EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel
December 17, 2020

UNIFORM FORMULARY REVIEW PROCESS

I. UF CLASS REVIEWS—ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD): STIMULANTS SUBCLASS

A. 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:

1. methamphetamine HCl (Desoxyn, generics)
2. mixed amphetamine salts IR tablets (Adderall, generics)
3. mixed amphetamine salts XR capsules (Adderall XR, generics)
4. dexmethylphenidate IR (Focalin, generics)
5. dexmethylphenidate ER (Focalin XR, generics)
6. methylphenidate CD (Metadate CD, generics)
7. methylphenidate chewable tablets and oral solution (Methylin, generics)
8. methylphenidate ER (Methylin ER, generics)
9. methylphenidate ER sprinkle caps (Aptensio XR, generics)
10. methylphenidate ER sprinkle capsules nighttime dosing (Jornay PM)
11. methylphenidate ER oral suspension (Quillivant XR)
12. methylphenidate IR (Ritalin, generics)
13. methylphenidate long-acting (LA) (Ritalin LA, generics)
14. 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

  1. amphetamine ER orally dissolving tablets (ODT) (Adzenys XR-ODT)
  2. amphetamine ER oral suspension (Adzenys ER)
  3. amphetamine ER oral suspension (Dyanavel XR)
  4. mixed amphetamine salts ER capsules triphasic release (Mydayis)
  5. methylphenidate transdermal system (Daytrana)
  6. methylphenidate ER chew tab (Quillichew ER)
  7. methylphenidate XR-ODT (Cotempla XR-ODT)

- Tier 4/Not Covered

  1. methylphenidate ER sprinkle caps (Adhansia XR)

B. 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

C. 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.

Summary of Physician's Perspective:

- This is the second time we have reviewed this class, and since 2015, there have been 10 drugs that we have previously evaluated as innovator drugs. For the formulary recommendation, the main changes are that everything remains the same, except that Vyvanse will now move from nonformulary to formulary status.

- Feedback from MTF providers showed that Vyvanse was commonly requested to be added back to the formulary.

- For Vyvanse, we are recommending a PA that will only apply to new patients, so existing patients will not have to go through the PA process. For ADHD, a review of prescription data from MTF patients did show that the majority had previously received methylphenidate formulations or Adderall. The PA will allow use for binge eating disorder, but only if the patient has tried other therapies first. Other health plans, including the VA also require PA for Vyvanse.

- The one current Tier 4 drug, Adhansia, will remain Tier 4. None of the providers we surveyed had any issues with this.

- There are currently about 27,000 patients receiving Vyvanse, so these patients will now see a reduction in their copay from Tier 3 (non-formulary) to Tier 2 (formulary). Since no letters are required, we will do a 30-day implementation period, to expedite the copay decrease at the Mail Order and Retail pharmacies.

Summary of Panel Questions and Comments:

Uniform Formulary/Tier 4/Not Covered Recommendation:

CAPT (Ret) Hostettler asked why the P&T Committee recommended/retained Adhansia XR for Tier 4 status and not the other drugs in this class. According to the minutes all the drugs are therapeutically interchangeable, the safety records are the same and it is not the most expensive.

MAJ Davies answers with there were several long-acting methamphetamine products that are on the UF, which included the alternatives that were listed, other long-acting duration agents and one that has similar duration of 16 hours. New data reviewed by P&T Committee did not change the previous conclusion. Additionally, provider feedback strongly reaffirmed that Adhansia XR has little to no additional clinical effectiveness relative to the similar agents that are on the UF or NF.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asks a questions about the Jornay PM. The manual PA criteria states the "provider must explain why the patient needs Jornay PM". The specific use is not

summarized in the PA criteria but the provider must justify why the patient needs the medication. Regardless, the patient must complete a combined total of 6 months of trials prior to receiving approval of the agent for developmental issues. If the provider identified the specific need, it is 3rd on the list for cost, why is the patient required to complete the other 4 steps in the manual PA criteria.

Dr. Bertin also has a question regarding the Manual PA criteria for Jornay PM. The written comments submitted raised significant questions. He states he does not have enough information to answer the questions and requests clarification. Some of the questions concern cost and he understands the Panel does not received information regarding cost.

MAJ Davies states he will respond to both questions. The decision for Jornay PM was based on both clinical and cost effectiveness. The PA Criteria was reviewed by the P&T Committee in August 2019 during the original new drug review and in November 2020 during the class review. The recommendations for each review were presented to the Panel. There were no changes made to the PA Criteria.

CAPT (Ret) Hostettler states that he appreciates there were no changes made, however the product was reviewed under different circumstances. The 1st review was as a new drug and the class review. The agent is 3rd for cost. Safety, tolerability and efficacy are equivalent. Was there anything specific mentioned during the P&T Committee review that would explain the manual PA Criteria?

MAJ Davies states that it was nothing specific. Again, the recommendation was made based on the both the clinical and cost effectiveness. Also, we have not had any complaints from providers that the current PA criteria is not changing or is excessively arduous.

CAPT (Ret) Hostettler states the "needs" specified by the provider are clinical reasons. There is a clinical advantage over the other agents with the PM dosing. Although the providers prefer this agent, the patient is required to complete all the steps because the PA criteria does not address their need for the PM dosing.

Dr. Bertin states that he believes the process is unnecessarily complicated. As a Panel member, one of our purposes is to be concerned about complications for patients.

Dr. Peloquin adds there was a statement regarding standardizing the clinical criteria across all points of service for Vyanase. As he looks through all the different criteria he understands that there are some differences with the amphetamine, methylphenidate. Has the PA's criteria been standardized across these drugs?

MAJ Davies states that comment for the Vyvanse was in regards to the indication that it has binge eating disorders. It was recommended for UF and that comment was directed towards that specific indication.

CAPT (Ret) Hostettler recommends adding a bullet to the PA Criteria that states this is for a developmentally challenged child. He believes that makes perfect sense rather than requiring the patient to complete the complicated process to state that a patient is developmentally challenged. If the patient is developmentally challenged, he doesn't know why the committee is restricting access to the medication.

MAJ Davies states he appreciates the comments and they will be noted. Also, note the current PA form that has not changed. There is a section on the form that allows the provider to provide additional, pertinent information about the patient. The provider can fill in the box, check off what they want, or submit it electronically. The form will be reviewed and a determination made on whether the patient complete the steps or not.

CAPT (Ret) Hostettler asks is it possible for the patient to get the product for a developmentally challenged child without completing all the steps in the PA criteria.

MAJ Davies states that he does not have an exact example for every exact situation. Therefore, as stated, when the form is submitted it will be reviewed.

CAPT (Ret) Hostettler states that he is looking at the criteria. Just to clarify, if the provider completes the form and adds that the agent is for a developmentally challenged child, is the patient required to complete all the steps in the PA criteria. If I am not mistaken, this is the only drug on the list that references developmentally challenges children.

MAJ Davies states that a developmental delay does not automatically mean approval of Jornay PM.

CAPT (Ret) Hostettler and Dr. Jay Peloquin agree that it needs more work.

MAJ Davies clarifies the comment from the provider regarding developmentally challenged patients is not an actual FDA-approved indication. It was a comment from a provider.

CAPT (Ret) Hostettler asks if comments were received from "a" provider or "multiple" providers.

MAJ Davies responds comments were received from "a" single provider and over 50 were surveyed.

Dr. Khoury clarifies that a developmental delay does not automatically preclude the use of the alternative agents.

CAPT (Ret) Hostettler asks how many physicians took the survey.

Dr. Khoury states a single provider out of over 50 that were surveyed provided this comment. I do not have an exact number of those that provided feedback. There was a

broad array of submissions from numerous specialties providing feedback. Please let me know if you need the number surveyed to make a comment.

CAPT (Ret) Hostettler states that it would be nice to know if there was only one psychiatrist on the list.

Dr. Khoury states that there were numerous providers that are of a child and adolescent psychiatry background.

Col Hoerner clarifies, when we come to the vote, the vote has to be either concur or non-concur with the P&T committee recommendation as it is written. If a Panel member non-concurs, comments may be provided summarizing the issues/concerns. To summarize, a Panel member can concur with the recommendation as written or non-concur and provide a comments addressing specific concerns with the recommendation.

Dr. Peloquin asks for an explanation regarding the decision to not change the current PA criteria.

MAJ Davies states that the decision for the Jornay PM was based on both clinical and cost effectiveness. The PA Criteria was presented to the Panel during the original new drug review in August 2019 and the class review in November 2020. Based on the discussions or each review, no changes were recommended. In addition to that, there were no complaints from any single provider having any issues of being able to obtain the product when they needed to.

Dr. Khoury also adds that the provider wanted Jornay PM available uniform formulary, which it is.

CAPT (Ret) Hostettler states that he knows we do not get the same level of detail as the 2-day P&T committee, but can you point to the specific clinical issue that drove that decision? You keep saying clinical and cost. What was the clinical issue that drove the decision? Is that possible to provide?

Dr. Khoury states it was not intended for this class to be a 4-hour review to discuss why one drug had a specific decision. Overall, the intent of the P&T committee is to maintain decisions/recommendations when there is no real reason to overturn those recommendations or decisions. I will note, these comments being referenced are from one company and one specific feedback and it is not consistent with anything else we have received regarding concerns about the UF recommendation.

There were no further questions or comments from the Panel. The Chair called for a vote on the UF/Tier 4/Not Covered Recommendation, Manual PA Criteria and UF/Tier 4/Not Covered and PA Implementation Plan for the ADHD: Stimulants Subclass.

- **ADHD: Stimulants Subclass—UF/Tier 4/Not Covered Recommendation**

  Concur: 5 Non-Concur: 1 Abstain: 0 Absent: 1

  Director, DHA:

  _____ These comments were taken under consideration prior to my final decision.

- **ADHD: Stimulants Subclass—Manual PA Criteria**

  Concur: 3 Non-Concur: 3 Abstain: 0 Absent: 1

  Additional Note: The Panel members non-concurred because they believe the process is unnecessarily complicated. One of our purposes on this Panel is to be concerned about complications for patients.

  Director, DHA:

  _____ These comments were taken under consideration prior to my final decision.

- **ADHD: Stimulants Subclass—UF/Tier 4/Not Covered and PA Implementation Plan:**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

  _____ These comments were taken under consideration prior to my final decision.

II. UF CLASS REVIEWS—RESPIRATORY INTERLEUKINS

A. 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

B. 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

a. Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids

OR

b. 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:

  a. Hospitalization for asthma in past year OR

  b. Two courses oral corticosteroids in past year OR

  c. 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:

  a. Long-acting beta agonist (LABA e.g., Serevent, Striverdi),

  b. Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or

  c. 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
    a. Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/mcL OR
    b. 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;
    a. Hospitalization for asthma in past year OR
    b. Two courses oral corticosteroids in past year OR
    c. 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:
    a. Long-acting beta agonist (LABA e.g., Serevent, Striverdi),
    b. Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or
    c. 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 an allergist, dermatologist, 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:

  a. **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

  b. **Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)**

  ~~c. 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:**

  a. **Presence of nasal polyposis is confirmed by imaging or direct visualization**

  AND

  b. **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

  a. Adequate duration of at least TWO different high-dose intranasal corticosteroids

     AND

  b. Nasal saline irrigation AND

  ~~c. The patient has failed a trial of two courses of oral corticosteroids in the past year or has a contraindication to oral corticosteroids AND~~

  d. 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

a. 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.

b. 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

c. 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
    a. Eosinophils $\geq$ 150 cells/mcL within past month while on oral corticosteroids OR
    b. 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:
    a. Hospitalization for asthma in past year OR
    b. Two courses of oral corticosteroids in past year OR
    c. 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:
    a. Long-acting beta agonist (LABA e.g., Serevent, Striverdi),
    b. Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or
    c. 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~~

~~a. 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

a. **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.**

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

C. 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.

Summary of Physician's Perspective:

- This is the first full review for the class, although all three drugs were previously evaluated as innovator drugs.
- We did take into consideration the comments from providers, so all three drugs will stay on the formulary, and all the copays will remain at the current Tier 2 levels.
- PAs currently apply to the class, and the PAs were updated to be consistent with the package labeling and professional guidelines.
- We do not have any guidance yet on whether these agents will be required to be given long term and we also do not know yet what the long-term adverse effects are. Some of the disease states treated, like atopic dermatitis, are not necessarily life-long conditions. So, we will continue to monitor the literature for updates in safety, and new indications.

Summary of Panel Questions and Comments:

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asks if Dupixent can be prescribed by an allergist, immunologist, pulmonologist, or otolaryngologist. Which of those four are able to do surgery? Prior surgery is a requirement or one of the steps in the PA criteria. If the patient has chronic rhinosinusitis with nasal polyposis, he believes the otolaryngologist is an ENT surgeon and the only one that could perform the procedure. If I am being followed by an allergist, I must receive a referral from a second specialist for the surgery in question. Rather than requiring the patient to meet the requirement for surgery, why not add the verbiage, "the patient and the provider have decided that the patient is not a good candidate for surgical intervention". In my opinion, this change to the PA criteria would be more effective.

Dr. Khoury responds this disease state is typically managed by multiple providers. That is what the data shows and is consistent with our feedback. Typically the outcomes suggest that surgery is very effective in managing this disease. Again, he is speaking about a higher level of this disease state and not just Dupixent. That is the reason for the language in the PA criteria. Certain teams of providers help manage these complicated patients. A patient cannot walk into a clinic, be diagnosed with polyposis and receive a prescription for Dupixent. Furthermore, Dupixent is a lifelong potential treatment not a nasal steroid treatment to be prescribed. We do not have a lot of information on how it engages over the long term or the

adverse side effects. We certainly do not have information to state in the PA Criteria that Dupixent is better than surgery and patient should be availed of surgery. The prior authorization is written in a way that ensures the patient has the most clinically effective and potentially cost effective agent. If the patient starts this therapy, this prescription probably equates to a new car price every year forever based on publicly available cost data as can be found on websites like goodrx.com. We want to make sure we are doing the right thing for the patient who could be paying a copay for life potentially if this is started and alternative treatment options are available.

CAPT (Ret) Hostettler thanks Dr. Khoury for providing the cost information. The example you provided about the cost being approximately the cost of a new car (40K) per year puts this this recommendation into prospective. This information was not previously provided in the meeting materials at the 1st review nor this review.

Dr. Peloquin asks for clarification regarding the renewal criteria. The renewal criteria for current patients will be renewed indefinitely. Does the PA criteria apply to new or current users?

CDR Raisor clarifies the Dupixent PAs had renewal criteria. There are some, prior to the change that had renewal criteria. We would expect that criteria to remain the same. The drugs, Faserna and Nucala, did not have criteria but will now have renewal criteria. It will apply to e new patients only.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria and the UF and PA Implementation Plan for the Respiratory Interleukins.

- **Respiratory Interleukins—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

- **Respiratory Interleukins—Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

- **Respiratory Interleukins—UF and Implementation Plan:**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

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

- **Newly Approved Drugs 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:

    1. azacitidine (Onureg) – Oral oncologic agent for acute myeloid leukemia (AML)
    2. budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri) – Triple combination Pulmonary-3 Agent for COPD
    3. cysteamine 0.37% ophthalmic solution (Cystadrops) – Miscellaneous Ophthalmic for corneal cystine crystal deposits
    4. decitabine/cedazuridine (Inqovi) – Oral combination oncologic agent for Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)
    5. factor VIIa [recombinant]-jncw (Sevenfact) – Antihemophilic Factor for hemophilia A or B

6. fostemsavir (Rukobia) – Oral antiretroviral for multi-drug resistant HIV-1 infection in heavily treatment-experienced adults

7. nifurtimox (Lampit) – Miscellaneous Anti-infective agent for Chagas Disease in pediatrics

8. ofatumumab injection (Kesimpta) – Multiple Sclerosis Agents

9. opicapone (Ongentys) – Oral agent for "off episodes" associated with Parkinson's Disease

10. pralsetinib (Gavreto) – Oral oncologic agent for non-small cell lung cancer (NSCLC)

11. risdiplam (Evrysdi) – Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)

12. satralizumab-mwge injection (Enspryng) – Miscellaneous Neurological Agent for neuromyelitis optica spectrum disorder (NMOSD)

13. triheptanoin oral solution (Dojolvi) – Miscellaneous Metabolic Agents; oral liquid for long-chain fatty acid oxidation disorders in pediatrics and adults

14. sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) – Wakefulness Promoting Agent for narcolepsy

- NF:

1. insulin glargine (Semglee, Semglee Pen) – Basal Insulin

2. monomethyl fumarate (Bafiertam) – Multiple Sclerosis

3. octreotide (Mycapssa) – Miscellaneous Endocrine Agent for acromegaly

4. oxymetazoline ophthalmic solution (Upneeq) – Miscellaneous Ophthalmic agent for acquired blepharoptosis

- Tier 4 (Not Covered):

1. budesonide extended-release (Ortikos) – Gastrointestinal -1 GI Steroid for mild to moderate Crohn's Disease

    a. 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.

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

2. dexamethasone (Hemady) 20 mg tablets – Corticosteroids-Immune Modulator for multiple myeloma

   a. 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.

      1) Formulary alternatives to Hemady include various strengths of generic dexamethasone.

3. fluticasone oral inhaler (Armonair Digihaler) – Pulmonary-1 Agents: Inhaled Corticosteroids (ICS) for asthma

   a. 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.

      1) 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)].

4. fluticasone/salmeterol oral inhaler (AirDuo Digihaler) – Pulmonary-1 ICS-Long-Acting Beta Agonist (LABA) Combinations for asthma and COPD

   a. 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.

      1) 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).

5. levamlodipine (Conjupri) – dihydropyridine calcium channel blocker for hypertension

a. 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.

1) Formulary alternatives to Conjupri include amlodipine, felodipine, and nifedipine, along with verapamil and diltiazem.

6. metoclopramide nasal spray (Gimoti) – Gastrointestinal-2 Agent for diabetic gastroparesis

a. 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.

1) Formulary alternatives to Gimoti nasal spray include metoclopramide oral tablets and oral solution (Reglan) and metoclopramide orally disintegrating tablet (Reglan ODT).

- **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)

1. **azacitidine (Onureg)**

   Manual PA is required for 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.

PA does not expire.

3. **insulin glargine (Semglee, Semglee Pen)**

Manual PA criteria apply to all new users of Semglee, Semglee Pen.

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

- Patient has acute pain due to minor strains, sprains, and/or contusions
- The patient must have tried and failed insulin glargine (Lantus).

Non-FDA-approved uses are not approved.

PA 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.

PA 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 criteria apply to 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.

PA does not expire.

7. **oxymetazoline ophthalmic solution (Upneeq)**

Manual PA is required for all new and current 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.

PA does not expire.

8. **Pralsetinib (Gavreto)**

Manual PA applies to 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.

PA 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.

PA 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 applies to new users Enspryng.

Manual PA Criteria: Enspryng 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.~~ Please note that there is a correction here; there is not a REMS program required for Enspryng.

Non-FDA-approved uses are not approved.

PA does not expire.

11. triheptanoin oral liquid (Dojolvi)

Manual PA applies to new users of Dojolvi.

Manual PA Criteria: Dojolvi 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:
    a. 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.

PA does not expire.

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

Manual PA applies to new users of Xywav.

Manual PA Criteria: Coverage of Xywav is approved if all 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.

  a. 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

  a. 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

  b. 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.

a. 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

  a. 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.

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF 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 upon the first Wednesday two weeks after signing of the minutes in all points of service.

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

Summary of Physician's Perspective:

- Out of the total of 25 new drugs reviewed at this meeting 15 were made UF and 4 will stay NF and 6 we are recommending for Tier 4/Not Covered status.

- For the 11 drugs where PAs were recommended, the criteria only effect new users, therefore all patients currently receiving the drug will be able to remain on therapy.

- For this meeting we have several drugs that were approved for orphan indications or rare diseases, where a very limited number of patients were studied in short-term trials, and where long-term safety and efficacy is unknown. The goals of the PA Criteria are to ensure that the most appropriate patients are selected.

- There was one insulin product, Semglee that was recommended to be NF. This drugs has the same active ingredient as Lantus. There is no data to show that Semglee would be more effective or safer than Lantus. Semglee is being marketed as a low cost insulin, however at MHS Lantus is very cost effective for our beneficiaries. Lantus currently has Tier 1 (generic) copay, and has 85% of the basal insulin market share. The committee did not feel that this new insulin offered a benefit to our patients.

- For the 6 drugs recommended for Tier 4 status, the active ingredients are all available in low cost preparations that are on the formulary. We did reach out to providers for their opinion on the Tier 4 drugs and there was a wide agreement among the respective specialties that these drugs do not offer clinical advantages and in some cases there were some safety concerns.

Summary of Panel Questions and Comments:

UF/Tier 4/Not Covered Recommendation:

CAPT (Ret) Hostettler asked for the formulary status of Mycapssa.

Dr. Lugo states that Mycapssa is NF. It is an octreotide oral capsule and Tier 3.

CAPT (Ret) Hostettler states that this is a new, breakthrough therapy. Until recently, patients have been treated with Injectables. They have a chance now to be treated with an oral. In his opinion, we should ensure the new therapy is available our beneficiary population. He request information about the difference in cost for the injectable and the new oral dosage capsule.

Dr. Lugo states they have reached out to multiple endocrinologists for their feedback. She appreciates that this is a new oral therapy where previously octreotide has been around for a really long time as an injectable. With the exception of the new oral capsule dosage form, there was nothing new clinically. Our endocrinologist did not believe it offered any significant additional value (keeping in mind clinical and cost effectiveness) which led to the recommendation of NF.

CAPT (Ret) Hostettler asked if they have ever considered surveying the patients in the beneficiary population on whether they prefer oral versus injectable and if they might be willing to spend in difference to get the oral capsule. He states that it would be a very interesting survey.

Dr. Lugo agrees that it would be interesting but difficult to do, however beneficiaries are able to provide feedback. One note is that we have noticed the NF copay does not prevent patients

from getting one of the alternatives. The NF copay is relatively reasonable compared to other health plans and it is not Tier 4. Mycapssa does not have multiple indications whereas in previous meetings we reviewed Bynfezia Pen and several other drugs that have 3 indications. Mycapssa only has 1 indication. All of these medications have a very narrow spectrum for use. She can appreciate reaching out to beneficiaries to ask their opinion, as she is a beneficiary herself.

CAPT (Ret) Hostettler states that he does not know the number of the beneficiaries that have acromegaly nor do I know the incidence of the disease state. He doesn't believe it is huge but it is a population that we are placing a burden by requiring them to switch from UF to NF in the form of a co-pay. He is wondering if it would be best to keep it UF instead of NF because of the small amount of patient they will not save that much more money.

Manual PA Criteria Recommendation:

Dr. Bertin asks what is the rationale for the age limitation in the PA for the Evrysdi?

CDR Rovey clarifies that the PA Criteria were developed based on the inclusion criteria and patient enrollment from the clinical trials used to gain FDA approval. For example, the trials were limited to patients between ages 1 month and 25 years, and they excluded patients with invasive ventilation or tracheostomy.

Dr. Bertin states his question was more towards the 25-year limitation versus what appears to be FDA approval of all ages. Is that not correct?

CDR Rovey states the FDA approval is from ages 2 months and up. The PA limits the drug for patients' ages 2 months to 25 years for a starting date to take the medication. It is based on the clinical trials, which only included patients from 1 month to 25 years. Therefore, there is no data in older patient to support use in that patient population as of yet or at the time of review for the new drugs. There is one thing to note, if a patient started taking the medication when they were 25, the patient would not be required to stop taking the medication when they reach 26. The patient does not age out of the medication and they may continue taking it.

CAPT (Ret) Hostettler states that the only other therapy up until now has been the intrathecal injections. There are a large number of patients over the age of 25 who are not taking anything. Probably because they can still function to some degree but do not want to go through the intrathecal injection but would be more than willing to take this drug. He does not understand why the PA criteria is more restrictive than the FDA approval. He does believe that the drug is being studied beyond the age of 25 at the moment. The PA criteria is limited to the study group. Is this recommendation consistent with past recommendations for new drugs? That seems to be not the norm.

CDR Rovey states that rather than relying on the FDA indications as our primary source for how we utilize medications, we rely on the clinical evidence, primary literature, and clinical practice guidelines to help determine the benefit.

CAPT (Ret) Hostettler replies I understand FDA indications. This recommendation is limited to the clinical inclusion criteria for the approval. I am not sure that the committee has ever limited a patient population from the clinical criterial and studies. In this instance, the restrictions applies to what is considered a generally healthy population. In his opinion, the PA criteria is overly restrictive when it doesn't need to be. Again, in his opinion, we should be doing all possible to ensure our patient/beneficiary population, with a clinical need, has access to innovative, new products rather than limiting access to these products.

CDR Rovey also states we have absolutely done this on multiple occasions. This is certainly not a new idea for the committee to only include patients that were included in the study trials. We have done that on numerous occasions, particularly in the cardiovascular drug space. If the committee recommends the drug, we want to make sure the drug is going to be effective. She points out, similar to the intrathecal products, which have a hefty price tag, we want to make sure we use it in a population that will benefit from the medications. However, we did reach out for provider feedback in regards to the PA criteria before the meeting. I believe you referenced the study, JEWELFISH. They are studying older patients who have previously tried the intrathecal products and we are looking forward to seeing the efficacy data from this study. If there is additional data we will continue to monitor for future consideration.

CAPT (Ret) Hostettler asks if she was able to obtain unpublished data from the manufacturers or anywhere else. He also inquired about the timeline of completion for the JEWELFISH study.

CDR Rovey states she only has the data provided at the time of the review. We will continue to monitor and review any data received or have an opportunity to review. She will need to further review the timeline for the JEWELFISH study but knows that it will not be within the next couple of months.

Dr. Khoury stated that every PA we can, and do, limit the age upwards. This agent is unique because it specifically targets a smaller, younger cohort for this disease state. We follow the same process for nearly every PA stating the age needs to be "greater than" based on the clinical study criteria the committee looked at in reviewing the drug.

CAPT (Ret) Hostettler states that he understands the study however, he does not understand the need to limit access to patients aged 25 and under in a population that actually needs this product.

CDR Rovey states that this helps delay progression for the patient. They are going to look for those patients that can still benefit from the drug and that is why they targeted the younger population. We do not know yet whether it will be effective in older age patients or patients that have progressed further. That is why I stated patients that are on ventilators were excluded.

CAPT (Ret) Hostettler reiterates that a survey of the population is needed. Why are patients not taking the intrathecal therapy if they are over the age of 25? Regardless, the patient has the chance to treat their problem in a more convenient and equitable way. Both the injection and the capsule are expensive. He believes it would be nice to know whether patients don't want to be treated or if they would take an option.

Dr. Khoury states there is no step therapy for this PA. Also, the JEWELFISH is estimated to be complete by January 2025. He shares that unfortunately many of the studies don't end up getting published by the manufacturers which is very concerning. We look forward to reviewing that data when it is available to determine if there are benefits in utilizing this drug in other age groups. We will share that information with the Panel once there are updates that change the recommendations. Additionally we reached out to manufacturers and they do provide information. Regarding the cost of drug, I believe I provided the example of a new car per year earlier with Dupixent. You stated there were 2 treatments for this disease but I want to clarify there are 3 including this one being reviewed. One of them has been in the news for being one of the 1st multi-million dollar costs for gene therapy which was in excess 2 million dollars. This information is also publically available. These drugs being discussed here are extremely expensive and for this Evrysdi agent, in contrast to the example of the agent earlier that costs a car per year, actually costs as much as a car per month. We are simply attempting to ensure that we get the medication to the right patient who is likely to benefit.

CAPT (Ret) Hostettler states that he does not know how many beneficiaries are affected by this recommendation. However, I do know that it can be devastating on families. He can only hope this was taken into consideration when making the recommendation.

Dr. Bertin thanks Dr. Khoury for responding and states he is relying on the committee to continue monitoring this drug.

Dr. Khoury responds the general epidemiology is around 1 in 11,000 live births are impacted by SMA but it is hard to identify patients that might qualify for this treatment as it is both a phenotypically and genotypically driven disease state. There are new screening techniques that will likely identify more patients due to those genetic screens. So, there are a lot of factors when you ask how many have it in the benefit. That number will evolve over time as screening evolves.

Dr. Peloquin responds, that was my question. Does the beneficiary population over 25 understand that the other drugs have not been included in the pharmacy benefit and this one is included? It is difficult to do the math and understand how it impacts patients with this disease state over the age of 25. He also asks if the renewal criteria will continue for patients beyond 25.

CDR Rovey agrees and states the renewal criteria does not re-ask patients their age. It simply asks if the drug continues to be effective. Therefore, they will be able to remain on the drug after the age of 25.

Mr. DuTeil clarifies that patients on the medication prior to the age of 25 will not be denied the medication after the age of 25. Is if available, if the patient is diagnosed after the age of 25?

CDR Rovey states the patient could have been diagnosed before the age of 25 but if it is the first request to use the medication after the age of 25 for the patient. At this point, awaiting other study data, the request would be denied.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF/Tier 4/Not Covered Recommendation, Manual PA Criteria, and UF/Tier 4/Not Covered and PA Implementation Plan for the Newly Approved Drugs per 32 CFR 199.21(g)(5).

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered Recommendation**

  Concur: 5 Non-Concur: 1 Abstain: 0 Absent: 1

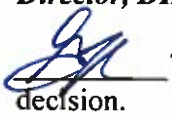
  Director, DHA:

   These comments were taken under consideration prior to my final decision.

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered and PA Implementation Plan:**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

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
    a. pain severe enough to require daily, around-the-clock, long-term opioid treatment

    OR

    b. 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

a. 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

  a. At least two of the following classes of non-opioid medications (unless the patient has a contraindication)

     1) gabapentin or pregabalin titrated to therapeutic dose

     2) a tricyclic antidepressant titrated to therapeutic dose

     3) duloxetine titrated to therapeutic dose

  b. Tramadol

  c. 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. New 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.

Summary of Physicians Perspective:

- There was only one drug where new PA Criteria was recommended, for the narcotic analgesic Nucynta ER, which has been on the formulary since 2015. This drug has unique safety concerns due to its actions that are not seen with other opioids, including risk of seizures.

- The committee did get comments from providers about the PA, and these providers felt that the other narcotic should be used first, due to the well-publicized risks of long-acting narcotics in opioid-naive patients. The PA will only apply to new users so any existing users will not be affected. The recommended PA is in line with what the VA and other commercial health plans have in place.

Summary of Panel Questions and Comments:

Manual PA Criteria Recommendation:

Dr. Jay Peloquin asks is the safety profile new and has there been recent escalations relative to the safety.

CDR Raisor stated that we regularly monitor utilization especially for the opioids because of the risk and national attention that opioids have received. With our continuous monitoring of these medication and based on clinical/cost effectiveness this one came to our attention.

There were no more questions or comments from the Panel. The Chair called for a vote on the recommendation for the New Manual PA Criteria and Implementation Plan

- **New Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

- **New Manual PA Criteria —Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

V. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

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.

Summary of Physician's Perspective:

- This section is where we give brief summaries on drugs with current PAs are updated for expanded age ranges or indications. From this meeting we had six drugs that had updates All the changes will result in an increased number of patients who will qualify for the drugs. For two drugs, we actually removed any mention of age in the criteria (Epidiolex and Haegarda.)

- We do continuously check for these types of updates from the package insert to ensure our PAs are not outdated.

Summary of Panel Questions and Comments:

Updated PA Criteria Recommendation:

CAPT (Ret) Hostettler mentioned concerns about age limitations for the Hepatitis C Agents, Anticonvulsants-Antimania Agents, and the Hereditary Angioedema Agents. He states that in these specific cases you did not limit yourself to the clinical criteria of the study that got these drugs approved yet there were limitations on drugs in a previous section. I am trying to differentiate why it is being treated differently.

Dr. Lugo stated that you cannot compare the two drugs, as there are very different with different outcomes. In this instance, we are expanding.

Mr. Ostrowski states the reason this was done was that the other drug limiting it to the age of 25 it is a very expensive drug and instead of expanding it to all ages like you are talking about above 25 at this time, they are just going to go strictly with what the company's studies show when they did their analysis and so forth. So this way they are adding the drug to that age group up to 25 and maybe later they will expand it but I think that drug was just so expensive that they did not want to expand it to what the FDA approved.

CAPT (Ret) Hostettler states that it is his job to represent the beneficiary. Beneficiaries who have adult children who are eligible for the TRICARE benefit means they are probably of retirees who need some help. Due to science and innovation we have an opportunity to help them. Rather than allowing access to the medications, there a restrictions.

Mr. Jon Ostrowski says that he agrees and I am not stating that the recommendation is right. However, I believe the restrictions are based on cost.

Dr. Khoury states that we are driven by clinical and relative cost effectiveness. The data drives our decision, when there is no data, we have a hard time making that decision. We pay over 9 billion dollars in drug costs but we want to make sure that the drug getting to the patient is safe and effective for those patients, that is the point of the Prior Authorizations.

Updated PA Implementation Plan

Dr. Jay Peloquin asked if 60 days should be sooner.

Dr. Lugo states that most of these have already been updated behind the scenes.

CAPT (Ret) Hostettler asks for clarity

Dr. Khoury states that we have the authority to provide PA guidance. These actions are to ensure that patients get access to drugs.

- There were no more questions or comments from the Panel. The Chair called for a vote on the Updated PA Criteria and the Updated PA Criteria—Implementation Plan for the Updated PA Criteria.

- **Updated PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

- **Updated PA Criteria—Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

  Director, DHA:

   These comments were taken under consideration prior to my final decision.

VI. BRAND ALBUTEROL HFA (PROAIR HFA) COPAYMENT CHANGE

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.

Summary of Physician's Perspective:

- This recommendation here is to lower the copay for the Brand ProAir Inhaler to the generic (Tier 1) copay for patient using the Retail pharmacy network. This is a "good news" message, as patients will see the reduced copay the next time they get their inhaler prescription filled

Summary of Panel Questions and Comments:

Brand Albuterol HFA (PROAIR HFA) Copayment Change:

CAPT (Ret) Hostettler states he would like to end on a positive note. He thanks the committed for the lowering of the co-pay.

There were no more questions or comments from the Panel. The Chair called for a vote on the PROAIR HFA Brand Co-Payment change and Implementation.

- **PROAIR HFA Brand Copay Change and Implementation Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:


These comments were taken under consideration prior to my final decision.

VII. 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

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.

Summary of Physician's Perspective:

- This is the first time that we have gone back to review the Tier 4 products. The first Tier 4 designations were done in February 2019, so we are at the one-year mark for implementation.

- For the three products that we reviewed again, we came to the same conclusion that we had agreed upon at the original decision. So these three drugs will remain Tier 4.

- We are not aware of any negative clinical impacts or outcomes as a result of the not covered status, other than the patient complaints on the out of pocket costs if they do not switch to a formulary alternative.

Summary of Panel Questions and Comments:

There were no questions or comment from the Panel. The Chair called for a vote on the 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.

- **TRICARE Tier 4/Not Covered Recommendation.**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

Director, DHA:


These comments were taken under consideration prior to my final decision.

Appendices:
- Appendix I – Brief list of Acronyms used in this Summary
- Appendix II – Informational Item—Summary of Recommendations and Beneficiary Impact December 2020
- Appendix III - Written Comments – Cure SMA
- Appendix IV - Written Comments – Ironshore Pharmaceuticals

Brief Listing of Acronyms used in this Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term "Pan" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group who is meeting in the subject of this report.

- ADR – Adverse reaction
- AML – Acute myeloid leukemia
- BCF – Basic Core Formulary
- BIA – Budget impact analysis
- CFR – Code of Federal Regulations
- CMA – Cost minimization analysis
- CMML – Chronic myelomonocytic leukemia
- COPD – Chronic obstructive pulmonary disease
- CRSwNP – Chronic rhinosinusitis with nasal polyposis
- DHA – Defense Health Agency
- DoD – Department of Defense
- EAACI – European Academy of Allergy and Clinical Immunology
- EGPA – Eosinophilic granulomatosis with polyangiitis
- EPOS – European Position Paper on Rhinosinusitis and Nasal Polyposis
- FDA – U.S. Food and Drug Administration
- HES – Hypereosinophilic Syndrome
- IST – Immunosuppressive therapy
- JNC – Joint National Contract
- LABA – Long acting beta agonist
- LAMA – Long acting muscarinic antagonist
- LC-FAOD – Long-chain fatty acid oxidation disorder
- mcL – Microliter
- MHS – Military Health System
- MN – Medical Necessity
- MTF –Military Treatment Facility
- NCCN – National Comprehensive Cancer Network
- NDAA – National Defense Authorization Act
- NMOSD – Neuromyelitis optica spectrum disorder
- NSAID – Nonsteroidal anti-inflammatory drugs
- ODT – Orally Dissolving Tablet
- OTC – Over the counter
- PA – Prior authorization

- POD – Pharmacy Operations Division
- POS – Point of service
- PPI – Proton Pump Inhibitor
- Rx – Medical Prescription
- SC – Subcutaneous
- SMA – Spinal muscular atrophy
- SMN2 – Survival of motor neurons 2

X. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT 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.	N/A • 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

Make today a breakthrough.

December 13, 2020

Uniform Formulary Beneficiary Advisory Panel (BAP)
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042–5101

Re: Newly Approved Drugs Review: risdiplam (Evrysdi)

Dear Uniform Formulary Beneficiary Advisory Panel Members:

On behalf of individuals with a neuromuscular disease known as spinal muscular atrophy (SMA), **Cure SMA urges the Uniform Formulary Beneficiary Advisory Panel to remove the age and other restrictions from the TRICARE policy for Evrysdi, a new SMA treatment, that conflict with the U.S. Food and Drug Administration (FDA) label.**

SMA is a progressive neurodegenerative disease that can significantly impact an individual's ability to walk, swallow, and—in the most severe cases—even breathe. SMA affects approximately 1 in 11,000 births, and about 1 in every 50 Americans is a genetic carrier. SMA can affect any race or gender.[i]

As the leading national organization dedicated to finding a cure and treatments for SMA, **Cure SMA is very concerned by the U.S. Department of Defense Pharmacy and Therapeutics Committee recommendations that would restrict access to Evrysdi for individuals with SMA who are older than 25 years old.**

The FDA approved Evrysdi on August 7, 2020 for the treatment of SMA in all individuals with SMA who are 2 months of age and older. The FDA's approval and broad label were based on clinical trials that demonstrated Evrysdi's effectiveness in both pediatric and adult patients.[ii] The FIREFISH (Part 1 & 2), SUNFISH, and JEWELFISH trials showed individuals with SMA who received Evrysdi achieved unprecedented developmental gains and milestones (i.e., swallowing, sitting, standing) and required fewer hospitalizations and reduced need for permanent ventilation and feeding support. In addition to the efficacy, the FDA thoroughly reviewed the SMA treatment for safety and concluded that the clinical trials data established that Evrysdi was safe for the treatment of SMA. Despite this strong body of evidence and the FDA's broad treatment label, the TRICARE policy limits Evrysdi to only individuals who are 25 years old or younger. **If approved, this policy would be among the most restrictive in the nation.**

Military families with SMA should be able to access an SMA treatment based on their individual choice and circumstance. In addition to the age restriction, Cure SMA is also concerned by the policy's restrictions related to ventilation support. There is no evidence to exclude individuals with SMA who are on permanent ventilation. The clinical data from Evrysdi showed gains in fine and gross motor function and found less dependency on ventilation.

925 Busse Road, Elk Grove Village, IL 60007 | 800-886-1762 | info@cureSMA.org | cureSMA.org

Cure SMA respectfully asks that this distinguished panel remove the restrictions and approve coverage of Evrysdi for all TRICARE beneficiaries with SMA who are 2 months of age and older, as recommended by the FDA.

Thank you for considering Cure SMA's recommendation for full coverage of Evrysdi. Please do not hesitate to contact Cure SMA if you have questions or need additional information. Cure SMA can be reached through Maynard Friesz, Vice President for Policy and Advocacy at Cure SMA, at maynard.friesz@curesma.org or 202-871-8004. Thank you for your consideration.

Sincerely,

Kenneth Hobby	Mary Schroth, M.D	Jill Jarecki, PhD
President	Chief Medical Officer	Chief Scientific Officer

[i] About Spinal Muscular Atrophy, Cure SMA, 2020 https://www.curesma.org/about-sma/
[ii] U.S. Food and Drug Administration, Evrysdi Prescribing Information, 2020, (Page 2), https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213535s000lbl.pdf

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Frank Bartolini, VP Market Access
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Phone: 984-224-5107

Date: December 11, 2020

Dear Colonel Hoerner,

Ironshore Pharmaceuticals Inc., the manufacturer of JORNAY PM® (methylphenidate HCl Extended-Release Capsules), appreciates the opportunity to comment on the prior authorization (PA) criteria and step therapy requirements recommended by the DoD Pharmacy and Therapeutics (P&T) Committee for products in the Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass.

The following table shows the DoD P&T Committee recommendations for formulary status and the number of steps that would apply to each of the brand name products that were evaluated in the Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass. The products are listed in the order of their respective costs, from lowest to highest, (as outlined on page 6 of the Beneficiary Advisory Panel (BAP) Background Information document).

	Brand Name Products (ranked from lowest cost to highest cost)	**Formulary Status**	**Number of Steps**
1	Evekeo ODT	UF	2
2	Quillivant XR	UF	0 – No PA
3	***Jornay PM***	***UF***	***4***
4	Zenzedi	UF	0 – No PA
5	Vyvanse	UF	2
6	Quillichew ER	NF	0 – No PA
7	Dyanavel XR	NF	0 – No PA
8	Mydayis	NF	2
9	Adzenys XR-ODT	NF	0 – No PA
10	Adhansia XR	Tier 4/Not Covered	NA
11	Adzenys ER	NF	0 – No PA
12	Daytrana	NF	0 – No PA
13	Cotempla XR-ODT	NF	3

As expected, the DoD P&T Committee recommended Uniform Formulary (UF) status for the lower cost brand name products and Non-Formulary (NF) status for the higher cost brand name products. The five lowest cost brand name products were recommended for UF status. The eight higher cost products were recommended for NF or Tier 4/Not Covered status.

However, the number of step therapy edits recommended by the DoD P&T Committee for brand name products does not correlate with the cost of the brand name products (as it does in the application of cost to their UF status). There is a disconnect between UF placement, product cost, and step therapy requirements. It is a well understood principle of pharmacy benefit management to use step therapy edits to encourage the use of less expensive products over more expensive products. The DoD P&T Committee recommendations for step therapy in this category do not adhere to this principle.

1. Faraone SV, et al. *J Clin Psychiatry*. 2020;81(1).

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IRONSHORE PHARMACEUTICALS

Military Health System (MHS) providers commented Jornay PM should remain UF, since it is helpful for children with developmental delays because of the bedtime dosing (see page 6 in the BAP Background information document). The benefit that UF formulary placement would convey upon this vulnerable patient populations appears negated by the requirement to step through four (4) formulary alternatives over the course of eight (8) months.

The DoD P&T Committee concluded that Jornay PM 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%. However, the FDA, in their Appeal Granted Letter, agreed with the assessment that insomnia rates noted in clinical trials were overestimated as an artifact of study design. An artifact equally noted in placebo insomnia rates (9%) which are proportionately higher compared to other methylphenidate formulations where insomnia occurred at rates of approximately 3%. This assessment is furthered when examining real world evidence where Jornay PM insomnia rates (0.1%, N=25,000) are observed to be similar to, or lower than other ADHD stimulants[1].

Ironshore encourages the BAP to consider the following questions:

1. Why are 4 steps recommended for Jornay PM—more steps than any other brand name product—when 10 of the 13 brand name products cost more than Jornay PM?

2. Why are 4 steps recommended for Jornay PM—which is a UF product—when all NF products have fewer steps?

3. Why do 6 products that cost more than Jornay PM (e.g., Zenzedi, Quillichew ER, Dyanavel XR, Adzenys XR-ODT, Adzenys ER and Daytrana) have no step therapy requirements while Jornay PM has 4 steps?

4. Why should TRICARE beneficiaries be required to try four other products over an eight-month period when Jornay PM costs less than nine other brand name products that are only subject to 0, 1, 2 or 3 steps?

The Defense Health Agency Pharmacy Operations Division Formulary Management Branch (DHA POD FMB) routinely encourages pharmaceutical companies to offer lower prices to achieve a formulary position and step therapy requirements that can result in increased utilization of their products. Pharmaceutical companies may be less willing to offer lower prices if the DoD P&T Committee imposes step therapy requirements that do not have a corollary relationship to the comparative costs of products. The arbitrary and capricious application of step therapy requirements within the ADHD Stimulants Subclass may serve to undermine the Uniform Formulary Blanket Purchase Agreement (UF BPA) and Uniform Formulary Additional Discount Program (UF ADP) quote process.

Ironshore respectfully requests that the BAP members consider the issues addressed above and convey their concerns and comments to the DHA Director. Thank you for your time and consideration.

Sincerely,

DocuSigned by:
Frank Bartolini
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Frank Bartolini
Vice President Market Access
Ironshore Pharmaceuticals Inc.

1. Faraone SV, et al. *J Clin Psychiatry*. 2020;81(1).

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
December 17, 2020
Washington, D.C.

Present Panel Members

- Mr. Jon Ostrowski, Non-Commissioned Officers Association, Chairperson
- Dr. Richard Bertin, Commissioned Officers Association of the US Public Health Service
- Mr. John Du Tiel, US Army Warrant Officers Association
- CAPT (Ret) Charles Hostettler, AMSUS, The Society of Federal Health Professionals
- Dr. Joseph McKeon, Humana
- Dr. Jay Peloquin, Express Scripts, Inc.

Absent Panel Members

- Dr. Karen Dager, Health Net Federal Services

Agenda

The agenda for the meeting of the Panel is as follows:

- Welcome and Opening Remarks
- Written Comments
- Therapeutic Class Reviews

Members of the DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the DoD Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended Tier 4/Not Covered candidates.

The P&T Committee made recommendations for the following drugs/drug classes during the November 2020 meeting:

1. Drug Class Reviews

    a. Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass

    b. Respiratory Interleukins

2. Newly Approved Drugs per 32 CFR 199.21(g)(5)

    a. azacitidine (Onureg) – Oral oncologic agent for acute myeloid leukemia (AML)

b. budesonide extended-release (Ortikos) – Gastrointestinal -1 GI Steroid for mild to moderate Crohn's Disease

c. budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri) – Triple combination Pulmonary-3 Agent for COPD

d. cysteamine 0.37% ophthalmic solution (Cystadrops) – Miscellaneous Ophthalmic for corneal cystine crystal deposits

e. decitabine/cedazuridine (Inqovi) – Oral combination oncologic agent for Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)

f. dexamethasone (Hemady) 20 mg tablets – Corticosteroids-Immune Modulator for multiple myeloma

g. factor VIIa [recombinant]-jncw (Sevenfact) – Antihemophilic Factor for hemophilia A or B

h. fluticasone oral inhaler (Armonair Digihaler) – Pulmonary-1 Agents: Inhaled Corticosteroids (ICS) for asthma

i. fluticasone/salmeterol oral inhaler (AirDuo Digihaler) – Pulmonary-1 ICS-Long Acting Beta Agonist (LABA) Combinations for asthma and COPD

j. fostemsavir (Rukobia) – Oral antiretroviral for multi-drug resistant HIV-1 infection in heavily treatment-experienced adults

k. insulin glargine (Semglee, Semglee Pen) – Basal Insulin

l. levamlodipine (Conjupri) – dihydropyridine calcium channel blocker for hypertension

m. metoclopramide nasal spray (Gimoti) – Gastrointestinal-2 Agent for diabetic gastroparesis

n. monomethyl fumarate (Bafiertam) – Multiple Sclerosis

o. nifurtimox (Lampit) – Miscellaneous Anti-infective agent for Chagas Disease in pediatrics

p. octreotide (Mycapssa) – Miscellaneous Endocrine Agent for acromegaly

q. ofatumumab injection (Kesimpta) – Multiple Sclerosis Agents

r. opicapone (Ongentys) – Oral agent for "off episodes" associated with Parkinson's Disease

s. oxymetazoline ophthalmic solution (Upneeq) – Miscellaneous Ophthalmic agent for acquired blepharoptosis

t. pralsetinib (Gavreto) – Oral oncologic agent for non-small cell lung cancer (NSCLC)

u. risdiplam (Evrysdi) – Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)

v. satralizumab-mwge injection (Enspryng) – Miscellaneous Neurological Agent for neuromyelitis optica spectrum disorder (NMOSD)

w. triheptanoin (Dojolvi) oral liquid – Miscellaneous Metabolic Agents; oral liquid for long-chain fatty acid oxidation disorders in pediatrics and adults

x. Sodium oxybate/calcium/magnesium/potassium oral solution (Xywav): Wakefulness Promoting Agent for narcolepsy

2. Utilization Management Issues

a. Prior Authorization Criteria—New Manual PA Criteria

- Narcotic Analgesics – Tapentadol ER (Nucynta ER)

b. Prior Authorization Criteria—Updated PA

- Targeted Immunomodulatory Biologics (TIBs)
  - etanercept (Enbrel)
  - guselkumab (Tremfya)
  - tofacitinib (Xeljanz, Xeljanz oral solution)
- Hepatitis C Agents: Direct Acting Agents — sofosbuvir/velpatasvir tablets (Epclusa)
- Anticonvulsants-Antimania Agents — cannabidiol oral solution (Epidiolex)
- Hereditary Angioedema Agents — C1 Esterase Inhibitor [Human} (Haegarda)

4. Brand Albuterol HFA (ProAir HFA) Copayment Change

5. 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

- Diabetes Non-Insulin Drugs – Biguanides Subclass: metformin ER gastric retention 24 hours (Glumetza brand and generics)
- Pain Agents – Combinations Subclass: naproxen/esomeprazole (Vimovo brand and generic)

- Corticosteroids-Immune Modulators – High Potency Topical Corticosteroid for Plaque Psoriasis: halobetasol propionate 0.05% foam (Lexette brand and generic)

- Panel Discussions

  The Beneficiary Advisory Panel members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will discuss the recommendations and vote to accept or reject them. The Panel will provide comments on their vote as directed by the Panel Chairman.

Opening Remarks

Col Paul Hoerner introduced himself as the Designated Federal Officer (DFO) for the Uniform Formulary (UF) Beneficiary Advisory Panel (BAP). The Panel has convened to comment on the recommendations of the DoD Pharmacy and Therapeutics (P&T) Committee meeting, which occurred on November 4-5, 2020.

Col Hoerner indicated Title 10, United States, (U.S.C.) section 1074g, subsection b requires the Secretary of Defense to establish a DoD Uniform Formulary (UF) of the pharmaceutical agent and established the P&T committee to review the formulary on a periodic basis to make additional recommendations regarding the formulary as the committee determines necessary and appropriate.

In addition, 10 U.S.C. Section 1074g, subsection c, also requires the Secretary to establish a UF Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. The Panel's comments must be considered by the Director of the Defense Health Agency (DHA) before establishing the UF or implementing changes to the UF. The Panel's meetings are conducted in accordance of the Federal Advisory Committee Act (FACA).

The duties of the Uniform Formulary Beneficiary Advisory Panel include the following:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. Comments to the Director, DHA, regarding recommended formulary status, pre-authorizations, and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director before making a final decision.

- To hold quarterly meetings in an open forum. The Panel may not hold meetings except at the call of or with the advance approval of the DFO in consultation with the Chairperson of the Panel.

- To prepare minutes of the proceedings and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared for the Director, DHA.

The DFO provided guidance regarding this meeting:

- The role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department appreciates that the BAP may be interested in the drug classes selected for review, drugs recommended for the basic core formulary (BCF), or specific pricing data, these topics do not fall under the purview of the BAP.

- The P&T Committee met for approximately 16 hours conducting its reviews of the drug class recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

- Detailed minutes of this meeting are being prepared. The BAP minutes, the DoD P&T Committee meeting minutes and the Director's decisions will be available on the TRICARE website in approximately four to six weeks.

The DFO provided a few ground rules for conduct during this virtual meeting:

- Due to travel, restrictions and guidance provided due to COVID-19, this meeting will be conducted in a remote access format.

- Audience participation is limited to private citizen comments received in writing prior to the meeting.

- Participants will be joined in listen-mode only.

- To ensure there are no disruptions to discussions and as precaution, please mute your phones.

- Panel and presenter guidance: presenters or anyone responding to questions are asked to state their name prior to asking your question or responding.

- The meeting is being recorded. Please speak clearly.

- All discussions are to take place in an open public virtual forum. There is to be no committee discussion outside the room or during breaks.

- Members of the FMB and P&T are available to answer questions related to the BAPs deliberations. Should a misstatement be made, these individuals may interrupt to ensure that the minutes accurately reflect relevant facts, regulations, or policy.

Col Hoerner introduced the individual Panel members (see list above) and noted housekeeping considerations.

Written comments from the following:

- Cure SMA

- Ironshore Pharmaceuticals

Chairman's Opening Remarks

Mr. Ostrowski thanked Col Hoerner and all of the participants for attending the meeting during these difficult times. He further explained that it is nice to get together, as a Panel, to discuss the Pharmacy and Therapeutics Committee recommendations. He thanked Col Hoerner for his team for their presentation and looks forward to it.

DRUG CLASS REVIEW PRESENTATION

GOOD MORNING. I am Lieutenant Colonel Ronald Khoury, Chief of the Formulary Management Branch (FMB) of the DHA Pharmacy Operations Division. Doctor and retired Army Colonel John Kugler, the Chairman of the Pharmacy and Therapeutics Committee is also here "virtually". Joining us virtually from the Formulary Management Branch include three clinical pharmacists, MAJ Adam Davies, Dr. Amy Lugo, and CDR Scott Raisor. CDR Heather Rovey, Chief of the P&T Section at the Formulary Management Branch was also on the call. I would also like to recognize Mr. Bryan Wheeler, Deputy General Counsel.

The DoD Formulary Management Branch supports the DoD P&T Committee by conducting the relative clinical effectiveness analyses and relative cost effectiveness analyses of the drugs and drug classes under review and consideration by the DoD P&T Committee for the Uniform Formulary (relative meaning in comparison to the other agents defined in the same class). We are here to present an overview of the analyses presented to the P&T Committee. 32 Code of Federal Regulations (CFR) establishes procedures for inclusion of pharmaceutical agents on the Uniform Formulary based upon both relative clinical effectiveness and relative cost effectiveness.

Additionally, all TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018, with the Final Rule published June 3, 2020.

The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P&T Committee but a summary of the processes and analyses presented to the DoD P&T Committee. These include:

1) A brief overview of the relative clinical effectiveness analyses considered by the DoD P&T Committee. All reviews include but are not limited to the sources of information listed in 32 CFR 199.21 (e)(1) and (g)(5). Also note that Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

2) A brief general overview of the relative cost effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.

3) The DoD P&T Committee's Uniform Formulary recommendation is based upon the Committee's collective professional judgment when considering the analyses from both the relative clinical and relative cost effectiveness evaluations.

The Committee reviewed the following:

a. Two Uniform Formulary Drug Classes, which included one subclass:

- Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass

- Respiratory Interleukins

A summary table of the UF drug class recommendations is found on page 48 of the background document.

b. The P&T Committee also evaluated 25 newly approved drugs per 32 CFR 199.21(g)(5), which are currently in pending status and available under terms comparable to Nonformulary drugs.

And,

c. For Utilization Management issues, we also discussed prior authorizations (PAs) for 7 drugs in 5 drug classes.

- Narcotic Analgesics – tapentadol ER (Nucynta ER)

- Targeted Immunomodulatory Biologics (TIBs) –3 drugs, etanercept (Enbrel), guselkumab (Tremfya), and tofacitinib (Xeljanz tablets and oral solution)

- Hepatitis C Agents: Direct Acting Agents – sofosbuvir/velpatasvir tablets (Epclusa)

- Anticonvulsants –Antimania Agents – cannabidiol oral solution (Epidiolex)

- Hereditary Angioedema Agents – C1 Esterase Inhibitor [Human] (Haegarda)

The DoD P&T Committee will make a recommendation as to the effective date of the agents being changed from the Uniform Formulary (UF) tier to Nonformulary (NF) tier or Tier 4 (not covered) status. Based on 32 CFR 199.21, such change will not be longer than 180 days from the final decision date but may be less.

The November P&T meeting, as with our 2 prior meetings, was held via teleconference due to the ongoing pandemic. I would like to briefly summarize the committee's activities that my staff will detail further for the panel. The committee recommended the entirety of two drug classes have no increase in copays for drugs that impact 206K patients per quarter on average and 1.9M 30-day equivalent prescriptions. Further, the committee recommended one of the most highly utilized branded agents be moved from NF to UF, reducing the copays of 27K unique utilizers per quarter by up to 83%. Additionally, the committee exercised its authority to move an agent to Tier 1 status again this meeting.

For the Newly Approved Drugs, 15 out of 25 drugs moved from Tier 3 (NF) to Tier 2 (UF) status (Dupixent Pen Line extension), and no CURRENT users will be impacted by the recommended prior authorizations for the newly approved drugs. These recommendations will again lower the

copay paid for these newly approved drugs for years to come for all 9.6M of our beneficiaries that may require them.

A total of six drugs were recommended for Tier 4 status, and these drugs currently affect 22 patients. I wish I could tell you all these new drugs are revolutionary advances in health care. The truth of the matter is they are not. This change will have a minimal impact on our patient population, working out to < 0.0003% of our beneficiaries. As will be reviewed by my staff, the drugs designated for Tier 4 have numerous alternatives that are clinically equivalent, or in some cases superior. Making them Tier 4, will hopefully ensure patients are directed to alternatives that are much lower cost, with the goal that patients will select UF products. Further mitigating the impact is the fact that the agents and disease states for which these Tier 4 products are used are often of a short-term nature.

Finally, we will close the meeting with an update and review of agents that were previously recommended and approved for Tier 4 designation originally in February 2019. For future meetings we will plan to only bring to the panel any significant clinical or cost-effectiveness updates brought forth after the original Committee decisions that may necessitate a change in Tier 4 status.

UNIFORM FORMULARY REVIEW PROCESS

I. UF CLASS REVIEWS—ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD): STIMULANTS SUBCLASS

A. ADHD: Stimulants Subclass–Relative Clinical Effectiveness 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

1. 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).

2. 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.

3. 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

1. 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

1. 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.

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

Clinical Considerations

1. 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.

    a. **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).

b. **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.

c. **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.

d. **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.

e. **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.

f. **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.

g. **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.

h. **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.

i. **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.

j. **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.

k. **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.

l. **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.

m. **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

1. 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

1. 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
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:

    1. methamphetamine HCl (Desoxyn, generics)
    2. mixed amphetamine salts IR tablets (Adderall, generics)
    3. mixed amphetamine salts XR capsules (Adderall XR, generics)
    4. dexmethylphenidate IR (Focalin, generics)
    5. dexmethylphenidate ER (Focalin XR, generics)
    6. methylphenidate CD (Metadate CD, generics)
    7. methylphenidate chewable tablets and oral solution (Methylin, generics)
    8. methylphenidate ER (Methylin ER, generics)
    9. methylphenidate ER sprinkle caps (Aptensio XR, generics)
    10. methylphenidate ER sprinkle capsules nighttime dosing (Jornay PM)
    11. methylphenidate ER oral suspension (Quillivant XR)
    12. methylphenidate IR (Ritalin, generics)
    13. methylphenidate long-acting (LA) (Ritalin LA, generics)
    14. 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

    1. amphetamine ER orally dissolving tablets (ODT) (Adzenys XR-ODT)
    2. amphetamine ER oral suspension (Adzenys ER)
    3. amphetamine ER oral suspension (Dyanavel XR)

4. mixed amphetamine salts ER capsules triphasic release (Mydayis)

5. methylphenidate transdermal system (Daytrana)

6. methylphenidate ER chew tab (Quillichew ER)

7. methylphenidate XR-ODT (Cotempla XR-ODT)

- Tier 4/Not Covered

1. 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.

F. Physician's Perspective:

- This is the second time we have reviewed this class, and since 2015, there have been 10 drugs that we have previously evaluated as innovator drugs. For the formulary recommendation, the main changes are that everything remains the same, except that Vyvanse will now move from nonformulary to formulary status.

- Feedback from MTF providers showed that Vyvanse was commonly requested to be added back to the formulary.

- For Vyvanse, we are recommending a PA that will only apply to new patients, so existing patients will not have to go through the PA process. For ADHD, a review of prescription data from MTF patients did show that the majority had previously received methylphenidate formulations or Adderall. The PA will allow use for binge eating disorder, but only if the patient has tried other therapies first. Other health plans, including the VA also require PA for Vyvanse.

- The one current Tier 4 drug, Adhansia, will remain Tier 4. None of the providers we surveyed had any issues with this.

- There are currently about 27,000 patients receiving Vyvanse, so these patients will now see a reduction in their copay from Tier 3 (non-formulary) to Tier 2 (formulary). Since no letters are required, we will do a 30-day implementation period, to expedite the copay decrease at the Mail Order and Retail pharmacies.

G. Panel Questions and Comments Regarding:

Uniform Formulary/Tier 4/Not Covered Recommendation:

CAPT (Ret) Hostettler asked why the P&T Committee recommended/retained Adhansia XR for Tier 4 status and not the other drugs in this class. According to the minutes all the drugs are therapeutically interchangeable, the safety records are the same and it is not the most expensive.

MAJ Davies answers with there were several long-acting methamphetamine products that are on the UF, which included the alternatives that were listed, other long-acting duration agents and one that has similar duration of 16 hours. New data reviewed by P&T Committee did not change the previous conclusion. Additionally, provider feedback strongly reaffirmed that Adhansia XR has little to no additional clinical effectiveness relative to the similar agents that are on the UF or NF.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asks a questions about the Jornay PM. The manual PA criteria states the "provider must explain why the patient needs Jornay PM". The specific use is not summarized in the PA criteria but the provider must justify why the patient needs the medication. Regardless, the patient must complete a combined total of 6 months of trials prior to receiving approval of the agent for developmental issues. If the provider identified the specific need, it is 3rd on the list for cost, why is the patient required to complete the other 4 steps in the manual PA criteria.

Dr. Bertin also has a question regarding the Manual PA criteria for Jornay PM. The written comments submitted raised significant questions. He states he does not have enough information to answer the questions and requests clarification. Some of the questions concern cost and he understands the Panel does not received information regarding cost.

MAJ Davies states he will respond to both questions. The decision for Jornay PM was based on both clinical and cost effectiveness. The PA Criteria was reviewed by the P&T Committee in August 2019 during the original new drug review and in November 2020 during the class review. The recommendations for each review were presented to the Panel. There were no changes made to the PA Criteria.

CAPT (Ret) Hostettler states that he appreciates there were no changes made, however the product was reviewed under different circumstances. The 1st review was as a new drug and the class review. The agent is 3rd for cost. Safety, tolerability and efficacy are equivalent. Was there anything specific mentioned during the P&T Committee review that would explain the manual PA Criteria?

MAJ Davies states that it was nothing specific. Again, the recommendation was made based on the both the clinical and cost effectiveness. Also, we have not had any complaints from providers that the current PA criteria is not changing or is excessively arduous.

CAPT (Ret) Hostettler states the "needs" specified by the provider are clinical reasons. There is a clinical advantage over the other agents with the PM dosing. Although the providers prefer this agent, the patient is required to complete all the steps because the PA criteria does not address their need for the PM dosing.

Dr. Bertin states that he believes the process is unnecessarily complicated. As a Panel member, one of our purposes is to be concerned about complications for patients.

Dr. Peloquin adds there was a statement regarding standardizing the clinical criteria across all points of service for Vyanase. As he looks through all the different criteria he understands that there are some differences with the amphetamine, methylphenidate. Has the PA's criteria been standardized across these drugs?

MAJ Davies states that comment for the Vyvanse was in regards to the indication that it has binge eating disorders. It was recommended for UF and that comment was directed towards that specific indication.

CAPT (Ret) Hostettler recommends adding a bullet to the PA Criteria that states this is for a developmentally challenged child. He believes that makes perfect sense rather than requiring the patient to complete the complicated process to state that a patient is developmentally challenged. If the patient is developmentally challenged, he doesn't know why the committee is restricting access to the medication.

MAJ Davies states he appreciates the comments and they will be noted. Also, note the current PA form that has not changed. There is a section on the form that allows the provider to provide additional, pertinent information about the patient. The provider can fill in the box, check off what they want, or submit it electronically. The form will be reviewed and a determination made on whether the patient complete the steps or not.

CAPT (Ret) Hostettler asks is it possible for the patient to get the product for a developmentally challenged child without completing all the steps in the PA criteria.

MAJ Davies states that he does not have an exact example for every exact situation. Therefore, as stated, when the form is submitted it will be reviewed.

CAPT (Ret) Hostettler states that he is looking at the criteria. Just to clarify, if the provider completes the form and adds that the agent is for a developmentally challenged child, is the patient required to complete all the steps in the PA criteria. If I am not mistaken, this is the only drug on the list that references developmentally challenges children.

MAJ Davies states that a developmental delay does not automatically mean approval of Jornay PM.

CAPT (Ret) Hostettler and Dr. Peloquin agree that it needs more work.

MAJ Davies clarifies the comment from the provider regarding developmentally challenged patients is not an actual FDA-approved indication. It was a comment from a provider.

CAPT (Ret) Hostettler asks if comments were received from "a" provider or "multiple" providers.

MAJ Davies responds comments were received from "a" single provider and over 50 were surveyed.

Dr. Khoury clarifies that a developmental delay does not automatically preclude the use of the alternative agents.

CAPT (Ret) Hostettler asks how many physicians took the survey.

Dr. Khoury states a single provider out of over 50 that were surveyed provided this comment. I do not have an exact number of those that provided feedback. There was a broad array of submissions from numerous specialties providing feedback. Please let me know if you need the number surveyed to make a comment.

CAPT (Ret) Hostettler states that it would be nice to know if there was only one psychiatrist on the list.

Dr. Khoury states that there were numerous providers that are of a child and adolescent psychiatry background.

Col Hoerner clarifies, when we come to the vote, the vote has to be either concur or non-concur with the P&T committee recommendation as it is written. If a Panel member non-

concurs, comments may be provided summarizing the issues/concerns. To summarize, a Panel member can concur with the recommendation as written or non-concur and provide a comments addressing specific concerns with the recommendation.

Dr. Peloquin asks for an explanation regarding the decision to not change the current PA criteria.

MAJ Davies states that the decision for the Jornay PM was based on both clinical and cost effectiveness. The PA Criteria was presented to the Panel during the original new drug review in August 2019 and the class review in November 2020. Based on the discussions or each review, no changes were recommended. In addition to that, there were no complaints from any single provider having any issues of being able to obtain the product when they needed to.

Dr. Khoury also adds that the provider wanted Jornay PM available uniform formulary, which it is.

CAPT (Ret) Hostettler states that he knows we do not get the same level of detail as the 2-day P&T committee, but can you point to the specific clinical issue that drove that decision? You keep saying clinical and cost. What was the clinical issue that drove the decision? Is that possible to provide?

Dr. Khoury states it was not intended for this class to be a 4-hour review to discuss why one drug had a specific decision. Overall, the intent of the P&T committee is to maintain decisions/recommendations when there is no real reason to overturn those recommendations or decisions. I will note, these comments being referenced are from one company and one specific feedback and it is not consistent with anything else we have received regarding concerns about the UF recommendation.

There were no further questions or comments from the Panel. The Chair called for a vote on the UF/Tier 4/Not Covered Recommendation, Manual PA Criteria and UF/Tier 4/Not Covered and PA Implementation Plan for the ADHD: Stimulants Subclass.

- **ADHD: Stimulants Subclass—UF/Tier 4/Not Covered Recommendation**

  Concur: 5 Non-Concur: 1 Abstain: 0 Absent: 1

- **ADHD: Stimulants Subclass—Manual PA Criteria**

  Concur: 3 Non-Concur: 3 Abstain: 0 Absent: 1

  Additional Note: The Panel members non-concurred because they believe the process is unnecessarily complicated. One of our purposes on this Panel is to be concerned about complications for patients.

- **ADHD: Stimulants Subclass—UF/Tier 4/Not Covered and PA Implementation Plan:**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

II. UF CLASS REVIEWS—RESPIRATORY INTERLEUKINS

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

1. 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.

2. 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

1. 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.

2. 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.

3. A 2017 Cochrane review concluded that Fasenra and Nucala roughly halved the rate of asthma exacerbations requiring systemic steroids or hospitalization.

4. 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

1. Dupilumab (Dupixent is currently the only respiratory biologic with an indication for atopic dermatitis.

2. 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.

3. 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.

4. 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.

5. Both benralizumab (Fasenra) and Nucala are currently undergoing studies for treating atopic dermatitis.

Chronic Rhinosinusitis with Nasal Polyposis

1. 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.

2. 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)

3. 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.

4. 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)

5. 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.

6. 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

1. 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.

2. 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

1. The three respiratory interleukins are associated with relatively mild adverse effects; injection site reactions and hypersensitivity can occur.

2. 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.

3. 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.

4. 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

1. 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.

2. 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.

3. 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

1. 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

1. 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 Respiratory Interleukins. 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
    a. Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids

        OR

    b. 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:
    a. Hospitalization for asthma in past year OR
    b. Two courses oral corticosteroids in past year OR
    c. 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:
    a. Long-acting beta agonist (LABA e.g., Serevent, Striverdi),
    b. Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or
    c. 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
    a. Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/mcL OR
    b. 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;
    a. Hospitalization for asthma in past year OR
    b. Two courses oral corticosteroids in past year OR
    c. 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:

  a. Long-acting beta agonist (LABA e.g., Serevent, Striverdi),

  b. Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or

  c. 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 an allergist, dermatologist, 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:

  a. 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

  b. Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)

  ~~c. 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:**

a. Presence of nasal polyposis is confirmed by imaging or direct visualization

AND

b. 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

  a. Adequate duration of at least TWO different high-dose intranasal corticosteroids

     AND

  b. Nasal saline irrigation AND

  ~~**c. The patient has failed a trial of two courses of oral corticosteroids in the past year or has a contraindication to oral corticosteroids AND**~~

  d. 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

a. 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.

b. 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

c. 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
    a. Eosinophils $\geq$ 150 cells/mcL within past month while on oral corticosteroids OR
    b. 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:
    a. Hospitalization for asthma in past year OR
    b. Two courses of oral corticosteroids in past year OR
    c. 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:

    a. Long-acting beta agonist (LABA e.g., Serevent, Striverdi),

    b. Long–acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or

    c. 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**~~

    ~~**a. 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

a. **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.**

b. **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.

F. Physician's Perspective:

- This is the first full review for the class, although all three drugs were previously evaluated as innovator drugs.

- We did take into consideration the comments from providers, so all three drugs will stay on the formulary, and all the copays will remain at the current Tier 2 levels.

- PAs currently apply to the class, and the PAs were updated to be consistent with the package labeling and professional guidelines.

- We do not have any guidance yet on whether these agents will be required to be given long term and we also do not know yet what the long-term adverse effects are. Some of the disease states treated, like atopic dermatitis, are not necessarily life-long conditions. So, we will continue to monitor the literature for updates in safety, and new indications.

G. Panel Questions and Comments Regarding:

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asks if Dupixent can be prescribed by an allergist, immunologist, pulmonologist, or otolaryngologist. Which of those four are able to do surgery? Prior surgery is a requirement or one of the steps in the PA criteria. If the patient has chronic rhinosinusitis with nasal polyposis, he believes the otolaryngologist is an ENT surgeon and the only one that could perform the procedure. If I am being followed by an allergist, I must receive a referral

from a second specialist for the surgery in question. Rather than requiring the patient to meet the requirement for surgery, why not add the verbiage, "the patient and the provider have decided that the patient is not a good candidate for surgical intervention". In my opinion, this change to the PA criteria would be more effective.

Dr. Khoury responds this disease state is typically managed by multiple providers. That is what the data shows and is consistent with our feedback. Typically the outcomes suggest that surgery is very effective in managing this disease. Again, he is speaking about a higher level of this disease state and not just Dupixent. That is the reason for the language in the PA criteria. Certain teams of providers help manage these complicated patients. A patient cannot walk into a clinic, be diagnosed with polyposis and receive a prescription for Dupixent. Furthermore, Dupixent is a lifelong potential treatment not a nasal steroid treatment to be prescribed. We do not have a lot of information on how it engages over the long term or the adverse side effects. We certainly do not have information to state in the PA Criteria that Dupixent is better than surgery and patient should be availed of surgery. The prior authorization is written in a way that ensures the patient has the most clinically effective and potentially cost effective agent. If the patient starts this therapy, this prescription probably equates to a new car price every year forever based on publicly available cost data as can be found on websites like goodrx.com. We want to make sure we are doing the right thing for the patient who could be paying a copay for life potentially if this is started and alternative treatment options are available.

CAPT (Ret) Hostettler thanks Dr. Khoury for providing the cost information. The example you provided about the cost being approximately the cost of a new car (40K) per year puts this this recommendation into prospective. This information was not previously provided in the meeting materials at the 1st review nor this review.

Dr. Peloquin asks for clarification regarding the renewal criteria. The renewal criteria for current patients will be renewed indefinitely. Does the PA criteria apply to new or current users?

CDR Raisor clarifies the Dupixent PAs had renewal criteria. There are some, prior to the change that had renewal criteria. We would expect that criteria to remain the same. The drugs, Faserna and Nucala, did not have criteria but will now have renewal criteria. It will apply to e new patients only.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, Manual PA Criteria and the UF and PA Implementation Plan for the Respiratory Interleukins.

- **Respiratory Interleukins—UF Recommendation**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Respiratory Interleukins—Manual PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Respiratory Interleukins—UF and Implementation Plan:**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

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

- **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).

- **Newly Approved Drugs 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:

    1. azacitidine (Onureg) – Oral oncologic agent for acute myeloid leukemia (AML)

    2. budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri) – Triple combination Pulmonary-3 Agent for COPD

    3. cysteamine 0.37% ophthalmic solution (Cystadrops) – Miscellaneous Ophthalmic for corneal cystine crystal deposits

    4. decitabine/cedazuridine (Inqovi) – Oral combination oncologic agent for Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML)

    5. factor VIIa [recombinant]-jncw (Sevenfact) – Antihemophilic Factor for hemophilia A or B

    6. fostemsavir (Rukobia) – Oral antiretroviral for multi-drug resistant HIV-1 infection in heavily treatment-experienced adults

7. nifurtimox (Lampit) – Miscellaneous Anti-infective agent for Chagas Disease in pediatrics

8. ofatumumab injection (Kesimpta) – Multiple Sclerosis Agents

9. opicapone (Ongentys) – Oral agent for "off episodes" associated with Parkinson's Disease

10. pralsetinib (Gavreto) – Oral oncologic agent for non-small cell lung cancer (NSCLC)

11. risdiplam (Evrysdi) – Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)

12. satralizumab-mwge injection (Enspryng) – Miscellaneous Neurological Agent for neuromyelitis optica spectrum disorder (NMOSD)

13. triheptanoin oral solution (Dojolvi) – Miscellaneous Metabolic Agents; oral liquid for long-chain fatty acid oxidation disorders in pediatrics and adults

14. sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) – Wakefulness Promoting Agent for narcolepsy

- NF:

1. insulin glargine (Semglee, Semglee Pen) – Basal Insulin

2. monomethyl fumarate (Bafiertam) – Multiple Sclerosis

3. octreotide (Mycapssa) – Miscellaneous Endocrine Agent for acromegaly

4. oxymetazoline ophthalmic solution (Upneeq) – Miscellaneous Ophthalmic agent for acquired blepharoptosis

- Tier 4 (Not Covered):

1. budesonide extended-release (Ortikos) – Gastrointestinal -1 GI Steroid for mild to moderate Crohn's Disease

    a. 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.

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

2. dexamethasone (Hemady) 20 mg tablets – Corticosteroids-Immune Modulator for multiple myeloma

    a. 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.

        1) Formulary alternatives to Hemady include various strengths of generic dexamethasone.

3. fluticasone oral inhaler (Armonair Digihaler) – Pulmonary-1 Agents: Inhaled Corticosteroids (ICS) for asthma

    a. 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.

        1) 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)].

4. fluticasone/salmeterol oral inhaler (AirDuo Digihaler) – Pulmonary-1 ICS-Long-Acting Beta Agonist (LABA) Combinations for asthma and COPD

    a. 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.

        1) 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).

5. levamlodipine (Conjupri) – dihydropyridine calcium channel blocker for hypertension

    a. 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.

1) Formulary alternatives to Conjupri include amlodipine, felodipine, and nifedipine, along with verapamil and diltiazem.

6. metoclopramide nasal spray (Gimoti) – Gastrointestinal-2 Agent for diabetic gastroparesis

a. 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.

1) Formulary alternatives to Gimoti nasal spray include metoclopramide oral tablets and oral solution (Reglan) and metoclopramide orally disintegrating tablet (Reglan ODT).

- **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)

1. azacitidine (Onureg)

Manual PA is required for 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.

PA does not expire.

3. insulin glargine (Semglee, Semglee Pen)

Manual PA criteria apply to all new users of Semglee, Semglee Pen.

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

- Patient has acute pain due to minor strains, sprains, and/or contusions

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

Non-FDA-approved uses are not approved.

PA 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.

PA 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 criteria apply to 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.

PA does not expire.

7. oxymetazoline ophthalmic solution (Upneeq)

Manual PA is required for all new and current 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.

PA does not expire.

8. Pralsetinib (Gavreto)

Manual PA applies to 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.

PA 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.

PA 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 applies to new users Enspryng.

Manual PA Criteria: Enspryng 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.~~ Please note that there is a correction here; there is not a REMS program required for Enspryng.

Non-FDA-approved uses are not approved.

PA does not expire.

11. triheptanoin oral liquid (Dojolvi)

Manual PA applies to new users of Dojolvi.

Manual PA Criteria: Dojolvi 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:

    a. 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.

PA does not expire.

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

Manual PA applies to new users of Xywav.

Manual PA Criteria: Coverage of Xywav is approved if all 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.

  a. 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

  a. 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

  b. 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.

  a. 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

  a. 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.

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF 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 upon the first Wednesday two weeks after signing of the minutes in all points of service.

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

- **Physician's Perspective:**

- Out of the total of 25 new drugs reviewed at this meeting 15 were made UF and 4 will stay NF and 6 we are recommending for Tier 4/Not Covered status.

- For the 11 drugs where PAs were recommended, the criteria only effect new users, therefore all patients currently receiving the drug will be able to remain on therapy.

- For this meeting we have several drugs that were approved for orphan indications or rare diseases, where a very limited number of patients were studied in short-term trials, and where long-term safety and efficacy is unknown. The goals of the PA Criteria are to ensure that the most appropriate patients are selected.

- There was one insulin product, Semglee that was recommended to be NF. This drugs has the same active ingredient as Lantus. There is no data to show that Semglee would be more effective or safer than Lantus. Semglee is being marketed as a low cost insulin, however at MHS Lantus is very cost effective for our beneficiaries. Lantus currently has Tier 1 (generic) copay, and has 85% of the basal insulin market share. The committee did not feel that this new insulin offered a benefit to our patients.

- For the 6 drugs recommended for Tier 4 status, the active ingredients are all available in low cost preparations that are on the formulary. We did reach out to providers for their opinion on the Tier 4 drugs and there was a wide agreement among the respective specialties that these drugs do not offer clinical advantages and in some cases there were some safety concerns.

- **Panel's Questions and Comments Regarding:**

  UF/Tier 4/Not Covered Recommendation:

  CAPT (Ret) Hostettler asked for the formulary status of Mycapssa.

  Dr. Lugo states that Mycapssa is NF. It is an octreotide oral capsule and Tier 3.

  CAPT (Ret) Hostettler states that this is a new, breakthrough therapy. Until recently, patients have been treated with Injectables. They have a chance now to be treated with an oral. In his opinion, we should ensure the new therapy is available our beneficiary population. He request information about the difference in cost for the injectable and the new oral dosage capsule.

  Dr. Lugo states they have reached out to multiple endocrinologists for their feedback. She appreciates that this is a new oral therapy where previously octreotide has been around for a really long time as an injectable. With the exception of the new oral capsule dosage form, there was nothing new clinically. Our endocrinologist did not believe it offered any significant additional value (keeping in mind clinical and cost effectiveness) which led to the recommendation of NF.

  CAPT (Ret) Hostettler asked if they have ever considered surveying the patients in the beneficiary population on whether they prefer oral versus injectable and if they might be willing to spend in difference to get the oral capsule. He states that it would be a very interesting survey.

  Dr. Lugo agrees that it would be interesting but difficult to do, however beneficiaries are able to provide feedback. One note is that we have noticed the NF copay does not prevent patients from getting one of the alternatives. The NF copay is relatively reasonable compared to other health plans and it is not Tier 4. Mycapssa does not have multiple indications whereas in previous meetings we reviewed Bynfezia Pen and several other drugs that have 3 indications. Mycapssa only has 1 indication. All of these medications have a very narrow spectrum for

use. She can appreciate reaching out to beneficiaries to ask their opinion, as she is a beneficiary herself.

CAPT (Ret) Hostettler states that he does not know the number of the beneficiaries that have acromegaly nor do I know the incidence of the disease state. He doesn't believe it is huge but it is a population that we are placing a burden by requiring them to switch from UF to NF in the form of a co-pay. He is wondering if it would be best to keep it UF instead of NF because of the small amount of patient they will not save that much more money.

Manual PA Criteria Recommendation:

Dr. Bertin asks what is the rationale for the age limitation in the PA for the Evrysdi?

CDR Rovey clarifies that the PA Criteria were developed based on the inclusion criteria and patient enrollment from the clinical trials used to gain FDA approval. For example, the trials were limited to patients between ages 1 month and 25 years, and they excluded patients with invasive ventilation or tracheostomy.

Dr. Bertin states his question was more towards the 25-year limitation versus what appears to be FDA approval of all ages. Is that not correct?

CDR Rovey states the FDA approval is from ages 2 months and up. The PA limits the drug for patients' ages 2 months to 25 years for a starting date to take the medication. It is based on the clinical trials, which only included patients from 1 month to 25 years. Therefore, there is no data in older patient to support use in that patient population as of yet or at the time of review for the new drugs. There is one thing to note, if a patient started taking the medication when they were 25, the patient would not be required to stop taking the medication when they reach 26. The patient does not age out of the medication and they may continue taking it.

CAPT (Ret) Hostettler states that the only other therapy up until now has been the intrathecal injections. There are a large number of patients over the age of 25 who are not taking anything. Probably because they can still function to some degree but do not want to go through the intrathecal injection but would be more than willing to take this drug. He does not understand why the PA criteria is more restrictive than the FDA approval. He does believe that the drug is being studied beyond the age of 25 at the moment. The PA criteria is limited to the study group. Is this recommendation consistent with past recommendations for new drugs? That seems to be not the norm.

CDR Rovey states that rather than relying on the FDA indications as our primary source for how we utilize medications, we rely on the clinical evidence, primary literature, and clinical practice guidelines to help determine the benefit.

CAPT (Ret) Hostettler replies I understand FDA indications. This recommendation is limited to the clinical inclusion criteria for the approval. I am not sure that the committee has ever limited a patient population from the clinical criterial and studies. In

this instance, the restrictions applies to what is considered a generally healthy population. In his opinion, the PA criteria is overly restrictive when it doesn't need to be. Again, in his opinion, we should be doing all possible to ensure our patient/beneficiary population, with a clinical need, has access to innovative, new products rather than limiting access to these products.

CDR Rovey also states we have absolutely done this on multiple occasions. This is certainly not a new idea for the committee to only include patients that were included in the study trials. We have done that on numerous occasions, particularly in the cardiovascular drug space. If the committee recommends the drug, we want to make sure the drug is going to be effective. She points out, similar to the intrathecal products, which have a hefty price tag, we want to make sure we use it in a population that will benefit from the medications. However, we did reach out for provider feedback in regards to the PA criteria before the meeting. I believe you referenced the study, JEWELFISH. They are studying older patients who have previously tried the intrathecal products and we are looking forward to seeing the efficacy data from this study. If there is additional data we will continue to monitor for future consideration.

CAPT (Ret) Hostettler asks if she was able to obtain unpublished data from the manufacturers or anywhere else. He also inquired about the timeline of completion for the JEWELFISH study.

CDR Rovey states she only has the data provided at the time of the review. We will continue to monitor and review any data received or have an opportunity to review. She will need to further review the timeline for the JEWELFISH study but knows that it will not be within the next couple of months.

Dr. Khoury stated that every PA we can, and do, limit the age upwards. This agent is unique because it specifically targets a smaller, younger cohort for this disease state. We follow the same process for nearly every PA stating the age needs to be "greater than" based on the clinical study criteria the committee looked at in reviewing the drug.

CAPT (Ret) Hostettler states that he understands the study however, he does not understand the need to limit access to patients aged 25 and under in a population that actually needs this product.

CDR Rovey states that this helps delay progression for the patient. They are going to look for those patients that can still benefit from the drug and that is why they targeted the younger population. We do not know yet whether it will be effective in older age patients or patients that have progressed further. That is why I stated patients that are on ventilators were excluded.

CAPT (Ret) Hostettler reiterates that a survey of the population is needed. Why are patients not taking the intrathecal therapy if they are over the age of 25? Regardless, the patient has the chance to treat their problem in a more convenient and equitable way.

Both the injection and the capsule are expensive. He believes it would be nice to know whether patients don't want to be treated or if they would take an option.

Dr. Khoury states there is no step therapy for this PA. Also, the JEWELFISH is estimated to be complete by January 2025. He shares that unfortunately many of the studies don't end up getting published by the manufacturers which is very concerning. We look forward to reviewing that data when it is available to determine if there are benefits in utilizing this drug in other age groups. We will share that information with the Panel once there are updates that change the recommendations. Additionally we reached out to manufacturers and they do provide information. Regarding the cost of drug, I believe I provided the example of a new car per year earlier with Dupixent. You stated there were 2 treatments for this disease but I want to clarify there are 3 including this one being reviewed. One of them has been in the news for being one of the 1st multi-million dollar costs for gene therapy which was in excess 2 million dollars. This information is also publically available. These drugs being discussed here are extremely expensive and for this Evrysdi agent, in contrast to the example of the agent earlier that costs a car per year, actually costs as much as a car per month. We are simply attempting to ensure that we get the medication to the right patient who is likely to benefit.

CAPT (Ret) Hostettler states that he does not know how many beneficiaries are affected by this recommendation. However, I do know that it can be devastating on families. He can only hope this was taken into consideration when making the recommendation.

Dr. Bertin thanks Dr. Khoury for responding and states he is relying on the committee to continue monitoring this drug.

Dr. Khoury responds the general epidemiology is around 1 in 11,000 live births are impacted by SMA but it is hard to identify patients that might qualify for this treatment as it is both a phenotypically and genotypically driven disease state. There are new screening techniques that will likely identify more patients due to those genetic screens. So, there are a lot of factors when you ask how many have it in the benefit. That number will evolve over time as screening evolves.

Dr. Peloquin responds, that was my question. Does the beneficiary population over 25 understand that the other drugs have not been included in the pharmacy benefit and this one is included? It is difficult to do the math and understand how it impacts patients with this disease state over the age of 25. He also asks if the renewal criteria will continue for patients beyond 25.

CDR Rovey agrees and states the renewal criteria does not re-ask patients their age. It simply asks if the drug continues to be effective. Therefore, they will be able to remain on the drug after the age of 25.

Mr. DuTeil clarifies that patients on the medication prior to the age of 25 will not be denied the medication after the age of 25. Is if available, if the patient is diagnosed after the age of 25?

CDR Rovey states the patient could have been diagnosed before the age of 25 but if it is the first request to use the medication after the age of 25 for the patient. At this point, awaiting other study data, the request would be denied.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF/Tier 4/Not Covered Recommendation, Manual PA Criteria, and UF/Tier 4/Not Covered and PA Implementation Plan for the Newly Approved Drugs per 32 CFR 199.21(g)(5).

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered Recommendation**

  Concur: 5 Non-Concur: 1 Abstain: 0 Absent: 1

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4/Not Covered and PA Implementation Plan:**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

IV. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

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
    a. pain severe enough to require daily, around-the-clock, long-term opioid treatment

    OR

    b. 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
    a. 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
    a. At least two of the following classes of non-opioid medications (unless the patient has a contraindication)
        1) gabapentin or pregabalin titrated to therapeutic dose
        2) a tricyclic antidepressant titrated to therapeutic dose
        3) duloxetine titrated to therapeutic dose
    b. Tramadol
    c. 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. New 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.

C. Physician's Perspective:

- There was only one drug where new PA Criteria was recommended, for the narcotic analgesic Nucynta ER, which has been on the formulary since 2015. This drug has unique safety concerns due to its actions that are not seen with other opioids, including risk of seizures.

- The committee did get comments from providers about the PA, and these providers felt that the other narcotic should be used first, due to the well-publicized risks of long-acting narcotics in opioid-naive patients. The PA will only apply to new users so any existing users will not be affected. The recommended PA is in line with what the VA and other commercial health plans have in place.

D. Panel's Questions and Comments Regarding:

Manual PA Criteria Recommendation:

Dr. Jay Peloquin asks is the safety profile new and has there been recent escalations relative to the safety.

CDR Raisor stated that we regularly monitor utilization especially for the opioids because of the risk and national attention that opioids have received. With our continuous monitoring of these medication and based on clinical/cost effectiveness this one came to our attention.

There were no more questions or comments from the Panel. The Chair called for a vote on the recommendation for the New Manual PA Criteria and Implementation Plan

- **New Manual PA Criteria**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **New Manual PA Criteria —Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

V. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

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.

C. Physician's Perspective:

- This section is where we give brief summaries on drugs with current PAs are updated for expanded age ranges or indications. From this meeting we had six drugs that had updates All the changes will result in an increased number of patients who will qualify for the drugs. For two drugs, we actually removed any mention of age in the criteria (Epidiolex and Haegarda.)

- We do continuously check for these types of updates from the package insert to ensure our PAs are not outdated.

D. Panel's Questions and Comments Regarding:

Updated PA Criteria Recommendation:

CAPT (Ret) Hostettler mentioned concerns about age limitations for the Hepatitis C Agents, Anticonvulsants-Antimania Agents, and the Hereditary Angioedema Agents. He states that in these specific cases you did not limit yourself to the clinical criteria of the study that got these drugs approved yet there were limitations on drugs in a previous section. I am trying to differentiate why it is being treated differently.

Dr. Lugo stated that you cannot compare the two drugs, as there are very different with different outcomes. In this instance, we are expanding.

Mr. Ostrowski states the reason this was done was that the other drug limiting it to the age of 25 it is a very expensive drug and instead of expanding it to all ages like you are talking about above 25 at this time, they are just going to go strictly with what the company's studies show when they did their analysis and so forth. So this way they are adding the drug to that age group up to 25 and maybe later they will expand it but I think that drug was just so expensive that they did not want to expand it to what the FDA approved.

CAPT (Ret) Hostettler states that it is his job to represent the beneficiary. Beneficiaries who have adult children who are eligible for the TRICARE benefit means they are probably of retirees who need some help. Due to science and innovation we have an opportunity to help them. Rather than allowing access to the medications, there a restrictions.

Mr. Jon Ostrowski says that he agrees and I am not stating that the recommendation is right. However, I believe the restrictions are based on cost.

Dr. Khoury states that we are driven by clinical and relative cost effectiveness. The data drives our decision, when there is no data, we have a hard time making that decision. We pay over 9 billion dollars in drug costs but we want to make sure that the drug getting to the patient is safe and effective for those patients, that is the point of the Prior Authorizations.

Updated PA Implementation Plan:

Dr. Jay Peloquin asked if 60 days should be sooner.

Dr. Lugo states that most of these have already been updated behind the scenes.

CAPT (Ret) Hostettler asks for clarity

Dr. Khoury states that we have the authority to provide PA guidance. These actions are to ensure that patients get access to drugs.

- There were no more questions or comments from the Panel. The Chair called for a vote on the Updated PA Criteria and the Updated PA Criteria—Implementation Plan for the Updated PA Criteria.

- **Updated PA Criteria**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

- **Updated PA Criteria—Implementation Plan**

  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

VI. BRAND ALBUTEROL HFA (PROAIR HFA) COPAYMENT CHANGE

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.

B. Physician's Perspective:

- This recommendation here is to lower the copay for the Brand ProAir Inhaler to the generic (Tier 1) copay for patient using the Retail pharmacy network. This is a "good news" message, as patients will see the reduced copay the next time they get their inhaler prescription filled

C. Panel's Questions and Comments Regarding:

Brand Albuterol HFA (PROAIR HFA) Copayment Change:

CAPT (Ret) Hostettler states he would like to end on a positive note. He thanks the committed for the lowering of the co-pay.

There were no more questions or comments from the Panel. The Chair called for a vote on the PROAIR HFA Brand Co-Payment change and Implementation.

- **PROAIR HFA Brand Copay Change and Implementation Recommendation**

Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

VII. 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

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.

C. Physician's Perspective:

- This is the first time that we have gone back to review the Tier 4 products. The first Tier 4 designations were done in February 2019, so we are at the one-year mark for implementation.

- For the three products that we reviewed again, we came to the same conclusion that we had agreed upon at the original decision. So these three drugs will remain Tier 4.

- We are not aware of any negative clinical impacts or outcomes as a result of the not covered status, other than the patient complaints on the out of pocket costs if they do not switch to a formulary alternative.

D. Panel's Questions and Comments Regarding:

There were no questions or comment from the Panel. The Chair called for a vote on the 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.

- **TRICARE Tier 4/Not Covered Recommendation.**

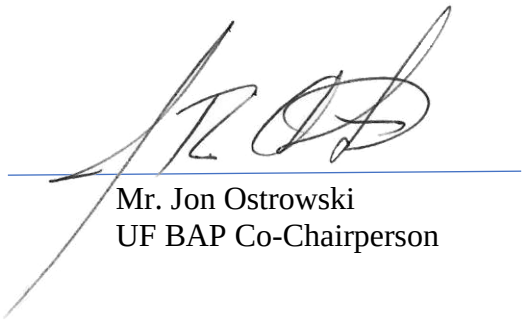
  Concur: 6 Non-Concur: 0 Abstain: 0 Absent: 1

Closing comments:

Mr. Ostrowski thanks the Panel members for attending the meeting as well as the participants. He wishes everyone a Happy Holiday and a better New Year that experienced in 2020. He thanks Col Hoerner and the Team for the presentation. Lastly he thanks Ms. Armstead for organizing the meeting.

Col Hoerner thanks the Panel members, FMB Team, P&T Committee, Ms. Armstead and the participants.

Adjourns meeting at 3:07 pm.



Mr. Jon Ostrowski
UF BAP Co-Chairperson

Appendices:

- Appendix I – Brief list of Acronyms used in this Summary
- Appendix II – Informational Item—Summary of Recommendations and Beneficiary Impact December 2020
- Appendix III - Written Comments – Cure SMA
- Appendix IV - Written Comments – Ironshore Pharmaceuticals

Brief Listing of Acronyms used in this Summary

Abbreviated terms are spelled out in full in this summary; when they are first used, the acronym is listed in parentheses immediately following the term. All of the terms commonly used as acronyms in the Panel discussions are listed below for easy reference. The term "Pan" in this summary refers to the "Uniform Formulary Beneficiary Panel," the group who is meeting in the subject of this report.

- ADR – Adverse reaction
- AML – Acute myeloid leukemia
- BCF – Basic Core Formulary
- BIA – Budget impact analysis
- CFR – Code of Federal Regulations
- CMA – Cost minimization analysis
- CMML – Chronic myelomonocytic leukemia
- COPD – Chronic obstructive pulmonary disease
- CRSwNP – Chronic rhinosinusitis with nasal polyposis
- DHA – Defense Health Agency
- DoD – Department of Defense
- EAACI – European Academy of Allergy and Clinical Immunology
- EGPA – Eosinophilic granulomatosis with polyangiitis
- EPOS – European Position Paper on Rhinosinusitis and Nasal Polyposis
- FDA – U.S. Food and Drug Administration
- HES – Hypereosinophilic Syndrome
- IST – Immunosuppressive therapy
- JNC – Joint National Contract
- LABA – Long acting beta agonist
- LAMA – Long acting muscarinic antagonist
- LC-FAOD – Long-chain fatty acid oxidation disorder
- mcL – Microliter
- MHS – Military Health System
- MN – Medical Necessity
- MTF –Military Treatment Facility
- NCCN – National Comprehensive Cancer Network
- NDAA – National Defense Authorization Act
- NMOSD – Neuromyelitis optica spectrum disorder
- NSAID – Nonsteroidal anti-inflammatory drugs
- ODT – Orally Dissolving Tablet
- OTC – Over the counter

- PA – Prior authorization
- POD – Pharmacy Operations Division
- POS – Point of service
- PPI – Proton Pump Inhibitor
- Rx – Medical Prescription
- SC – Subcutaneous
- SMA – Spinal muscular atrophy
- SMN2 – Survival of motor neurons 2

X. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT 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.	N/A • 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

Make today a breakthrough.

December 13, 2020

Uniform Formulary Beneficiary Advisory Panel (BAP)
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042–5101

Re: Newly Approved Drugs Review: risdiplam (Evrysdi)

Dear Uniform Formulary Beneficiary Advisory Panel Members:

On behalf of individuals with a neuromuscular disease known as spinal muscular atrophy (SMA), **Cure SMA urges the Uniform Formulary Beneficiary Advisory Panel to remove the age and other restrictions from the TRICARE policy for Evrysdi, a new SMA treatment, that conflict with the U.S. Food and Drug Administration (FDA) label.**

SMA is a progressive neurodegenerative disease that can significantly impact an individual's ability to walk, swallow, and—in the most severe cases—even breathe. SMA affects approximately 1 in 11,000 births, and about 1 in every 50 Americans is a genetic carrier. SMA can affect any race or gender.[i]

As the leading national organization dedicated to finding a cure and treatments for SMA, **Cure SMA is very concerned by the U.S. Department of Defense Pharmacy and Therapeutics Committee recommendations that would restrict access to Evrysdi for individuals with SMA who are older than 25 years old.**

The FDA approved Evrysdi on August 7, 2020 for the treatment of SMA in all individuals with SMA who are 2 months of age and older. The FDA's approval and broad label were based on clinical trials that demonstrated Evrysdi's effectiveness in both pediatric and adult patients.[ii] The FIREFISH (Part 1 & 2), SUNFISH, and JEWELFISH trials showed individuals with SMA who received Evrysdi achieved unprecedented developmental gains and milestones (i.e., swallowing, sitting, standing) and required fewer hospitalizations and reduced need for permanent ventilation and feeding support. In addition to the efficacy, the FDA thoroughly reviewed the SMA treatment for safety and concluded that the clinical trials data established that Evrysdi was safe for the treatment of SMA. Despite this strong body of evidence and the FDA's broad treatment label, the TRICARE policy limits Evrysdi to only individuals who are 25 years old or younger. **If approved, this policy would be among the most restrictive in the nation.**

Military families with SMA should be able to access an SMA treatment based on their individual choice and circumstance. In addition to the age restriction, Cure SMA is also concerned by the policy's restrictions related to ventilation support. There is no evidence to exclude individuals with SMA who are on permanent ventilation. The clinical data from Evrysdi showed gains in fine and gross motor function and found less dependency on ventilation.

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Cure SMA respectfully asks that this distinguished panel remove the restrictions and approve coverage of Evrysdi for all TRICARE beneficiaries with SMA who are 2 months of age and older, as recommended by the FDA.

Thank you for considering Cure SMA's recommendation for full coverage of Evrysdi. Please do not hesitate to contact Cure SMA if you have questions or need additional information. Cure SMA can be reached through Maynard Friesz, Vice President for Policy and Advocacy at Cure SMA, at maynard.friesz@curesma.org or 202-871-8004. Thank you for your consideration.

Sincerely,

Kenneth Hobby
President

Mary Schroth, M.D
Chief Medical Officer

Jill Jarecki, PhD
Chief Scientific Officer

[i] About Spinal Muscular Atrophy, Cure SMA, 2020 https://www.curesma.org/about-sma/
[ii] U.S. Food and Drug Administration, Evrysdi Prescribing Information, 2020, (Page 2), https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213535s000lbl.pdf

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Colonel Paul J. Hoerner, USAF
7700 Arlington Boulevard
Suite 5101
Falls Church, VA 22042-5101

Frank Bartolini, VP Market Access
Ironshore Pharmaceuticals Inc.
frank.bartolini@ironshorepharma.com
Phone: 984-224-5107

Date: December 11, 2020

Dear Colonel Hoerner,

Ironshore Pharmaceuticals Inc., the manufacturer of JORNAY PM® (methylphenidate HCl Extended-Release Capsules), appreciates the opportunity to comment on the prior authorization (PA) criteria and step therapy requirements recommended by the DoD Pharmacy and Therapeutics (P&T) Committee for products in the Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass.

The following table shows the DoD P&T Committee recommendations for formulary status and the number of steps that would apply to each of the brand name products that were evaluated in the Attention Deficit Hyperactivity Disorder (ADHD): Stimulants Subclass. The products are listed in the order of their respective costs, from lowest to highest, (as outlined on page 6 of the Beneficiary Advisory Panel (BAP) Background Information document).

	Brand Name Products (ranked from lowest cost to highest cost)	**Formulary Status**	**Number of Steps**
1	Evekeo ODT	UF	2
2	Quillivant XR	UF	0 – No PA
3	***Jornay PM***	***UF***	***4***
4	Zenzedi	UF	0 – No PA
5	Vyvanse	UF	2
6	Quillichew ER	NF	0 – No PA
7	Dyanavel XR	NF	0 – No PA
8	Mydayis	NF	2
9	Adzenys XR-ODT	NF	0 – No PA
10	Adhansia XR	Tier 4/Not Covered	NA
11	Adzenys ER	NF	0 – No PA
12	Daytrana	NF	0 – No PA
13	Cotempla XR-ODT	NF	3

As expected, the DoD P&T Committee recommended Uniform Formulary (UF) status for the lower cost brand name products and Non-Formulary (NF) status for the higher cost brand name products. The five lowest cost brand name products were recommended for UF status. The eight higher cost products were recommended for NF or Tier 4/Not Covered status.

However, the number of step therapy edits recommended by the DoD P&T Committee for brand name products does not correlate with the cost of the brand name products (as it does in the application of cost to their UF status). There is a disconnect between UF placement, product cost, and step therapy requirements. It is a well understood principle of pharmacy benefit management to use step therapy edits to encourage the use of less expensive products over more expensive products. The DoD P&T Committee recommendations for step therapy in this category do not adhere to this principle.

1. Faraone SV, et al. *J Clin Psychiatry.* 2020;81(1).

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IRONSHORE PHARMACEUTICALS

Military Health System (MHS) providers commented Jornay PM should remain UF, since it is helpful for children with developmental delays because of the bedtime dosing (see page 6 in the BAP Background information document). The benefit that UF formulary placement would convey upon this vulnerable patient populations appears negated by the requirement to step through four (4) formulary alternatives over the course of eight (8) months.

The DoD P&T Committee concluded that Jornay PM 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%. However, the FDA, in their Appeal Granted Letter, agreed with the assessment that insomnia rates noted in clinical trials were overestimated as an artifact of study design. An artifact equally noted in placebo insomnia rates (9%) which are proportionately higher compared to other methylphenidate formulations where insomnia occurred at rates of approximately 3%. This assessment is furthered when examining real world evidence where Jornay PM insomnia rates (0.1%, N=25,000) are observed to be similar to, or lower than other ADHD stimulants[1].

Ironshore encourages the BAP to consider the following questions:

1. Why are 4 steps recommended for Jornay PM—more steps than any other brand name product—when 10 of the 13 brand name products cost more than Jornay PM?

2. Why are 4 steps recommended for Jornay PM—which is a UF product—when all NF products have fewer steps?

3. Why do 6 products that cost more than Jornay PM (e.g., Zenzedi, Quillichew ER, Dyanavel XR, Adzenys XR-ODT, Adzenys ER and Daytrana) have no step therapy requirements while Jornay PM has 4 steps?

4. Why should TRICARE beneficiaries be required to try four other products over an eight-month period when Jornay PM costs less than nine other brand name products that are only subject to 0, 1, 2 or 3 steps?

The Defense Health Agency Pharmacy Operations Division Formulary Management Branch (DHA POD FMB) routinely encourages pharmaceutical companies to offer lower prices to achieve a formulary position and step therapy requirements that can result in increased utilization of their products. Pharmaceutical companies may be less willing to offer lower prices if the DoD P&T Committee imposes step therapy requirements that do not have a corollary relationship to the comparative costs of products. The arbitrary and capricious application of step therapy requirements within the ADHD Stimulants Subclass may serve to undermine the Uniform Formulary Blanket Purchase Agreement (UF BPA) and Uniform Formulary Additional Discount Program (UF ADP) quote process.

Ironshore respectfully requests that the BAP members consider the issues addressed above and convey their concerns and comments to the DHA Director. Thank you for your time and consideration.

Sincerely,

DocuSigned by:
Frank Bartolini
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Frank Bartolini
Vice President Market Access
Ironshore Pharmaceuticals Inc.

1. Faraone SV, et al. *J Clin Psychiatry.* 2020;81(1).