EXECUTIVE SUMMARY

Uniform Formulary Beneficiary Advisory Panel
September 23, 2020

I. UF CLASS REVIEWS—SLEEP DISORDERS: WAKEFULNESS PROMOTING AGENTS SUBCLASS

A. Sleep disorders: wakefulness promoting agents subclass—uf/tier 4/not covered recommendation

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

- UF
  - armodafinil
  - modafinil
  - sodium oxybate (Xyrem)
- NF
  - solriamfetol (Sunosi)
  - pitolisant (Wakix)
- Tier 4/Not Covered
  - None

B. Sleep Disorders: Wakefulness Promoting Agents Subclass—Manual PA Criteria

Manual PA criteria currently apply to Xyrem (originally placed in February 2012, and most recently updated in August 2019 for pediatric use); solriamfetol (Sunosi) from the August 2019 meeting; and pitolisant (Wakix) from the November 2019 meeting. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) minor updates to the manual PA criteria for new users of solriamfetol and pitolisant, to more accurately reflect the inclusion criteria from the clinical trials used to gain FDA approval. No changes were recommended for the sodium oxybate PA criteria.
The PA criteria are as follows. Updates from the August 2020 meeting are in bold:

1. pitolisant (Wakix)

Manual PA is required for all new users of Wakix.

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

- **Provider acknowledges that PA is not required for modafinil or armodafinil.**
- Patient is 18 years of age or older
- Wakix is not approved for use in children, adolescents, or pregnant patients.
- Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy **and an Epworth Sleepiness Scale (ESS) score ≥ 14**
- Narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing
- Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Patient is not concurrently taking any of the following:
    1. Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate
- Patient must have tried and failed and had an inadequate response to modafinil
- Patient must have tried and failed and had an inadequate response to armodafinil
- Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)
- Patient does not have a history of severe hepatic impairment
- Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea

2. solriamfetol (Sunosi)

Manual PA is required for all new users of Sunosi.

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

- **Provider acknowledges that PA is not required for modafinil or armodafinil.**
- Patient is 18 years of age or older
- Sunosi is not approved for use in children, adolescents, or pregnant patients.

- Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy or a documented diagnosis of obstructive sleep apnea (OSA) **and an Epworth Sleepiness Scale (ESS) score ≥ 10**

- For narcolepsy: narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing

- For narcolepsy: Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea

- For OSA: Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least 1 month prior to initiation, and the patient demonstrated adherence to therapy during this time

- For OSA: Patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of treatment

- Sunosi is prescribed by a neurologist, psychiatrist, or sleep medicine specialist

- The patient is not concurrently taking any of the following:

    1. Central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic

    2. Monoamine oxidase inhibitor (MAOI) within the past 14 days

    3. Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate

- The patient must have tried and failed and had an inadequate response to modafinil

- The patient must have tried and failed and had an inadequate response to armodafinil

- The patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)

- Patient and provider agree to monitor blood pressure and heart rate at baseline and periodically throughout treatment. If the patient has hypertension, the blood pressure is controlled.

- Patient does not have unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems

3. sodium oxybate (Xyrem)

Note that there were no changes to the PA criteria from Xyrem made at the November 2019 meeting. I won't go over the PA criteria, but they are hear for your awareness.

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

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

  AND

- Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.

  1. Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR

- Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy

  AND

  1. The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND

- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

  OR

- Patient is 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
- Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist

AND

- Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.

    1. Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR

- Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy

    AND

    1. 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)

C. Sleep Disorders: Wakefulness Promoting Agents Subclass—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent): an effective date of the first Wednesday one week after signing of the P&T minutes at all points of service (POS).

Summary of Physician's Perspective:

- We previously reviewed this class in 2012, and the two new drugs (Wakix and Sunosi) were evaluated as innovators within the past year. The reason for another look at this class was because of the new entrants, and update the committee on any new clinical information for the older agents (Xyrem, modafinil and armodafinil).

- There were no changes to the formulary status for the drugs; Sunosi and Wakix will remain nonformulary. The minor changes made to the PAs for Sunosi and Wakix bring our PAs into alignment with that from other groups, including the VA.

- Xyrem will remain on the formulary for now, however, there are some similar agents in the pipeline. There potentially could be nonformulary options made for narcolepsy drugs in the future, when the investigational products come to the market.

- Overall, there was no significant change of note with the committee's recommendations.

Summary of Panel Questions and Comments:

Uniform Formulary/Tier 4/Not Covered Recommendation*:*

CAPT (Ret) Hostettler asked for clarification regarding the P&T Committee vote on page 4. During the presentation, 5 opposed was stated. Was the P&T Committee recommendation (18 for, 0 opposed, 0 abstained, 0 absent)?

Dr. Lugo confirms that he is correct; it's 0.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler states that prior authorization was placed on this product. It is fourth in line. By the time the patient tries all the products, it should meet the requirements for medical necessity. Therefore should be UF. Was any consideration given to that during the meeting?

Dr. Lugo asks for which two products.

CAPT (Ret) Hostettler replies the two that are non-formulary – Sunosi and Wakix. To clear the PA criteria, the patient has to try two (2) other products (armodafinil and modafinil), which happen to be the products on the UF. Which means the patient has failed and the only thing left are these two products should meet medical necessity. Therefore they should be UF. UF with that PA plan would work just as well and wouldn't penalize the patient between cost shares of UF and NF. Most likely the patient is not smart enough to process the medical necessary requirements. When you put that onerous of PA in place, it seems logical to me that they would be UF but behind 3 other drugs. Was there no consideration for that at all?

Dr. Lugo thanks him for his comments. You don't have to try Xyrem before the two branded agents. There are requirements for modafinil or armodafinil, which were indicated as stimulants but not all of them.

CAPT (Ret) Hostettler says that it reads that the stimulants are there.

Dr. Lugo says not Xyrem. The stimulants are technically not part of this class.

CAPT (Ret) Hostettler says that they are part of the PA.

UF/Tier 4/Not Covered and PA Implementation Plan:

CAPT (Ret) Hostettler asked why a short implementation plan?

Dr. Lugo answered because there were no changes to formulary status and minor changes to the PA.

CAPT (Ret) Hostettler confirms that no patients were affected.

Dr. Lugo answered that is correct.

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 Sleep Disorders: Wakefulness Promoting Agents Subclass.

- **Sleep Disorders: Wakefulness Promoting Agents Subclass—UF/Tier 4/Not Covered Recommendation**

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

  Director, DHA:

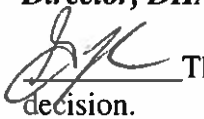
   These comments were taken under consideration prior to my final decision.

- **Sleep Disorders: Wakefulness Promoting Agents Subclass—Manual PA Criteria**

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

  Mr. Hostettler reiterates what he said before. The onerous PA of having to try all 3, even one that is not part of the class before you can you get to the NF products. Just seems to be over the top for him.

  Director, DHA:

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

- **Sleep Disorders: Wakefulness Promoting Agents Subclass—UF/Tier 4/Not Covered and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

II. UF CLASS REVIEWS—WHITE BLOOD CELL STIMULANTS: FILGRASTIMS AND PEGFILGRASTIMS

A. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—UF and Step Therapy Recommendation

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

FILGRASTIMS

- UF and step-preferred
    1. tbo-filgrastim vial and syringe (Granix) *(Granix vials moves from NF to UF and step-preferred status)*
    2. filgrastim-aafi vial and syringe (Nivestym) *(moves from NF to UF and step-preferred status)*
- UF and non-step-preferred
    1. filgrastim vial and syringe (Neupogen) *(moves to non-step-preferred status)*
    2. filgrastim-sndz syringe (Zarxio) *(moves to non-step-preferred status)*
    3. Note that as part of the formulary recommendation, a trial of both Granix and Nivestym are required in new users before patients can try Neupogen or Zarxio.
- NF – None
- Tier 4/Not Covered — None

PEGFILGRASTIMS

- UF and step-preferred
    1. pegfilgrastim-cbqv syringe (Udenyca)
    2. pegfilgrastim-jmdb syringe (Fulphila)
- UF and non-step-preferred
    1. pegfilgrastim syringe (Neulasta) *(moves to non-step-preferred status)*
    2. pegfilgrastim on-body injector (Neulasta OnPro) *(moves to non-step-preferred status)*

3. pegfilgrastim-bmez syringe (Ziextenzo) (*moves to non-step-preferred status)*

4. Note that as part of the formulary recommendation, a trial of both Udenyca and Fulphila are required in new users before patients can try Neulasta, Neulasta OnPro, or Ziextenzo.

- NF — None

- Tier 4/Not Covered — None

B. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Manual PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the non-step-preferred WBC stimulants, requiring the step-preferred products first, unless the patient has had an inadequate response or could not tolerate the preferred WBC stimulants. For new users of Neupogen and Zarxio, a trial of Granix and Nivestym is required. New users of Neulasta, Neulasta OnPro, or Ziextenzo are required to try Udenyca and Fulphila first. Patients requiring a pegfilgrastim who cannot self-inject will be able to receive Neulasta OnPro.

The PA criteria are as follows:

1. Filgrastims: filgrastim (Neupogen) and filgrastim-sndz (Zarxio)

Manual PA criteria apply to all new users of filgrastim (Neupogen) and filgrastim-sndz (Zarxio).

Manual PA Criteria: Coverage will be approved if all criteria are met:

- Provider acknowledges that tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) are the TRICARE preferred filgrastims and are available without a PA

- Drug is prescribed by or in consultation with a hematologist or oncologist

- Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio)

- Patient has experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio)

PA does not expire.

2. pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo)

Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo).

Manual PA Criteria: Coverage will be approved if all criteria are met:

- Provider acknowledges that pegfilgrastim-cbqv (Udenyca) and pegfilgrastim-jmdb (Fulphila) are the TRICARE preferred pegfilgrastims and are available without a PA
- Drug is prescribed by or in consultation with a hematologist or oncologist
- For Neulasta OnPro: Patient requires use of an on-body injector because the patient and/or caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration

OR

- Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-cbqv (Udenyca) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo)
- Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo)

PA does not expire.

C. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Tier 1 Cost Share

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) lowering the current Tier 2 cost-share for the filgrastim Granix (both syringe and vial) and the pegfilgrastim Udenyca (both syringe and vial) to the generic Tier 1 cost-share.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes." Lowering the cost-share for both Granix and Udenyca will provide a greater incentive for beneficiaries to use the most cost-effective WBC stimulant for the filgrastims and pegfilgrastims, in the purchased care points of service.

D. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims UF, PA, and Tier 1 Cost Share Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service.

Summary of Physician's Perspective:

- This is the first time we are evaluating a drug class that has biosimilars. For the WBC Stimulants, we did decide to keep all the products on the formulary. The factors influencing why we kept everything UF was because these drugs are used in oncology patients, for usually limited durations of therapy.

- Two products from each subclass were designated as preferred. However, only new patients will be subject to the step therapy requirements ("grandfathering"). For the non-preferred products, we are requiring a trial of two preferred drugs first, rather than one; but this requirement is similar to other commercial health care plans. This will also help in any shortage situations.

- The recommendation to go with the step therapy is because the step should be very effective at moving market share, without forcing patients to pay a nonformulary copay. We want to encourage providers to go with the preferred products for new patients, due to the fact that these are clinically interchangeable drugs.

- The Committee did not recommend Tier 4 for this drug class, after considering both the cost implications, beneficiary ramifications and existing market share.

- While patients will be grandfathered regarding agents they and their provider have selected, all new and current patients will be eligible for the Tier 1 designation. Up to 7000 prescriptions will be eligible for the lowest Tier 1 or a zero dollar copay if the drug is obtained at an MTF.

Summary of Panel Questions and Comments:

UF and Step Therapy Recommendation:

Dr. Peloquin requested clarification regarding the step preferred recommendation with two different Tiers. One of the steps is tiered differently than the other preferred.

CDR Raisor clarifies the question you've noticed for both filgrastims and pegfilgrastims there are 2 step preferred agents. When talking about Tier 1 status, only one (1) of the two (2) products is Tier 1. Why aren't both products Tier 1.

Dr. Peloquin confirms. Is it step-step preferred or preferred-preferred step?

CDR Raisor clarified with the two step-preferred agents, there isn't a preference for the Tier 1 over the other step preferred agent. They are both equally preferred. If the provider or the patient chooses the Tier 1 agent they will only pay a tier 1 copay.

Dr. Hostettler clarifies, in each classification there is one step preferred Tier 1 product?

CDR Raisor said yes. There is a filgrastims and a pegfilgrastims, of the two step preferred that do have a Tier 1 copay.

CAPT (Ret) Hostettler asked how the patient would know to make that choice. They aren't going to have the information needed to make that choice. They will show up at the pharmacy and pay a UF price. No one will ever tell the patient that the product was available at the Tier 1 co-pay. How is that information shared with the beneficiary or the provider for that matter?

CDR Raisor clarified how does the patient know that there is a Tier 1 copay? The formulary search tool is one way that the patient and provider can use to check Tier 1 status. Additionally, comments can be placed on the prior authorization to specify that the products have Tier 1 co-pay.

Mr. Hostettler said the comments on the PA form would be beneficial. He doesn't know how many providers and/or patients are in their doctor's office pull up the formulary search tool. The practically of that doesn't seem to ring true. Putting it on the form might have some benefits.

Dr. Peloquin asked how many new patients are impacted by the decision.

CDR Raisor clarified how many new patients? At any one time, we have about 300 patients. There are not a lot of patients on these agents. We have a new user rate of 30%. So 30% of 300 would be the ball park.

CAPT (Ret) Hostettler brings up a housekeeping issue. On Page 12, para B – the white blood stimulants… says CMA and BIA were performed to evaluate the topical pain agents. Is that correct?

CDR Raisor said the votes are for the filgrastims and pegfilgrastims. The topical pain agents are an error. Thanks for bringing that to our attention.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asked a question about the cost analysis for Neulasta OnPro. When cost analysis are conducted, are the multiple visits to have the injection added to the cost comparison as well as the MTF and/or doctor's visits to the MHS and to copays to patients each time they go in for a shot?

CDR Raisor clarified we did include the cost to the patients and to the clinics when evaluating the OnPro. When cost reviews are conducted the BIA is specific to the pharmacy budget. We do take into account unique characteristics or other factors when we review other drugs, including OnPro.

CAPT (Ret) Hostettler asked if a consideration was given to the overall outside of pharmacy cost to the MHS and out of pocket cost to the patient in your cost analysis of OnPro. Seems like we could be saving nickels and spending dollars in other places.

Lt Col Khoury asked Mr. Hostettler to specify what out of pocket costs he is referring to.

CAPT (Ret) Hostettler said anytime a patient goes back to the provider for an injection or any other reason there is a copay. That's the patient's cost. The time spent in the MHS at the doctor's office, the clinic, and the MTF are all costs to the system in lost appointments because patients are rescheduling appointment to meet the PA criteria. If nothing else, there is an opportunity lost. There are costs for the MTF or doctor's office because now they have a patient sitting there when they could be sitting at home in a more comfortable position.

Lt Col Khoury repeated CDR Raisor response about our assessment to pharmacy and the budget impact. It sounds like you're looking at a global cost impact. This is not under the P&T Committee purview.

CAPT (Ret) Hostettler says he doesn't believe it's out of the benefit purview. I am looking at the MHS cost and the total cost to the benefit. I know that, my benefit, as a beneficiary includes more than just pharmacy, and the pharmacy can impact that benefit in deleterious ways if it's not taken into account. It is in my benefit.

Lt Col Khoury reiterates that global costs are not under the purview of the P&T Committee. We did assess the other factors unique to the agents of this class. Neulesta OnPro is UF and has the same copay unless it's been designated different from a Tier 2 to Tier 1. Regarding other costs, that is not in our purview to be able to assess. That is a wide range depending on the patient and individual factors that go into that. I'll venture to say that is impossible to get that number and defer to the experts to those who have access. We definitely don't.

CAPT (Ret) Hostettler believes that it's a legitimate question to see what the impact of P&T Committee decisions are on the whole MHS enterprise. It's that budget that really makes a difference at the end of the day. He has made his point and will move on.

UF PA and Tier 1 Cost Share Implementation Plan Recommendation:

Dr. Peloquin asked why a 60 day implementation plan versus a 90 or 30 day plan.

Lt Col Khoury said they try to take into account the changes that are occurring for the PAs to ensure that they are implemented and the contractor can ensure they're adjudicated well. Do you think it's too fast? Too slow? Just right?

Dr. Peloquin responded I know this is shorter and patients are on the product for a shorter period of time. The decision affects new patients and I want to ensure oncology understands what it the preferred item.

Lt Col Khoury said we didn't want to delay the reduced cost for the patients.

Dr. Peloquin replied with good point.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF and Step Therapy Recommendation, Manual PA Criteria, Tier 1 Cost Share and UF PA and Tier 1 Cost Share implementation plan for White Blood Cell Stimulants: Figrastims and Pegfilgrastims.

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—UF and Step Therapy Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  CAPT (Ret) Hostettler wants to add to his concurrence with the caveat that they will put on the PA form about which one is tier one cost share versus tier 2.

  Director, DHA:

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

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Manual PA Criteria**

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

  Director, DHA:

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

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Tier 1 Cost Share**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0
  Director, DHA:
   These comments were taken under consideration prior to my final decision.

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—UF PA, and Tier 1 Cost Share Implementation Period**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:
   These comments were taken under consideration prior to my final decision.

III. UF CLASS REVIEWS—PSORIASIS AGENTS

A. Psoriasis Agents—Topical Psoriasis Agents UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following formulary recommendations for the Psoriasis Agents as outlines below, based on clinical and cost-effectiveness:

- UF
  - calcipotriene 0.005% ointment (Calcitrene, generics)
  - calcipotriene 0.005% cream (Dovonex, generics)
  - calcipotriene 0.005% solution (generics)
  - tazarotene 0.1% cream (generics)
- NF *(all move from UF to NF Status)*
  - calcipotriene 0.005% foam (Sorilux)
  - calcitriol 3 mcg/g ointment (Vectical, generics)
  - calcipotriene 0.005%/betamethasone 0.064% ointment (Taclonex, generics)
  - calcipotriene 0.005%/betamethasone 0.064% foam (Enstilar)
  - tazarotene 0.1% gel (Tazorac)
  - tazarotene 0.05% cream (Tazorac)
  - tazarotene 0.05% gel (Tazorac)

- Tier 4/Not Covered

  - calcipotriene 0.005%/betamethasone 0.064% suspension (Taclonex) (moves from UF to Tier 4 status)

    For Taclonex suspension, which was recommended for Tier 4/Not Covered status, the P&T Committee concluded that it provides very little to no additional clinical effectiveness relative to the other psoriasis agents. Overall, the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other combination products, and by use of the single ingredient vitamin D analogs and corticosteroids used separately.

B. Psoriasis Agents—Manual PA Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Sorilux foam, Enstilar foam and Taclonex ointment in all new and current users, requiring a trial of a high potency corticosteroid and calcipotriene first, due to the large number of clinically and cost-effective formulary alternatives available. Manual PA criteria were also recommended for new and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel, requiring a trial of tazarotene 0.1% cream and a high potency topical steroid, for plaque psoriasis affecting the body. For acne, a trial of tazarotene 0.1% cream will be required before the other Tazorac formulations.

The Manual PA are as follows:

1. calcipotriene 0.005% foam (Sorilux)

Manual PA criteria apply to all new and current users of Sorilux foam.

Manual PA Criteria: Coverage will be approved if all criteria are met:

- The provider acknowledges that Sorilux has several cost-effective alternatives, including generic calcipotriene 0.005% cream, ointment, and solution, which do not require a PA. Calcipotriene 0.005% solution can be applied to the scalp.

- Patient is 12 years of age or older

- The patient has diagnosis of plaque psoriasis

- The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one formulary high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution)

- For scalp psoriasis: the patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% solution OR

- For all other body areas: the patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% ointment, cream, AND solution

Non-FDA-approved uses are not approved.

PA does not expire.

2. calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex) and calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar)

Manual PA criteria apply to all new and current users of Enstilar foam and Taclonex ointment.

Manual PA Criteria: Coverage will be approved if all criteria are met:

- The provider acknowledges that Enstilar foam and Taclonex ointment have several cost effective alternatives, including the following, none of which require PA.

    1. For the calcipotriene (vitamin D analog) component, alternatives include generic calcipotriene 0.005% cream, ointment, and solution.

    2. For the betamethasone (high-potency topical corticosteroid) component, alternatives include clobetasol propionate 0.05% ointment, cream, solution, and shampoo and fluocinonide 0.05% cream, ointment, and solution.

- Patient is 12 years of age or older

- The patient has diagnosis of plaque psoriasis

- The patient must have tried for at least 2 weeks and failed or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution)

- The patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% ointment, cream, OR solution

- The patient must have tried and failed an individual calcipotriene agent (calcipotriene 0.005% ointment, cream or solution) AND an individual high-potency topical corticosteroid agent used concurrently

- Additionally, the provider must describe why Enstilar foam or Taclonex ointment is required as opposed to available alternatives.

    Non-FDA-approved uses are not approved.

PA does not expire.

3. tazarotene 0.05% cream (Tazorac), tazarotene 0.05% gel (Tazorac) and tazarotene 0.1% gel (Tazorac)

Manual PA criteria apply to all new users and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel.

Manual PA Criteria: Coverage will be approved if all criteria are met:

- The provider acknowledges that tazarotene 0.1% cream is a cost effective alternative that does not require a PA.
- The patient has a diagnosis of acne vulgaris or plaque psoriasis
- For acne vulgaris:
    1. Patient is 12 years of age or older
    2. The patient must have tried and failed, have a contraindication to, or have had an adverse reaction to tazarotene 0.1% cream.
- For scalp psoriasis:
    1. Patient is 18 years of age or older
    2. The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% solution, shampoo; fluocinonide 0.05% solution)
- For plaque psoriasis in other body areas:
    1. Patient is 18 years of age or older
    2. The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution) AND
    3. The patient must have tried and failed or have had an adverse reaction to tazarotene 0.1% cream.

Non-FDA-approved uses are not approved.

PA does not expire.

C. Psoriasis Agents—UF/Tier 4/Not Covered, and PA Implementation Period

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 120 days after the signing of the minutes; 2) DHA send letters to beneficiaries who are affected by the by the change from UF to NF status and PA requirements, and 3) DHA send letters to beneficiaries who are affected by the Tier 4/not covered recommendations at 30 and 60 days prior to implementation.

Physician's Perspective:

- This class is comprised of drugs with different mechanisms of actions that are all used topically. We received input from the dermatology community when making the formulary recommendations. The products that will remain on the formulary are those that the specialists said are required. Note that there are several alternatives for the nonformulary and Tier 4 candidates.

- While the Committee considered making several of the Vitamin D/steroid combinations Tier 4, based on the dermatology feedback, the recommendation was to designate them nonformulary with a PA instead. The Tier 4 recommendation for Taclonex suspension will affect about 350 patients out of the total 14,000 unique utilizers for the class. Based on our utilization data this drug is most often filled one time and not filled again. Additionally the providers felt that having patients avoid certain combinations, as long as the two separate products were available, may be beneficial from a clinical perspective.

- The Committee was also aware that if patients fail one of these topical therapies, they could receive one of the newer expensive biologic therapies (like Stelara and Taltz). The products staying on the formulary will provide the necessary range of options needed for the management of this disease for our patients and the clinicians that treat it.

Summary of Panel Questions and Comments:

UF/Tier 4/Not Covered Recommendation:

CAPT (Ret) Hostettler asked how many beneficiaries were affected this this decision. Looks like a total of 2,045 from the UF to NF change. Curious how many were combination products.

LCDR Hansen repeats, how many total patients on combination products will be affected not just asking about one that moved from UF to Tier 4? Is that correct?

CAPT (Ret) Hostettler answered Tier 4 is Tier 4. I'm more worried about Tier 3. According to the documents, 2,045 patients were affected. I don't know which products those 2000 patients were taking or utilizing. I'm curious how many of them were combination products. Small numbers? 1000? Half?

LCDR Hansen responded we will provide an answer when we can identify that number.

CAPT (Ret) Hostettler asked if it is a small or large number.

Lt Col Khoury interjects that there are about 1000 patients.

CAPT (Ret) Hostettler stated about half of the patients affected are taking combination products and the process to get those products is now more difficult if not impossible.

Lt Col Khoury says most of the patients are one and done. If they chose to get it, they can with the new copay.

CAPT (Ret) Hostettler said working through the PA as well.

Lt Col Khoury said correct. The Committee wanted to ensure the clinically appropriate and most cost effective agents are selected first for the patient and the benefit.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asked if there was an automated look back which would allow the patient to get through the PA process quicker than 6 weeks. If there was any automation that could be applied to that look back, that could be very worthwhile.

Lt Col Khoury asked what the 6 weeks was referring to.

CAPT (Ret) Hostettler said there are multiple steps to go through in order to get some of the combination products. That takes time and multiple visits. Anything you can do to reduce the time while still maintaining the step therapy would be beneficial to the patient. I understand that this could be done with an automatic look back through the system. I am just asking is that feasible in this situation?

Lt Col Khoury said there is not a way to do automation for this product.

UF/Tier 4/Not Covered and PA Implementation Period:

CAPT (Ret) Hostettler said thank you for the time and the 120 days to get that done. This decision impacts a lot of beneficiaries and more visits will be needed to make the change.

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 period for Psoriasis Agents.

- **Psoriasis Agents – Topical Psoriasis Agents UF/Tier 4/Not Covered Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

- **Psoriasis Agents – Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

- **Psoriasis Agents – UF/Tier 4/Not Covered, and PA Implementation Period**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

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

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

The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF:

- apomorphine sublingual film (Kynmobi)
- capmatinib (Tabrecta)
- elagolix/estradiol/norethindrone (Oriahnn)
- fenfluramine oral solution (Fintepla)
- lemborexant (Dayvigo)
- insulin lispro-aabc (Lyumjev)
- nimodipine oral syringe (Nymalize)
- octreotide acetate injection (Bynfezia Pen)
- osilodrostat (Isturisa)
- ozanimod (Zeposia)
- pemigatinib (Pemazyre)
- ripretinib (Qinlock)
- selpercatinib (Retevmo)
- selumetinib (Koselugo)
- tucatinib (Tukysa)

- NF:

  - bempedoic acid/ezetimibe (Nexlizet)
  - diclofenac epolamine 1.3% patch (Licart)
  - lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi)
  - leuprolide acetate injection (Fensolvi)
  - levonorgestrel/ethinyl estradiol transdermal system (Twirla)
  - minocycline 1.5% topical foam (Zilxi)

- Tier 4 (Not Covered):

  - halcinonide 0.1% topical solution (Halog)

    1. Halog topical solution was recommended for Tier 4 status as it has no clinical benefit relative to other high potency topical corticosteroids, and the needs of TRICARE beneficiaries are met by alternative agents.

       - Formulary alternatives to Halog topical solution include betamethasone propylene glycol 0.05% cream, clobetasol propionate 0.05% cream and ointment, clobetasol propionate/emollient 0.05% cream, desoximetasone 0.25% cream and ointment, fluocinonide 0.05% cream and ointment, fluocinonide/emollient base 0.05% cream, halobetasol propionate 0.05% ointment.

  - tazarotene 0.045% lotion (Arazlo)

    1. Arazlo lotion was recommended for Tier 4 status as it has no clinical benefit relative to other topical acne agents, and the needs of TRICARE beneficiaries are met by alternative agents.

2. Formulary alternatives to Arazlo lotion include adapalene (cream, gel, lotion), tazarotene (cream), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel).

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

The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- Topical Acne and Rosacea Agents: Applying step therapy criteria to new and current users of Zilxi foam that is currently in place for the other non-step-preferred rosacea agents, including Mirvaso and Soolantra, requiring a trial of topical metronidazole first.

- Insomnia Drugs: Applying manual PA criteria to new and current users of Dayvigo that is currently in place for the other dual orexin receptor antagonists for insomnia, requiring a trial of zolpidem ER (Ambien CR generic) and eszopiclone (Lunesta generic) first.

- Miscellaneous contraceptives: Applying manual PA criteria to new users of the Twirla patch and Phexxi vaginal gel.

- Oncologic drugs: Applying manual PA criteria to new users of Koselugo, Pemazyre, Qinlock, Retevmo, Tabrecta, and Tukysa.

- Applying manual PA criteria to new users of Fintepla, Isturisa, Licart patch, Nexlizet, Oriahnn, and Zeposia.

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

1. bempedoic acid/ezetimibe (Nexlizet) / bempedoic acid (Nexletol)
(Note that updates were also made to Nexletol which was reviewed in May 2020)

Manual PA is required for all new users of Nexletol and Nexlizet.

Manual PA Criteria: Nexletol and Nexlizet is approved if all criteria are met:

- Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization)

- Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following:

- History of clinical (ASCVD), including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA), peripheral artery disease (PAD) OR

- Heterozygous Familial Hypercholesterolemia (HeFH)

- For Nexletol:

  - Patient is taking concurrent ezetimibe and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR

  - Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR

- For Nexlizet:

  - Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started, and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) OR

- Patient is statin intolerant based on one of the following:

  - Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, cramp) with at least 2 statins OR
  - History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR

  - History of statin-associated rhabdomyolysis OR

- Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy)

  Non-FDA-approved uses other than use without concurrent statin not allowed.

  PA does not expire.

2. Capmatinib (Tabrecta)

Manual PA is required for all new users of Tabrecta.

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

- The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

- Patient is 18 years of age or older

- Must be prescribed by or in consultation with a hematologist/oncologist

- Patient will be monitored for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity

- Provider is aware and has counseled patient that capmatinib can cause photosensitivity and has counseled patients to avoid direct UV exposure

- 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.

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation.

  Non-FDA-approved uses are NOT approved except as noted above.

  PA does not expire.

3. diclofenac epolamine 1.3% patch (Licart)

Manual PA criteria apply to all new users of Licart.

Manual PA Criteria: Licart approved if all criteria are met:

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

- Patient is 18 years of age or older

- Patient cannot tolerate an oral NSAID due to renal insufficiency, history of gastrointestinal bleed, or other adverse events OR

- Patient has tried and failed TWO oral NSAIDs

Non-FDA-approved uses are not approved.

PA expires after 6 months.

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

4. elagolix/estradiol/norethindrone (Oriahnn)

Manual PA is required for all new users of Oriahnn.

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

- Patient is 18 years of age or older
- Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD)
- Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist
- Patient is not pregnant confirmed by (-) HCG
- Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment
- Patient does not have current or history of thrombotic or thromboembolic disorders or an increased risk for these events
- Patient is not a smoker over the age of 35 years
- Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs, or if the patient has a sudden unexplained partial or complete loss of vision, proptosis (abnormal protrusion of the eye), diplopia (double vision), papilledema (optic disc swelling), or retinal vascular lesions
- Patient does not have uncontrolled hypertension
- Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly
- Patient does not have osteoporosis

- Provider agrees to assess baseline and periodic bone mineral density
- Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes
- Patient does not have a history of breast cancer or other hormonally-sensitive malignancies
- Patient does not have known liver impairment or disease
- Provider agrees to counsel patients on the signs and symptoms of liver injury
- Patient does not have undiagnosed abnormal uterine bleeding
- Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors

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

  PA expires after 24 months (lifetime expiration).

5. fenfluramine oral solution (Fintepla)

Manual PA is required for all new users of Fintepla.

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

- Must be prescribed by a neurologist
- Patient has a diagnosis of Dravet Syndrome
- Must be used as adjunct therapy with other anticonvulsant medications
- Prescriber must abide by and the patient has been informed of the REMS program including safety risks and requirements of regular echocardiogram (ECHO) monitoring for valvular heart disease and pulmonary hypertension

  Non-FDA approved uses are not approved including for weight loss.

  PA does not expire.

6. lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi)

Manual PA criteria apply to all new users of Phexxi.

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

- Provider acknowledges that numerous contraceptives are available without a PA and are more effective than Phexxi (e.g. norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, and medroxyprogesterone injection); providers are encouraged to consider changing the prescription to a formulary contraceptive.

- Phexxi is being used for contraceptive purposes

- Patient has tried a nonoxynol-9 spermicide and has experienced significant adverse effects

  Non-FDA-approved uses are not approved.

  PA does not expire.

7. lemborexant (Dayvigo)

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

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

- Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance

- Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene

- Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release

- Patient has tried and failed or had clinically significant adverse effects to eszopiclone

- Patient has no current or previous history of narcolepsy

- Patient has no current or previous history of drug abuse

  Non-FDA-approved uses are not approved.

8. levonorgestrel/ethinyl estradiol transdermal system (Twirla)

Manual PA applies to new users of Twirla.

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

- Provider acknowledges that norelgestromin/ethinyl estradiol transdermal system (Xulane) and numerous other contraceptives are available for TRICARE patients that do not require a PA. Providers are encouraged to consider changing the prescription to Xulane or another formulary contraceptive.

- Patient has had an adverse reaction to Xulane that is not expected to occur with Twirla OR

- Patient has tried Xulane and could not tolerate it

- Patient does not have a contraindication to an estrogen-containing contraceptive (e.g., history of estrogen-dependent neoplasia, breast cancer, deep venous thrombosis (DVT)/ pulmonary embolism (PE), etc.)

- Patient's body mass index (BMI) is less than 30 kg/m2; note that Twirla is contraindicated in patients with a BMI ≥ 30 kg/m2

- Provider acknowledges that patients with a BMI between 25 to 30 kg/m2 have decreased contraceptive effectiveness per the FDA label

  Non-FDA-approved uses are not approved.
  PA does not expire.

9. minocycline 1.5% topical foam (Zilxi)

All new and current users of Zilxi are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream), which is the current step therapy requirements for Soolantra and Mirvaso.

Automated PA Criteria:

- The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days

Manual PA Criteria: If automated PA criteria is not met, Zilxi is approved if all criteria are met:

- Patient is 18 years of age or older

  1. Patient is at least 18 years of age and has the following diagnosis:

  2. For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea

- For Soolantra and Zilxi: Patient has inflammatory lesions (papulopustular) of rosacea

  AND

- Patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) AND

- Patient has tried and failed topical azelaic acid

  Non-FDA approved uses are not approved.

  PA expires in 365 days.

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

10. osilodrostat (Isturisa)

Manual PA applies to new users Isturisa.

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

- Patient is 18 years of age or older
- Documented diagnosis of Cushing's disease
- Patient has persistent or recurrent Cushing's disease despite pituitary surgery

OR

- Patient in whom pituitary surgery is not indicated
- Drug is prescribed by an Endocrinologist, Oncologist, or Neurosurgeon
- Provider agrees to correct hypokalemia or hypomagnesemia prior to starting Isturisa
- Provider agrees to obtain baseline electrocardiogram (ECG) prior to starting Isturisa and use with caution in patients with risk factors for QTc prolongation

- Patient will be monitored closely for hypocortisolism and potentially life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary

- Patient will be monitored for hypokalemia, worsening of hypertension, edema, and hirsutism

Non-FDA-approved uses are not approved.

PA does not expire.

11. ozanimod (Zeposia)

Manual PA applies to new users of Zeposia.

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

- Prescribed by a neurologist

- Patient has a documented diagnosis of relapsing forms of multiple sclerosis (MS)

- Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunamide [Aubagio])

- Patient has not previously failed a treatment course of fingolimod (Gilenya)

- Patient has not previously failed a treatment course of siponimod (Mayzent)

- Provider acknowledges that all recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), and macular edema screening as indicated

- Zeposia will not be used in patients with significant cardiac history, including:

    1. Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization

    2. Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker

Non-FDA-approved uses are not approved.

PA does not expire.

12. pemigatinib (Pemazyre)

Manual PA applies to new users of Pemazyre.

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

- The patient has a diagnosis of pathologically confirmed unresectable or advanced/metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist/oncologist
- Patient will be monitored for ophthalmologic disorders including pre-treatment screening for retinal disorders
- Patient will be monitored for hyperphosphatemia
- 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
- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

Non-FDA-approved uses are not approved except as noted above.

PA does not expire.

13. ripretinib (Qinlock)

Manual PA applies to new users of Qinlock.

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist/oncologist
- Patient has pathologically confirmed advanced gastrointestinal stromal tumor (GIST)
- Patient has experienced disease progression on or had documented intolerance to imatinib (Gleevec)
- Patient has experienced disease progression on or had documented intolerance to sunitinib (Sutent)
- Patient has experienced disease progression on or had documented intolerance to regorafenib (Stivarga)
- Female patients of childbearing age are not pregnant confirmed by (-) HCG
- Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment
- Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy
- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

Non-FDA-approved uses are not approved except as noted above.

PA does not expire.

14. selpercatinib (Retevmo)

Manual PA applies to new users of Retevmo.

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

- Prescribed by or in consultation with a hematologist/oncologist
- Patient has one of the following indications:

1. Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)

2. Patients 12 years and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy

3. Patients 12 years and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

- Patient will be monitored for hepatotoxicity and QT prolongation
- Patient does not have uncontrolled hypertension
- Provider is aware and has counseled patient that selpercatinib can cause life-threatening hemorrhage and allergic reactions
- 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
- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

Non-FDA-approved uses are not approved except as noted above.

PA does not expire.

15. selumetinib (Koselugo)

Manual PA applies to new users of Koselugo.

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

- Prescribed by or in consultation with a hematologist/oncologist
- Patient is diagnosed with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas
- Patient will be monitored for cardiomyopathy including a left ventricular functional assessment prior to initiation and at regular intervals during treatment

- Patient will be monitored for ocular toxicity including retinal vein occlusion and retinal detachment via ophthalmic exams prior to initiation and at regular intervals during treatment

- Patient will be monitored for gastrointestinal toxicity and will receive co-administration of an anti-diarrheal if patient develops loose stools

- Patient will be monitored for severe skin rashes

- Patient will be monitored for rhabdomyolysis

- Provider is aware that Koselugo contains Vitamin E, which can increase bleeding risk if co-administered with a Vitamin K antagonist (e.g., warfarin)

- 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

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

  Non-FDA-approved uses are not approved except as noted above.

  PA does not expire.

16. tucatinib (Tukysa)

Manual PA applies to new users of Tukysa.

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

- The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting

- Patient is 18 years of age or older

- Medication is prescribed by or consultation with a hematologist or oncologist

- Tucatinib will be used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda)

- Provider agrees to monitor for hepatotoxicity

- Patient has been counseled on risk of diarrhea

- 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 the cessation of therapy

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

  Non-FDA-approved uses are not approved except as noted above.

  PA does not expire.

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

The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 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:

- There were a total of 23 new drugs reviewed, with 15 drugs that will go to UF status. There were 6 drugs recommended to maintain NF status, and two Tier 4 candidates.

- Prior authorization criteria will apply to 16 of the drugs. The PAs for 12 of the drugs are in classes were PA is already required. "No grandfathering," where both new and current users will be affected by the PA, is recommended for two of the drugs – the

insomnia drug Dayvigo and acne drug Zilxi. There is already step therapy for these two classes, and there are several alternative formulary agents available.

- The two drugs recommended for Tier 4 status are in the topical steroid class (Halog topical solution) and acne drugs (Arazlo lotion), where there are numerous alternatives. The Committee vote was unanimous here. The Tier 4 drugs will affect about 50 patients.

    1. For Halog, this is a new topical solution that does not offer any benefit over the other topical steroids. At the August 2019 meeting, Halog cream and ointment were designated Tier 4, so this follow-on product will also be Tier 4.

    2. Arazlo contains a concentration of 0.045% tazarotene, which is slightly lower than what has been previously marketed. In the Psoriasis drug class review discussed earlier, the concentration of the 0.1% tazarotene cream which is also indicated for acne will be UF, with the 0,05% concentrations made NF. Several other retinoids are available for treating acne.

    3. We will ensure patient have sufficient time to modify their current regimen, in line with prior Tier 4 recommendations.

- I have a few comments about two of the new drugs designated NF with a PA

    1. **Twirla** is the second birth control patch available on the market. The Committee felt this drug should be NF, based on clinical issues alone, since it is less effective than other contraceptives, especially in heavier weight women. The Ob-gyn Committee member agreed with the NF formulary status, and also recommended having a PA in place early, because of the concerns of reduced efficacy in women with higher body weights. So far no patients have been started on Twirla. The Committee did feel that having the NF status with a PA would be appropriate, rather than going with Tier 4 status. This would ensure access to this drug for the patients that may benefit from this agent.

    2. The **Licart diclofenac patch** was also recommended for NF status with a PA. The topical pain medications were reviewed at the Feb 2020 meeting, and another similar diclofenac patch (Flector) was made Tier 4. Licart was approved based on the data from Flector, and does not offer a benefit over the oral NSAIDs or diclofenac gel (Voltaren). Although this is a medication labeled for acute pain for minor muscle strains and sprains, the oral NSAIDS will have a rapid onset of effect, and other non-pharmacological treatments like ice and elevations are frequently used. We did reach out to providers who stated overall, they didn't feel that this product was needed. The PA was placed early for Licart, because the committee was actually fine with having this type of drug be Tier 4. We wanted to avoid having patients start on the drug, and then have the PA apply at the next fill. So far there are no patients on Licart.

Summary of Panel Questions and Comments:

UF/Tier 4 Not Covered Recommendation:

Dr. Peloquin asked why Licart wasn't it moved to Tier 4. It is similar to other agents that were moved to Tier 4.

Dr. Lugo clarified, why diclofenac epolamine 1.3% patch (Licart) wasn't made Tier 4.

Dr. Peloquin is curious why other similar medications were made Tier 4 and this one wasn't. LCDR Raisor replied each review is a combination of a clinical and cost analysis. The committee looking at clinical and believed Licart could fall in line with Tier 4. However, based on the additional cost evaluation, the Committee felt that could be available as an option for patients and decided to go with Tier 3 with a PA.

CAPT (Ret) Hostettler states that as a beneficiary, I commend you for making it Tier 3 with a PA as opposed to NF or completely Tier 4. However, I would've posed the question differently in why didn't the Committee designate the other products Tier 3 with a PA as well.

PA Criteria:

Dr, Peloquin stated, so that I understand, due to the market drugs complexity and the requirement to make sure it is appropriately prescribed by a specialist. I believe that some of the PA criteria goes very much in to practice of the prescriber's actions and what they should do rather than criteria for the drugs. An example, there was a gynecologist or specialist prescribing the product. The criteria is lays out a lot of the "provider will" or the "provider agrees to". Those 15-20 questions and other is just validating that the prescriber is practicing appropriately.

Dr. Lugo repeated his statement. You're saying for the agents where we require a specialist to prescribe in the first place, why is the PA so complexed?

Dr. Peloquin says some of the criteria goes to what a specialist should or shouldn't do or would likely do because of the specialist's understanding of how to manage and monitor the product. Yes, Dr. Lugo that was a good summary.

Dr. Lugo said that's a fair question. In some of the PAs, we allow for the specialist to prescribe or in consultation with the specialist. We want to be sure that safety concerns are there and that nothing accidentally falls through the loop. That's something they can take back.

CAPT (Ret) Hostettler adds to Dr. Peloquin's comments. The criteria almost takes the words practice of medicine out of the question. You're basically doing it my way or the highway is what it looks like that to me. I understand the concern for safety, etc. but it seems to go further than that at times.

Dr. Lugo added that it's important to them that they define an appropriate scope of practice and ensure safety and appropriate usage. They appreciate the comments.

CAPT (Ret) Hostettler requested an explanation on page 29 for Nexlizet. I got confused with the "Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet." Can you explain that or help me understand.
Dr. Lugo says that Nexlizet has ezetimibe in it. So you can't say that you can't have a tolerance to ezetimbe to get Nexlizet. It's a combo agent. Nexlatol is a single agent. Nexlizet is a combo.

CAPT (Ret) Hostettler asked if Licart has an automated PA.

Dr. Lugo says she doesn't think that Licart Diclofenac patch had an automated PA. She'll defer to CDR Raisor.

CDR Raisor clarifies that there is no automation on Licart. It is for acute use.

CAPT (Ret) Hostettler has a question regarding Minocycline 1.5% topical foam (Zilxi). This product has an automated PA criteria. At the end of the criteria it states new prescriptions after it passed the automated criteria, they come back a year later with another prescription. The patient has to go back through the entire manual process again. Of course, they won't meet the 180 days but they were when they started the product. That just seems like too much to me.

Dr. Lugo said there is automation on that product and it will look back for a history Zilxi. It looks back for the other preferred agents and a history of Zilxi.

CAPT (Ret) Hostettler says he's looking at the PA criteria – says no renewal allowed. When the PA expires, the next fill/refill requires a new PA. Maybe I don't understand the process. If they cleared with the automated process before their next prescription for that product, minocycline, then their next prescription would not require a PA. It also stated that new and current users are impacted by the decision.

Dr. Lugo said that many of the acne agents have an expiration of one year also. So it's not just this agent. They also don't need a manual PA if they meet the automation criteria. Therefore no renewal is required.

CAPT (Ret) Hostettler replied that the automation only goes back 180 days.

Dr. Lugo said that's just the automated piece, and at that point it will turn to a manual.
CAPT (Ret) Hostettler said after 365 days, they will require a manual PA.

Dr Lugo said that is the way it is written. Yes, there will be another PA.

CAPT (Ret) Hostettler asked if that was the intent of the committee.

Dr. Lugo replied yes.

CAPT (Ret) Hostettler clarifies the product is approved for a year. After the year, the patient is required to go back through the process to obtain another PA, if needed. What value does that have other than slowing process down and disrupting care potentially?

Dr. Lugo replied that this is not an acute use medication. It's for acne. Secondly, there are numerous minoycline alternatives or acne alternatives. This is just another foam. There are other topical minocyclines that are easy to get without any PA whatsoever. It's another formulation that's a foam.

CAPT (Ret) Hostettler says he doesn't understand why it is prescribed to the patient for a year then stop them from continuing that therapy and try to force them into something else. You should have done that a year ago. I f you're going to go down that path. He further states the PA criteria for Qinlock states the patient has experienced disease progression on or had documented intolerance to three (3) drugs (Gleevec, Sutent, and Stivarga). This product, new to the market, has no advantage to any of the other three (3) drugs. They would have to use all three of those first.

Dr. Lugo said this one is for last line. Actually it's in their label as an indication.

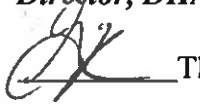
CAPT (Ret) Hostettler said he didn't know that either. Thank you.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, 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 Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

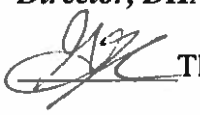
   These comments were taken under consideration prior to my final decision.

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

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Mr. Hostettler will concur with the exception of the minocycline. I think that should only apply to new users.

  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: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

V. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

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

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for tramadol 100 mg immediate release (IR) tablets and Trinaz (regardless of the woman's age) in new and current users, due to significant cost differences compared with numerous available alternative agents.

1. Narcotic Analgesics and Combinations—tramadol 100mg IR tablet

Cost-effective formulations of tramadol IR 50 mg tablets have been widely available from several manufacturers. The branded Ultram 100 mg tablets have been discontinued. A single manufacturer is now marketing a 100 mg IR tablet that is not cost-effective. The Committee recommended manual PA to encourage use of tramadol 50 mg IR tablets and to discourage the use of the 100 mg strength.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of tramadol 100mg IR.

Manual PA Criteria: tramadol 100mg IR is approved if all criteria are met:

- Provider is aware and acknowledges that tramadol 50 mg IR is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred tramadol 50 mg immediate release tablets.

- The provider must explain why the patient requires tramadol 100 mg IR tablets and cannot take the cost-effective tramadol 50 mg IR tablets.

  Non-FDA-approved uses are not approved.

  PA does not expire.

2. Vitamins: Prenatal—prenatal multivitamin (Trinaz)

Trinaz is a prenatal dietary supplement manufactured by a single company and requires a prescription prior to dispensing. The primary ingredients of Trinaz are similar to that found in Azesco and Zalvit, which require manual PA. Several prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria. Manual PA criteria were recommended for Trinaz, to require a trial of cost-effective formulary prenatal vitamins first.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of Trinaz, regardless of the woman's age.

Manual PA Criteria: Azesco, Zalvit, or **Trinaz** is approved if all criteria are met:

- Provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, and Prenatal Plus DHA are the preferred products and are covered without a prior authorization for women who are under the age of 45 years and planning to become pregnant or who are pregnant. The provider is encouraged to consider changing the prescription to one of these agents.

- The provider must explain why the patient requires Azesco, Zalvit or Trinaz, and cannot take the available alternatives.

Non-FDA-approved uses are not approved.

PA does not expire.

B. New Manual PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria manual PA criteria for Striverdi Respimat in new users and for Gattex in new users.

1) Pulmonary-2 Agents: Long-Acting Beta Agonists (LABAs)—olodaterol (Striverdi Respimat)

Striverdi Respimat was designated as UF when reviewed at the February 2016 P&T Committee meeting. It was the sixth marketed LABA oral inhaler approved for maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). The LABA oral inhalers have seen declining utilization, primarily due to safety concerns, and have been largely replaced by the combination LABA/inhaled corticosteroid products (e.g., Advair) and long-acting muscarinics (e.g., Spiriva). There has been a significant price increase for Striverdi Respimat. Manual PA was recommended to require a trial of a widely used and cost effective alternative and are as follows:

Manual PA criteria apply to new users of Striverdi Respimat.

Manual PA Criteria: Striverdi Respimat is approved if all criteria are met:

- The patient has tried and failed salmeterol (Serevent Diskus) OR
- The patient is unable to produce inspiratory flow necessary to use a dry powder inhaler

Non-FDA-approved uses are not approved.

PA does not expire.

2) Gastrointestinal-2 Agents—teduglutide (Gattex)

Gattex is approved for patients with chronic short bowel syndrome (SBS) who are dependent on total parenteral nutrition (TPN), despite aggressive use of conventional measures. The product labeling states the drug should be discontinued in patients where minimal or no response is noted (shown as a clinically meaningful reduction in parenteral support or reduction in days requiring parenteral support), or who experience intolerable side effects. Gattex was identified as a high-cost specialty drug with a potential for off-label use. Provider feedback was solicited to develop manual PA criteria to ensure appropriate use for the small patient population who will benefit, consistent with the package labeling. Manual PA criteria will apply to new patients, with renewal criteria required for the patient to continue therapy after initial approval.

The manual PA criteria are as follows:

Manual PA criteria apply to new users of Gattex.

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

- Patient is 1 year of age or older.
- Gattex is prescribed by or in consultation with a gastroenterologist
- Patient has a documented diagnosis of Short Bowel Syndrome
- The patient is currently receiving parenteral nutrition on 3 or more days per week

Non-FDA-approved uses are not approved including patients not receiving parenteral nutrition.
PA expires after 6 months. Renewal PA criteria: expires in one year.

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

- Documented improvement (a decrease from baseline) in the weekly volume of parenteral nutrition or a reduction in the number of days requiring parenteral support

C. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the following implementation periods.

- **PAs for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5):** (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for tramadol 100 mg IR tablets and Trinaz will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

- New PAs: (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for Striverdi Respimat and Gattex in new users will become effective the first Wednesday 60-days after the signing of the minutes.

Summary of Physician's Perspective:

There were four drugs where new PA criteria were recommended.

- **Narcotic Analgesics and Combinations—tramadol 100mg IR tablet** The original Ultram 50 mg tablets have been available for several years in cost-effective generic formulations, and are widely used. This new product is a 100 mg tablet that is

significantly more expensive than the 50 mg tablets. We've had several examples of new products that are minor updates of existing formulations that offer no value over the original products. The Committee did not see any clinical reason why a patient should not be able to take two of the 50 mg tablets. We will mail letters to the patients, since current users will be affected by the PA.

- **Prenatal Vitamin (Trinaz) –** This prenatal vitamin is a supplement that the manufacturer has marketed as requiring a prescription; it is not an FDA-approved drug. Other prenatal vitamins similar to this product also have PAs (Zalvit in February 2020, and Azesco in August 2019). This product is significantly more expensive than the other prescription prenatal vitamins. We are treating this product the same way we've done with the other supplements.

- For the last two products, the **Striverdi Respimat inhaler and the short bowel syndrome drug Gattex**, the PAs will apply only to new users, as existing patients will be grandfathered.

    1. For Striverdi, the PA will require the patient to try the most commonly used Serevent inhaler first.

    2. For Gattex, the GI specialists we reached out to did feel that a PA would be reasonable.

Summary of Panel Questions and Comments:

CAPT (Ret) Hostettler asked for the cost of the 100mg of the tramadol versus the 50 mg. Two (2) tablets is more cost effective than then 100mg.

MAJ Davies replied yes, that is correct. There was a pre-meeting before and the Panel mentioned commercial access for looking up drug cost. I implore you to look up drug cost for that one.

CAPT (Ret) Hostettler asked what is the formulary position of tramadol 100 mg? Is it UF with PA or NF with PA?

MAJ Davies repeated that he's looking for the current formulary position for tramadol. It's currently UF and no PA. This would be adding the PA to it.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, PA Criteria and UF and PA implementation plan for the New Manual PA Criteria.

- **New Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

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

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Director, DHA:

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

IX. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

A. Updated Manual PA Criteria Updated PA Criteria for Reasons other than New FDA Indications, NCCN Guideline Updates, or Age Ranges

Updates to the manual PA criteria and step therapy for several drugs were recommended due to a variety of reasons, including safety information, age indications, new FDA-approved indications, and availability of cost-effective alternative treatments. The updated PAs and step therapy outlined below will apply to new users with the exceptions of isotretinoin (Absorica and Absorica LD) and minocycline ER (Solodyn) which will apply to new and current users.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Absorica, Absorica LD, Solodyn and generics, and Addyi.

The updates are as follows, with the changes in bold and strikethrough lettering:

1. **Gynecological Agents Miscellaneous—flibanserin (Addyi)**—Manual PA criteria for Addyi were initially recommended at the November 2015 P&T Committee meeting. In October 2019, the FDA removed the Addyi risk evaluation and mitigation strategy (REMS) program and alcohol contraindication; now the boxed warning outlines the risks of concurrent alcohol consumption with Addyi. The Committee agreed to update the manual

PA in new users to reflect these safety changes, and to include criteria similar to other agent in the class, bremelanotide (Vyleesi), regarding cognitive-behavioral therapy and counseling.

Manual PA criteria apply to new users of Addyi. Updates are in bold and strikethrough.

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

- **Patient is 18 years of age or older**
- The drug is prescribed for a premenopausal female with hypoactive sexual desire disorder (HSDD) not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance
- **Patient has been counseled to wait 2 hours after consuming 1 or 2 standard alcoholic drinks before taking Addyi at bedtime or to skip their Addyi dose if they have consumed 3 or more standard alcoholic drinks that evening. After taking Addyi, the patient should not use alcohol until the following day**
- Patient does not have hepatic impairment (Child-Pugh score > 6)
- Patient not on a concomitant moderate or strong CYP3A4 inhibitor (e.g. ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)
- ~~Prescription written from provider who is certified/enrolled in the flibanserin REMS program~~
- **The patient has been informed that other treatment options such as cognitive-behavior therapy, sexual therapy, or couples therapy, may provide benefit without risk of side effects**

Non-FDA-approved uses are not approved.

PA expires after 3 months. Renewal PA criteria: will be approved indefinitely.

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

- Patient has documented improvement in symptoms without serious side effects and continues to abstain from alcohol

2. **Acne Agents: Isotretinoids—isotretinoin (Absorica, Absorica LD)—**Several AB-rated generic formulations of the original proprietary product Accutane are marketed (e.g., Amnesteem, Claravis, Myorisan). Absorica and Absorica LD are new isotretinoin products

specifically formulated to allow for absorption without regard to meals. Other than patient convenience, they offer no compelling advantages over generic isotretinoin for patients with recalcitrant acne. Generic formulations of Absorica are expected in 2021. Existing PA criteria from November 2015 for Absorica and Absorica LD allow use if the patient is unable to comply with the dietary requirements for the generic products. The existing manual PA criteria for Absorica and Absorica LD, were updated to require a trial of generic isotretinoin first in new and current users, due to cost effectiveness.

Manual PA criteria apply to new and current users of Absorica and Absorica LD.

Manual PA Criteria: Absorica and Absorica LD are approved if all criteria are met:

- **The provider acknowledges that generic isotretinoin products (Amnesteem, Claravis, Myorisan) are available without a PA. Providers are encouraged to consider changing the prescription to one of these agents**

- **Patient has tried and failed at least one of the following oral isotretinoin products: Amnesteem, Claravis, or Myorisan, AND**

- Patient is unable to comply with the dietary requirements of an AB-rated generic oral isotretinoin (e.g., Amnesteem, Claravis or Myorisan).

  Non-FDA-approved uses are not approved.

  PA does not expire.

3. **Antibiotics: Tetracyclines—minocycline ER (Solodyn, generics)—**The February 2017 Tetracycline drug class review concluded there was no data to support that minocycline ER (Solodyn, generic) formulations are more effective or safer than generic minocycline IR preparations for treating acne. There is a substantial cost difference between the generic IR and ER formulations. Step therapy currently requires a trial of generic doxycycline IR and generic minocycline IR first. The existing Solodyn PA criteria were updated in new and current users to also require the provider to state the clinical reason as to why the patient cannot take generic minocycline IR. Automated step therapy will no longer apply. The new PA criteria will not expire, so patients meeting the updated criteria will not be required to fill out renewal criteria.

   Manual PA criteria apply to new and current users of minocycline ER and brand Solodyn. Updates are in bold and strikethrough.

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

   - **Provider acknowledges that minocycline immediate release (IR) is available to DoD beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to minocycline IR.**

- Patient has acne with inflammatory lesions AND

- ~~Patient is unable to tolerate generic minocycline IR due to gastrointestinal adverse events~~

- **The provider must describe why the patient requires minocycline extended release and cannot be treated with minocycline immediate release.** Non-FDA-approved uses are not approved.

  PA does not expire.

  The following section was not recorded but was part of the items updated as part of the PA Criteria. The items addressed were commented on by the P&T Chair, Dr. Kugler, and officially voted on by the BAP at this meeting. They were available in the background materials provided to the Panel. They are included here for completeness.

A. Updated PA Criteria for New FDA Indications, NCCN Guideline Updates, or Age Ranges

Several drugs had updates to PA criteria. Note that since these updates allow for expanded indications or broader age ranges, the updated PAs are not detailed as minor changes were made. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the updates to the manual PA criteria for Aczone, Ofev, and Dupixent, the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs Humira, Stelara, Taltz, and Cosentyx.

The updates are as follows:

1) **Acne Agents: Topical Acne and Rosacea—dapsone 5% and 7.5% gel (Aczone)—**Aczone 7.5% gel is only available in a proprietary formulation; however, generic dapsone 5% gel was first marketed in October 2017. Aczone 7.5% recently received approval for treating acne in patients as young as 9 years of age. Generic dapsone 5% has not been studied in patients younger than age 12. After reviewing clinical trial data, the Committee agreed to remove the age restrictions for both dapsone formulations. The committee also agreed that dapsone was unlikely to be used in children younger than 9, as acne is not commonly seen in this age group. Providers can therefore use the more cost-effective generic dapsone 5% rather than Aczone 7.5% for children. The PA criteria still requires a diagnosis of acne vulgaris and a trial of at least 3 step preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

2) **Respiratory Interleukins—dupilumab injection (Dupixent)—**Manual PA criteria for Dupixent were updated to reflect a lowered age indication for pediatric patients with moderate to severe atopic dermatitis 6 years of age or older; the previous age was 12 years. Note that the current age requirements for the other indications are not changed, including patients older than 18 years for chronic sinusitis and for patients as young as 12 years for asthma.

3) **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)—nintedanib (Ofev)—**The IPF drugs were reviewed for formulary status in May 2017, with step therapy requiring a trial of pirfenidone (Esbriet) prior to Ofev. Ofev recently gained a new indication for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. Esbriet lacks this indication, therefore the step therapy requirements for a trial of Esbriet first will not apply here. The renewal criteria from the May 2017 class review was also clarified to exclude concomitant use of Esbriet and Ofev.

4) **Oncologic Agents: ovarian cancer [niraparib (Zejula), olaparib (Lynparza), and rucaparib (Rubraca)]; melanoma [encorafenib (Braftovi)] and multiple myeloma [selinexor (Xpovio)]**—Updates to the manual PA criteria for these oncologic agents reflects more detailed safety information, including standardized embryo-fetal toxicity information and male reproductive concerns. New FDA-approved indications or NCCN guideline-supported indications were also updated. A synopsis of the changes are summarized below.

   - **niraparib (Zejula)**—Allow use for the new FDA-approved indication as a first-line treatment for ovarian cancer

   - **olaparib (Lynparza) and rucaparib (Rubraca)**—Updated for the new FDA-approved indications for treating prostate cancer, and added a urologist as an allowable prescriber, in addition to a hematologist/oncologist. The Lynparza criteria was also updated to allow use for a new pancreatic cancer indication.

   - **encorafenib (Braftovi)**—Allow use for the new FDA-approved indication for treating colorectal cancer

   - **selinexor (Xpovio)—**Allow use for the new FDA-approved indication for treating diffuse large B-cell lymphoma

5) **Targeted Immunomodulatory Biologics (TIBs)—**Several updates for the TIBs including both off-label and new FDA-approved indications and

clarifications of step therapy requirements were made. A synopsis of the changes are summarized below.

- **adalimumab (Humira)—**Allow off-label use for moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids, based on supporting clinical data. Additionally, patients with PG or fistulizing Crohn's Disease (CD) can use Humira without a trial of non-biologic systemic therapy (e.g., methotrexate, azathioprine, sulfasalazine, mesalamine, or corticosteroids) first.

- **ustekinumab (Stelara)—**Updated the PA to include the new indication for pediatric patients down to the age of 6 years for plaque psoriasis; the previous indication was down to the age of 12 years. A trial of Humira is not required in pediatric patients 6 to 17 years old with a diagnosis of plaque psoriasis, since Humira is not indicated for children for this condition.

- **ixekizumab (Taltz)—**Updated the criteria to allow use in adults with non-radiographic axial spondyloarthritis (nr-axSpA); a trial of both Humira and Cosentyx are required first for this indication. The criteria were also updated for the new indication of plaque psoriasis in pediatric patients 6 to 17 years old. Note that a trial of Humira and Cosentyx are not required in patient's age 6 to 17 years. However, the requirement to try Stelara first for children between 6 to 17 years of age for this indication still applies.

- **secukinumab (Cosentyx)—**Updated to allow for the new nr-axSpA indication, requiring a trial of Humira first. Also updated to include coverage for moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and to remove "psoriasis of the scalp", since plaque psoriasis also encompasses all body areas.

B. Updated Manual PA Criteria—Implementation Plan

The P&T Committee recommended the following implementation periods:

- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Absorica, Absorica LD, and Solodyn in new and current users will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to the beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Aczone, Addyi, Dupixent, Ofev, and the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs Humira, Stelara, Taltz, and Cosentyx in new users will become effective the first Wednesday 60-days after the signing of the minutes.

Summary of Physician's Perspective:

- There were 17 drugs where we updated the PA criteria. Here, we had updates from nine drug classes; most of the changes were to allow use in expanded patient populations, for example pediatric patients or for new oncology indications.

- For the two acne drugs from two different classes – Absorica and Solodyn, we are strengthening the existing PAs, because the respective generics are significantly less costly, and there is no difference in efficacy or safety. We are taking the approach of changing the PA, rather than recommending these Tier 4 products at this time. Both new and current users are affected, so patients will be receiving letters.

- As you can see from the changes made at this meeting, a lot of time and effort is made to ensure that the PAs are updated to reflect the current package inserts.

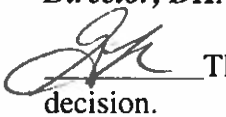
Summary of Panel Questions and Comments:

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

- **Updated PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

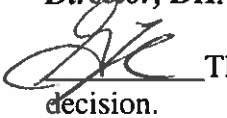
  Director, DHA:

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

- **Updated PA Criteria – Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  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 August 2020

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's meeting in the subject of this report.

- AAD – American Academy of Dermatology
- AASM – American Academy of Sleep Medicine
- ACS – Acute Coronary Syndrome
- ADR – Adverse Drug Reactions
- ASCO – American Society of Clinical Oncology
- ASCVD – Atherosclerotic Cardiovascular Disease
- AV - Atrioventricular
- BAP- Benefit Advisory Panel
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- CAD - Coronary Artery Disease
- CBC – Complete Blood Count
- CFR – Code of Federal Regulation
- CK – Creatine Kinase
- CMA – Cost-Minimization Analysis
- COVID – Corona Virus Disease
- CPAP – Continuous Positive Airway Pressure
- DEA – Drug Enforcement Agency
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DNRI – Dopamine and Nonrepinephrine Reuptake Inhibitor
- DoD – Department of Defense
- ECG -Electrocardiogram
- ECHO - Echocardiogram
- EDS – Excessive Daytime Sleepiness
- ER – Extended Release
- ESS – Epsworth Sleepiness Scale
- FACA – Federal Advisory Committee Act
- FDA – Federal Drug Administration
- FMB – Formulary Management Branch
- GIST -Gastrointestinal Stromal Tumors
- HeFH – Heterozygous Familial Hypercholesterolemia
- ILD – Interstitial Lung Disease
- IPF – Idiopathic Pulmonary Fibrosis
- IUD – Intrauterine Device

- LABAs – Long-Acting Beta Agonists
- LFT – Liver Function Tests
- MAOI – Monoamine Oxidase Inhibitor
- MET – Mesenchymal-epithelial Transition
- MHS – Military Health System
- MS – Multiple Sclerosis
- MSLT – Mean Sleep Latency Time
- MTC – Mutant Medullary Thyroid Cancer
- NCCN – National Comprehensive Cancer Network
- NF – Non Formulary
- NSCLC – Mon-Small Cell Lung Cancer
- OATP – Organic Anion Transporting Polypeptide
- OSA – Obstructive Sleep Apnea
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- PAD – Peripheral Artery Disease
- REMS – Risk Evaluation and Mitigation Strategy
- TIA – Transient Ischemic Attack
- TIBs – Targeted Immunomodulatory Biologics
- UF – Uniform Formulary
- ULN – Upper Limit of Normal
- VZV – Varicella Zoster Virus
- WBC – White Blood Cell

X. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT AUGUST 2020

Table of Implementation Status of UF Recommendations/Decisions Summary

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Sleep Disorders: Wakefulness Promoting Agents Subclass	▪ armodafinil ▪ modafinil ▪ sodium oxybate (Xyrem)	▪ solriamfetol (Sunosi) ▪ pitolisant (Wakix)	▪ None	Pending the first Wednesday one week after the signing of the minutes	N/A – no copay changes or new PAs; only minor updates to PAs

WBC Stimulants: Filgrastims Subclass and Pegfilgrastims Subclass	FILGRASTIMS ▪ tbo-filgrastim vial and syringe (Granix) ▪ filgrastim-aafi vial and syringe (Nivestym) ▪ filgrastim vial and syringe (Neupogen) ▪ filgrastim-sndz syringe (Zarxio) PEGFILGRASTIMS ▪ pegfilgrastim-cbqv syringe (Udenyca) ▪ pegfilgrastim-jmdb syringe (Fulphila) ▪ pegfilgrastim syringe (Neulasta) ▪ pegfilgrastim on-body injector (Neulasta OnPro) ▪ pegfilgrastim-bmez syringe (Ziextenzo)	FILGRASTIMS ▪ None PEGFILGRASTIMS ▪ None	FILGRASTIMS ▪ None PEGFILGRASTIMS ▪ None	Pending signing of the minutes / 60 days	N/A - New PAs for non-step-preferred drugs affect only new users.
Psoriasis Agents	▪ calcipotriene 0.005% ointment (Calcitrene, generics) ▪ calcipotriene 0.005% cream (Dovonex, generics) ▪ calcipotriene 0.005% solution (generics) ▪ tazarotene 0.1% cream (generics)	▪ calcipotriene 0.005% foam (Sorilux) ▪ calcitriol 3 mcg/g ointment (Vectical, generics) ▪ calcipotriene 0.005%/betamethasone 0.064% ointment (Taclonex, generics) ▪ calcipotriene 0.005%/betamethasone 0.064% foam (Enstilar) ▪ tazarotene 0.1% gel (Tazorac) ▪ tazarotene 0.05% cream (Tazorac) ▪ tazarotene 0.05% gel (Tazorac)	▪ calcipotriene 0.005%/betamethasone 0.064% suspension (Taclonex)	Pending signing of the minutes / 120 days	<u>Unique Users Affected (NF candidates)</u> Mail – 583 MTF – 442 Retail – 1020 Total – 2045 <u>Unique Users Affected (Tier 4 candidates)</u> Mail – 115 MTF – 88 Retail – 149 Total: 352 **Note that the info in the BAP Background document is incorrect. The document says 555 users but it is 352 users**

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
tramadol 100 mg IR tab	0	20	90	110
prenatal MVI (Trinaz)	0	0	0	0
isotretinoin (Absorica and Absorica LD)	0	76	153	229
minocycline ER (Solodyn)	21	8	18	47

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 23, 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
- Dr. Karen Dager, Health Net Federal Services
- 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

- None

Agenda

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

- Welcome and Opening Remarks
- Public Citizen Comments
- Therapeutic Class Reviews

1. Drug Class Reviews

    a. *Sleep Disorders: Wakefulness Promoting Agents Subclass*
    b. *White Blood Cell Stimulants: Filgrastims and Pegfilgrastims*
    c. *Psoriasis Agents*

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

    a. *apomorphine sublingual film (Kynmobi) – new formulation of apomorphine for Parkinson's disease*

    b. *bempedoic acid/ezetimibe (Nexlizet) – antilipidemic-1 fixed dose combination for atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH)*

c. *capmatinib (Tabrecta) – oncological agent for non-small cell lung cancer (NSCLC)*

d. *diclofenac epolamine 1.3% patch (Licart) – NSAID patch for acute pain*

e. *elagolix/estradiol/norethindrone (Oriahnn) – luteinizing hormone-releasing hormone agonists-antagonists for heavy bleeding with fibroids*

f. *fenfluramine (Fintepla) – anticonvulsant for Dravet syndrome*

g. *halcinonide 0.1% topical solution (Halog) – high potency topical corticosteroid*

h. *insulin lispro-aabc (Lyumjev) – another insulin lispro formulation for diabetes mellitus*

i. *lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi) – miscellaneous contraceptive vaginal gel for on-demand contraception*

j. *lemborexant (Dayvigo) – dual orexin receptor antagonist for insomnia*

k. *leuprolide acetate injection (Fensolvi) – leuprolide formulation for central precocious puberty*

l. *levonorgestrel/ethinyl estradiol transdermal system (Twirla) – Miscellaneous contraceptive*

m. *minocycline 1.5% topical foam (Zilxi) – topical formulation of minocycline for rosacea*

n. *nimodipine oral syringe (Nymalize) – new oral syringe formulation of nimodipine*

o. *octreotide acetate injection (Bynfezia Pen) – new formulation of octreotide in a pre-filled pen*

p. *osilodrostat (Isturisa) – miscellaneous endocrine agent for Cushing's disease*

q. *ozanimod (Zeposia) – Multiple Sclerosis agent*

r. *pemigatinib (Pemazyre) – oncological agent for cholangiocarcinoma*

s. *ripretinib (Qinlock) – oncological agent for gastrointestinal stromal tumors (GIST)*

t. *selpercatinib (Retevmo) – oncological agent for NSCLC and thyroid cancer*

u. *selumetinib (Koselugo) – oncological agent for Neurofibromatosis*

v. *type 1*

w. *tazarotene 0.045% lotion (Arazlo) – topical acne and rosacea agent*

x. *tucatinib (Tukysa) – oncological agent for breast cancer*

3. Utilization Management Issues

a. Prior Authorization Criteria – New Manual PA Criteria

- Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet
- Vitamins: Prenatal—prenatal multivitamin (Trinaz)
- Pulmonary-2 Agents: Long-Acting Beta Agonists (LABAs)—olodaterol (Striverdi Respimat)
- Gastrointesinal-2 Agents—teduglutide (Gattex)

b. Prior Authorization Criteria – Updated PA

- Gynecological Agents Miscellaneous—flibanserin (Addyi)
- Acne Agents: Isotretinoids—isotretinoin (Absorica, Absorica LD)
- Antibiotics: Tetracyclines—minocycline extended release (ER) (Solodyn, generics)
- Acne Agents: Topical Acne and Rosacea—dapsone 5% and 7.5% gel
- (Aczone)
- Respiratory Interleukins—dupilumab injection (Dupixent)
- Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)—nintedanib (Ofev)
- Oncologic Agents:

1. ovarian cancer: niraparib (Zejula), olaparib (Lynparza), and rucaparib (Rubraca)
2. melanoma: encorafenib (Braftovi)
3. multiple myeloma: selinexor (Xpovio

- Targeted Immunomodulatory Biologics (TIBs)
    1. adalimumab (Humira)
    2. ustekinumab (Stelara)
    3. ixekizumab (Taltz)
    4. secukinumab (Cosentyx)

- 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 August 5-6, 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 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.

No written public comments were received.

Chairman's Opening Remarks

Mr. Ostrowski thanks Col Hoerner and welcomes everyone online.

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 our Navy internal medicine physician, LCDR Todd Hansen, and three clinical pharmacists MAJ Adam Davies, Dr. Amy Lugo, and CDR Scott Raisor. 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 112018, 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:

1) Three Uniform Formulary Drug Classes, which includes four suclasses:

- Sleep Disorders: Wakefulness Promoting Agents Subclass
- White Blood Cell Stimulants: Filgrastims and Pegfilgrastims
- Psoriasis Agents

A summary table of the UF drug class recommendations and the numbers of affected utilizers is found on pages 56 to 57 of the background document.

2) The P&T Committee also evaluated 23 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,

3) We also discussed prior authorizations (PAs) for 21 drugs in 11 drug classes.

   - Narcotic Analgesics – tramadol IR 100 mg IR
   - Prenatal Vitamins – Trinaz
   - Pulmonary-2 Agents: Long-Acting Beta Agonists (LABAs) – Striverdi Respimat
   - Gastrointestinal-2 Agents: Gattex
   - Gynecological Agents Miscellaneous- Addyi
   - Acne Agents – 4 drugs from 2 subclasses (isotretinoin – Absorica, Absorica LD); Topical acne and rosacea (Dapsone 5%, and 7.5%)
   - Antibiotics: Tetracyclines (Solodyn)
   - Respiratory Interleukins: Dupixent
   - Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (Ofev)
   - Oncologic Agents: 5 drugs from 3 subclasses (ovarian: Zejula, Lynparza, Rubraca); Melanoma (Braftovi), Multiple Myeloma (Xpovio)
   - TIBs: 4 drugs (Humira, Stelara, Taltz, Cosentyx)

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. Based on 32 CFR 199.21, such change will not be longer than 180 days from the final decision date but may be less.

This P&T meeting, as with our May meeting, was held via teleconference due to the ongoing pandemic. Given the limited nature of the May meeting which focused on Newly Approved Drugs, this August meeting was quite full to ensure we addressed items that required the committee's attention. 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 three drug subclasses have no increase in copays for patients. Further, the committee engaged their ability to recommend lower copays, and in the White Blood Cell stimulants subclass we will have two drugs recommended for the Tier 1 (generic) copay. This copay reduction will benefit 35% of the patients in the class, and if prior utilization patterns continue, over 7,000 prescriptions may benefit from this lower copay annually. For the Newly Approved Drugs, 15 out of 23 drugs moved from Tier 3 (NF) to Tier 2 (UF) status. These recommendations will again lower the copay paid for these drugs for years to come. A total of three of these drugs were recommended for Tier 4 status, and these 3 drugs currently affect 403 patients. This change will have a minimal impact on our patient population, working out to < 0.005% of our beneficiaries. As will be reviewed by my staff, the drugs designated for Tier 4 have numerous alternatives that are clinically equivalent or even superior. Further mitigating the impact is the fact that the agents and disease states for which they are used are typically of a short term nature.

UF CLASS REVIEWS—SLEEP DISORDERS: WAKEFULNESS PROMOTING AGENTS SUBCLASS

A. Sleep disorders: wakefulness promoting agents subclass–relative clinical effectiveness conclusion

Background—The Wakefulness Promoting Agents were last reviewed for formulary status in February 2012. The drugs in the subclass include modafinil, armodafinil, sodium oxybate (Xyrem), solriamfetol (Sunosi), and pitolisant (Wakix). The two newest entrants were previously reviewed as new drugs, solriamfetol (Sunosi) in August 2019, and pitolisant (Wakix) in November 2019. The FDA indications vary between agents; all five drugs are approved to treat excessive daytime sleepiness (EDS) associated with narcolepsy. Modafinil, armodafinil, and solriamfetol are also approved for obstructive sleep apnea (OSA), while modafinil and armodafinil also carry an indication for shift work sleep disorder. Sodium oxybate (Xyrem) is the only drug in the class approved for cataplexy associated with narcolepsy. The wakefulness promoting agents differ in several other aspects including mechanism of action, drug enforcement agency (DEA) scheduling, and safety profiles.

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

- **Narcolepsy and cataplexy** guidelines from the American Academy of Sleep Medicine (AASM) (2007) discuss modafinil and sodium oxybate as effective treatments for EDS due to narcolepsy. An updated guideline is in progress that will address the newer products solriamfetol and pitolisant.

    1. Stimulant medications (e.g., amphetamine, methylphenidate) are widely used for a variety of sleep disorders and are mentioned in the 2007 AASM guidelines.

- **For OSA**, the AASM 2019 guidelines, and VA/DoD 2019 clinical practice guideline both recommend sleep hygiene and continuous positive airway pressure as key interventions.

- **Modafinil and armodafinil** have been available for many years to treat EDS due to narcolepsy or OSA, and are available in generic formulations. With regard to efficacy, safety and tolerability, there are no clinically relevant differences between modafinil and armodafinil.

- **Sodium oxybate (Xyrem)** fills a unique niche in therapy for cataplexy associated with narcolepsy for adults and children as young as 7 years. However, limitations include a boxed warning for abuse/misuse (C-III) and a restricted distribution program requiring dispensing from one centralized pharmacy.

1. Off-label unsupportable uses of sodium oxybate include fibromyalgia, jet lag disorder, and OSA, among other sleep disorders.

2. The most common adverse drug reactions (ADRs) leading to discontinuation of sodium oxybate include headache, nausea, vomiting, and anxiety.

- **Solriamfetol (Sunosi)** is a new dopamine and norepinephrine reuptake inhibitor (DNRI) approved in March 2019 for wakefulness in adult patients with EDS associated with narcolepsy or OSA.

  1. Solriamfetol was evaluated in 4 placebo-controlled trials conducted to gain FDA approval; modest efficacy was shown in a patient's ability to remain awake during usual daily activities.

  2. Advantages of Sunosi include the additional indication for OSA and no requirements for restricted distribution. Solriamfetol is a C-IV scheduled drug. Disadvantages include the lack of comparative efficacy studies, and adverse reactions of increased blood pressure, heart rate, and psychiatric symptoms, including anxiety, insomnia, and irritability. It should be used with caution in patients with a history of psychosis or bipolar disorder.

- **Pitolisant (Wakix)** was approved in August 2019 for EDS in patients with narcolepsy. It is the only non-scheduled drug in the class for this indication.

  1. In clinical trials, pitolisant was superior to placebo but did not meet non-inferiority requirements when compared to modafinil.

  2. Common adverse effects include nausea, anxiety, and insomnia.

  3. Advantages of Wakix include its novel mechanism of action and non-controlled option for narcolepsy, however, efficacy is not superior to existing therapies, and it has several safety issues including renal and hepatic impairment, drug interactions with CYP2D6 inhibitors and CYP3A4 inducers, and QT prolongation. Wakix is subject to restricted distribution requirements.

- Reviewers from the Oregon Health Science University Drug Effectiveness Review Project concluded there is insufficient evidence to evaluate long-term efficacy or safety of solriamfetol and pitolisant.

- Statements regarding comparative efficacy among the drugs in the subclass are difficult to make, given the lack of head-to head studies and heterogeneity in clinical trial designs.

- Military Health System (MHS) Provider feedback from sleep medicine specialists supports use of stimulants (methylphenidate and mixed amphetamine salts) and the

older drugs, modafinil and armodafinil, prior to use of the newer agents for their respective indications.

- For narcolepsy, the wakefulness promoting agents are highly therapeutically interchangeable. However, multiple wakefulness promoting drugs with differing mechanisms of action and indications are needed on the formulary to meet the needs of DoD beneficiaries.

B. Sleep disorders: wakefulness promoting agents subclass—relative cost-effectiveness analysis and conclusion

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

- CMA results showed that armodafinil (Nuvigil, generics) and modafinil (Provigil, generics) were the most cost-effective wakefulness promoting agents when compared to pitolisant (Wakix), sodium oxybate (Xyrem), and solriamfetol (Sunosi).

- 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 armodafinil, modafinil, and sodium oxybate (Xyrem) as UF, with pitolisant (Wakix) and solriamfetol (Sunosi) as NF demonstrated significant cost avoidance for the Military Health System (MHS).

C. Sleep disorders: wakefulness promoting agents subclass—uf/tier 4/not covered recommendation

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

- UF
  - armodafinil
  - modafinil
  - sodium oxybate (Xyrem)
- NF
  - solriamfetol (Sunosi)
  - pitolisant (Wakix)
- Tier 4/Not Covered
  - None

D. Sleep Disorders: Wakefulness Promoting Agents Subclass—Manual PA Criteria

Manual PA criteria currently apply to Xyrem (originally placed in February 2012, and most recently updated in August 2019 for pediatric use); solriamfetol (Sunosi) from the August 2019 meeting; and pitolisant (Wakix) from the November 2019 meeting. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) minor updates to the manual PA criteria for new users of solriamfetol and pitolisant, to more accurately reflect the inclusion criteria from the clinical trials used to gain FDA approval. No changes were recommended for the sodium oxybate PA criteria.
The PA criteria are as follows. Updates from the August 2020 meeting are in bold:

1. pitolisant (Wakix)

Manual PA is required for all new users of Wakix.

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

- **Provider acknowledges that PA is not required for modafinil or armodafinil.**
- Patient is 18 years of age or older
- Wakix is not approved for use in children, adolescents, or pregnant patients.
- Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy **and an Epworth Sleepiness Scale (ESS) score ≥ 14**
- Narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing
- Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Patient is not concurrently taking any of the following:
    1. Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate
- Patient must have tried and failed and had an inadequate response to modafinil
- Patient must have tried and failed and had an inadequate response to armodafinil
- Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)
- Patient does not have a history of severe hepatic impairment

- Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea

2. solriamfetol (Sunosi)

Manual PA is required for all new users of Sunosi.

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

- **Provider acknowledges that PA is not required for modafinil or armodafinil.**
- Patient is 18 years of age or older
- Sunosi is not approved for use in children, adolescents, or pregnant patients.
- Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy or a documented diagnosis of obstructive sleep apnea (OSA) **and an Epworth Sleepiness Scale (ESS) score ≥ 10**
- For narcolepsy: narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
- For narcolepsy: Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea
- For OSA: Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least 1 month prior to initiation, and the patient demonstrated adherence to therapy during this time
- For OSA: Patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of treatment
- Sunosi is prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- The patient is not concurrently taking any of the following:

    1. Central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic
    2. Monoamine oxidase inhibitor (MAOI) within the past 14 days
    3. Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate

- The patient must have tried and failed and had an inadequate response to modafinil

- The patient must have tried and failed and had an inadequate response to armodafinil

- The patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)

- Patient and provider agree to monitor blood pressure and heart rate at baseline and periodically throughout treatment. If the patient has hypertension, the blood pressure is controlled.

- Patient does not have unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems

3. sodium oxybate (Xyrem)

Note that there were no changes to the PA criteria from Xyrem made at the November 2019 meeting. I won't go over the PA criteria, but they are hear for your awareness.

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

- Patient is 18 years of age or older

- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic

- Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist

  AND

- Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.

  1. Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR

- Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy

  AND

1. The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND

- Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

OR

- Patient is 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

- Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist

AND

- Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.

1. Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR

- Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy

AND

1. 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)

E. Sleep Disorders: Wakefulness Promoting Agents Subclass—UF/Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent): an effective date of the first Wednesday one week after signing of the P&T minutes at all points of service (POS).

F. Physician's Perspective

- We previously reviewed this class in 2012, and the two new drugs (Wakix and Sunosi) were evaluated as innovators within the past year. The reason for another look at this class was because of the new entrants, and update the committee on any new clinical information for the older agents (Xyrem, modafinil and armodafinil).

- There were no changes to the formulary status for the drugs; Sunosi and Wakix will remain nonformulary. The minor changes made to the PAs for Sunosi and Wakix bring our PAs into alignment with that from other groups, including the VA.

- Xyrem will remain on the formulary for now, however, there are some similar agents in the pipeline. There potentially could be nonformulary options made for narcolepsy drugs in the future, when the investigational products come to the market.

- Overall, there was no significant change of note with the committee's recommendations.

G. Panel Questions and Comments Regarding:

***Uniform Formulary/Tier 4/Not Covered Recommendation**:*

CAPT (Ret) Hostettler asked for clarification regarding the P&T Committee vote on page 4. During the presentation, 5 opposed was stated. Was the P&T Committee recommendation (18 for, 0 opposed, 0 abstained, 0 absent)?

Dr. Lugo confirms that he is correct; it's 0.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler states that prior authorization was placed on this product. It is fourth in line. By the time the patient tries all the products, it should meet the requirements for medical necessity. Therefore should be UF. Was any consideration given to that during the meeting?

Dr. Lugo asks for which two products.

CAPT (Ret) Hostettler replies the two that are non-formulary – Sunosi and Wakix. To clear the PA criteria, the patient has to try two (2) other products (armodafinil and modafinil), which happen to be the products on the UF. Which means the patient has failed and the only thing left are these two products should meet medical necessity. Therefore they should be UF. UF with that PA plan would work just as well and wouldn't penalize the patient between cost shares of UF and NF. Most likely the patient is not smart enough to process the medical necessary requirements. When you put that

onerous of PA in place, it seems logical to me that they would be UF but behind 3 other drugs. Was there no consideration for that at all?

Dr. Lugo thanks him for his comments. You don't have to try Xyrem before the two branded agents. There are requirements for modafinil or armodafinil, which were indicated as stimulants but not all of them.

CAPT (Ret) Hostettler says that it reads that the stimulants are there.

Dr. Lugo says not Xyrem. The stimulants are technically not part of this class.

CAPT (Ret) Hostettler says that they are part of the PA.

UF/Tier 4/Not Covered and PA Implementation Plan:

CAPT (Ret) Hostettler asked why a short implementation plan?

Dr. Lugo answered because there were no changes to formulary status and minor changes to the PA.

CAPT (Ret) Hostettler confirms that no patients were affected.

Dr. Lugo answered that is correct.

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 Sleep Disorders: Wakefulness Promoting Agents Subclass.

- **Sleep Disorders: Wakefulness Promoting Agents Subclass—UF/Tier 4/Not Covered Recommendation**

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

- **Sleep Disorders: Wakefulness Promoting Agents Subclass—Manual PA Criteria**

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

  Mr. Hostettler reiterates what he said before. The onerous PA of having to try all 3, even one that is not part of the class before you can you get to the NF products. Just seems to be over the top for him.

- **Sleep Disorders: Wakefulness Promoting Agents Subclass—UF/Tier 4/Not Covered and PA Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

UF CLASS REVIEWS—WHITE BLOOD CELL STIMULANTS: FILGRASTIMS AND PEGFILGRASTIMS

A. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Relative Clinical Effectiveness Analysis and Conclusion

Background— The White Blood Cell (WBC) Stimulants are comprised of the filgrastims and pegfilgrastims. The class has not been previously reviewed for formulary status, although several products were reviewed as newly approved drugs. There are four filgrastims and four pegfilgrastims in the class.

This is first time that the P&T Committee is evaluating biosimilars and follow-on biologics for formulary status as part of a drug class review. The FDA definition of a biosimilar is that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

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

- The filgrastims and pegfilgrastims are most commonly used for the prophylaxis of chemotherapy-related febrile neutropenia in patients with nonmyeloid malignancies.

- Several professional guidelines from the American Society of Clinical Oncology (ASCO, 2015), European Society for Medical Oncology (2016), and the National Comprehensive Cancer Network (NCCN, 2020), state that all the products are effective for preventing febrile neutropenia; that pegfilgrastim is equally effective as filgrastim; and that biosimilars provide an opportunity to decrease healthcare expenditures while ensuring patients receive high-quality cancer care. The guidelines do not give a preference for one individual product over another.

- A systematic review of 90 studies evaluating switching between a variety of reference products and their biosimilars reported no differences in safety, efficacy, or immunogenicity (Hillel, 2018). One study specifically studying switching between the filgrastim reference product and biosimilars in breast cancer patients also showed no differences in efficacy, overall safety or immunogenicity development (Blackwell, 2015).

- The filgrastims require once daily dosing for febrile neutropenia, in contrast to the pegfilgrastims, which have a longer half-life and are administered once per chemotherapy cycle. However, the filgrastims are used in patients receiving weekly chemotherapy regimens, since the pegfilgrastims cannot be administered between 14 days prior to and 24 hours after the administration of chemotherapy.

- The safety profiles of the filgrastims and pegfilgrastims are similar. Bone pain and pain in the extremities are the most commonly reported adverse reactions, which are seen more frequently with the pegfilgrastims.

- Data from the FDA-approved labeling show there is a low incidence of immunogenicity for the filgrastims and pegfilgrastims.

Filgrastims

- **filgrastim (Neupogen)** is the reference biologic for the filgrastims. Advantages include availability in both a syringe and vial, and approval for both subcutaneous (SC) and intravenous (IV) administration. One disadvantage is that the syringe (but not the vial) contains latex, which is a concern in patients with latex allergy.

- **tbo-filgrastim (Granix)** is a follow-on biologic to Neupogen, which means it was approved via a different pathway than the biosimilars. Granix is available in both syringes and vials, which do not contain latex. Both formulations are only approved for SC administration.

- **filgrastim-sndz (Zarxio)** disadvantages include that it is only available in a syringe, which contains latex, and that volumes smaller than 0.3 mL cannot be accurately measured due to limitations of the measuring units in the syringe.

- **filgrastim-aafi (Nivestym)** advantages include availability in both a syringe and vial, that it does not contain latex and can be administered by both SC and IV routes.

Pegfilgrastims

- The pegfilgrastims are only available in syringes and not vials, and are only approved for SC administration. None of the syringes are designed to administer doses less than 0.6 mL although pediatric dosing with lower mL doses are listed in the package labeling for the products.

- **pegfilgrastim (Neulasta)** is the reference biologic for the pegfilgrastims. In addition to the syringe, it also comes in an on-body injector (Neulasta OnPro) which allows for delayed administration 27 hours after application. This provides a convenience for patients who cannot self-inject at home. Both formulations contain latex.

- **pegfilgrastim-jmdb (Fulphila)** and **pegfilgrastim-cbqv (Udenyca)** do not contain latex. Udenyca has the highest utilization of the pegfilgrastims in the MHS.

- **pegfilgrastim-bmez (Ziextenzo)** has latex in the syringe, and has very low utilization in the MHS.

- According to FDA guidance, providers can interchange biosimilars at the time of prescribing, but the FDA requires further data for substitution by other than the prescriber (e.g., a pharmacist cannot substitute products at the pharmacy window). However, overall, there is a very high degree of interchangeability within the filgrastims subclass, and within the pegfilgrastims subclass.

- The overall choice for prescribing a particular filgrastim or pegfilgrastim should be based on the patient's chemotherapy regimen (e.g., cycle frequency and the risk for causing febrile neutropenia), convenience, and cost.

B. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the White Blood Cell Stimulants. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- Filgrastims: CMA results showed that for the filgrastims, Granix and Nivestym were more cost-effective than Neupogen, and Zarxio.

- Pegfilgrastims: For the pegfilgrastims, CMA showed that Udenyca and Fulphila were more cost-effective than Neulasta and Ziextenzo.

- Filgrastims: BIA was performed to evaluate the potential impact of designating selected filgrastims as formulary, NF, or Tier 4 on the UF. BIA results showed that for the filgrastims, designating Granix and Nivestym as UF and step-preferred, with Neupogen and Zarxio as UF and non-step-preferred demonstrated significant cost avoidance for the MHS.

- Pegfilgrastims: For the pegfilgrastims, the BIA showed that designating Udenyca and Fulphila as UF and step-preferred, with Neulasta syringes, Neulasta OnPro infuser, and Ziextenzo as UF and non-step-preferred demonstrated significant cost avoidance for the MHS.

C. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—UF and Step Therapy Recommendation

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

FILGRASTIMS

- UF and step-preferred

1. tbo-filgrastim vial and syringe (Granix) *(Granix vials moves from NF to UF and step-preferred status)*

2. filgrastim-aafi vial and syringe (Nivestym) *(moves from NF to UF and step-preferred status)*

- UF and non-step-preferred

1. filgrastim vial and syringe (Neupogen) *(moves to non-step-preferred status)*

2. filgrastim-sndz syringe (Zarxio) *(moves to non-step-preferred status)*

3. Note that as part of the formulary recommendation, a trial of both Granix and Nivestym are required in new users before patients can try Neupogen or Zarxio.

- NF – None

- Tier 4/Not Covered — None

PEGFILGRASTIMS

- UF and step-preferred

1. pegfilgrastim-cbqv syringe (Udenyca)

2. pegfilgrastim-jmdb syringe (Fulphila)

- UF and non-step-preferred

1. pegfilgrastim syringe (Neulasta) *(moves to non-step-preferred status)*

2. pegfilgrastim on-body injector (Neulasta OnPro) *(moves to non-step-preferred status)*

3. pegfilgrastim-bmez syringe (Ziextenzo) (*moves to non-step-preferred status)*

4. Note that as part of the formulary recommendation, a trial of both Udenyca and Fulphila are required in new users before patients can try Neulasta, Neulasta OnPro, or Ziextenzo.

- NF — None

- Tier 4/Not Covered — None

D. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Manual PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the non-step-preferred WBC stimulants, requiring the step-preferred products first, unless the patient has had an inadequate response or could not tolerate the preferred WBC stimulants. For new users of Neupogen and Zarxio, a trial of Granix and Nivestym is required. New users of Neulasta, Neulasta OnPro, or Ziextenzo are required to try Udenyca and Fulphila first. Patients requiring a pegfilgrastim who cannot self-inject will be able to receive Neulasta OnPro.

The PA criteria are as follows:

1. Filgrastims: filgrastim (Neupogen) and filgrastim-sndz (Zarxio)

Manual PA criteria apply to all new users of filgrastim (Neupogen) and filgrastim-sndz (Zarxio).

Manual PA Criteria: Coverage will be approved if all criteria are met:

- Provider acknowledges that tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) are the TRICARE preferred filgrastims and are available without a PA
- Drug is prescribed by or in consultation with a hematologist or oncologist
- Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio)
- Patient has experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-sndz (Zarxio)

PA does not expire.

2. pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo)

Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo).

Manual PA Criteria: Coverage will be approved if all criteria are met:

- Provider acknowledges that pegfilgrastim-cbqv (Udenyca) and pegfilgrastim-jmdb (Fulphila) are the TRICARE preferred pegfilgrastims and are available without a PA

- Drug is prescribed by or in consultation with a hematologist or oncologist

- For Neulasta OnPro: Patient requires use of an on-body injector because the patient and/or caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration

OR

- Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-cbqv (Udenyca) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo)

- Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo)

PA does not expire.

E. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Tier 1 Cost Share

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) lowering the current Tier 2 cost-share for the filgrastim Granix (both syringe and vial) and the pegfilgrastim Udenyca (both syringe and vial) to the generic Tier 1 cost-share.

The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes." Lowering the cost-share for both Granix and Udenyca will provide a greater incentive for beneficiaries to use the most cost-effective WBC stimulant for the filgrastims and pegfilgrastims, in the purchased care points of service.

F. White Blood Cell Stimulants: Filgrastims and Pegfilgrastims UF, PA, and Tier 1 Cost Share Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service.

G. Physician's Perspective

- This is the first time we are evaluating a drug class that has biosimilars. For the WBC Stimulants, we did decide to keep all the products on the formulary. The factors influencing why we kept everything UF was because these drugs are used in oncology patients, for usually limited durations of therapy.

- Two products from each subclass were designated as preferred. However, only new patients will be subject to the step therapy requirements ("grandfathering"). For the non-preferred products, we are requiring a trial of two preferred drugs first, rather than one; but this requirement is similar to other commercial health care plans. This will also help in any shortage situations.

- The recommendation to go with the step therapy is because the step should be very effective at moving market share, without forcing patients to pay a nonformulary copay. We want to encourage providers to go with the preferred products for new patients, due to the fact that these are clinically interchangeable drugs.

- The Committee did not recommend Tier 4 for this drug class, after considering both the cost implications, beneficiary ramifications and existing market share.

- While patients will be grandfathered regarding agents they and their provider have selected, all new and current patients will be eligible for the Tier 1 designation. Up to 7000 prescriptions will be eligible for the lowest Tier 1 or a zero dollar copay if the drug is obtained at an MTF.

H. Panel Questions and Comments Regarding:

UF and Step Therapy Recommendation:

Dr. Peloquin requested clarification regarding the step preferred recommendation with two different Tiers. One of the steps is tiered differently than the other preferred.

CDR Raisor clarifies the question you've noticed for both filgrastims and pegfilgrastims there are 2 step preferred agents. When talking about Tier 1 status, only one (1) of the two (2) products is Tier 1. Why aren't both products Tier 1.

Dr. Peloquin confirms. Is it step-step preferred or preferred-preferred step?

CDR Raisor clarified with the two step-preferred agents, there isn't a preference for the Tier 1 over the other step preferred agent. They are both equally preferred. If the provider or the patient chooses the Tier 1 agent they will only pay a tier 1 copay.

Dr. Hostettler clarifies, in each classification there is one step preferred Tier 1 product?

CDR Raisor said yes. There is a filgrastims and a pegfilgrastims, of the two step preferred that do have a Tier 1 copay.

CAPT (Ret) Hostettler asked how the patient would know to make that choice. They aren't going to have the information needed to make that choice. They will show up at the pharmacy and pay a UF price. No one will ever tell the patient that the product was available at the Tier 1 co-pay. How is that information shared with the beneficiary or the provider for that matter?

CDR Raisor clarified how does the patient know that there is a Tier 1 copay? The formulary search tool is one way that the patient and provider can use to check Tier 1 status. Additionally, comments can be placed on the prior authorization to specify that the products have Tier 1 co-pay.

Mr. Hostettler said the comments on the PA form would be beneficial. He doesn't know how many providers and/or patients are in their doctor's office pull up the formulary search tool. The practically of that doesn't seem to ring true. Putting it on the form might have some benefits.

Dr. Peloquin asked how many new patients are impacted by the decision.

CDR Raisor clarified how many new patients? At any one time, we have about 300 patients. There are not a lot of patients on these agents. We have a new user rate of 30%. So 30% of 300 would be the ball park.

CAPT (Ret) Hostettler brings up a housekeeping issue. On Page 12, para B – the white blood stimulants… says CMA and BIA were performed to evaluate the topical pain agents. Is that correct?

CDR Raisor said the votes are for the filgrastims and pegfilgrastims. The topical pain agents are an error. Thanks for bringing that to our attention.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asked a question about the cost analysis for Neulasta OnPro. When cost analysis are conducted, are the multiple visits to have the injection added to the cost comparison as well as the MTF and/or doctor's visits to the MHS and to copays to patients each time they go in for a shot?

CDR Raisor clarified we did include the cost to the patients and to the clinics when evaluating the OnPro. When cost reviews are conducted the BIA is specific to the pharmacy budget. We do take into account unique characteristics or other factors when we review other drugs, including OnPro.

CAPT (Ret) Hostettler asked if a consideration was given to the overall outside of pharmacy cost to the MHS and out of pocket cost to the patient in your cost analysis of OnPro. Seems like we could be saving nickels and spending dollars in other places.

Lt Col Khoury asked Mr. Hostettler to specify what out of pocket costs he is referring to.

CAPT (Ret) Hostettler said anytime a patient goes back to the provider for an injection or any other reason there is a copay. That's the patient's cost. The time spent in the MHS at the doctor's office, the clinic, and the MTF are all costs to the system in lost appointments because patients are rescheduling appointment to meet the PA criteria. If nothing else, there is an opportunity lost. There are costs for the MTF or doctor's office because now they have a patient sitting there when they could be sitting at home in a more comfortable position.

Lt Col Khoury repeated CDR Raisor response about our assessment to pharmacy and the budget impact. It sounds like you're looking at a global cost impact. This is not under the P&T Committee purview.

CAPT (Ret) Hostettler says he doesn't believe it's out of the benefit purview. I am looking at the MHS cost and the total cost to the benefit. I know that, my benefit, as a beneficiary includes more than just pharmacy, and the pharmacy can impact that benefit in deleterious ways if it's not taken into account. It is in my benefit.

Lt Col Khoury reiterates that global costs are not under the purview of the P&T Committee. We did assess the other factors unique to the agents of this class. Neulesta OnPro is UF and has the same copay unless it's been designated different from a Tier 2 to Tier 1. Regarding other costs, that is not in our purview to be able to assess. That is a wide range depending on the patient and individual factors that go into that. I'll venture to say that is impossible to get that number and defer to the experts to those who have access. We definitely don't.

CAPT (Ret) Hostettler believes that it's a legitimate question to see what the impact of P&T Committee decisions are on the whole MHS enterprise. It's that budget that really makes a difference at the end of the day. He has made his point and will move on.

UF PA and Tier 1 Cost Share Implementation Plan Recommendation:

Dr. Peloquin asked why a 60 day implementation plan versus a 90 or 30 day plan.

Lt Col Khoury said they try to take into account the changes that are occurring for the PAs to ensure that they are implemented and the contractor can ensure they're adjudicated well. Do you think it's too fast? Too slow? Just right?

Dr. Peloquin responded I know this is shorter and patients are on the product for a shorter period of time. The decision affects new patients and I want to ensure oncology understands what it the preferred item.

Lt Col Khoury said we didn't want to delay the reduced cost for the patients.

Dr. Peloquin replied with good point.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF and Step Therapy Recommendation, Manual PA Criteria, Tier 1 Cost Share and UF PA and Tier 1 Cost Share implementation plan for White Blood Cell Stimulants: Figrastims and Pegfilgrastims.

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—UF and Step Therapy Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  CAPT (Ret) Hostettler wants to add to his concurrence with the caveat that they will put on the PA form about which one is tier one cost share versus tier 2.

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Manual PA Criteria**

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

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—Tier 1 Cost Share**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims—UF PA, and Tier 1 Cost Share Implementation Period**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

III. UF CLASS REVIEWS—PSORIASIS AGENTS

A. Psoriasis Agents—Relative Clinical Effectiveness Analysis and Conclusion

Background—The Psoriasis Agents have not previously been reviewed for formulary status. The twelve members in the class are classified by their mechanisms of action, which include the topical vitamin D analogs (calcipotriene, calcitriol), retinoids (tazarotene), and combinations of topical vitamin D analogs with topical corticosteroids (calcipotriene/betamethasone).

The tazarotene cream and gel formulations are classified as Psoriasis Agents for purposes of formulary considerations, even though they are also labeled for acne.

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

- The psoriasis drugs have a long history of use and are well established in professional treatment guidelines and clinical practice. These agents are used to treat localized plaque psoriasis affecting less than 20% of the body surface area. Patients who have a more widespread disease are candidates for systemic therapy or phototherapy, rather than topical treatment.

- The 2009 American Academy of Dermatology (AAD) guidelines support topical corticosteroids as first-line therapy for localized plaque psoriasis. However, well recognized adverse effects limit treatment duration to 2 to 4 weeks. Patients with limited disease who are refractory to higher potency topical corticosteroids typically transition to the topical vitamin D analogs or retinoids.

- The psoriasis agents are available in several vehicles (e.g., cream, ointment, gel, solution/suspension, foam). However, the vehicles all have alternatives, which can attain the same clinical effect while treating various body areas. Scalp-friendly vehicles in the class include lotions, foams, solutions, topical suspensions, and gels.

- Drugs with the same mechanism of action are clinically interchangeable (e.g., among the vitamin D analogs and among the retinoids, respectively), provided that any differences in vehicle formulation will not affect the application site.

- For non-corticosteroid therapies, the AAD recognizes both the vitamin D analogs (calcipotriene and calcitriol), and the retinoids (tazarotene) as having the highest quality of evidence for treating plaque psoriasis. (Level 1 with grade "A" strength of recommendation)

- Combining a topical corticosteroid with either a vitamin D analog or retinoid can replace or supplement higher potency corticosteroids by providing greater efficacy than the individual components, while reducing total cumulative corticosteroid exposure.

- The fixed-dose combinations of a vitamin D analog with a higher potency topical corticosteroid provide a convenience to the patient. However, combined therapy that uses two products separately (e.g., vitamin D analog applied in the morning and corticosteroid applied at night) achieves similar effects, allows for more dosing flexibility, and is as well tolerated as using a fixed-dose combination product.

- The **vitamin D analogs** are either equivalent or superior to other treatment options. Common adverse reactions of the vitamin D analogs include application site irritation, contact dermatitis, and potential increases in serum calcium levels.

- **Calcipotriene 0.005% cream, ointment, and solution** together comprise approximately 50% of the MHS utilization for the entire psoriasis drug class. Provider feedback frequently mentioned calcipotriene cream as a preferred and required agent for the formulary.

- **Calcitriol 3 mcg/g ointment (Vectical)** is clinically interchangeable with calcipotriene ointment and has low utilization across the MHS.

- **Calcipotriene 0.005% foam (Sorilux)** offers no therapeutic advantages over other scalp-friendly products, including calcipotriene solution.

- **The retinoid tazarotene** may be less effective and is used less frequently than the vitamin D analogs. Adverse reactions associated with tazarotene include embryo-fetal toxicity (pregnancy category X rating), local irritation, and photosensitivity. Tazarotene has a higher discontinuation rate due to adverse events than the vitamin D analogs (18% vs. 4.6%, respectively). Tazarotene provides a niche for treating areas with very thick plaques or disease affecting the fingernails.

  - **Tazarotene 0.1% cream** has the highest utilization of the retinoids in the MHS.

  - **Tazarotene 0.05% gel and cream (Tazorac), and tazarotene 0.01% gel (Tazorac)** offer little to no therapeutic advantages over the 0.1% cream.

- Other than providing patient convenience, the **vitamin D analogs/corticosteroid combination** products offer no therapeutic advantages over applying an individual calcipotriene and a high-potency topical corticosteroid concurrently.

  - **Calcipotriene 0.005% / betamethasone 0.064% ointment (Taclonex, generic**) offers no compelling clinical advantages over the other products.

  - **Calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar)** provides a scalp-friendly vehicle, but is flammable.

  - **Calcipotriene 0.005% / betamethasone 0.064% suspension (Taclonex)** can be used on the scalp, however there are numerous alternatives including using the individual agents applied concurrently, as well as Enstilar foam.

- In order to meet the needs of MHS patients, for the vitamin D analogs, at least one ointment, cream, and scalp-friendly agent are each required on the formulary. For the retinoids, a cream is required.

B. Psoriasis Agents—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA at the time of the review, showed that formulations ranked from most cost effective to least cost effective in the class are as follows: calcipotriene 0.005% cream (Dovonex, generics), calcipotriene 0.005% solution (generics), calcipotriene 0.005% ointment (Calcitrene, generics), tazarotene 0.1% cream (Tazorac, generics), calcitriol 3 mcg/g ointment (Vectical, generics), tazarotene 0.05% cream (Tazorac), tazarotene 0.1% gel (Tazorac), tazarotene 0.05% gel (Tazorac), calcipotriene 0.005% foam (Sorilux), Enstilar foam, calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex), and calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex).

- A BIA was performed to evaluate the potential financial impact of various formulary placement scenarios by designating selected psoriasis agents as Tier 4, NF, and UF. The BIA results showed that designating calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex) as Tier 4 and with all remaining psoriasis agents designated as UF or NF, demonstrated significant cost avoidance for the MHS.

C. Psoriasis Agents—Topical Psoriasis Agents UF/Tier 4/Not Covered Recommendation

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the following formulary recommendations for the Psoriasis Agents as outlines below, based on clinical and cost-effectiveness:

- UF

    - calcipotriene 0.005% ointment (Calcitrene, generics)
    - calcipotriene 0.005% cream (Dovonex, generics)
    - calcipotriene 0.005% solution (generics)
    - tazarotene 0.1% cream (generics)

- NF *(all move from UF to NF Status)*

    - calcipotriene 0.005% foam (Sorilux)
    - calcitriol 3 mcg/g ointment (Vectical, generics)
    - calcipotriene 0.005%/betamethasone 0.064% ointment (Taclonex, generics)
    - calcipotriene 0.005%/betamethasone 0.064% foam (Enstilar)
    - tazarotene 0.1% gel (Tazorac)
    - tazarotene 0.05% cream (Tazorac)
    - tazarotene 0.05% gel (Tazorac)

- Tier 4/Not Covered

  - calcipotriene 0.005%/betamethasone 0.064% suspension (Taclonex) (moves from UF to Tier 4 status)

    For Taclonex suspension, which was recommended for Tier 4/Not Covered status, the P&T Committee concluded that it provides very little to no additional clinical effectiveness relative to the other psoriasis agents. Overall, the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other combination products, and by use of the single ingredient vitamin D analogs and corticosteroids used separately.

D. Psoriasis Agents—Manual PA Criteria

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Sorilux foam, Enstilar foam and Taclonex ointment in all new and current users, requiring a trial of a high potency corticosteroid and calcipotriene first, due to the large number of clinically and cost-effective formulary alternatives available. Manual PA criteria were also recommended for new and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel, requiring a trial of tazarotene 0.1% cream and a high potency topical steroid, for plaque psoriasis affecting the body. For acne, a trial of tazarotene 0.1% cream will be required before the other Tazorac formulations.

The Manual PA are as follows:

1. calcipotriene 0.005% foam (Sorilux)

Manual PA criteria apply to all new and current users of Sorilux foam.

Manual PA Criteria: Coverage will be approved if all criteria are met:

- The provider acknowledges that Sorilux has several cost-effective alternatives, including generic calcipotriene 0.005% cream, ointment, and solution, which do not require a PA. Calcipotriene 0.005% solution can be applied to the scalp.

- Patient is 12 years of age or older

- The patient has diagnosis of plaque psoriasis

- The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one formulary high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution)

- For scalp psoriasis: the patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% solution OR

- For all other body areas: the patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% ointment, cream, AND solution

Non-FDA-approved uses are not approved.

PA does not expire.

2. calcipotriene 0.005%-betamethasone 0.064% ointment (Taclonex) and calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar)

Manual PA criteria apply to all new and current users of Enstilar foam and Taclonex ointment.

Manual PA Criteria: Coverage will be approved if all criteria are met:

- The provider acknowledges that Enstilar foam and Taclonex ointment have several cost effective alternatives, including the following, none of which require PA.

    1. For the calcipotriene (vitamin D analog) component, alternatives include generic calcipotriene 0.005% cream, ointment, and solution.

    2. For the betamethasone (high-potency topical corticosteroid) component, alternatives include clobetasol propionate 0.05% ointment, cream, solution, and shampoo and fluocinonide 0.05% cream, ointment, and solution.

- Patient is 12 years of age or older

- The patient has diagnosis of plaque psoriasis

- The patient must have tried for at least 2 weeks and failed or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution)

- The patient must have tried and failed or have had an adverse reaction to calcipotriene 0.005% ointment, cream, OR solution

- The patient must have tried and failed an individual calcipotriene agent (calcipotriene 0.005% ointment, cream or solution) AND an individual high-potency topical corticosteroid agent used concurrently

- Additionally, the provider must describe why Enstilar foam or Taclonex ointment is required as opposed to available alternatives.

Non-FDA-approved uses are not approved.

PA does not expire.

3. tazarotene 0.05% cream (Tazorac), tazarotene 0.05% gel (Tazorac) and tazarotene 0.1% gel (Tazorac)

Manual PA criteria apply to all new users and current users of Tazorac 0.05% gel and cream, and Tazorac 0.1% gel.

Manual PA Criteria: Coverage will be approved if all criteria are met:

- The provider acknowledges that tazarotene 0.1% cream is a cost effective alternative that does not require a PA.
- The patient has a diagnosis of acne vulgaris or plaque psoriasis
- For acne vulgaris:
    1. Patient is 12 years of age or older
    2. The patient must have tried and failed, have a contraindication to, or have had an adverse reaction to tazarotene 0.1% cream.
- For scalp psoriasis:
    1. Patient is 18 years of age or older
    2. The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% solution, shampoo; fluocinonide 0.05% solution)
- For plaque psoriasis in other body areas:
    1. Patient is 18 years of age or older
    2. The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to at least one high-potency topical corticosteroid (e.g., clobetasol 0.05% ointment, cream, solution, shampoo; fluocinonide 0.05% cream, ointment, solution) AND
    3. The patient must have tried and failed or have had an adverse reaction to tazarotene 0.1% cream.

Non-FDA-approved uses are not approved.

PA does not expire.

E. Psoriasis Agents—UF/Tier 4/Not Covered, and PA Implementation Period

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 120 days after the signing of the minutes; 2) DHA send letters to beneficiaries who are affected by the by the change from UF to NF status and PA requirements, and 3) DHA send letters to beneficiaries who are affected by the Tier 4/not covered recommendations at 30 and 60 days prior to implementation.

F. Physician's Perspective

- This class is comprised of drugs with different mechanisms of actions that are all used topically. We received input from the dermatology community when making the formulary recommendations. The products that will remain on the formulary are those that the specialists said are required. Note that there are several alternatives for the nonformulary and Tier 4 candidates.

- While the Committee considered making several of the Vitamin D/steroid combinations Tier 4, based on the dermatology feedback, the recommendation was to designate them nonformulary with a PA instead. The Tier 4 recommendation for Taclonex suspension will affect about 350 patients out of the total 14,000 unique utilizers for the class. Based on our utilization data this drug is most often filled one time and not filled again. Additionally the providers felt that having patients avoid certain combinations, as long as the two separate products were available, may be beneficial from a clinical perspective.

- The Committee was also aware that if patients fail one of these topical therapies, they could receive one of the newer expensive biologic therapies (like Stelara and Taltz). The products staying on the formulary will provide the necessary range of options needed for the management of this disease for our patients and the clinicians that treat it.

G. Panel Questions and Comments Regarding:

UF/Tier 4/Not Covered Recommendation:

CAPT (Ret) Hostettler asked how many beneficiaries were affected this this decision. Looks like a total of 2,045 from the UF to NF change. Curious how many were combination products.

LCDR Hansen repeats, how many total patients on combination products will be affected not just asking about one that moved from UF to Tier 4? Is that correct?

CAPT (Ret) Hostettler answered Tier 4 is Tier 4. I'm more worried about Tier 3. According to the documents, 2,045 patients were affected. I don't know which products those 2000 patients were taking or utilizing. I'm curious how many of them were combination products. Small numbers? 1000? Half?

LCDR Hansen responded we will provide an answer when we can identify that number.

CAPT (Ret) Hostettler asked if it is a small or large number.

Lt Col Khoury interjects that there are about 1000 patients.

CAPT (Ret) Hostettler stated about half of the patients affected are taking combination products and the process to get those products is now more difficult if not impossible.

Lt Col Khoury says most of the patients are one and done. If they chose to get it, they can with the new copay.

CAPT (Ret) Hostettler said working through the PA as well.

Lt Col Khoury said correct. The Committee wanted to ensure the clinically appropriate and most cost effective agents are selected first for the patient and the benefit.

Manual PA Criteria Recommendation:

CAPT (Ret) Hostettler asked if there was an automated look back which would allow the patient to get through the PA process quicker than 6 weeks. If there was any automation that could be applied to that look back, that could be very worthwhile.

Lt Col Khoury asked what the 6 weeks was referring to.

CAPT (Ret) Hostettler said there are multiple steps to go through in order to get some of the combination products. That takes time and multiple visits. Anything you can do to reduce the time while still maintaining the step therapy would be beneficial to the patient. I understand that this could be done with an automatic look back through the system. I am just asking is that feasible in this situation?

Lt Col Khoury said there is not a way to do automation for this product.

UF/Tier 4/Not Covered and PA Implementation Period:

CAPT (Ret) Hostettler said thank you for the time and the 120 days to get that done. This decision impacts a lot of beneficiaries and more visits will be needed to make the change.

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 period for Psoriasis Agents.

- **Psoriasis Agents – Topical Psoriasis Agents UF/Tier 4/Not Covered Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Psoriasis Agents – Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

- **Psoriasis Agents – UF/Tier 4/Not Covered, and PA Implementation Period**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

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

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

The P&T Committee agreed for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent), and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF:

  - apomorphine sublingual film (Kynmobi)
  - capmatinib (Tabrecta)
  - elagolix/estradiol/norethindrone (Oriahnn)
  - fenfluramine oral solution (Fintepla)
  - lemborexant (Dayvigo)
  - insulin lispro-aabc (Lyumjev)
  - nimodipine oral syringe (Nymalize)

- octreotide acetate injection (Bynfezia Pen)
- osilodrostat (Isturisa)
- ozanimod (Zeposia)
- pemigatinib (Pemazyre)
- ripretinib (Qinlock)
- selpercatinib (Retevmo)
- selumetinib (Koselugo)
- tucatinib (Tukysa)

- NF:

  - bempedoic acid/ezetimibe (Nexlizet)
  - diclofenac epolamine 1.3% patch (Licart)
  - lactic acid; citric acid; potassium bitartrate vaginal gel (Phexxi)
  - leuprolide acetate injection (Fensolvi)
  - levonorgestrel/ethinyl estradiol transdermal system (Twirla)
  - minocycline 1.5% topical foam (Zilxi)

- Tier 4 (Not Covered):

  - halcinonide 0.1% topical solution (Halog)

    1. Halog topical solution was recommended for Tier 4 status as it has no clinical benefit relative to other high potency topical corticosteroids, and the needs of TRICARE beneficiaries are met by alternative agents.

       - Formulary alternatives to Halog topical solution include betamethasone propylene glycol 0.05% cream, clobetasol propionate 0.05% cream and ointment, clobetasol propionate/emollient 0.05% cream, desoximetasone 0.25% cream and ointment, fluocinonide 0.05% cream and ointment, fluocinonide/emollient base 0.05% cream, halobetasol propionate 0.05% ointment.

  - tazarotene 0.045% lotion (Arazlo)

    1. Arazlo lotion was recommended for Tier 4 status as it has no clinical benefit relative to other topical acne agents, and the needs of TRICARE beneficiaries are met by alternative agents.

       - Formulary alternatives to Arazlo lotion include adapalene (cream, gel, lotion), tazarotene (cream), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel).

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

The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 absent) the following:

- Topical Acne and Rosacea Agents: Applying step therapy criteria to new and current users of Zilxi foam that is currently in place for the other non-step-preferred rosacea agents, including Mirvaso and Soolantra, requiring a trial of topical metronidazole first.

- Insomnia Drugs: Applying manual PA criteria to new and current users of Dayvigo that is currently in place for the other dual orexin receptor antagonists for insomnia, requiring a trial of zolpidem ER (Ambien CR generic) and eszopiclone (Lunesta generic) first.

- Miscellaneous contraceptives: Applying manual PA criteria to new users of the Twirla patch and Phexxi vaginal gel.

- Oncologic drugs: Applying manual PA criteria to new users of Koselugo, Pemazyre, Qinlock, Retevmo, Tabrecta, and Tukysa.

- Applying manual PA criteria to new users of Fintepla, Isturisa, Licart patch, Nexlizet, Oriahnn, and Zeposia.

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

1. bempedoic acid/ezetimibe (Nexlizet) / bempedoic acid (Nexletol)
(Note that updates were also made to Nexletol which was reviewed in May 2020)

Manual PA is required for all new users of Nexletol and Nexlizet.

Manual PA Criteria: Nexletol and Nexlizet is approved if all criteria are met:

- Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization)

- Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following:

  - History of clinical (ASCVD), including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA), peripheral artery disease (PAD) OR

- Heterozygous Familial Hypercholesterolemia (HeFH)

- For Nexletol:

  - Patient is taking concurrent ezetimibe and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR

  - Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal; OR

- For Nexlizet:

  - Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started, and is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) OR

- Patient is statin intolerant based on one of the following:

  - Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, cramp) with at least 2 statins OR
  - History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR

  - History of statin-associated rhabdomyolysis OR

- Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy)

  Non-FDA-approved uses other than use without concurrent statin not allowed.

  PA does not expire.

2. Capmatinib (Tabrecta)

Manual PA is required for all new users of Tabrecta.

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

- The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

- Patient is 18 years of age or older
- Must be prescribed by or in consultation with a hematologist/oncologist
- Patient will be monitored for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity
- Provider is aware and has counseled patient that capmatinib can cause photosensitivity and has counseled patients to avoid direct UV exposure
- 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.
- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation.

  Non-FDA-approved uses are NOT approved except as noted above.

  PA does not expire.

3. diclofenac epolamine 1.3% patch (Licart)

Manual PA criteria apply to all new users of Licart.

Manual PA Criteria: Licart approved if all criteria are met:

- Patient has acute pain due to minor strains, sprains, and/or contusions
- Patient is 18 years of age or older
- Patient cannot tolerate an oral NSAID due to renal insufficiency, history of gastrointestinal bleed, or other adverse events OR
- Patient has tried and failed TWO oral NSAIDs

  Non-FDA-approved uses are not approved.

  PA expires after 6 months.

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

4. elagolix/estradiol/norethindrone (Oriahnn)

Manual PA is required for all new users of Oriahnn.

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

- Patient is 18 years of age or older
- Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD)
- Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist
- Patient is not pregnant confirmed by (-) HCG
- Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment
- Patient does not have current or history of thrombotic or thromboembolic disorders or an increased risk for these events
- Patient is not a smoker over the age of 35 years
- Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs, or if the patient has a sudden unexplained partial or complete loss of vision, proptosis (abnormal protrusion of the eye), diplopia (double vision), papilledema (optic disc swelling), or retinal vascular lesions
- Patient does not have uncontrolled hypertension
- Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly
- Patient does not have osteoporosis
- Provider agrees to assess baseline and periodic bone mineral density

- Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes

- Patient does not have a history of breast cancer or other hormonally-sensitive malignancies

- Patient does not have known liver impairment or disease

- Provider agrees to counsel patients on the signs and symptoms of liver injury

- Patient does not have undiagnosed abnormal uterine bleeding

- Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors

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

  PA expires after 24 months (lifetime expiration).

5. fenfluramine oral solution (Fintepla)

Manual PA is required for all new users of Fintepla.

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

- Must be prescribed by a neurologist

- Patient has a diagnosis of Dravet Syndrome

- Must be used as adjunct therapy with other anticonvulsant medications

- Prescriber must abide by and the patient has been informed of the REMS program including safety risks and requirements of regular echocardiogram (ECHO) monitoring for valvular heart disease and pulmonary hypertension

  Non-FDA approved uses are not approved including for weight loss.
  PA does not expire.

6. lactic acid/citric acid/potassium bitartrate vaginal gel (Phexxi)

Manual PA criteria apply to all new users of Phexxi.

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

- Provider acknowledges that numerous contraceptives are available without a PA and are more effective than Phexxi (e.g. norethindrone tablets, norgestimate/ethinyl estradiol tablets, etonogestrel/ethinyl estradiol vaginal ring, and medroxyprogesterone injection); providers are encouraged to consider changing the prescription to a formulary contraceptive.

- Phexxi is being used for contraceptive purposes

- Patient has tried a nonoxynol-9 spermicide and has experienced significant adverse effects

  Non-FDA-approved uses are not approved.

  PA does not expire.

7. lemborexant (Dayvigo)

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

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

- Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance

- Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene

- Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release

- Patient has tried and failed or had clinically significant adverse effects to eszopiclone

- Patient has no current or previous history of narcolepsy

- Patient has no current or previous history of drug abuse

  Non-FDA-approved uses are not approved.

8. levonorgestrel/ethinyl estradiol transdermal system (Twirla)

Manual PA applies to new users of Twirla.

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

- Provider acknowledges that norelgestromin/ethinyl estradiol transdermal system (Xulane) and numerous other contraceptives are available for TRICARE patients that do not require a PA. Providers are encouraged to consider changing the prescription to Xulane or another formulary contraceptive.

- Patient has had an adverse reaction to Xulane that is not expected to occur with Twirla OR

- Patient has tried Xulane and could not tolerate it

- Patient does not have a contraindication to an estrogen-containing contraceptive (e.g., history of estrogen-dependent neoplasia, breast cancer, deep venous thrombosis (DVT)/ pulmonary embolism (PE), etc.)

- Patient's body mass index (BMI) is less than 30 kg/m2; note that Twirla is contraindicated in patients with a BMI ≥ 30 kg/m2

- Provider acknowledges that patients with a BMI between 25 to 30 kg/m2 have decreased contraceptive effectiveness per the FDA label

Non-FDA-approved uses are not approved.
PA does not expire.

9. minocycline 1.5% topical foam (Zilxi)

All new and current users of Zilxi are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream), which is the current step therapy requirements for Soolantra and Mirvaso.

Automated PA Criteria:

- The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days

Manual PA Criteria: If automated PA criteria is not met, Zilxi is approved if all criteria are met:

- Patient is 18 years of age or older

1. Patient is at least 18 years of age and has the following diagnosis:

2. For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea

- For Soolantra and Zilxi: Patient has inflammatory lesions (papulopustular) of rosacea

  AND

- Patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) AND

- Patient has tried and failed topical azelaic acid

  Non-FDA approved uses are not approved.

  PA expires in 365 days.

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

10. osilodrostat (Isturisa)

Manual PA applies to new users Isturisa.

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

- Patient is 18 years of age or older
- Documented diagnosis of Cushing's disease
- Patient has persistent or recurrent Cushing's disease despite pituitary surgery

OR

- Patient in whom pituitary surgery is not indicated
- Drug is prescribed by an Endocrinologist, Oncologist, or Neurosurgeon
- Provider agrees to correct hypokalemia or hypomagnesemia prior to starting Isturisa
- Provider agrees to obtain baseline electrocardiogram (ECG) prior to starting Isturisa and use with caution in patients with risk factors for QTc prolongation
- Patient will be monitored closely for hypocortisolism and potentially life-threatening adrenal insufficiency. Dosage reduction or interruption may be necessary
- Patient will be monitored for hypokalemia, worsening of hypertension, edema, and hirsutism

Non-FDA-approved uses are not approved.

PA does not expire.

11. ozanimod (Zeposia)

Manual PA applies to new users of Zeposia.

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

- Prescribed by a neurologist
- Patient has a documented diagnosis of relapsing forms of multiple sclerosis (MS)
- Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunamide [Aubagio])
- Patient has not previously failed a treatment course of fingolimod (Gilenya)
- Patient has not previously failed a treatment course of siponimod (Mayzent)
- Provider acknowledges that all recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), and macular edema screening as indicated
- Zeposia will not be used in patients with significant cardiac history, including:

    1. Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization

    2. Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker

    Non-FDA-approved uses are not approved.

    PA does not expire.

12. pemigatinib (Pemazyre)

Manual PA applies to new users of Pemazyre.

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

- The patient has a diagnosis of pathologically confirmed unresectable or advanced/metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist/oncologist
- Patient will be monitored for ophthalmologic disorders including pre-treatment screening for retinal disorders
- Patient will be monitored for hyperphosphatemia
- 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
- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

  Non-FDA-approved uses are not approved except as noted above.

  PA does not expire.

13. ripretinib (Qinlock)

Manual PA applies to new users of Qinlock.

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist/oncologist
- Patient has pathologically confirmed advanced gastrointestinal stromal tumor (GIST)

- Patient has experienced disease progression on or had documented intolerance to imatinib (Gleevec)

- Patient has experienced disease progression on or had documented intolerance to sunitinib (Sutent)

- Patient has experienced disease progression on or had documented intolerance to regorafenib (Stivarga)

- Female patients of childbearing age are not pregnant confirmed by (-) HCG

- Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment

- Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

  Non-FDA-approved uses are not approved except as noted above.

  PA does not expire.

14. selpercatinib (Retevmo)

Manual PA applies to new users of Retevmo.

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

- Prescribed by or in consultation with a hematologist/oncologist

- Patient has one of the following indications:

  1. Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)

  2. Patients 12 years and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy

  3. Patients 12 years and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

- Patient will be monitored for hepatotoxicity and QT prolongation

- Patient does not have uncontrolled hypertension
- Provider is aware and has counseled patient that selpercatinib can cause life-threatening hemorrhage and allergic reactions

- 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

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

  Non-FDA-approved uses are not approved except as noted above.

  PA does not expire.

15. selumetinib (Koselugo)

Manual PA applies to new users of Koselugo.
Manual PA Criteria: Koselugo is approved if all criteria are met:

- Prescribed by or in consultation with a hematologist/oncologist

- Patient is diagnosed with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas

- Patient will be monitored for cardiomyopathy including a left ventricular functional assessment prior to initiation and at regular intervals during treatment

- Patient will be monitored for ocular toxicity including retinal vein occlusion and retinal detachment via ophthalmic exams prior to initiation and at regular intervals during treatment

- Patient will be monitored for gastrointestinal toxicity and will receive co-administration of an anti-diarrheal if patient develops loose stools

- Patient will be monitored for severe skin rashes

- Patient will be monitored for rhabdomyolysis

- Provider is aware that Koselugo contains Vitamin E, which can increase bleeding risk if co-administered with a Vitamin K antagonist (e.g., warfarin)

- 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

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

  Non-FDA-approved uses are not approved except as noted above.

  PA does not expire.

16. tucatinib (Tukysa)

Manual PA applies to new users of Tukysa.

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

- The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting

- Patient is 18 years of age or older

- Medication is prescribed by or consultation with a hematologist or oncologist

- Tucatinib will be used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda)

- Provider agrees to monitor for hepatotoxicity

- Patient has been counseled on risk of diarrhea

- 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 the cessation of therapy

- Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation

Non-FDA-approved uses are not approved except as noted above.

PA does not expire.

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

The P&T Committee recommended for group 1: (17 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 1 abstained, 0 absent); and group 3: (16 for, 0 opposed, 0 abstained, 2 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.

E. Physician's Perspective

- There were a total of 23 new drugs reviewed, with 15 drugs that will go to UF status. There were 6 drugs recommended to maintain NF status, and two Tier 4 candidates.

- Prior authorization criteria will apply to 16 of the drugs. The PAs for 12 of the drugs are in classes were PA is already required. "No grandfathering," where both new and current users will be affected by the PA, is recommended for two of the drugs – the insomnia drug Dayvigo and acne drug Zilxi. There is already step therapy for these two classes, and there are several alternative formulary agents available.

- The two drugs recommended for Tier 4 status are in the topical steroid class (Halog topical solution) and acne drugs (Arazlo lotion), where there are numerous alternatives. The Committee vote was unanimous here. The Tier 4 drugs will affect about 50 patients.

1. For Halog, this is a new topical solution that does not offer any benefit over the other topical steroids. At the August 2019 meeting, Halog cream and ointment were designated Tier 4, so this follow-on product will also be Tier 4.

2. Arazlo contains a concentration of 0.045% tazarotene, which is slightly lower than what has been previously marketed. In the Psoriasis drug class review discussed earlier, the concentration of the 0.1% tazarotene cream which is also indicated for acne will be UF, with the 0,05% concentrations made NF. Several other retinoids are available for treating acne.

3. We will ensure patient have sufficient time to modify their current regimen, in line with prior Tier 4 recommendations.

- I have a few comments about two of the new drugs designated NF with a PA

1. **Twirla** is the second birth control patch available on the market. The Committee felt this drug should be NF, based on clinical issues alone, since it is less effective than other contraceptives, especially in heavier weight women. The Ob-gyn Committee member agreed with the NF formulary status, and also recommended having a PA in place early, because of the concerns of reduced efficacy in women with higher body weights. So far no patients have been started on Twirla. The Committee did feel that having the NF status with a PA would be appropriate, rather than going with Tier 4 status. This would ensure access to this drug for the patients that may benefit from this agent.

2. The **Licart diclofenac patch** was also recommended for NF status with a PA. The topical pain medications were reviewed at the Feb 2020 meeting, and another similar diclofenac patch (Flector) was made Tier 4. Licart was approved based on the data from Flector, and does not offer a benefit over the oral NSAIDs or diclofenac gel (Voltaren). Although this is a medication labeled for acute pain for minor muscle strains and sprains, the oral NSAIDS will have a rapid onset of effect, and other non-pharmacological treatments like ice and elevations are frequently used. We did reach out to providers who stated overall, they didn't feel that this product was needed. The PA was placed early for Licart, because the committee was actually fine with having this type of drug be Tier 4. We wanted to avoid having patients start on the drug, and then have the PA apply at the next fill. So far there are no patients on Licart.

F. Panel's Questions and Comments Regarding:

UF/Tier 4 Not Covered Recommendation:

Dr. Peloquin asked why Licart wasn't it moved to Tier 4. It is similar to other agents that were moved to Tier 4.

Dr. Lugo clarified, why diclofenac epolamine 1.3% patch (Licart) wasn't made Tier 4.

Dr. Peloquin is curious why other similar medications were made Tier 4 and this one wasn't. LCDR Raisor replied each review is a combination of a clinical and cost analysis. The committee looking at clinical and believed Licart could fall in line with Tier 4. However, based on the additional cost evaluation, the Committee felt that could be available as an option for patients and decided to go with Tier 3 with a PA.

CAPT (Ret) Hostettler states that as a beneficiary, I commend you for making it Tier 3 with a PA as opposed to NF or completely Tier 4. However, I would've posed the question differently in why didn't the Committee designate the other products Tier 3 with a PA as well.

PA Criteria:

Dr, Peloquin stated, so that I understand, due to the market drugs complexity and the requirement to make sure it is appropriately prescribed by a specialist. I believe that some of the PA criteria goes very much in to practice of the prescriber's actions and what they should do rather than criteria for the drugs. An example, there was a gynecologist or specialist prescribing the product. The criteria is lays out a lot of the "provider will" or the "provider agrees to". Those 15-20 questions and other is just validating that the prescriber is practicing appropriately.

Dr. Lugo repeated his statement. You're saying for the agents where we require a specialist to prescribe in the first place, why is the PA so complexed?

Dr. Peloquin says some of the criteria goes to what a specialist should or shouldn't do or would likely do because of the specialist's understanding of how to manage and monitor the product. Yes, Dr. Lugo that was a good summary.

Dr. Lugo said that's a fair question. In some of the PAs, we allow for the specialist to prescribe or in consultation with the specialist. We want to be sure that safety concerns are there and that nothing accidentally falls through the loop. That's something they can take back.

CAPT (Ret) Hostettler adds to Dr. Peloquin's comments. The criteria almost takes the words practice of medicine out of the question. You're basically doing it my way or the highway is what it looks like that to me. I understand the concern for safety, etc. but it seems to go further than that at times.

Dr. Lugo added that it's important to them that they define an appropriate scope of practice and ensure safety and appropriate usage. They appreciate the comments.

CAPT (Ret) Hostettler requested an explanation on page 29 for Nexlizet. I got confused with the "Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet." Can you explain that or help me understand.

Dr. Lugo says that Nexlizet has ezetimibe in it. So you can't say that you can't have a tolerance to ezetimbe to get Nexlizet. It's a combo agent. Nexlatol is a single agent. Nexlizet is a combo.

CAPT (Ret) Hostettler asked if Licart has an automated PA.

Dr. Lugo says she doesn't think that Licart Diclofenac patch had an automated PA. She'll defer to CDR Raisor.

CDR Raisor clarifies that there is no automation on Licart. It is for acute use.

CAPT (Ret) Hostettler has a question regarding Minocycline 1.5% topical foam (Zilxi). This product has an automated PA criteria. At the end of the criteria it states new prescriptions after it passed the automated criteria, they come back a year later with another prescription. The patient has to go back through the entire manual process again. Of course, they won't meet the 180 days but they were when they started the product. That just seems like too much to me.

Dr. Lugo said there is automation on that product and it will look back for a history Zilxi. It looks back for the other preferred agents and a history of Zilxi.

CAPT (Ret) Hostettler says he's looking at the PA criteria – says no renewal allowed. When the PA expires, the next fill/refill requires a new PA. Maybe I don't understand the process. If they cleared with the automated process before their next prescription for that product, minocycline, then their next prescription would not require a PA. It also stated that new and current users are impacted by the decision.

Dr. Lugo said that many of the acne agents have an expiration of one year also. So it's not just this agent. They also don't need a manual PA if they meet the automation criteria. Therefore no renewal is required.

CAPT (Ret) Hostettler replied that the automation only goes back 180 days.

Dr. Lugo said that's just the automated piece, and at that point it will turn to a manual. CAPT (Ret) Hostettler said after 365 days, they will require a manual PA.

Dr Lugo said that is the way it is written. Yes, there will be another PA.

CAPT (Ret) Hostettler asked if that was the intent of the committee.

Dr. Lugo replied yes.

CAPT (Ret) Hostettler clarifies the product is approved for a year. After the year, the patient is required to go back through the process to obtain another PA, if needed. What value does that have other than slowing process down and disrupting care potentially?

Dr. Lugo replied that this is not an acute use medication. It's for acne. Secondly, there are numerous minoycline alternatives or acne alternatives. This is just another foam. There are other topical minocyclines that are easy to get without any PA whatsoever. It's another formulation that's a foam.

CAPT (Ret) Hostettler says he doesn't understand why it is prescribed to the patient for a year then stop them from continuing that therapy and try to force them into something else. You should have done that a year ago. I f you're going to go down that path. He further states the PA criteria for Qinlock states the patient has experienced disease progression on or had documented intolerance to three (3) drugs (Gleevec, Sutent, and Stivarga). This product, new to the market, has no advantage to any of the other three (3) drugs. They would have to use all three of those first.

Dr. Lugo said this one is for last line. Actually it's in their label as an indication.

CAPT (Ret) Hostettler said he didn't know that either. Thank you.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, 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 Recommendation**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

  Mr. Hostettler will concur with the exception of the minocycline. I think that should only apply to new users.

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

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

V. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

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

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for tramadol 100 mg immediate release (IR) tablets and Trinaz (regardless of the

woman's age) in new and current users, due to significant cost differences compared with numerous available alternative agents.

1. Narcotic Analgesics and Combinations—tramadol 100mg IR tablet

Cost-effective formulations of tramadol IR 50 mg tablets have been widely available from several manufacturers. The branded Ultram 100 mg tablets have been discontinued. A single manufacturer is now marketing a 100 mg IR tablet that is not cost-effective. The Committee recommended manual PA to encourage use of tramadol 50 mg IR tablets and to discourage the use of the 100 mg strength.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of tramadol 100mg IR.

Manual PA Criteria: tramadol 100mg IR is approved if all criteria are met:

- Provider is aware and acknowledges that tramadol 50 mg IR is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred tramadol 50 mg immediate release tablets.
- The provider must explain why the patient requires tramadol 100 mg IR tablets and cannot take the cost-effective tramadol 50 mg IR tablets.

Non-FDA-approved uses are not approved.

PA does not expire.

2. Vitamins: Prenatal—prenatal multivitamin (Trinaz)

Trinaz is a prenatal dietary supplement manufactured by a single company and requires a prescription prior to dispensing. The primary ingredients of Trinaz are similar to that found in Azesco and Zalvit, which require manual PA. Several prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria. Manual PA criteria were recommended for Trinaz, to require a trial of cost-effective formulary prenatal vitamins first.

The manual PA criteria are as follows:

Manual PA criteria apply to new and current users of Trinaz, regardless of the woman's age.

Manual PA Criteria: Azesco, Zalvit, or **Trinaz** is approved if all criteria are met:

- Provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, and Prenatal Plus DHA are the preferred products and are covered without a prior authorization for women who are under the age of 45 years and planning to become pregnant or who are pregnant. The provider is encouraged to consider changing the prescription to one of these agents.

- The provider must explain why the patient requires Azesco, Zalvit or Trinaz, and cannot take the available alternatives.

Non-FDA-approved uses are not approved.

PA does not expire.

B. New Manual PA Criteria

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria manual PA criteria for Striverdi Respimat in new users and for Gattex in new users.

1) Pulmonary-2 Agents: Long-Acting Beta Agonists (LABAs)—olodaterol (Striverdi Respimat)

Striverdi Respimat was designated as UF when reviewed at the February 2016 P&T Committee meeting. It was the sixth marketed LABA oral inhaler approved for maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). The LABA oral inhalers have seen declining utilization, primarily due to safety concerns, and have been largely replaced by the combination LABA/inhaled corticosteroid products (e.g., Advair) and long-acting muscarinics (e.g., Spiriva). There has been a significant price increase for Striverdi Respimat. Manual PA was recommended to require a trial of a widely used and cost effective alternative and are as follows:

Manual PA criteria apply to new users of Striverdi Respimat.

Manual PA Criteria: Striverdi Respimat is approved if all criteria are met:

- The patient has tried and failed salmeterol (Serevent Diskus) OR

- The patient is unable to produce inspiratory flow necessary to use a dry powder inhaler

Non-FDA-approved uses are not approved.

PA does not expire.

2) Gastrointestinal-2 Agents—teduglutide (Gattex)

Gattex is approved for patients with chronic short bowel syndrome (SBS) who are dependent on total parenteral nutrition (TPN), despite aggressive use of conventional measures. The product labeling states the drug should be discontinued in patients where minimal or no response is noted (shown as a clinically meaningful reduction in parenteral support or reduction in days requiring parenteral support), or who experience intolerable side effects. Gattex was identified as a high-cost specialty drug with a potential for off-label use. Provider feedback was solicited to develop manual PA criteria to ensure appropriate use for the small patient population who will benefit, consistent with the package labeling. Manual PA criteria will apply to new patients, with renewal criteria required for the patient to continue therapy after initial approval.

The manual PA criteria are as follows:

Manual PA criteria apply to new users of Gattex.

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

- Patient is 1 year of age or older.
- Gattex is prescribed by or in consultation with a gastroenterologist
- Patient has a documented diagnosis of Short Bowel Syndrome
- The patient is currently receiving parenteral nutrition on 3 or more days per week

Non-FDA-approved uses are not approved including patients not receiving parenteral nutrition.

PA expires after 6 months. Renewal PA criteria: expires in one year.

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

- Documented improvement (a decrease from baseline) in the weekly volume of parenteral nutrition or a reduction in the number of days requiring parenteral support

C. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the following implementation periods.

- **PAs for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5):** (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for tramadol 100 mg IR tablets and Trinaz will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

- New PAs: (16 for, 0 opposed, 0 abstained, 2 absent) The new PAs for Striverdi Respimat and Gattex in new users will become effective the first Wednesday 60-days after the signing of the minutes.

D. Physician's Perspective

There were four drugs where new PA criteria were recommended.

- **Narcotic Analgesics and Combinations—tramadol 100mg IR tablet** The original Ultram 50 mg tablets have been available for several years in cost-effective generic formulations, and are widely used. This new product is a 100 mg tablet that is significantly more expensive than the 50 mg tablets. We've had several examples of new products that are minor updates of existing formulations that offer no value over the original products. The Committee did not see any clinical reason why a patient should not be able to take two of the 50 mg tablets. We will mail letters to the patients, since current users will be affected by the PA.

- **Prenatal Vitamin (Trinaz) –** This prenatal vitamin is a supplement that the manufacturer has marketed as requiring a prescription; it is not an FDA-approved drug. Other prenatal vitamins similar to this product also have PAs (Zalvit in February 2020, and Azesco in August 2019). This product is significantly more expensive than the other prescription prenatal vitamins. We are treating this product the same way we've done with the other supplements.

- For the last two products, the **Striverdi Respimat inhaler and the short bowel syndrome drug Gattex**, the PAs will apply only to new users, as existing patients will be grandfathered.

    1. For Striverdi, the PA will require the patient to try the most commonly used Serevent inhaler first.

    2. For Gattex, the GI specialists we reached out to did feel that a PA would be reasonable.

E. Panel's Questions and Comments Regarding:

CAPT (Ret) Hostettler asked for the cost of the 100mg of the tramadol versus the 50 mg. Two (2) tablets is more cost effective than then 100mg.

MAJ Davies replied yes, that is correct. There was a pre-meeting before and the Panel mentioned commercial access for looking up drug cost. I implore you to look up drug cost for that one.

CAPT (Ret) Hostettler asked what is the formulary position of tramadol 100 mg? Is it UF with PA or NF with PA?

MAJ Davies repeated that he's looking for the current formulary position for tramadol. It's currently UF and no PA. This would be adding the PA to it.

There were no more questions or comments from the Panel. The Chair called for a vote on the UF Recommendation, PA Criteria and UF and PA implementation plan for the New Manual PA Criteria.

- **New Manual PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

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

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

IX. UTILIZATION MANAGEMENT—UPDATED MANUAL PA CRITERIA

A. Updated Manual PA Criteria Updated PA Criteria for Reasons other than New FDA Indications, NCCN Guideline Updates, or Age Ranges

Updates to the manual PA criteria and step therapy for several drugs were recommended due to a variety of reasons, including safety information, age indications, new FDA-approved indications, and availability of cost-effective alternative treatments. The updated PAs and step therapy outlined below will apply to new users with the exceptions of isotretinoin (Absorica and Absorica LD) and minocycline ER (Solodyn) which will apply to new and current users.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Absorica, Absorica LD, Solodyn and generics, and Addyi.

The updates are as follows, with the changes in bold and strikethrough lettering:

1. **Gynecological Agents Miscellaneous—flibanserin (Addyi)—**Manual PA criteria for Addyi were initially recommended at the November 2015 P&T Committee meeting. In October 2019, the FDA removed the Addyi risk evaluation and mitigation strategy (REMS) program and alcohol contraindication; now the boxed warning outlines the risks of

concurrent alcohol consumption with Addyi. The Committee agreed to update the manual PA in new users to reflect these safety changes, and to include criteria similar to other agent in the class, bremelanotide (Vyleesi), regarding cognitive-behavioral therapy and counseling.

Manual PA criteria apply to new users of Addyi. Updates are in bold and strikethrough.
Manual PA Criteria: Addyi is approved if all criteria are met:

- **Patient is 18 years of age or older**

- The drug is prescribed for a premenopausal female with hypoactive sexual desire disorder (HSDD) not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance

- **Patient has been counseled to wait 2 hours after consuming 1 or 2 standard alcoholic drinks before taking Addyi at bedtime or to skip their Addyi dose if they have consumed 3 or more standard alcoholic drinks that evening. After taking Addyi, the patient should not use alcohol until the following day**

- Patient does not have hepatic impairment (Child-Pugh score > 6)

- Patient not on a concomitant moderate or strong CYP3A4 inhibitor (e.g. ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)

- ~~Prescription written from provider who is certified/enrolled in the flibanserin REMS program~~

- **The patient has been informed that other treatment options such as cognitive-behavior therapy, sexual therapy, or couples therapy, may provide benefit without risk of side effects**

  Non-FDA-approved uses are not approved.

  PA expires after 3 months. Renewal PA criteria: will be approved indefinitely.

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

  - Patient has documented improvement in symptoms without serious side effects and continues to abstain from alcohol

2. **Acne Agents: Isotretinoids—isotretinoin (Absorica, Absorica LD)—**Several AB-rated generic formulations of the original proprietary product Accutane are marketed (e.g., Amnesteem, Claravis, Myorisan). Absorica and Absorica LD are new isotretinoin products

specifically formulated to allow for absorption without regard to meals. Other than patient convenience, they offer no compelling advantages over generic isotretinoin for patients with recalcitrant acne. Generic formulations of Absorica are expected in 2021. Existing PA criteria from November 2015 for Absorica and Absorica LD allow use if the patient is unable to comply with the dietary requirements for the generic products. The existing manual PA criteria for Absorica and Absorica LD, were updated to require a trial of generic isotretinoin first in new and current users, due to cost effectiveness.

Manual PA criteria apply to new and current users of Absorica and Absorica LD.

Manual PA Criteria: Absorica and Absorica LD are approved if all criteria are met:

- **The provider acknowledges that generic isotretinoin products (Amnesteem, Claravis, Myorisan) are available without a PA. Providers are encouraged to consider changing the prescription to one of these agents**

- **Patient has tried and failed at least one of the following oral isotretinoin products: Amnesteem, Claravis, or Myorisan, AND**

- Patient is unable to comply with the dietary requirements of an AB-rated generic oral isotretinoin (e.g., Amnesteem, Claravis or Myorisan).

  Non-FDA-approved uses are not approved.

  PA does not expire.

3. **Antibiotics: Tetracyclines—minocycline ER (Solodyn, generics)—**The February 2017 Tetracycline drug class review concluded there was no data to support that minocycline ER (Solodyn, generic) formulations are more effective or safer than generic minocycline IR preparations for treating acne. There is a substantial cost difference between the generic IR and ER formulations. Step therapy currently requires a trial of generic doxycycline IR and generic minocycline IR first. The existing Solodyn PA criteria were updated in new and current users to also require the provider to state the clinical reason as to why the patient cannot take generic minocycline IR. Automated step therapy will no longer apply. The new PA criteria will not expire, so patients meeting the updated criteria will not be required to fill out renewal criteria.

   Manual PA criteria apply to new and current users of minocycline ER and brand Solodyn. Updates are in bold and strikethrough.

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

   - **Provider acknowledges that minocycline immediate release (IR) is available to DoD beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to minocycline IR.**

- Patient has acne with inflammatory lesions AND

- ~~Patient is unable to tolerate generic minocycline IR due to gastrointestinal adverse events~~

- **The provider must describe why the patient requires minocycline extended release and cannot be treated with minocycline immediate release.** Non-FDA-approved uses are not approved.

  PA does not expire.

  The following section was not recorded but was part of the items updated as part of the PA Criteria. The items addressed were commented on by the P&T Chair, Dr. Kugler, and officially voted on by the BAP at this meeting. They were available in the background materials provided to the Panel. They are included here for completeness.

A. Updated PA Criteria for New FDA Indications, NCCN Guideline Updates, or Age Ranges

Several drugs had updates to PA criteria. Note that since these updates allow for expanded indications or broader age ranges, the updated PAs are not detailed as minor changes were made. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the updates to the manual PA criteria for Aczone, Ofev, and Dupixent, the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs Humira, Stelara, Taltz, and Cosentyx.

The updates are as follows:

1) **Acne Agents: Topical Acne and Rosacea—dapsone 5% and 7.5% gel (Aczone)—**Aczone 7.5% gel is only available in a proprietary formulation; however, generic dapsone 5% gel was first marketed in October 2017. Aczone 7.5% recently received approval for treating acne in patients as young as 9 years of age. Generic dapsone 5% has not been studied in patients younger than age 12. After reviewing clinical trial data, the Committee agreed to remove the age restrictions for both dapsone formulations. The committee also agreed that dapsone was unlikely to be used in children younger than 9, as acne is not commonly seen in this age group. Providers can therefore use the more cost-effective generic dapsone 5% rather than Aczone 7.5% for children. The PA criteria still requires a diagnosis of acne vulgaris and a trial of at least 3 step preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide.

2) **Respiratory Interleukins—dupilumab injection (Dupixent)—**Manual PA criteria for Dupixent were updated to reflect a lowered age indication for pediatric patients with moderate to severe atopic dermatitis 6 years of age or older; the previous age was 12 years. Note that the current age requirements for the other indications are not changed, including patients older than 18 years for chronic sinusitis and for patients as young as 12 years for asthma.

3) **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)—nintedanib (Ofev)—**The IPF drugs were reviewed for formulary status in May 2017, with step therapy requiring a trial of pirfenidone (Esbriet) prior to Ofev. Ofev recently gained a new indication for chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. Esbriet lacks this indication, therefore the step therapy requirements for a trial of Esbriet first will not apply here. The renewal criteria from the May 2017 class review was also clarified to exclude concomitant use of Esbriet and Ofev.

4) **Oncologic Agents: ovarian cancer [niraparib (Zejula), olaparib (Lynparza), and rucaparib (Rubraca)]; melanoma [encorafenib (Braftovi)] and multiple myeloma [selinexor (Xpovio)]**—Updates to the manual PA criteria for these oncologic agents reflects more detailed safety information, including standardized embryo-fetal toxicity information and male reproductive concerns. New FDA-approved indications or NCCN guideline-supported indications were also updated. A synopsis of the changes are summarized below.

    - **niraparib (Zejula)**—Allow use for the new FDA-approved indication as a first-line treatment for ovarian cancer

    - **olaparib (Lynparza) and rucaparib (Rubraca)**—Updated for the new FDA-approved indications for treating prostate cancer, and added a urologist as an allowable prescriber, in addition to a hematologist/oncologist. The Lynparza criteria was also updated to allow use for a new pancreatic cancer indication.

    - **encorafenib (Braftovi)**—Allow use for the new FDA-approved indication for treating colorectal cancer

    - **selinexor (Xpovio)—**Allow use for the new FDA-approved indication for treating diffuse large B-cell lymphoma

5) **Targeted Immunomodulatory Biologics (TIBs)—**Several updates for the TIBs including both off-label and new FDA-approved indications and

clarifications of step therapy requirements were made. A synopsis of the changes are summarized below.

- **adalimumab (Humira)—**Allow off-label use for moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids, based on supporting clinical data. Additionally, patients with PG or fistulizing Crohn's Disease (CD) can use Humira without a trial of non-biologic systemic therapy (e.g., methotrexate, azathioprine, sulfasalazine, mesalamine, or corticosteroids) first.

- **ustekinumab (Stelara)—**Updated the PA to include the new indication for pediatric patients down to the age of 6 years for plaque psoriasis; the previous indication was down to the age of 12 years. A trial of Humira is not required in pediatric patients 6 to 17 years old with a diagnosis of plaque psoriasis, since Humira is not indicated for children for this condition.

- **ixekizumab (Taltz)—**Updated the criteria to allow use in adults with non-radiographic axial spondyloarthritis (nr-axSpA); a trial of both Humira and Cosentyx are required first for this indication. The criteria were also updated for the new indication of plaque psoriasis in pediatric patients 6 to 17 years old. Note that a trial of Humira and Cosentyx are not required in patient's age 6 to 17 years. However, the requirement to try Stelara first for children between 6 to 17 years of age for this indication still applies.

- **secukinumab (Cosentyx)—**Updated to allow for the new nr-axSpA indication, requiring a trial of Humira first. Also updated to include coverage for moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and to remove "psoriasis of the scalp", since plaque psoriasis also encompasses all body areas.

B. Updated Manual PA Criteria—Implementation Plan

The P&T Committee recommended the following implementation periods:

- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Absorica, Absorica LD, and Solodyn in new and current users will become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to the beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA.

- (16 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Aczone, Addyi, Dupixent, Ofev, and the oncology drugs Zejula, Lynparza, Rubraca, Braftovi, and Xpovio, and the TIBs Humira, Stelara, Taltz, and Cosentyx in new users will become effective the first Wednesday 60-days after the signing of the minutes.

C. Physician's Perspective

- There were 17 drugs where we updated the PA criteria. Here, we had updates from nine drug classes; most of the changes were to allow use in expanded patient populations, for example pediatric patients or for new oncology indications.

- For the two acne drugs from two different classes – Absorica and Solodyn, we are strengthening the existing PAs, because the respective generics are significantly less costly, and there is no difference in efficacy or safety. We are taking the approach of changing the PA, rather than recommending these Tier 4 products at this time. Both new and current users are affected, so patients will be receiving letters.

- As you can see from the changes made at this meeting, a lot of time and effort is made to ensure that the PAs are updated to reflect the current package inserts.

D. Panel's Questions and Comments Regarding:

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

- **Updated PA Criteria**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

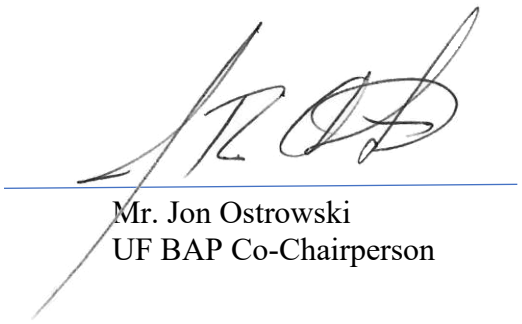
- **Updated PA Criteria – Implementation Plan**

  Concur: 7 Non-Concur: 0 Abstain: 0 Absent: 0

Mr. Ostrowski thanks everyone for the incredibly long meeting in this important presentation. He thanks Col Hoerner for this team and the P&T Committee.

Col Hoerner thanks everyone for dialing in and special thanks to the Branch.

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 August 2020

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's meeting in the subject of this report.

- AAD – American Academy of Dermatology
- AASM – American Academy of Sleep Medicine
- ACS – Acute Coronary Syndrome
- ADR – Adverse Drug Reactions
- ASCO – American Society of Clinical Oncology
- ASCVD – Atherosclerotic Cardiovascular Disease
- AV - Atrioventricular
- BAP- Benefit Advisory Panel
- BCF – Basic Core Formula
- BIA – Budget Impact Analysis
- CAD - Coronary Artery Disease
- CBC – Complete Blood Count
- CFR – Code of Federal Regulation
- CK – Creatine Kinase
- CMA – Cost-Minimization Analysis
- COVID – Corona Virus Disease
- CPAP – Continuous Positive Airway Pressure
- DEA – Drug Enforcement Agency
- DFO – Designated Federal Officer
- DHA – Defense Health Agency
- DNRI – Dopamine and Nonrepinephrine Reuptake Inhibitor
- DoD – Department of Defense
- ECG -Electrocardiogram
- ECHO - Echocardiogram
- EDS – Excessive Daytime Sleepiness
- ER – Extended Release
- ESS – Epsworth Sleepiness Scale
- FACA – Federal Advisory Committee Act
- FDA – Federal Drug Administration
- FMB – Formulary Management Branch
- GIST -Gastrointestinal Stromal Tumors
- HeFH – Heterozygous Familial Hypercholesterolemia
- ILD – Interstitial Lung Disease
- IPF – Idiopathic Pulmonary Fibrosis
- IUD – Intrauterine Device

- LABAs – Long-Acting Beta Agonists
- LFT – Liver Function Tests
- MAOI – Monoamine Oxidase Inhibitor
- MET – Mesenchymal-epithelial Transition
- MHS – Military Health System
- MS – Multiple Sclerosis
- MSLT – Mean Sleep Latency Time
- MTC – Mutant Medullary Thyroid Cancer
- NCCN – National Comprehensive Cancer Network
- NF – Non Formulary
- NSCLC – Mon-Small Cell Lung Cancer
- OATP – Organic Anion Transporting Polypeptide
- OSA – Obstructive Sleep Apnea
- P&T – Pharmacy & Therapeutics
- PA – Prior Authorization
- PAD – Peripheral Artery Disease
- REMS – Risk Evaluation and Mitigation Strategy
- TIA – Transient Ischemic Attack
- TIBs – Targeted Immunomodulatory Biologics
- UF – Uniform Formulary
- ULN – Upper Limit of Normal
- VZV – Varicella Zoster Virus
- WBC – White Blood Cell

X. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT AUGUST 2020

Table of Implementation Status of UF Recommendations/Decisions Summary

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Sleep Disorders: Wakefulness Promoting Agents Subclass	▪ armodafinil ▪ modafinil ▪ sodium oxybate (Xyrem)	▪ solriamfetol (Sunosi) ▪ pitolisant (Wakix)	▪ None	Pending the first Wednesday one week after the signing of the minutes	N/A – no copay changes or new PAs; only minor updates to PAs

WBC Stimulants: Filgrastims Subclass and Pegfilgrastims Subclass	FILGRASTIMS ▪ tbo-filgrastim vial and syringe (Granix) ▪ filgrastim-aafi vial and syringe (Nivestym) ▪ filgrastim vial and syringe (Neupogen) ▪ filgrastim-sndz syringe (Zarxio) PEGFILGRASTIMS ▪ pegfilgrastim-cbqv syringe (Udenyca) ▪ pegfilgrastim-jmdb syringe (Fulphila) ▪ pegfilgrastim syringe (Neulasta) ▪ pegfilgrastim on-body injector (Neulasta OnPro) ▪ pegfilgrastim-bmez syringe (Ziextenzo)	FILGRASTIMS ▪ None PEGFILGRASTIMS ▪ None	FILGRASTIMS ▪ None PEGFILGRASTIMS ▪ None	Pending signing of the minutes / 60 days	N/A - New PAs for non-step-preferred drugs affect only new users.
Psoriasis Agents	▪ calcipotriene 0.005% ointment (Calcitrene, generics) ▪ calcipotriene 0.005% cream (Dovonex, generics) ▪ calcipotriene 0.005% solution (generics) ▪ tazarotene 0.1% cream (generics)	▪ calcipotriene 0.005% foam (Sorilux) ▪ calcitriol 3 mcg/g ointment (Vectical, generics) ▪ calcipotriene 0.005%/betamethasone 0.064% ointment (Taclonex, generics) ▪ calcipotriene 0.005%/betamethasone 0.064% foam (Enstilar) ▪ tazarotene 0.1% gel (Tazorac) ▪ tazarotene 0.05% cream (Tazorac) ▪ tazarotene 0.05% gel (Tazorac)	▪ calcipotriene 0.005%/betamethasone 0.064% suspension (Taclonex)	Pending signing of the minutes / 120 days	<u>Unique Users Affected (NF candidates)</u> Mail – 583 MTF – 442 Retail – 1020 Total – 2045 <u>Unique Users Affected (Tier 4 candidates)</u> Mail – 115 MTF – 88 Retail – 149 Total: 352 **Note that the info in the BAP Background document is incorrect. The document says 555 users but it is 352 users**

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
tramadol 100 mg IR tab	0	20	90	110
prenatal MVI (Trinaz)	0	0	0	0
isotretinoin (Absorica and Absorica LD)	0	76	153	229
minocycline ER (Solodyn)	21	8	18	47