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

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING DAY #1 AM – refer to the posted Agenda for meeting dates and times https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with Section 1074g of Title 10, United States Code (USC) , as implemented by Section 199.21 of Title 32, Code of Federal Regulations (CFR) , the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA) or their designee, on formulary or complete exclusion status, prior authorizations (PAs), pre-authorizations, and the effective date for a pharmaceutical agent's change from formulary to nonformulary (NF) or to complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEW—SLEEP DISORDERS: WAKEFULNESS PROMOTING SUBCLASS

P&T Comments

A. Sleep Disorders: Wakefulness Promoting Subclass—Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the Wakefulness Promoting Agents. The subclass was previously reviewed for formulary status in August 2020. Drugs in this subclass include modafinil (Provigil, generics), armodafinil (Nuvigil, generics), sodium oxybate oral solution (Xyrem, authorized generics), sodium oxybate calcium/magnesium/potassium oral solution (Xywav), sodium oxybate extended release (ER) packets for oral suspension, (Lumryz), solriamfetol (Sunosi), and pitolisant (Wakix). The drugs in the class vary in their FDA-approved indications, which include excessive daytime sleepiness due to shift work sleep disorder, obstructive sleep apnea, or narcolepsy, cataplexy associated with narcolepsy, and idiopathic hypersomnia.

Relative Clinical Effectiveness Conclusion—The current review focused on evidence from updated professional clinical practice guidelines and network meta-analyses with systematic reviews. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Clinical Practice Guidelines

- *Narcolepsy*: The 2021 American Academy of Sleep Medicine (AASM) Guideline for Treatment of Central Disorders of Hypersomnolence lists a variety of agents which may be considered for treating excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy. Modafinil, Wakix, sodium oxybate and Sunosi are listed as a "strong" strength of recommendation for EDS associated with narcolepsy, with Wakix and sodium oxybate listed as a "strong" strength of recommendation for cataplexy. Armodafinil and dextroamphetamines are listed as "conditional" for EDS associated with narcolepsy.
- *Obstructive Sleep Apnea (OSA)*: The 2024 French Sleep Research and Medicine Society Guideline for Assessment and Management of Residual Sleepiness in OSA recommends comprehensive medical assessment and management before consideration of pharmacotherapy. Individual drug selection should be based on clinical judgement and managed by appropriate specialists.

Efficacy

- *Narcolepsy* A network meta-analysis and systematic review concludes that Sunosi, Xyrem, Xywav, Wakix, and modafinil result in statistically significant and clinically meaningful reductions in Epworth Sleepiness Scale (ESS) Scores compared to placebo. Additionally, Wakix and Xyrem were found to significantly reduce cataplexy rate when compared to placebo.
- *OSA*: A network meta-analysis and systematic review concludes that Sunosi, Wakix, armodafinil and modafinil treatment result in statistically significant and clinically meaningful reductions in ESS Scores versus placebo. The results were listed as "high certainty" for Sunosi, and "moderate certainty" for armodafinil, modafinil and Wakix
- For all indications, the data is limited by the lack of head-to-head trials and low adherence to pharmacological treatments. Non-pharmacologic measures are also recommended (e.g., sleep hygiene, continuous positive air pressure for OSA). Additionally, the Wakefulness Promoting drugs only treat the disease symptoms and do not alter the underlying disease course.

Safety

- *Narcolepsy*: A network meta-analysis and systematic review demonstrated a statistically significant increase in neurologic adverse events for armodafinil and Sunosi; gastrointestinal events for armodafinil, Sunosi, and Xyrem; and psychiatric events for Sunosi, when compared to placebo. Notably, treatment withdrawal due to adverse events was significantly increased for Xyrem. None of the agents resulted in a significantly increased risk for serious adverse events compared to placebo.

- *OSA*: A network meta-analysis and systematic review demonstrated an increased risk for discontinuation due to adverse effects for armodafinil and modafinil vs. placebo (high certainty) in patients treated for excessive daytime sleepiness and OSA.

Other Factors

- *armodafinil (Nuvigil, generics) and modafinil (Provigil, generics)* are both indicated for adults with EDS due to narcolepsy, shift work disorder or OSA and are available in generic formulations. Unique safety issues include serious rashes and anaphylaxis. They are both C-IV scheduled products (low potential for abuse). Generic formulations are available.
- *pitolisant (Wakix)* does not provide compelling clinical advantages other than it is not a controlled substance. It is approved for patients as young as 6 years of age with EDS associated with narcolepsy and for adults with cataplexy. Unique safety concerns include QT interval prolongation.
- *sodium oxybate*: There are three formulations of sodium oxybate, Xyrem, Xywav, and Lumryz. All the products carry a warning for central nervous system depression, respiratory depression and risk of abuse, misuse and diversion; are subject to risk evaluation and mitigation strategies (REMS) requirements; and are controlled substances and labeled as schedule C-III drug (moderate potential for abuse). The sodium oxybate products can only be dispensed by certified pharmacies. All three products are approved for treating EDS or cataplexy associated with narcolepsy in adults and children as young as 7 years of age.
    - *sodium oxybate oral solution (Xyrem)* is the original formulation and is now available in an authorized generic formulation. Dosing is administered at bedtime, with a second dose given 2.5 to 4 hours later.
    - *sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)* is the only drug in the subclass approved for adults with idiopathic hypersomnia; for this indication the dosing is once or twice nightly. Xywav contains less sodium than the original Xyrem formulation. There is a lack of robust data regarding this reduced sodium content, thereby limiting definitive conclusions for cardiovascular outcomes for narcolepsy patients.
    - *sodium oxybate ER packets for oral suspension (Lumryz)* is dosed once daily at bedtime.
- *solriamfetol (Sunosi)* is a C-IV scheduled product indicated for adults with EDS associated with narcolepsy or OSA. Safety concerns include hypertension and tachycardia.

Overall Conclusions

- For narcolepsy and excessive daytime sleepiness, there is a high degree of interchangeability between all the products. For narcolepsy with cataplexy, Wakix and the sodium oxybate formulations (Xyrem, Xywav, and Lumryz) have a moderate degree of therapeutic interchangeability and for sleepiness with OSA, modafinil, armodafinil and Sunosi have a moderate degree of therapeutic interchangeability.
- In order to meet the needs of Military Health System (MHS) beneficiaries, at least one agent is required for the treatment of each clinical indication.

B. Sleep Disorders: Wakefulness Promoting Subclass—Relative Cost Effectiveness Conclusion

The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Sunosi was the most cost-effective branded Wakefulness Promoting agent.
- BIA results showed that designating the Wakefulness Promoting Agents with the formulary status below generated significant cost avoidance for the MHS.

C. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation

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

- UF generics
  - modafinil (Provigil, generics)
  - armodafinil (Nuvigil, generics)
- UF brands
  - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)
  - solriamfetol (Sunosi) *moves from NF to UF*
- NF
  - sodium oxybate oral solution (Xyrem and authorized generics) *moves from UF to NF*
  - sodium oxybate ER packets for oral suspension (Lumryz)
  - pitolisant (Wakix)
- Complete Exclusion: none

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

PA criteria are not required for armodafinil or modafinil. PA criteria for the branded products have been in place since the original review and require the following: management by the appropriate specialist, confirmation of the diagnosis by objective testing, use of generic products first when clinically appropriate, and ruling out of other causes for sleep disorders. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria in new users, as outlined below.

- For the indication of EDS associated with narcolepsy in adults, a trial of stimulants (e.g., methylphenidate, dextroamphetamine) and armodafinil or modafinil is required first. For children, a trial of armodafinil or modafinil is not required, due to the limited evidence and lack of FDA-approval.
- For cataplexy associated with narcolepsy, a trial of stimulants is required, but armodafinil or modafinil is not required, due to limited evidence.
- For OSA, a trial of generic armodafinil or modafinil is required first.
- For Sunosi, an automated specialist bypass and age edit will apply. For manual PA criteria, if the patient is an adult and the provider is a neurologist, psychiatrist, sleep medicine specialist, pulmonologist, or cardiologist, then PA is not required.
- For Xywav, language now specifies that treatment for cataplexy does not require a trial of modafinil or armodafinil.
- For Xyrem, Lumryz, and Wakix, for EDS due to narcolepsy in adults, a trial of stimulants, armodafinil or modafinil, Sunosi and Xywav are required first, based on clinical and cost effectiveness. For cataplexy, the requirement for a trial of modafinil or armodafinil and Sunosi does not apply.

The Manual PA criteria is as follows.

1. pitolisant (Wakix)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

<u>Manual PA Criteria</u>:

- Provider acknowledges that PA is not required for modafinil or armodafinil
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy

- Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
- Patient is 18 years of age or older:
  - The patient has history of failure, contraindication, or intolerance to all of the following:
    - modafinil or armodafinil
      - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
    - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
    - **sodium oxybate (Xywav)**
    - **solriamfetol (Sunosi)**
      - **Treatment for cataplexy does not require trial of Sunosi**
- Patient is 6 years of age or older:
  - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)

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

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

2. sodium oxybate ER packets for oral suspension (Lumryz) and sodium oxybate oral solution (Xyrem brand)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

Manual PA Criteria:

- **Provider acknowledges that PA is not required for modafinil or armodafinil**
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy

- Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
- Patient is 18 years of age or older:
  - The patient has history of failure, contraindication, or intolerance to all of the following:
    - **modafinil or armodafinil**
      - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
    - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
    - **sodium oxybate (Xywav)**
    - **solriamfetol (Sunosi)**
      - **Treatment for cataplexy does not require trial of Sunosi**
- Patient is 7 years of age or older:
  - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)

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

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

3. sodium oxybate oral solution (Xyrem authorized generic)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

Manual PA Criteria:

- Provider will include a patient-specific justification as to why the Xyrem brand cannot be used in this patient: _____ (fill in the blank)
  - Acceptable reasons include a patient has had an adverse reaction not expected to occur with the generic

- **Provider acknowledges that PA is not required for modafinil or armodafinil**
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy
  - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
  - Patient is 18 years of age or older:
    - The patient has history of failure, contraindication, or intolerance to all of the following:
      - **modafinil or armodafinil**
        - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
      - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
      - **sodium oxybate (Xywav)**
      - **solriamfetol (Sunosi)**
        - **Treatment for cataplexy does not require trial of Sunosi**
  - Patient is 7 years of age or older:
    - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)
- 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)
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

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

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

Manual PA Criteria:

- **Provider acknowledges that PA is not required for modafinil or armodafinil**
- Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
- Prescribed for the treatment of idiopathic hypersomnia OR
- Prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy
  - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
  - Patient is 18 years of age or older:
    - The patient has history of failure, contraindication, or intolerance to all of the following:
      - **modafinil or armodafinil**
        - **Treatment for cataplexy does not require trial of modafinil or armodafinil**
      - stimulant-based therapy (amphetamine-based therapy or methylphenidate)
  - Patient is 7 years of age or older:
    - The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate)
- 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)
- The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic

Non-FDA approved uses are not approved

Prior Authorization expires after 1 year

A new PA must be submitted annually

5. solriamfetol (Sunosi)

Changes from the February 2025 meeting are in bold

PA criteria apply to all new users

<u>Automated PA Criteria</u>: When the patient is 18 years of age or older, and when prescribed by a neurologist, psychiatrist, sleep medicine specialist, pulmonologist or cardiologist, prior authorization is not required.

Manual PA Criteria: If automated criteria are not met, then Sunosi is approved if:

- Provider acknowledges that PA is not required for modafinil or armodafinil
- Patient is 18 years of age or older
- Sunosi is prescribed for either:
  - Excessive daytime sleepiness associated with narcolepsy
    - Prescribed by a neurologist, psychiatrist, or sleep medicine specialist
    - Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing
    - Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea
    - The patient must have tried and failed, had a contraindication to, or had an inadequate response to modafinil or armodafinil
    - The patient must have tried and failed, had a contraindication to, or had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate)
  - Excessive daytime sleepiness associated with obstructive sleep apnea:
    - Prescribed by a specialist who treats patients with obstructive sleep apnea (e.g., pulmonologist, cardiologist, sleep medicine)
    - Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least one month prior to initiation, and the patient demonstrated adherence to therapy during this time, and the patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of therapy
    - The patient must have tried and failed, had a contraindication to, or had an inadequate response to modafinil or armodafinil
- The patient is not concurrently taking a central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic

Non-FDA-approved uses are not approved

Prior authorization expires in 1 year

A new PA must be submitted annually

E. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation, PA Criteria and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving sodium oxybate (Xyrem) and authorized generics who will be affected by the formulary status change and PA.

III. UF DRUG CLASS REVIEW—SLEEP DISORDERS: WAKEFULNESS PROMOTING SUBCLASS

UF BAP Comments

A. Sleep Disorders: Wakefulness Promoting Subclass—UF Recommendation

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

- UF generics
  - modafinil (Provigil, generics)
  - armodafinil (Nuvigil, generics)
- UF brands
  - sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)
  - solriamfetol (Sunosi) *moves from NF to UF*
- NF
  - sodium oxybate oral solution (Xyrem, authorized generics) *moves from UF to NF*
  - sodium oxybate ER packets for oral suspension (Lumryz)
  - pitolisant (Wakix)
- Complete Exclusion: none

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended PA criteria in new users as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Sleep Disorders: Wakefulness Promoting Subclass —UF Recommendation, PA Criteria and Implementation Plan

The P&T Committee recommended for the Wakefulness Promoting Agents an effective date of the first Wednesday 90 days after signing of the minutes in all points of service and that DHA send letters to the patients affected by the formulary change for Xyrem.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—NARCOTIC ANALGESICS AND COMBINATIONS: BUPRENORPHINE AND COMBINATIONS SUBCLASS

P&T Comments

A. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—Relative Clinical Effectiveness Conclusion

The Narcotic Analgesics and Combinations include older generic opioids and abuse-deterrent products, along with two subclasses, the Transmucosal Immediate Release Fentanyl Products and the Buprenorphine and Combinations subclasses. The Narcotic Analgesics are routinely monitored to ensure alignment with clinical practice guidelines, emerging clinical evidence and Military Health System (MHS) utilization trends.

- Older generic opioids and abuse-deterrent formulations: New entries to the market are routinely evaluated for formulary status as part of the newly approved drugs program pursuant to 32 CFR 199.21(g)(5). Numerous clinically and cost effective opioid options are available on the formulary that do not require PA, overall utilization has decreased and an updated full class review of opioid agents is not warranted.
- Transmucosal Immediate Release Fentanyl products: There are no compelling clinical advancements or updated guidelines to warrant a full review since the original subclass review in 2015.
- Buprenorphine and Combinations: Joint clinical practice guidelines from the DoD and U. S. Department of Veteran's Affairs (VA) were recently updated and increasing MHS spend has been noted for the subclass. As a result, the current review focused on the Buprenorphine and Combinations Subclass. The drugs in the subclass include various formulations of buprenorphine, which are FDA-approved for managing severe and persistent pain, and combinations of buprenorphine with naloxone, which are approved for managing opioid use disorder.

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

Clinical Practice Guidelines:

- *Chronic Pain:* The 2022 DoD/VA guidelines for the use of opioids in the management of chronic pain assigned buprenorphine as a "weak for" recommendation, due to limitations in the available body of evidence, but superior safety profile over traditional opioids.
- The 2024 updated guidance continues to recommend non-opioid medications in combination with non-pharmacologic interventions as the preferred treatment for chronic pain. Many non-opioid options are available to TRICARE beneficiaries and are regularly added to the UF through the new drug program. Buprenorphine was acknowledged to retain many of the same risks associated with use of full agonist opioids yet demonstrates less risk of respiratory depression. However, the guidelines further state when treatment with opioids is indicated, buprenorphine may be preferred over full agonist opioids due to a unique mechanism of action and safety profile.
- *Opioid Use Disorder*: The 2022 Center for Disease Control clinical practice guideline for prescribing opioids for pain specifically mentions buprenorphine for opioid use disorder. Overall, evidenced-based treatment should be used. Buprenorphine can also be considered due to reduced overdosage risk compared to the risks seen with full agonist opioids.

Efficacy

- *Chronic Pain*
  - There are no head-to-head data comparing the buprenorphine formulations approved for chronic persistent pain. Based on indirect evidence, the buprenorphine patch (Butrans) and sublingual (SL) film (Belbuca) both demonstrate comparable efficacy in moderate-to-severe chronic pain.
  - A 2018 network meta-analysis and systematic review assessed the effectiveness and tolerability of buprenorphine for pain in adults and children with cancer. The conclusion was that there was insufficient evidence to designate buprenorphine as a valid first-line choice alongside standard therapies including morphine, oxycodone and fentanyl. Buprenorphine could be considered a fourth-line option.
  - Another 2023 meta-analysis and systematic review from the International Anesthesia Research Society compared the analgesic efficacy of buprenorphine to a control group for treating chronic noncancer pain. Both the transdermal and buccal administration routes produced statistically

significant reductions in pain and can be considered as an alternative to traditional analgesics for non-cancer pain.

- *Opioid Use Disorder*
  - When used for opioid use disorder, buprenorphine reduces withdrawal symptoms and opioid cravings.

Safety

- *Chronic Pain*: The labeling for all the buprenorphine agents carries similar safety warnings and adverse effect profiles.
  - *buprenorphine vs. other narcotic analgesics*: Buprenorphine has an analgesic ceiling effect, reducing the risk of respiratory depression and overdose. Additionally, there is a lower risk of misuse and dependence compared to full opioid agonists.
  - *buprenorphine products:* Both the Butrans patch and Belbuca buccal film have similar adverse effects and contain the same warnings seen with other opioids, including nausea, constipation, addiction, abuse, misuse, life-threatening respiratory depression, and risks with concurrent use with other central nervous system depressants.
- *Opioid Use Disorder*: For opioid use disorder, buprenorphine/naloxone combinations when compared to methadone are safer overall and safer in overdose, are more accessible, and require less frequent dosing. However, the ceiling effect may limit efficacy in some cases.

Individual Product Characteristics

- *Chronic Pain*
  - *buprenorphine transdermal system (Butrans, generics):* The patch requires once weekly application. Butrans is labeled for patients previously taking more than 80 oral morphine milligram equivalents daily. Advantages include the long duration of action. Disadvantages include the low bioavailability (15% with Butrans vs. 45% to 65% with Belbuca), risk of application-site pruritus and QTc interval prolongation at doses greater than 20 mcg/hour, which limits use in patients with unstable cardiac disease. It is contraindicated in patients with severe liver impairment.
  - *buprenorphine buccal film (Belbuca):* The buccal film has a 12-hour dosing frequency. Labeling includes patients previously taking less than 160 oral morphine milligram equivalents daily. Advantages include the high bioavailability via mucosal absorption and lower risk of QTc interval prolongation (risk is increased with doses above 900 mcg/hour). Disadvantages include adverse dental effects, including dental caries. The restriction regarding avoidance of eating, drinking and oral hygiene for 60 minutes following application may limit use.
- *Opioid Use Disorder*

- *buprenorphine/naloxone formulations:* The combinations with naloxone include SL tablets and an oral film. Compared with the generic Suboxone SL tabs, the branded Zubsolv SL tabs are available in more dosage strengths (6 dosages vs. 5 with Suboxone), have a higher bioavailability, reported better taste, and shorter dissolution time. For opioid use disorder, target maintenance doses can exceed 24 mg buprenorphine daily.
- *buprenorphine SL tabs (Subutex, generics):* This generic oral buprenorphine formulation is available in 2 mg and 8 mg SL tablets.

Overall Conclusions

- In terms of efficacy and safety for chronic pain treatment, there is a moderate to high degree of therapeutic interchangeability within the buprenorphine agents indicated for pain, with differences primarily based on dosing flexibility, administration routes, adverse event profiles and formulation-specific risks.
- In order to meet the needs of Military Health System (MHS) beneficiaries, multiple dosage formulations are preferred.

B. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA, BIA, and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following

- CMA results showed that generic Butrans was more cost effective than Belbuca, and generic buprenorphine agents for opioid use disorder were more cost effective than Zubsolv.
- BIA results found that designating Belbuca as UF resulted in increased spend, especially considering the recent price increase.

C. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—UF Recommendation

The P&T Committee recommended (19 for, 2 opposed, 0 abstained, 0 absent) the following.

- UF
  - buprenorphine transdermal patch (Butrans, generics)
  - buprenorphine buccal film (Belbuca) *moves from NF to UF*
  - buprenorphine SL tablets (Subutex, generic)
  - buprenorphine/naloxone SL tabs (Zubsolv)
  - buprenorphine/naloxone SL film (Suboxone)
  - buprenorphine/naloxone SL tabs (Suboxone tabs, generic)
- NF: none

- Complete exclusion: none

D. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—Manual PA Criteria

PA criteria currently apply to the Butrans patch since it was reviewed as a new drug in August 2011 due to concerns regarding respiratory depression at high doses. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the Butrans patch PA, as the other buprenorphine formulations do not have a PA, and to maintain alignment with clinical practice guidelines for chronic pain.

E. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—NARCOTIC ANALGESICS AND COMBINATIONS: BUPRENORPHINE AND COMBINATIONS SUBCLASS

UF BAP Comments

A. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass—UF Recommendation

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

- UF
  - buprenorphine transdermal patch (Butrans, generics)
  - buprenorphine buccal film (Belbuca) *moves from NF to UF*
  - buprenorphine SL tablets (Subutex, generic)
  - buprenorphine/naloxone SL tabs (Zubsolv)
  - buprenorphine/naloxone SL film (Suboxone)
  - buprenorphine/naloxone SL tabs (Suboxone tabs, generic)
- NF: none
- Complete exclusion: none

UF BAP Comments

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

B. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —Manual PA Criteria Removal

The P&T Committee recommended removing the manual PA criteria for Butrans patch, as outlined above.

UF BAP Comments

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

C. Narcotic Analgesics and Combinations: Buprenorphine and Combinations Subclass —UF Recommendation, PA Criteria Removal, and Implementation Period

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

UF BAP Comments

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

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

P&T Comments

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

The P&T Committee agreed (19 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

Addition of new medical devices to the TRICARE pharmacy benefit is also reviewed in this section. Medical devices are primarily covered by the TRICARE medical benefit, and any additions to the TRICARE pharmacy benefit are not meant to replace this pathway for procuring medical devices. The Committee identified one medical device for review at this meeting, Omnipod 5 Intro G6/Libre 2 Plus.

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

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

- UF
  - acoramidis (Attruby) – Miscellaneous Neurological Agents for transthyretin amyloidosis
  - arimoclomol (Miplyffa) – Miscellaneous Neurological Agents for Niemann-Pick disease
  - crinecerfont (Crenessity) – Miscellaneous Endocrine Agents for congenital adrenal hyperplasia
  - inavolisib (Itovebi) – Oncological Agents: Breast Cancer
  - marstacimab-hncq (Hympavzi) – Antihemophilic Agents
  - nilotinib tartrate tablets (Danziten) – Oncological Agents: Chronic Myeloid Leukemia
  - olezarsen (Tryngolza) – Antilipidemics-2 for familial chylomicronemia syndrome
  - Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits – Insulins: Miscellaneous Insulin Devices; this device was also added to the TRICARE Pharmacy benefit
  - revumenib (Revuforj) – Oncological Agents for Acute Leukemia
  - ustekinumab-auub (Wezlana) – Targeted Immunomodulatory Biologics: Interleukin-23 (IL-23) inhibitors
  - vanzacaftor/tezacaftor/deutivacaftor (Alyftrek) – Cystic Fibrosis Agents
- NF
  - aripiprazole oral film (Opipza) – Antipsychotic Agents: Atypical
  - filgrastim-txid (Nypozi) – White Blood Cell Stimulants: Filgrastim
  - imatinib 80 mg/mL oral solution (Imkeldi) – Oncological Agents: Chronic Myeloid Leukemia
  - minocycline 40 mg ER capsules (Emrosi) – Antibiotics: Tetracyclines
- Completely Excluded: none

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

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

- Applying manual PA criteria to new users of Wezlana, the biosimilar to Stelara, similar to what is required for all non-step-preferred Interleukin-23 inhibitors. A trial of adalimumab (Humira) and ixekizumab (Taltz) will be required first.
- Applying manual PA criteria to new users of Omnipod 5 Intro G6/Libre2 Plus pods and kits, similar to what is required for the Omnipod 5 G6/G7 pods and kits. Note that corresponding updates were also made to the Omnipod 5 G6/G7 PA criteria (see page 32).
- Applying manual PA criteria to Nypozi, similar to what is in place for the other non-step-preferred filgrastims. New patients receiving Nypozi or one of the other non-step-preferred filgrastims (Releuko and Neupogen) will be required to have a trial of Granix, Nivestym and Zarxio first.
- Applying manual PA criteria to new users of the oncology drugs Danziten, Imkeldi, Itovebi, and Revuforj.
- Applying manual PA criteria to new users of Alyftrek, Crenessity, Hympavzi, Opipza, and Tryngolza.
- Applying manual PA criteria to new users of Emrosi, requiring a trial of generic minocycline and other products for rosacea first, similar to what is required for other non-step-preferred minocycline products.
- Applying manual PA criteria to new users of Attruby. Accordingly, updates were made to the other drugs used for transthyretin amyloidosis (Vyndaqel, Vyndamax and Wainua); (see the utilization management section on page 32.)
- Applying manual PA criteria to new users of Miplyffa; updates were also made to the Aqneursa PA, the other drug approved for Niemann-Pick disease, to allow concomitant use with Miplyffa; (see the utilization management section on page 32.)

The Manual PA criteria are as follows:

1. **acoramidis (Attruby)**

   Manual PA criteria apply to all new users of the Attruby

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

   - The patient is 18 years of age or older
   - The requested medication is prescribed by or in consultation with a specialist who manages transthyretin amyloidosis (for example, cardiologist, geneticist, or neurologist)
   - Patient has a diagnosis of transthyretin-mediated amyloidosis
   - The patient is not receiving concurrent treatment with tafamidis (Vyndaqel, Vyndamax), Tegsedi (inotersen), Onpattro (patisiran), or Amvuttra (vutrisiran

Non-FDA approved uses are not approved, including ATTR-polyneuropathy

PA does not expire

2. arimoclomol (Miplyffa)

Manual PA criteria apply to all new users of Miplyffa

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

- Patient is 2 years of age or older
- Prescribed by a physician who specializes in the treatment of Niemann-Pick disease type C
- Patient has a genetically confirmed diagnosis of Niemann-Pick disease type C
- Patient is able to walk independently or with assistance
- Patient has one or more neurologic symptoms (e.g., loss of motor function, difficulty swallowing, and speech and cognitive impairment)
- Patent has tried and failed or experienced an adverse reaction or has a contraindication to levacetylleucine (Aqneursa)
- Patient will use the requested medication with miglustat

Non-FDA approved uses are not approved

PA does not expire

3. aripiprazole oral film (Opipza)

Manual PA criteria apply to all new users of Opipza

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

- Opipza is prescribed by a neurologist, psychiatrist, or developmental pediatrician
- The provider must explain why the patient requires Opipza and cannot take the generic formulary alternatives: aripiprazole ODT and oral solution (fill-in blank)
  - Acceptable responses include
    - The patient has had an adverse reaction to an excipient in aripiprazole ODT and oral solution that would not be likely to occur with Opipza oral film OR
    - The patient has documented oral aversion (e.g., due to developmental delay, sensory aversion) requiring an alternative formulation for treatment

Non-FDA-approved uses are not approved

Prior Authorization does not expire

4. crinecerfont (Crenessity)

Manual PA criteria apply to all new users of Crenessity

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

- Patient is 4 years of age or older
- The drug is prescribed by an endocrinologist, urologist, or a physician who specializes in the treatment of adrenal hyperplasia
- Patient has a diagnosis of 21-hydroxylase deficiency Congenital Adrenal Hyperplasia (CAH)
- Patient will take Crenessity in combination with systemic glucocorticoids

Non-FDA approved uses are not approved

PA does not expire

5. filgrastim-txid (Nypozi)

Manual PA criteria apply to all new users of Nypozi

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

- Provider acknowledges that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) are the TRICARE preferred filgrastims and are available without a prior authorization. Please consider changing the prescription to a formulary preferred medication. Note: Granix and Nivestym are available at the generic (Tier 1) copay at the Mail Order and Retail pharmacies
- Prescribed by or in consultation with a hematologist or oncologist
- Patient experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi)
- Patient experienced an inadequate treatment response or intolerance to filgrastim-aafi (Nivestym) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi)
- Patient experienced an inadequate treatment response or intolerance to filgrastim-sndz (Zarxio) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) or filgrastim-txid (Nypozi)

PA does not expire

6. imatinib 80 mg/mL oral solution (Imkeldi)

Manual PA criteria apply to all new users of Imkeldi

Age edit: PA is not required for patients 6 years or age or younger

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

- Patient is 12 years of age or older
- Provider acknowledges that generic imatinib tablets can be dissolved in water or juice and are available to DoD beneficiaries without requiring prior authorization
- Prescribed by an oncologist
- Patient has had an adverse reaction to an excipient in imatinib tablets that would not be likely to occur with Imkeldi OR
- Patient has tried and failed treatment with dissolving imatinib tablets in liquid

Non-FDA approved uses are not approved

PA does not expire

7. inavolisib (Itovebi)

Manual PA criteria apply to all new users of Itovebi

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Patient has locally advanced or metastatic hormone receptor (HR)-positive disease
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease
- Patient has PIK3CA-mutated breast cancer as detected by an FDA approved test
- Patient has disease recurrence on or after completing adjuvant endocrine therapy
- Medication will be used in combination with Ibrance (palbociclib capsules and tablets) and fulvestrant injection
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number _____.

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

PA does not expire

8. marstacimab-hncq (Hympavzi)

Manual PA criteria apply to all new users of Hympavzi

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

- Patient is 12 years of age or older
- The drug is prescribed by or in consultation with a hematologist
- Patient has moderate to severe hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors
- Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding

Non-FDA approved uses are not approved

PA does not expire

9. minocycline 40 mg ER caps (Emrosi)

Manual PA criteria apply to all new users of Emrosi

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

- Provider acknowledges that minocycline immediate release (IR), metronidazole gel and cream, and azelaic acid 15% gel are available to DoD beneficiaries without the need of prior authorization. The provider is encouraged to change the prescription to one of these preferred agents
- Patient is 18 years of age or older
- Prescribed by or in consultation with a dermatologist
- Patient has inflammatory lesions (papulopustular) of rosacea
- Patient has tried and failed or has a contraindication to an oral minocycline or doxycycline product
- Patient has tried and failed or has a contraindication to topical ivermectin
- Patient has tried and failed or has a contraindication to one of the following medications for rosacea: topical azelaic acid, topical metronidazole, isotretinoin, or topical minocycline
- Prescriber will provide the name and date of trial for the three above-mentioned drugs below:
  - Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____
  - Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____

- Drug name: _____ Date of Trial and Failure: _____ Contraindication: _____

Non-FDA approved uses are not approved

PA does not expire

10. nilotinib tartrate tablets (Danziten)

Manual PA criteria apply to all new users of Danziten

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

- Provider acknowledges PA is not required for Tasigna
- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist
- Patient has a diagnosis of:
  - Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR
  - Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib
- Patient has tried Tasigna and had an adverse reaction not expected to occur with Danziten, OR
- Patient cannot avoid food 2 hours before and one hour after taking Tasigna
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number _____.

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

PA does not expire

11. olezarsen (Tryngolza)

Manual PA criteria apply to all new users of Tryngolza

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

- Patient is 18 years of age or older
- Prescribed by cardiologist, an endocrinologist, or an internal medicine physician experienced in treating disorders related to severe hypertriglyceridemia
- Patient has undergone genetic testing to confirm the diagnosis of familial chylomicronemia syndrome
- Patient has fasting triglyceride level of 880 mg/dL or greater

- Patient will adhere to a low fat-diet (less than or equal to 20 g fat per day) while receiving Tryngolza

Non-FDA approved uses are not approved

PA does not expire

12. Omnipod 5 Intro G6/Libre2 Plus pods and kits

Manual PA criteria apply to all new users of Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits

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

- Patient is 18 years of age or older
- The Omnipod 5 device is being used to monitor diabetes mellitus
- Provider acknowledges that a current approved TRICARE PA for Omnipod 3 or Omnipod 4 does not grant automatic approval for Omnipod 5. New PA is required.
- Omnipod 5 is prescribed by or in consultation with an endocrinologist
- Patient is receiving multiple daily injections of insulin
- Patient has completed a comprehensive diabetes education program (to include teaching patient and caregiver how to administer insulin via syringe)
- Patient has demonstrated willingness and ability to play an active role in diabetes self-management

Non-FDA approved uses are not approved

PA expires in 1 year

Renewal Criteria: Note that initial Tricare PA approval is required for renewal. Coverage will be continued indefinitely for continuation of therapy if all criteria are met:

- Patient has been successful with therapy as shown by an increase in blood glucose time in range or improved A1c
- Patient has experienced a decrease in hypoglycemic episodes

13. revumenib (Revuforj)

Manual PA criteria apply to all new users of Revuforj

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

- The drug is prescribed by or in consultation with an oncologist
- Patient has relapsed or refractory acute leukemia

- Disease is positive for lysine methyltransferase 2A (KMT2A) gene translocation
- The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number _____.

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

PA does not expire

14. vanzacaftor/tezacaftor/deutivacaftor (Alyftrek)

Manual PA criteria apply to all new users of Alyftrek

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

- Patient is 6 years of age or older
- Prescribed by or in consultation with a pulmonologist
- Patient has diagnosis of cystic fibrosis
- Patient has at least one F508del mutation or another responsive mutation to Alyftrek in the CFTR gene and if the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation

Non-FDA approved uses are not approved

PA does not expire

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

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

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

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

UF BAP Comments

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

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

- UF
    - Attruby
    - Miplyffa
    - Crenessity
    - Itovebi
    - Hympavzi
    - Danziten
    - Tryngolza
    - Omnipod 5 Intro G6/Libre 2 Plus Pods and Kits
    - Revuforj
    - Wezlana
    - Alyftrek
- NF
    - Opipza
    - Nypozi
    - Imkeldi
    - Emrosi
- Complete Exclusion - none

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended the PA criteria for the new drugs as stated previously.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended implementation period of two weeks for the drugs recommended for UF and NF status, as discussed above.

UF BAP Comments

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

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

P&T Comments

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

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

a) **Narcotic Analgesics and Combinations—tramadol 75 mg tablet—**There are other tramadol formulations available, including scored tramadol 50 mg tablets, that are more cost-effective than this 75 mg formulation made by a sole manufacturer.

The Manual PA criteria are as follows:

1. tramadol 75 mg tablets

Manual PA criteria apply to all new and current users of tramadol 75 mg tablets

Manual PA criteria: tramadol 75 mg tablets are approved if all criteria are met:

- Provider is aware and acknowledges that tramadol 50 mg tablets are available to DoD beneficiaries without the need of prior authorization. Providers are encouraged to consider changing the prescription to the preferred tramadol 50 mg.
- Provider must explain why the patient requires tramadol 75 mg and cannot take the cost-effective generic tramadol 50 mg formulations (fill-in the blank)

- Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg tablets

Non-FDA-approved uses are not approved

Prior authorization does not expire

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for tramadol 75 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

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

UF BAP Comments

The P&T Committee recommended manual PA for tramadol 75 mg tablets as stated above and an effective date the first Wednesday 60 days after signing of the minutes and the DHA will send letters to the affected beneficiaries.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users.

a) **Atopy—dupilumab (Dupixent)—**The manual PA criteria were updated to allow for Dupixent use in patients with chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype after a trial of triple therapy with traditional inhalers approved for COPD.

b) **Oncological Agents—asciminib (Scemblix)—**The manual PA criteria were expanded to include newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Additionally, other updates were done to include the standard wording found in the other oncology PAs, including updating the National Comprehensive Cancer Network (NCCN) guidelines question and removing warnings and precautions language.

c) **Psoriasis Agents—tapinarof 1% cream (Vtama)—**The manual PA criteria were updated to allow for treatment of atopic dermatitis in patients 2 years of age or older.

d) **TIBs: Miscellaneous Interleukins—nemolizumab-ilto (Nemluvio)—**The manual PA criteria were updated to allow for treatment of atopic dermatitis in patients 12 years of age or older.

e) **TIBs: IL-17s—bimekizumab-bkzx (Bimzelx)—**Bimzelx received a new indication for hidradenitis suppurativa in adults. The manual PA criteria were updated and require a trial of Humira and Cosentyx first.

f) **Weight Loss Agents—tirzepatide (Zepbound)—**Zepbound is now indicated for moderate to severe obstructive sleep apnea in adults with obesity. The manual PA criteria were updated. A trial of phentermine will not be required for this new indication, due to the increased risk of cardiovascular events. Patients are required to have a body mass index of at least 30 and have a documented diagnosis of sleep apnea.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Scemblix, Vtama, Nemluvio, Bimzelx, Zepbound, and Dupixent in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Dupixent, Scemblix, Vtama, Nemluvio, Bimzelx and Zepbound in new users and an implementation effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users.

a) **Antidepressants and Non-Opioid Pain Syndrome Agents: Selective Serotonin Reuptake Inhibitors—vortioxetine (Trintellix)—**An automated drug lookback was added to the Trintellix PA allowing approval if a patient has tried two formulary antidepressants in the past 720 days.

b) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants—lisdexamfetamine capsule, chew tab (Vyvanse)—**An automated drug look back was added, allowing approval of the Vyvanse PA if a patient has had a trial of at least one amphetamine and one methylphenidate product within the past 720 days.

c) **Atopy: Oral Janus Kinase-1 (JAK-1) Inhibitors**

- **upadacitinib (Rinvoq)—**At the November 2024 P&T meeting, ixekizumab (Taltz) was selected as the step-preferred IL-17 inhibitor. The PA criteria for Rinvoq previously required a secukinumab (Cosentyx) trial first. The PA criteria was updated to replace Cosentyx with the step-preferred IL-17 Taltz. The PA was also modified with the other TIBs standardization edits (e.g., removing the monitoring and safety questions).
- **abrocitinib (Cibinqo)—**The Cibinqo PA was standardized and the exception to allow for concomitant use with apremilast (Otezla) was removed, as Cibinqo and Otezla do not have overlapping indications.

d) **Neurologic Agents: Miscellaneous drugs for Niemann-Pick disease—** levacetylleucine (Aqneursa)—The Aqneursa PA was updated to allow for concomitant use with arimoclomol (Miplyffa); (see new drug section on page 19).

e) **Neurologic Agents: Miscellaneous drugs for transthyretin amyloidosis—tafamidis (Vyndaqel), tafamidis meglumine (Vyndamax) and eplontersen (Wainua)—**The manual PA criteria for Vyndaqel, Vyndamax and Wainua were updated due to the recent approval of acoramidis (Attruby), (see new drugs section on page 19). The PAs were updated to expand the list of other amyloidosis drugs where concomitant use is prohibited.

f) **Oncological Agents—encorafenib (Braftovi)—**The Braftovi PA was updated as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for NCCN guideline updates.

g) **Ophthalmic: Dry Eye Agents—cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose**)—The Restasis PA was updated to add an automated specialist bypass for optometrists and ophthalmologists. Clinical criteria will still apply.

h) **TIBs: Tumor necrosis factor (TNF) inhibitors—etanercept (Enbrel)—**The Enbrel PA and MN criteria were updated to require a trial of ixekizumab (Taltz) in addition to adalimumab (Humira) first, based on the recommendations made at the November 2024 IL-17 class review. The Taltz step therapy requirement will not apply to adult patients with rheumatoid arthritis or pediatric patients with juvenile idiopathic arthritis or juvenile psoriatic arthritis.

   Other changes were made to standardize the PA, consistent with the PA criteria in place for other TIBs. Examples of these standardization edits across the TIBs class include removing monitoring and safety questions, adding a trial of NSAIDs for axial spondyloarthritis, and editing the non-biologic systemic therapy step. Additionally, the current automated PA criteria for Enbrel were removed.

i) **TIBs: Miscellaneous**

   - **baricitinib (Olumiant)—**Similar to the Cibinqo PA, the Olumiant PA wording was standardized and the exception to allow for concomitant use with Otezla was removed. Additionally, the automated PA criteria currently in place were removed.
   - **deucravacitinib (Sotyktu)—**The Sotyktu PA and MN criteria were updated to require a trial of Taltz in addition to Humira and Cosentyx before Sotyktu. Other TIBs standardization edits were also made.
   - **tofacitinib (Xeljanz)—**The Xeljanz PA wording was standardized and the automated PA criteria currently in place were removed. In addition, the PA criteria that mentioned dosing requirements were removed as this is not found in other PAs within the class.

j) **TIBs—ustekinumab (Stelara), guselkumab (Tremfya), risankizumab on-body injector (Skyrizi OBI), mirikizumab (Omvoh), vedolizumab (Entyvio), and infliximab (Zymfentra): Updates for Inflammatory Bowel Disease PA Criteria—**Recent guideline updates for inflammatory bowel disease (IBD) prompted a review of the TIBs used for ulcerative

colitis (UC) and Crohn's Disease (CD). Similar to existing guidelines for CD, the American Gastroenterological Association's (AGA) 2024 UC guidelines now recommend early biologic use and recommend against requiring monotherapy with non-biologic step-up therapy. Humira is listed as a lower efficacy medication for UC for both biologic therapy-naïve and biologic therapy-experienced patients. Intravenous (IV) infliximab (Remicade – available under the TRICARE Medical benefit) is listed as a highly effective medication for UC and for all special populations of CD.

Based on the AGA guideline update, the following changes were recommended for Stelara, Tremfya, Skyrizi OBI, and Omvoh: the non-biologic requirement for the UC indication was removed and a trial of IV infliximab is allowed in lieu of Humira for UC and CD. Additionally, the PA criteria for Omvoh were updated to allow for the new FDA indication for CD. The Entyvio and Zymfentra PAs were updated to add an automated specialist bypass for gastroenterologists, and to remove the requirements to try Humira or infliximab first. As with the other IBD agents, the requirement of non-biologic therapy for UC was removed.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained and 0 absent) updated manual PA criteria for Trintellix, Vyvanse, Rinvoq, Cibinqo, Aqneursa, Vyndaqel, Vyndamax, Wainua, Braftovi, Restasis, Enbrel, Olumiant, Sotyktu, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra in new users.

- Implementation for Aqneursa, Vyndaqel, Vyndamax, and Wainua will be effective the first Wednesday 2 weeks after signing of the minutes, along with the PA criteria implementation for the other drugs in their respective classes.
- Implementation for Enbrel, Sotyktu, Rinvoq, Cibinqo, Olumiant, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and Zymfentra will be effective the first Wednesday 30 days after signing of the minutes.
- Implementation for Braftovi, Restasis, Vyvanse and Trintellix will be effective the first Wednesday 60 days after signing of the minutes.

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

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Trintellix, Vyvanse, Rinvoq, Cibinqo, Aqneursa, Vyndaqel, Vyndamax, Wainua, Braftovi, Restasis, Enbrel, Olumiant, Sotyktu, Xeljanz, Stelara, Tremfya, Skyrizi OBI, Omvoh, Entyvio, and

Zymfentra, with the implementation effective at two weeks, 30-days or 60-days after signing of the minutes as outlined above.

UF BAP Comments

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

XIV. REMOVAL OF PAs—MIGRAINE AGENTS AND GASTROINTESTINAL-2 AGENTS, RETURN OF FROVA TO UF STATUS, AND IMPLEMENTATION PLAN

P&T Comments

A. Migraine Agents—frovatriptan (Frova, generics) and naratriptan (Amerge, generics)

Both frovatriptan (designated as NF) and naratriptan (designated as UF) require PA. They are available as generics, have relatively low utilization and cost, and a high PA approval rate. The PAs for frovatriptan and naratriptan will be removed, and frovatriptan will move to UF status.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for frovatriptan and naratriptan, and moving frovatriptan from NF to UF status. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Gastrointestinal-2 Agents: Chronic Idiopathic Constipation: Constipation-predominant Irritable Bowel Syndrome (CIC/IBS-C)—linaclotide (Linzess) and lubriprostone (Amitiza)

Currently, both Linzess and Amitiza are designated as UF requiring PA. They account for a high PA volume, and several commercial plans do not require a PA for these drugs. A review of the clinical and cost data supports removing the PAs for these two drugs.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for Linzess, and Amitiza. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

XV. REMOVAL OF PAs for MIGRAINE AGENTS AND GASTROINTESTIANL-2 AGENTS RETURN OF FROVATRIPTAN TO UF STATUS, AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended removing the PA criteria for frovatriptan, naratriptan, Linzess, and Amitiza. Additionally, frovatriptan will move from NF to UF

status. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent: