeloid leukemia (AML)
    - budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri) – Triple combination Pulmonary-3 Agent for COPD

- cysteamine 0.37% ophthalmic solution (Cystadrops) – Miscellaneous Ophthalmic for corneal cystine crystal deposits
- decitabine/cedazuridine (Inqovi) – Oral combination oncologic agent for Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)
- factor VIIa [recombinant]-jncw (Sevenfact) – Antihemophilic Factor for hemophilia A or B
- fostemsavir (Rukobia) – Oral antiretroviral for multi-drug resistant HIV-1 infection in heavily treatment-experienced adults
- nifurtimox (Lampit) – Miscellaneous Anti-infective agent for Chagas Disease in pediatrics
- ofatumumab injection (Kesimpta) – Multiple Sclerosis Agents
- opicapone (Ongentys) – Oral agent for "off episodes" associated with Parkinson's Disease
- pralsetinib (Gavreto) – Oral oncologic agent for non-small cell lung cancer (NSCLC)
- risdiplam (Evrysdi) – Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)
- satralizumab-mwge injection (Enspryng) – Miscellaneous Neurological Agent for neuromyelitis optica spectrum disorder (NMOSD)
- triheptanoin oral solution (Dojolvi) – Miscellaneous Metabolic Agents; oral liquid for long-chain fatty acid oxidation disorders in pediatrics and adults
- sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) – Wakefulness Promoting Agent for narcolepsy

- NF
  - insulin glargine (Semglee, Semglee Pen) – Basal Insulin
  - monomethyl fumarate (Bafiertam) – Multiple Sclerosis
  - octreotide (Mycapssa) – Miscellaneous Endocrine Agent for acromegaly
  - oxymetazoline ophthalmic solution (Upneeq) – Miscellaneous Ophthalmic agent for acquired blepharoptosis
- Tier 4/Not Covered
  - budesonide extended-release (Ortikos) – Gastrointestinal -1 GI Steroid for mild to moderate Crohn's Disease
    - Ortikos was recommended for Tier 4/Not Covered status as it is has little to no clinical benefit relative to other formulations of

budesonide, and the needs of TRICARE beneficiaries are met by alternative agents.

- Formulary alternatives to Ortikos include budesonide (Entocort EC) generics and other corticosteroids.

- dexamethasone (Hemady) 20 mg tablets – Corticosteroids-Immune Modulator for multiple myeloma
  - Hemady was recommended for Tier 4/Not Covered status as it is has little to no clinical benefit relative to other formulations of dexamethasone, significant safety concerns exist due to potential dosing errors, and the needs of TRICARE beneficiaries are met by alternative agents.
    - Formulary alternatives to Hemady include various strengths of generic dexamethasone.

- fluticasone oral inhaler (Armonair Digihaler) – Pulmonary-1 Agents: Inhaled Corticosteroids (ICS) for asthma
  - Armonair Digihaler was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other ICS approved for treating asthma symptoms and the needs of TRICARE beneficiaries are met by alternative agents.
    - Formulary alternatives to Armonair Digihaler include both step-preferred [fluticasone (Flovent Diskus and Flovent HFA)] and non-step preferred agents [beclomethasone (QVAR), budesonide (Pulmicort Flexhaler), ciclesonide (Alvesco), flunisolide (Aerospan), mometasone (Asmanex Twisthaler), and fluticasone (ArmonAir Respiclick)].

- fluticasone/salmeterol oral inhaler (AirDuo Digihaler) – Pulmonary-1 ICS-Long-Acting Beta Agonist (LABA) Combinations for asthma and COPD
  - AirDuo Digihaler was recommended for Tier 4 status/Not Covered as it is has little to no clinical benefit relative to other ICS/LABA Combination inhalers and the needs of TRICARE beneficiaries are met by alternative agents.
    - Formulary alternatives to AirDuo Digihaler include the step-preferred agent fluticasone/salmeterol (Advair Diskus and Advair HFA), as well as non-step-preferred agents fluticasone/vilanterol (Breo Ellipta), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort), and fluticasone/salmeterol (AirDuo Respiclick).

- levamlodipine (Conjupri) – dihydropyridine calcium channel blocker for hypertension
    - Conjupri was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to the other calcium channel blockers, there is a significant safety risk compared to the others in the class due to the potential for dosing errors, and the needs of TRICARE beneficiaries are met by alternative agents.
        - Formulary alternatives to Conjupri include amlodipine, felodipine, and nifedipine, along with verapamil and diltiazem.

- metoclopramide nasal spray (Gimoti) – Gastrointestinal-2 Agent for diabetic gastroparesis
    - Gimoti nasal spray was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other metoclopramide formulations, there is a significant safety risk compared to the other metoclopramide products due to the inability to adjust doses in patients with renal dysfunction, and the needs of TRICARE beneficiaries are met by alternative agents.
        - Formulary alternatives to Gimoti nasal spray include metoclopramide oral tablets and oral solution (Reglan) and metoclopramide orally disintegrating tablet (Reglan ODT).

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

The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Basal Insulins: Applying the same manual PA criteria to new users of Semglee that applies to the other non-step-preferred basal insulins, requiring a trial of Lantus first.
- Multiple sclerosis agents: Applying manual PA criteria to new users of Bafiertam and Kesimpta.
- Oncologic drugs: Applying manual PA criteria to new users of Gavreto, Inqovi, and Onureg.
- Applying manual PA criteria to new users of Dojolvi, Enspryng, Evrysdi, Mycapssa, and Upneeq.

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

1. **azacitidine (Onureg)**

   Manual PA criteria apply to all new users of Onureg.

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

   - The drug is prescribed by or in consultation with a hematologist/oncologist
   - The patient is 18 years of age or older
   - Patient does not have a myelodysplastic syndrome (MDS)
   - Patient will use Onureg for maintenance therapy of acute myeloid leukemia (AML) following complete remission (CR) or complete remission with incomplete blood count recovery (CRi) achieved after intensive induction chemotherapy with or without consolidation therapy
   - Patient is not able to complete intensive curative therapy
   - Onureg will not be used for parenteral routes of administration
   - The provider agrees to monitor for myelosuppression/cytopenias
   - Female patients of childbearing age are not pregnant confirmed by (-) HCG.
   - Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment.
   - Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 months after cessation of therapy if female; 3 months if male.
   - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____

   Non-FDA approved uses are not approved.

   PA does not expire

2. **decitabine/cedazuridine (Inqovi)**
   Manual PA is required for all new users of Inqovi.

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

- The drug is prescribed by or in consultation with a hematologist/oncologist
- The patient is 18 years of age or older
- Patient has myelodysplastic syndromes (MDS) with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.
- The provider agrees to monitor for myelosuppression/cytopenias
- Female patients of childbearing age are not pregnant confirmed by (-) HCG.
- Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment.
- Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 months after cessation of therapy if female; 3 months if male.
- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

3. insulin glargine (Semglee, Semglee Pen)

Manual PA is required for all new users of Semglee, Semglee Pen.

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

- The patient must have tried and failed insulin glargine (Lantus).

Non-FDA-approved uses are not approved

Prior authorization does not expire.

4. monomethyl fumarate (Bafiertam)

Manual PA is required for all new users of Bafiertam.

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

- Patient has a documented diagnosis of a relapsing form of Multiple Sclerosis (MS)
- Patient must have had at least a two-week trial of Tecfidera and has failed therapy
- Complete blood count drawn within six months prior to initiation of therapy, due to risk of lymphopenia
- Coverage NOT provided for concomitant use with other disease-modifying drugs of MS

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

5. octreotide (Mycapssa)

Manual PA is required for all new users of Mycapssa.

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

- Patient has a diagnosis of acromegaly
- The drug is prescribed by or in consultation with an endocrinologist
- Patient has tried an injectable formulation of octreotide (e.g., Sandostatin generics, Sandostatin LAR Depot, Bynfezia) and failed therapy due to lack of response

Non-FDA-approved uses are NOT approved including vasoactive intestinal peptide tumors (VIPomas) and carcinoid tumors.

Prior authorization does not expire.

6. ofatumumab injection (Kesimpta)

Manual PA is required for all new users of Kesimpta.

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

- The patient is 18 years of age or older
- The drug is prescribed by a neurologist
- The patient has a documented diagnosis of relapsing forms of MS
- The patient is not currently using another disease-modifying therapy (e.g., interferon, glatiramer, Tecfidera, Vumerity, Aubagio, Gilenya, Mayzent, Zeposia, Mavenclad, etc.)

- Patient does not have an active hepatitis B virus infection
- Patient has not failed a course of Ocrevus

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

7. oxymetazoline ophthalmic solution (Upneeq)

Manual PA is required for all new users of Upneeq.

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

- The patient is 13 years of age or older
- Patient has a diagnosis of acquired blepharoptosis affirmed by all of the following
    - Positive phenylephrine test indicating ptosis correction is achievable with Müller's muscle contraction
    - Marginal reflex distance 1 (MRD1) of less than 2 mm
- Patient and provider have decided that the patient is not a good candidate for surgical intervention

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

8. pralsetinib (Gavreto)

Manual PA is required for all new users of Gavreto.

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

- The drug prescribed by or in consultation with a hematologist/oncologist
- The patient is 18 years of age or older
- Patient has unresectable locally advanced or metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
- Provider will monitor for hepatotoxicity
- Patient does not have uncontrolled hypertension
- Provider is aware and has counseled patient that pralsetinib can cause life-threatening lung disease and hemorrhage

- Female patients of childbearing age are not pregnant confirmed by (-) HCG
- Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment
- Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy if male; 2 weeks, if female
- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

9. risdiplam (Evrysdi)

Manual PA is required for all new users of Evrysdi.

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

- The patient is between the ages of 2 months to 25 years of age (Fill-in-the-blank)
- The drug is prescribed by a pediatric or adult neurologist
- Patient has genetic confirmation of homozygous deletion or compound heterozygosity predictive of loss of function of the SMN1 gene (documentation required)
- Patient has confirmation of at least two SMN2 gene copies (documentation required)
- Patient has a confirmed diagnosis of Spinal Muscular Atrophy Types 1, 2, or 3 (Fill-in-the-blank)
- Female patients of childbearing age are not pregnant confirmed by (-) HCG
- Female patients of childbearing potential have been counseled to use effective contraception during treatment and for at least 1 month after the cessation of therapy
- Male patients of reproductive potential are counseled about the potential effects on fertility
- Patient does not have evidence of hepatic impairment
- Patient does not have permanent ventilator dependence

- Patient does not have complete paralysis of all limbs
- Evrysdi will not be used concurrently with Spinraza (nusinersen injection for intrathecal use)
- Patient weight must be documented (Fill-in-the-blank) – (Any answer acceptable)
- Patient dose in total mg/day and mg/kg per day must be documented (Fill-in-the blank)
    - The dose must be 0.2 mg/kg if the patient is 2 months to < 2 years of age; OR 0.25 mg/kg for patients ≥ 2 years of age who weigh < 20 kg; OR 5 mg for patients ≥ 2 years of age who weigh ≥ 20 kg

Non-FDA-approved uses are not approved.

Prior authorization expires in 6 months.

Renewal criteria: (Initial TRICARE PA approval is required for renewal)

- According to the prescriber, the patient's level of disease has improved or stabilized to warrant continuation on Evrysdi as determined by an objective measurement and/or assessment tool and/or clinical assessment of benefit. (documentation required)

Renewal criteria expires in 1 year.

10. satralizumab-mwge injection (Enspryng)

Manual PA is required for all new users of Enspryng.

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 or in consultation with a neurologist
- The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and is aquaporin-4 (AQP4) antibody positive
- Patient has clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening
- Patient has laboratory evidence of HBV negative and TB negative

- Patient and provider are enrolled in REMS program

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

11. triheptanoin oral liquid (Dojolvi)

Manual PA is required for all new users of Dojolvi.

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

- Patient has a documented diagnosis (molecularly confirmed) of a long-chain fatty acid oxidation disorder (LC-FAOD)
- Dojolvi is prescribed by or in consultation with a geneticist, neurologist, or LC-FAOD expert
- Patient must be experiencing symptoms of deficiency exhibited by the presence of at least 1 of the following:
    - Severe neonatal hypoglycemia, hepatomegaly, cardiomyopathy, exercise intolerance, frequent episodes of myalgia, recurrent rhabdomyolysis induced by exercise, fasting or illness, cardiomyopathy, and an associated decreased quality of life

Non-FDA-approved uses are not approved including use for weight loss in a ketogenic diet.

Prior authorization does not expire.

12. sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)

Manual PA criteria apply to all new users of Xywav.

Manual PA Criteria: Coverage of Xywav is approved if the following criteria are met:

- Patient is 18 years of age or older AND
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND
- Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND

- Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.
    - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR
- Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND
    - The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND
    - Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

OR

- Patient is a child 7 years of age or older AND
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND
- Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND
- Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.
    - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR
- Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND
    - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND
- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders)

Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.

PA expires after 1 year.

Renewal PA criteria; Renewal not allowed. A new prescription will require a new PA to be submitted.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, TIER 4/NOT COVERED, and PA IMPLEMENTATION PLAN

The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and group 3: (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- **New Drugs Recommended for UF or NF Status, and PA criteria:** 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 Status:** 1) An effective date of the first Wednesday after a 120-day implementation period at all POS; 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, and on 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**
  - Onureg
  - Breztri
  - Cystadrops
  - Inqovi
  - Sevenfact
  - Rukobia
  - Lampit
  - Kesimpta
  - Ongentys
  - Gavreto

- Evrysdi
- Enspryng
- Dojolvi
- Xywav

- **NF**
  - Semglee, Semglee Pen
  - Bafiertam
  - Mycapssa
  - Upneeq

- **Tier 4/Not Covered**
  - Ortikos
  - Hemady
  - Armonair Digihaler
  - AirDuo Digihaler
  - Conjupri
  - Gimoti

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

- **New Drugs Recommended for UF or NF Status, and PA criteria:** 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 Status:** 1) An effective date of the first Wednesday after a 120-day implementation period at 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 and on implementation.

BAP Comment: □ Concur □ Non-concur

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. New Manual PA Criteria

1) Narcotic Analgesics – Tapentadol ER (Nucynta ER)

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Nucynta ER in new users to ensure that other therapies for neuropathic or non-neuropathic pain are tried first.

Nucynta ER has been designated as UF since February 2012. Tapentadol has a similar mechanism of action to tramadol, which includes mu-opioid activation and norepinephrine reuptake inhibition. It is indicated for treatment of both non-neuropathic pain and neuropathic pain (e.g., diabetic peripheral neuropathy) severe enough to require daily, around-the-clock, long-term opioid treatment. Tapentadol ER has additional warnings and risk of adverse reactions due to its dual mechanism of action that are not seen with the other narcotic analgesics.

The previous P&T Committee conclusion was that there is no evidence that pain control with tapentadol ER is superior to oxycodone ER. A survey of

MHS providers noted that since tapentadol ER is a long-acting opioid it should be reserved for use after a trial of other non-opioid and short-acting opioid agents. Provider feedback supported implementing a PA for this medication based on relative clinical and cost effectiveness concerns.

The manual PA criteria are as follows:

Manual PA criteria applies to new users of Nucynta ER.

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

- The patient is 18 years of age or older
- The patient has a diagnosis of one of the following
    - pain severe enough to require daily, around-the-clock, long-term opioid treatment OR
    - neuropathic pain associated with diabetic peripheral neuropathy in adults severe enough to require daily, around-the-clock, long-term opioid treatment
- For non-neuropathic pain, the patient has tried and failed at least one of the following short-acting opioids
    - morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, tapentadol IR
- For neuropathic pain, the patient has tried and failed all of the following drugs/drug classes
    - At least two of the following classes of non-opioid medications (unless the patient has a contraindication)
        - gabapentin or pregabalin titrated to therapeutic dose
        - a tricyclic antidepressant titrated to therapeutic dose
        - duloxetine titrated to therapeutic dose
    - Tramadol
    - At least one of the following short acting opioids morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, tapentadol IR

Non-FDA-approved uses are NOT approved.

Prior authorization does not expire.

B. Updated Manual PA Criteria—Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the new PA for tapentadol ER (Nucynta ER) become effective in new users the first Wednesday 30 days after the signing of the minutes.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. New Manual PA Criteria

The P&T Committee recommended manual PA criteria for Nucynta ER 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 the Nucynta ER become effective at 30 days.

BAP Comment: ☐ Concur ☐ Non-concur

X. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

P&T Comments

A. Updated Manual PA Criteria

Updates to the manual PA criteria and step therapy for several drugs were recommended due to expanded age indications and new FDA-approved indications. The updated PAs and step therapy outlined below will apply to new users. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2

absent) updates to the manual PA criteria for Enbrel, Tremfya, Xeljanz and Xeljanz oral solution, Epclusa, Epidiolex, and Haegarda.

The updates are as follows:

1) **Targeted Immunomodulatory Biologics (TIBs)**
   - **etanercept (Enbrel)**—Etanercept (Enbrel) has been labeled for use in children as young as 4 years of age for plaque psoriasis since 2016. Use of Enbrel in this population has been exempt from the requirement to try ustekinumab (Stelara) first, as Stelara was only approved for children down to the age of 12 years with plaque psoriasis. After the August 2020 P&T meeting, Stelara received FDA-approval for treating patients as young as 6 years of age with plaque psoriasis. Therefore, a trial of Stelara for pediatric patients ages 6 and older with plaque psoriasis will be required before Enbrel. The current PA form for Enbrel will note that a trial of Stelara is not required first in patients 4 to 5 years of age.
   - **guselkumab (Tremfya)**—Updated the manual PA criteria to include the new indication of active psoriatic arthritis for patients 18 years of age and older.
   - **tofacitinib (Xeljanz, Xeljanz oral solution)**—Updated the manual PA criteria to include the new indication for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.

2) **Hepatitis C Agents: Direct Acting Agents—sofosbuvir/velpatasvir tablets (Epclusa)—**Updated the manual PA criteria to include the expanded age indication for patients 6 years of age or older or those weighing at least 17 kg with chronic HCV genotype 1, 2, 3, 4, 5, or 6.

3) **Anticonvulsants-Antimania Agents — cannabidiol oral solution (Epidiolex)**—Updated the manual PA criteria to include the new indication for treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year of age or older. Note that the PA will not specify an age limit.

4) **Hereditary Angioedema Agents — C1 Esterase Inhibitor [Human] (Haegarda)—**Updated the manual PA criteria to include the expanded age indication for use in patients 6 years of age or older for routine prophylaxis to prevent hereditary angioedema. Previous manual PA criteria specified use in 12 years of age or older. Note that the PA will not specify an age limit.

B. Updated Manual PA Criteria—Implementation Plan

The P&T Committee recommended the following implementation periods:

- (15 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Enbrel, Tremfya, Xeljanz, and Xeljanz oral solution, Epclusa, Epidiolex, and Haegarda in new users will become effective the first Wednesday 60 days after the signing of the minutes.

XI. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

BAP Comments

A. Updated PA Criteria

The P&T Committee recommended updates to the manual PA criteria for the drugs discussed above, Enbrel, Tremfya, Xeljanz, Epclusa, Epidiolex, and Haegarda.

BAP Comment: ☐ Concur ☐ Non-concur

B. Updated PA Criteria—Implementation Plan

The P&T Committee recommended the updates to the PA criteria for the drugs discussed above become effective at 60 days.

BAP Comment: ☐ Concur ☐ Non-concur

XII. BRAND ALBUTEROL HFA (PROAIR HFA) COPAYMENT CHANGE

P&T Comments

ProAir HFA oral inhaler has been designated BCF since November 2013. Pricing for the branded ProAir HFA inhaler is more cost-effective than the AB-rated generic formulations for albuterol HFA, which were launched earlier this year (February 2020). Currently at the Mail Order point of service, patients pay a Tier 1 copay for the branded product, since DoD has instructed ESI to dispense the branded product rather than a generic albuterol inhaler. However, at Retail Network pharmacies the Tier 2 copay applies.

Applying the Tier 1 copay at both Retail and Mail will ensure the same copay for patients across the purchased care points of service, and will also encourage use of the most cost-effective branded ProAir HFA product. Additionally, lowering the copay is also 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."

A. PROAIR HFA BRAND COPAYMENT CHANGE AND IMPLEMENTATION—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) changing the copay for ProAir HFA from Tier 2 (brand) to the Tier 1 (generic) copay at the purchased care points of service. Implementation will occur the first Wednesday two weeks after signing of the minutes.

XIII. BRAND ALBUTEROL HFA (PROAIR HFA) COPAYMENT CHANGE

BAP Comments

A. ProAir HFA Brand Copayment Change and Implementation
The P&T Committee recommended changing the brand ProAir HFA copay to Tier 1 at the purchased care points of service, with implementation occurring two weeks after signing of the minutes, as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

XIV. SECTION 702, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2018: TRICARE TIER 4/NOT COVERED DRUGS PER 32 CFR 199.21(E)(3) RE-REVIEW

P&T Comments

Background—The interim rule allowing for complete exclusion of drugs from TRICARE pharmacy benefit coverage was initially published on December 11, 2018, with the Final Rule published June 3, 2020. The Committee considers several factors in addition to cost when identifying Tier 4/Not Covered candidates, including the quality of clinical efficacy evidence available, determination of significant safety issues in which

risks may outweigh potential benefit, identification of drugs that contain ingredients not covered by the TRICARE pharmacy benefit, or other negative concerns.

The first Tier 4/Not Covered products were designated at the February 2019 Committee meeting, with implementation occurring on August 28, 2019. For the purposes of the re-review, the Committee considered whether there was any new compelling published clinical data, and evaluated any change in relative cost effectiveness.

Relative Clinical and Cost Effectiveness Summary

1. **Diabetes Non-Insulin Drugs – Biguanides Subclass: metformin ER gastric retention 24 hours (Glumetza brand and generics)** is an extended release metformin formulation, which uses a polymer-based oral drug delivery system that makes the tablet swell, causing retention in the stomach. Clinical trials show Glumetza is at least as efficacious as metformin immediate-release (IR) (Glucophage) in all measures of glycemic control. There is no evidence to suggest that differences in the extended-release properties of Glumetza confer any benefits in efficacy or safety compared to the other metformin ER formulations (Glucophage XR). A CMA failed to detect any significant changes in cost effectiveness from the February 2019 review.

2. **Pain Agents – Combinations Subclass: naproxen/esomeprazole** (**Vimovo brand and generic**) is a fixed-dose combination of two over-the-counter (OTC) drugs, which offers patients a convenient formulation for improving adherence. However, this particular combination of a nonsteroidal anti-inflammatory drug (NSAID), which is typically targeted for short-term use, and a proton pump inhibitor (PPI), which has limited data to support use beyond eight weeks, is potentially harmful. There is no data to suggest that using other prescription or OTC NSAIDs concurrently with PPIs would not provide the claimed benefit of the individual ingredients found. A CMA failed to detect any significant changes in cost effectiveness from the February 2019 review.

3. **Corticosteroids-Immune Modulators – High Potency Corticosteroid for Plaque Psoriasis: halobetasol propionate 0.05% foam (Lexette brand and generic)** is a high potency topical steroid, which can be applied on the scalp and other body areas. There are currently 28 other high-potency topical corticosteroids on the formulary, including 12 products formulated in a hair-friendly vehicle, including foam, gel, lotion, shampoo, and solution. Overall, there is a high degree of therapeutic interchangeability in the class. A CMA failed to detect any significant changes in cost effectiveness from the February 2019 review.

   Overall, the information reviewed by the P&T Committee did not change the previous conclusions that Glumetza, Vimovo and Lexette foam have little to no additional clinical effectiveness relative to similar drugs in their respective classes, and the needs of TRICARE beneficiaries are met by alternative agents.

A. TRICARE TIER 4/NOT COVERED RECOMMENDATION—The P&T Committee recommended maintaining the following products as Tier 4/Not Covered under the TRICARE pharmacy benefits program.

- (15 for, 0 opposed, 0 abstained, 2 absent) metformin ER gastric retention 24 hours (Glumetza brand and generics)
- (14 for, 0 opposed, 0 abstained, 3 absent) naproxen/esomeprazole (Vimovo brand and generics)
- (14 for, 0 opposed, 0 abstained, 3 absent) halobetasol propionate 0.05% foam (Lexette brand and generics)

B. IMPLEMENTATION PLAN: Not applicable; Glumetza, Vimovo and Lexette are currently designated Tier 4.

XV. SECTION 702, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2018: TRICARE TIER 4/NOT COVERED DRUGS PER 32 CFR 199.21(E)(3) RE-REVIEW

BAP Comments

A. TRICARE TIER 4/NOT COVERED RECOMMENDATION

The P&T Committee recommended maintaining Tier 4/Not Covered status for the following drugs:

- Glumetza brand and generics
- Vimovo brand and generics
- Lexette brand and generics

BAP Comment: ☐ Concur ☐ Non-concur

XVI. INFORMATION ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT

Table of implementation Status of UF Recommendations/Decisions Summary December 2020

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants Subclass	▪ amphetamine sulfate (Evekeo, generic) ▪ amphetamine sulfate ODT (Evekeo ODT) ▪ dextroamphetamine (Dexedrine Spansule ER cap, generic, Dextrostat tab, ProCentra sol, generic) ▪ dextroamphetamine (Zenzedi tab) ▪ lisdexamfetamine capsule and chewable tablet (Vyvanse) ▪ methamphetamine HCL (Desoxyn, generic) ▪ mixed amphetamine salts IR (Adderall, generic) ▪ dexmethylphenidate IR (Focalin, generic) ▪ dexmethylphenidate ER (Focalin XR, generic) ▪ methylphenidate CD (Metadate CD, generic) ▪ methylphenidate chewable tablet and solution (Methylin, generic) ▪ methylphenidate ER (Metadate ER, Methylin ER, generic) ▪ methylphenidate ER (Aptensio, generic) ▪ methylphenidate ER OS (Quillivant XR) ▪ methylphenidate IR (Ritalin, generic) ▪ methylphenidate LA (Ritalin LA, generic) ▪ methylphenidate XR sprinkle capsule (Jornay PM)	▪ amphetamine ER-ODT (Adzenys XR-ODT) ▪ amphetamine ER OS (Adzenys ER) ▪ amphetamine XR OS (Dyanavel XR) ▪ mixed amphetamine salts ER triphasic release (Mydayis) ▪ methylphenidate ER chewable tablet (Quillichew ER) ▪ methylphenidate XR-ODT (Cotempla XR-ODT) ▪ methylphenidate patch (Daytrana)	▪ methylphenidate ER sprinkle caps (Adhansia XR)	Pending signing of the minutes / 30 days.	• No changes made to the current NF and Tier 4 drugs • Vyvanse moves from NF to UF • New Vyvanse PA only affects new uses
Respiratory Interleukins Class	▪ benralizumab (Fasenra) ▪ dupilumab (Dupixent) ▪ mepolizumab (Nucala)	▪ None	▪ None	Pending signing of the minutes / 30 days.	• All 3 products remain UF • PA updates only apply to new patients

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

Drug	Total
budesonide extended-release (Ortikos)	16
dexamethasone (Hemady)	0
fluticasone oral inhaler (Armonair Digihaler)	0
fluticasone/salmeterol oral inhaler (AirDuo Digihaler)	4
levamlodipine (Conjupri)	0
metoclopramide nasal spray (Gimoti)	2