DEPARTMENT OF WAR
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE AUGUST 2026 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING SEPTEMBER 23, 2026

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 (DoW) 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—ONCOLOGICAL AGENTS: B-RAF PROTO-ONCOGENE, SERINE/THREONINE KINASE (BRAF) MITOGEN-ACTIVATED EXTRACELLULAR SIGNAL-REGULATED KINASE (MEK) INHIBITORS SUBCLASS

P&T Comments

A. Oncological Agents: BRAF MEK Inhibitors Subclass—Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the BRAF-MEK inhibitor subclass used for advanced or metastatic melanoma as well as other malignancies. The drugs in the class include encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), cobimetinib (Cotellic), dabrafenib (Tafinlar) and trametinib (Mekinist). The subclass has not previously been reviewed.

Relative Clinical Effectiveness Conclusion— The following clinical review focused on the uses of the BRAF MEK inhibitors for metastatic melanoma. For melanoma, the products are frequently used in combinations of Braftovi with Mektovi, Zelboraf with Cotellic and Tafinlar with Mekinist. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Efficacy

- For metastatic melanoma all BRAF/MEK combinations carry the same National Comprehensive Cancer Network (NCCN) recommendation for level of evidence.

- Indirect comparison between combinations of agents is challenging due to the varying treatment arms, study durations, and inclusion criteria in the respective clinical trials.
- These agents also carry FDA-approved indications outside of melanoma, in combination and as single agent therapy.

Safety

- Adverse events that are commonly associated with this class include rash, secondary squamous cell carcinoma, retinopathy, arthralgia/myalgia, fatigue and headache.
- Dabrafenib/trametinib (Tafinlar/Mekinist) has the highest rates of pyrexia.
- Encorafenib/binimetinib (Braftovi/Mektovi) has the most favorable tolerability profile, although it can cause gastrointestinal issues and blurred vision.
- Vemurafenib/cobimetinib (Zelboraf/Cotellic) has the highest rates of rash and hepatotoxicity.

Individual Product Characteristics

- The combination of dabrafenib/trametinib (Tafinlar/Mekinist) is unique in that it has clinical trial data in adjuvant settings for melanoma and is the only combination in the class indicated in pediatric populations. When brain metastases are present, dabrafenib/trametinib (Tafinlar/Mekinist) is the preferred combination.
- Compared to other agents, the vemurafenib/cobimetinib combination (Zelboraf/Cotellic) is preferred for treating histiocytic and central nervous system neoplasms.
- The preferred combinations for non-small cell lung carcinoma (NSCLC) are encorafenib/binimetinib (Braftovi/Mektovi) and dabrafenib/trametinib (Tafinlar/Mekinist). These combinations are also useful in thyroid cancer treatment.
- Encorafenib (Braftovi) is the only product in the class which is preferred for colorectal carcinoma treatment.

Overall Clinical Conclusion

- The BRAF-MEK inhibitors are used in a variety of malignancies and are supported by the NCCN guidelines.
- Although there is a high degree of therapeutic interchangeability among the BRAF-MEK inhibitors, the selection of agents is highly dependent on patient history and tolerance to adverse effects.

- At least one BRAF-MEK combination agent is required on the formulary in order to meet the needs of Military Health System (MHS) beneficiaries for treatment of metastatic melanoma. Other agents should remain available to treat other malignancies or special populations (e.g., brain metastases and children) and due to the differing toxicity profiles.

B. Oncological Agents: BRAF MEK Inhibitors Subclass—Relative Cost Effectiveness Conclusion

Cost Minimization Analysis (CMA) and Budget Impact Analysis (BIA) were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that encorafenib/binimetinib (Braftovi and Mektovi) and vemurafenib/cobimetinib (Zelboraf and Cotellic) were the most cost effective BRAF-MEK inhibitors.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating all the BRAF MEK inhibitors as UF demonstrated cost avoidance for the MHS.

C. Oncological Agents: BRAF MEK Inhibitors Subclass —UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the formulary recommendations as outlined below.

- UF
  - encorafenib (Braftovi)
  - binimetinib (Mektovi)
  - vemurafenib (Zelboraf)
  - cobimetinib (Cotellic)
  - dabrafenib (Tafinlar)
  - trametinib (Mekinist)
- NF
  - None
- Complete Exclusion
  - None

D. Oncological Agents: BRAF MEK Inhibitors Subclass —Manual PA Criteria

PA currently applies to all the drugs. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to Zelboraf, Cotellic, Braftovi, Mektovi, and Mekinist PAs as outlined below.

- vemurafenib (Zelboraf), cobimetinib (Cotellic), encorafenib (Braftovi) and binimetinib (Mektovi): Adding automated specialist bypass in new users; no PA is needed when prescribed by a hematologist/oncologist.
- encorafenib (Braftovi): remove the combination drug requirement.
- trametinib (Mekinist): All of the drugs except Mekinist have been standardized for the wording regarding NCCN guidelines and simplified for the safety criteria. The Mekinist PA was updated in new users, consistent with the previous oncology PA standardization efforts.

The Manual PA criteria are as follows.

1. encorafenib (Braftovi)

Updates from the August 2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Braftovi.

Automated PA criteria: When prescribed by an oncologist or hematologist, prior authorization is not required

Manual PA criteria: If automated PA criteria are not met Braftovi 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 confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test
- Patient has a diagnosis of:
  - Unresectable or metastatic melanoma
  - Unresectable or metastatic colorectal cancer
  - Metastatic non-small cell lung cancer
- ~~**Braftovi is being taken in combination with Mektovi, Vectibix, or Erbitux**~~
- Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version and page number _____.

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

PA does not expire

2. binimetinib (Mektovi)

Updates from the August 2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Mektovi.

Automated PA criteria: When prescribed by an oncologist or hematologist, prior authorization is not required

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

- Patient is 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Has unresectable or metastatic melanoma or metastatic non-small cell lung cancer
- Has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test
- Mektovi is being taken in combination with Braftovi
- Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)
- The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis: _____.~~ **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.

3. cobimetinib (Cotellic)

Updates from the August 2026 meeting are in bold

Manual PA criteria apply to all new users of Cotellic

Automated PA criteria: When prescribed by an oncologist or hematologist, prior authorization is not required

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

- Prescribed by or in consultation with a hematologist or oncologist
- Patient is 18 years of age or older.
- Patient has one of the following:
  - Unresectable metastatic melanoma AND has confirmed BRAF V600E or V600K mutation by an FDA-approved test AND Cotellic is being taken in combination with vemurafenib (Zelboraf) AND Patient

is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist) OR

- Histiocytic neoplasms

- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version, and page number: _____.

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

Prior authorization does not expire

4. vemurafenib (Zelboraf)

Updates from the August 2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Zelboraf

Automated PA criteria: When prescribed by an oncologist or hematologist, prior authorization is not required

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

- Prescribed by or in consultation with a hematologist/oncologist
- Documented diagnosis of unresectable or metastatic melanoma with BRAF V600E mutation AND melanoma that is not wild-type BRAF
- Patient has Erdheim-Chester Disease with BRAF V600 mutation
- Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist)
- 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 ~~**If so**~~, please list the diagnosis, guideline version, and page numbe**r**: _____.

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

PA does not expire

5. dabrafenib (Tafinlar)

Manual PA criteria apply to all new users of Tafinlar.

Manual PA criteria: Coverage will be approved if:

- Prescribed by or in consultation with a hematologist/oncologist

- Single agent for treatment of unresectable or metastatic melanoma with BRAF V600E mutation
- In combination with trametinib (Mekinist) for the treatment of patients with:
  - Unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations ~~**OR**~~
  - Adjuvant treatment of patients of melanoma with BRAF-V600E or BRAF-V600K mutation and involvement of lymph node(s), following complete resection
  - Metastatic non-small cell lung cancer (NSCLC) with BRAF V600E Mutation
  - Locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options
  - Unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options
  - Low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy
- Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)
- The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version, and page number: _____.

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

PA does not expire

6. trametinib (Mekinist)

Manual PA criteria apply to all new users of Mekinist.

<u>Manual PA criteria</u>: Coverage will be approved if:

- Prescribed by or in consultation with a hematologist/oncologist
- Monotherapy for treatment of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation in BRAF-inhibitor treatment naïve patients
- Combination with dabrafenib (Tafinlar) for the treatment of patients with:
  - Unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation

- Adjuvant treatment of patients of melanoma with BRAF-V600E or BRAF-V600K mutation and involvement of lymph node(s), following complete resection
- Metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation
- Locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options
- Unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options
- Low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

- Coverage not approved as a single agent in patients who have received prior BRAF inhibitor therapy
- Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)
- The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guideline version, and page number: _____.

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

PA does not expire

E. Oncological Agents: BRAF MEK Inhibitors Subclass —UF recommendation, PA and Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

III. UF DRUG CLASS REVIEW— ONCOLOGICAL AGENTS: BRAF MEK INHIBITORS SUBCLASS

UF BAP Comments

A. Oncological Agents: BRAF MEK Inhibitors Subclass —UF Recommendation

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

- UF
  - encorafenib (Braftovi)
  - binimetinib (Mektovi)
  - vemurafenib (Zelboraf)

- cobimetinib (Cotellic)
- dabrafenib (Tafinlar)
- trametinib (Mekinist)

- NF
  - None
- Complete Exclusion
  - None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Oncological Agents: BRAF MEK Inhibitors Subclass —Manual PA Criteria

The P&T Committee recommended updating the PA criteria for Zelboraf, Cotellic, Braftovi, Mektovi, and Mekinist as outlined above, including adding automated specialist bypass for Zelboraf, Cotellic, Braftovi and Mektovi.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Oncological Agents: BRAF MEK Inhibitors Subclass—UF Recommendation, PA Criteria, and Implementation Plan

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) STIMULANTS SUBCLASS

P&T Comments

A. ADHD: Stimulants Subclass—Clinical Effectiveness Conclusion

Background—The ADHD Stimulants were most recently reviewed for formulary status in November 2020. There are currently 41 products in the subclass, primarily comprised of methylphenidate, mixed amphetamine salts, and amphetamine formulations. Several products are available in generic formulations, including lisdexamfetamine capsules (Vyvanse), which saw generic competition in 2023.

The 10 remaining branded products without generic alternatives include methylphenidate formulations (Jornay PM, Quillichew ER, Quillivant XR, Azstarys, Cotempla XR-ODT); amphetamine products (Adzenys XR-ODT, Dyanavel XR); one mixed amphetamine salt (Mydayis); one dextroamphetamine (Xelstrym); and lisdexamfetamine (Arynta) oral solution.

The clinical review focused on new data published since the last review. The P&T Committee specifically evaluated the 10 branded products that do not have generic equivalents available. Factors discussed included duration of action, efficacy and safety, data from FDA summary reviews, published primary literature, previous clinical conclusions, formulary status from commercial health plans, and MHS provider feedback.

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

Professional Treatment Guidelines and Systematic Reviews

- Guidelines recommend medications only after behavioral or environmental modification have failed, particularly for children (e.g., American Academy of Pediatrics).
- The Canadian ADHD 2020 guidelines support previous P&T conclusions that methylphenidate and amphetamines have similar efficacy and tolerability profiles at the population level and that no specific clinical profile can predict which medication may result in improved symptom control over other agents.
- The Canadian Pediatric 2024 guidelines maintain that differences in effectiveness or adverse event profiles among stimulant brands are idiosyncratic. Switching from one stimulant formulation to another is recommended over switching from a stimulant medication to a nonstimulant.
- A 2025 systematic review and meta-analysis assessing the impact of pharmacological ADHD therapies on the quality of life (QoL) found that amphetamines, methylphenidate and the non-stimulant atomoxetine were significantly more efficacious than placebo in improving QoL. However, no one specific medication showed significantly improved QoL compared to the other drugs.

Efficacy

- No significant new clinical studies evaluating comparative efficacy between individual branded drugs or generic ADHD products were published since 2020.

Safety

- A 2025 systematic review and safety meta-analysis did not report significant differences between the ADHD medications for cardiovascular effects, including changes in systolic blood pressure, diastolic blood pressure, heart rate, or incidence of myocardial infarction or stroke. Specific adverse events that occurred at a higher rate in stimulant groups compared to placebo were decreased appetite, headache, insomnia, dry mouth, nausea, irritability, and anxiety.
- Azstarys was shown to have a significantly lower incidence of insomnia and end-of-dose crashes compared to amphetamine ER and lisdexamfetamine in one small study of 700 patients. There was no difference in the incidence of poor appetite or return of symptoms. Study limitations include lack of information on patient treatments tried prior to observation period. This study was funded by the manufacturer of Azstarys.

Special Populations

- Many alternative dosage forms are available for patients with swallowing difficulties. The contents of Vyvanse capsules are dissolvable in water and lisdexamfetamine chewable tablets are also an option. Adderall XR, Focalin XR, Metadate CD, Ritalin LA, and Azstarys are formulated in capsules that can be opened and sprinkled into applesauce. Aptensio XR sprinkle capsule, Methylin oral solution, ProCentra oral solution, and Quillivant XR oral suspension are currently available on the UF for patients with swallowing difficulties.
- Multiple generic ADHD stimulants are currently on the formulary that are approved for children ranging in age from the 6 to 17 years.

Individual Product Characteristics for Select Branded Agents

- Lisdexamfetamine (Vyvanse) is now available as generic capsules or chewable tablets. It is the only ADHD medication with additional approval for binge eating disorder.
- Lisdexamfetamine 10 mg/mL oral solution (Arynta) was designated NF when reviewed as a new drug in May 2026. It has no new clinical efficacy studies and was approved via the 505(b)(2) pathway, using data from Vyvanse. The duration of action ranges between 8 to 14 hours and is approved for children as young as 6 years. This new formulation provides little to no compelling clinical advantage over existing agents in the class.
- Methylphenidate ER sprinkle capsule nighttime dosing (Jornay PM) was the twelfth methylphenidate product marketed and is approved for patients as young

as 6. Jornay PM is administered at night before bedtime and has a delayed onset of action, so that therapeutic effects occur 8 hours after administration, in the morning. Stimulating effects may last 10 to 14 hours.

- Methylphenidate ER orally disintegrating tablets (Cotempla XR ODT) effects can last 12 hours, similar to other methylphenidate ER formulations. Cotempla XR ODT offers no compelling advantages over the existing UF ADHD drugs.
- Methylphenidate ER oral suspension (Quillivant XR) is the only long-acting methylphenidate oral suspension marketed in the US. Immediate release methylphenidate (Methylin) and dextroamphetamine (ProCentra) oral solutions are therapeutic alternatives to Quillivant XR but must be dosed twice daily.
- Methylphenidate ER chewable tablet (Quillichew ER chew tab) is the first 8 hour duration chewable tablet. While Quillichew ER tablets provide an alternative ADHD dosage form, there are several UF products available for patients with swallowing difficulties. It is currently designated as NF.
- Methylphenidate ER tab (Relexxi) was approved in 2021 based on the data for Concerta. Several other extended-release methylphenidate formulations are available on the UF without PA, including generic Concerta and methylphenidate ER/CD/LA, Quillivant XR, and Aptensio XR.
- Amphetamine ER oral suspensions (Dyanavel XR OS and Adzenys ER OS) provide alternative amphetamine dosage formulations; however, they do not offer any additional clinical effectiveness, safety, or tolerability benefit over other amphetamine ER products. They are currently designated as NF.
- Amphetamine ER orally disintegrating tablet (Adzenys XR ODT) is the only amphetamine ER product available in an ODT formulation, however, amphetamine (as a single ingredient without the mixed amphetamine salts) is not a first-line drug for ADHD treatment in children, and other alternative dosage products are available.
- Amphetamine mixed salts ER capsule triphasic release (Mydayis) is approved for children down to 13 years of age, but not for younger children as the effects of insomnia and appetite suppression can last up to 16 hours. Mydayis offers no compelling advantage over existing formulary agents, and is currently designated as UF
- Serdexmethylphenidate/dexmethylphenidate (Azstarys) was approved in 2021 via the 505(b)(2) pathway using data from dexmethylphenidate. It is a prodrug and potentially is an option for managing symptoms in adults and adolescents who are responsive to Focalin, but at higher risk of abuse. It is classified as a schedule II drug, similar to the other ADHD drugs.

- Dextroamphetamine patch (Xelstrym) provides no compelling clinical advantage over existing agents and has some precautions for use. It is NF with a PA and MN.

Therapeutic Interchangeability

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

Overall Clinical Conclusion

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

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

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

- CMA results showed that the products with generic formulations are generally significantly more cost-effective than brand-only products.
- CMA results for the branded products showed that the cost-effectiveness for several agents varied depending on formulary status, and that Vyvanse chewable tablet was the least costly agent, followed by Mydayis, Dyanavel XR, Quillichew, then Quillivant XR, and finally by Adzenys ODT, Xelstrym and Cotempla XR ODT which were the costliest agents.
- BIA results for all branded products with generic formulations showed that maintaining the existing formulary status was the most cost-effective.

C. ADHD: Stimulants Subclass—UF Recommendation

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintain the current formulary status for the ADHD drugs as described below:

- UF
  - dextroamphetamine ER (Dexedrine Spansule, generics; Dextrostat tabs. generics)
  - dextroamphetamine IR tablets (Zenzedi, generics)
  - dextroamphetamine oral solution (ProCentra, generics)

    - lisdexamfetamine capsules and chewable tablets (Vyvanse)
    - mixed amphetamine salts IR tablets (Adderall, generics)
    - mixed amphetamine salts XR capsules (Adderall XR, generics)
    - dexmethylphenidate IR (Focalin, generics)
    - dexmethylphenidate ER (Focalin XR, generics)
    - methylphenidate CD (Metadate CD, generics)
    - methylphenidate chewable tablets and oral solution (Methylin, generics)
    - methylphenidate ER (Methylin ER, generics)
    - methylphenidate ER sprinkle caps (Aptensio XR, generics)
    - methylphenidate ER sprinkle capsules nighttime dosing (Jornay PM)
    - methylphenidate ER oral suspension (Quillivant XR)
    - methylphenidate IR (Ritalin, generics)
    - methylphenidate long-acting (LA) (Ritalin LA, generics)
    - methylphenidate osmotic controlled release oral delivery system (OROS) tablets and other (Concerta, generics)
    - serdexmethylphenidate/dexmethylphenidate (Azstarys)
- NF
    - amphetamine ER orally disintegrating tablets (ODT) (Adzenys XR-ODT)
    - amphetamine ER oral suspension (Dyanavel XR)
    - amphetamine ER chew tab (Dyanavel XR)
    - dextroamphetamine transdermal system (Xelstrym)
    - lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)
    - mixed amphetamine salts ER capsules triphasic release (Mydayis)
    - methylphenidate ER (Relexxi)
    - methylphenidate transdermal system (generics)
    - methylphenidate ER chew tab (Quillichew ER)
    - methylphenidate XR-ODT (Cotempla XR ODT)
- Complete Exclusion – None
- For the products that were discontinued from the market, Evekeo ODT, Adzenys ER oral suspension and Adhansia XR if they return to market they will retain the previous formulary and PA status.

D. ADHD: Stimulants Subclass—Manual PA Criteria

PA criteria currently apply to Azstarys, Arynta, Cotempla XR ODT, Jornay PM, Mydayis, Relexxi, Vyvanse, Xelstrym. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the PA updates below,

- Updating the current manual PA criteria for new users of Azstarys and Jornay PM to reflect changes to the required drugs that must be tried first.
- Adding manual PA criteria to new users of Adzenys ODT to require the provider justify the need for this drug, primarily an inability to tolerate chewable, sprinkled or liquid preparations.
- Maintaining the current PA criteria for Vyvanse. At the February 2025 meeting, an automated lookback was added for both the Vyvanse capsules and chew tabs, 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. Implementation occurred on July 1, 2026.
- Maintaining the current manual PA criteria for Arynta, Mydayis, Cotempla XR-ODT, Relexxi and Xelstrym.

The Manual PA criteria are as follows:

1. amphetamine ER ODT tab (Adzenys XR ODT

New PA from the August 2026 meeting

Manual PA criteria apply to all new users

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

- Patient is 6 years of age or older
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record
- Provider must document why the patient must have Adzenys XR ODT: write-in
  - Acceptable reasons include: Patient can't swallow solid dosage forms of both methylphenidate and amphetamine products and can't tolerate chewable or liquid dosage forms as well as sprinkles mixed with food of these products

Non-FDA-approved uses are not approved

Prior authorization does not expire

2. lisdexamfetamine capsule, chew tab (Vyvanse)

No changes from the August 2026 meeting

Manual PA apply to all new users of Vyvanse

Automated PA Criteria: The patient has filled a prescription for one amphetamine and one methylphenidate at any MHS pharmacy point of service (MTFs, Retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days OR

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

ADHD

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

Binge Eating Disorder

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

Non-FDA-approved uses are not approved to include weight loss/obesity

Prior authorization does not expire

3. lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)

No changes from the August 2026 meeting

Manual PA criteria apply to all new users of Arynta

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

- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient is 6 years of age or older
- Patient tried and failed mixed amphetamine salts ER (Adderall XR, generics) or another long-acting amphetamine or amphetamine derivative type drug
- Patient tried and failed methylphenidate OROS (Concerta, generics) or another long-acting methylphenidate or methylphenidate derivative type drug
- Provider must document why the patient cannot take lisdexamfetamine dimesylate capsules or chewable tablets
  - Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in lisdexamfetamine dimesylate capsules; OR the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

  OR

- Patient has a diagnosis of moderate to severe Binge Eating Disorder (BED)
- Patient is 18 years of age or older
- Patient tried and failed OR has a contraindication to an SSRI (for example, citalopram, fluoxetine, sertraline)
- Patient tried and failed OR has a contraindication to topiramate or zonisamide
- Provider must document why the patient cannot take lisdexamfetamine dimesylate capsules or chewable tablets.
  - Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in lisdexamfetamine dimesylate capsules; OR the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

4. dextroamphetamine transdermal system (Xelstrym)

No changes from the August 2026 meeting

Manual PA criteria apply to all new users of dextroamphetamine transdermal system (Xelstrym)

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

- Patient is 6 years of age and older.
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record.
- Provider is aware of the warnings, screening and monitoring precautions for Xelstrym.
- Patient must have tried and failed or have a contraindication to one medication from each of the following categories:
  - amphetamines (single or mixed salt medications)
  - methylphenidate
- Patient has documented swallowing dysfunction requiring alternative formulation for treatment

Non-FDA approved uses are not approved

PA does not expire

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

No changes from the August 2026 meeting

Manual PA Criteria: Cotempla XR-ODT is approved if all criteria are met:

- Patient is 6 to 17 years of age
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- Patient has tried and failed OR has a contraindication to generic Adderall XR
- Patient has tried and failed OR has a contraindication to generic Concerta
- Patient has tried and failed OR has a contraindication to Quillivant XR (methylphenidate ER oral suspension), or Aptensio XR (methylphenidate ER cap)

Non-FDA-approved uses are not approved

Prior authorization does not expire

6. methylphenidate extended release tablets (Relexxii)

No changes from the August 2026 meeting

Manual PA criteria apply to all new and current users of methylphenidate extended release tablets (Relexxii).

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

- Provider is aware and acknowledges that several other long-acting methylphenidate ER formulations, including generic Concerta, generic Metadate CD, generic Methylin ER, generic Aptensio XR, and generic Ritalin, and Quillivant XR are available to DoD beneficiaries without requiring prior authorization
- The provider must explain why the patient requires Relexxii 72 mg ER tablets and cannot take the available alternatives.
    - Acceptable reasons the patient cannot swallow multiple tablets/capsules and has documentation of swallowing difficulties

Non-FDA-approved uses are not approved

Prior authorization does not expire

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

Updates from the August 2026 meeting are in bold and strikethrough

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

- Patient is 6 years of age or older
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record
- Patient has had at least a 2 month trial and failure of generic **methylphenidate ER/CD/LA** (Concerta**, Metadate, etc)** OR has difficulty swallowing pills
- ~~Patient has had at least a 2 month trial and failure of another long-acting methylphenidate (Methylphenidate ER/CD/LA, Quillivant XR, Aptensio XR)~~
- Patient has had at least a 2-month trial and failure of **dextroamphetamine/amphetamine** (Adderall XR **~~(generic~~**) OR has a contraindication to **dextroamphetamine/amphetamine** ~~Adderall XR~~
- Patient has tried, for at least two months, an immediate release formulation methylphenidate product in conjunction with **~~generic Concerta or~~** another long-acting methylphenidate
- Provider will explain why the patient requires Jornay PM:_____
    - Acceptable reasons include: Attempts to titrate with alternative treatments have not managed ADHD symptoms OR patient belongs to the exceptional family member program

Non-FDA-approved uses are not approved

Prior authorization does not expire

8. serdexmethylphenidate/ dexmethylphenidate (Azstarys)

Updates from the August 2026 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Azstarys

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

- Patient is 6 years of age or older
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record
- Patient has tried for at least two months and failed, had an inadequate response, or has a contraindication to methylphenidate OROS (Concerta, generic) or other long-acting methylphenidate
- Patient has tried for at least two months and failed, had an inadequate response, or has a contraindication to amphetamine mixed salts XR (Adderall XR generic) or other long-acting amphetamine
- Patient has tried for at least two months and failed, had an inadequate response, or has a contraindication to another long-acting methylphenidate (methylphenidate ER/CD/LA, ~~**Quillivant XR**~~, Aptensio XR)
- Patient has tried, for at least two months, an immediate release formulation methylphenidate product in conjunction with generic Concerta or another long-acting methylphenidate
- Please explain why the patient needs Azstarys: *(fill-in blank question)*
  - Acceptable reasons include: an attempt to titrate with alternative treatments has not managed ADHD symptoms or patient belongs to the exceptional family member program

Non-FDA-approved uses are not approved

Prior authorization does not expire

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

No changes from the August 2026 meeting

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

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

Non-FDA-approved uses are not approved

Prior authorization does not expire

E. ADHD: Stimulants Subclass —UF recommendation, PA, and Implementation Period

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—ADHD STIMULANTS SUBCLASS

UF BAP Comments

A. ADHD: Stimulants Subclass—UF Recommendation

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

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

    - serdexmethylphenidate/dexmethylphenidate (Azstarys)
- NF
    - amphetamine ER orally disintegrating tablets (ODT) (Adzenys XR-ODT)
    - amphetamine ER oral suspension (Dyanavel XR)
    - amphetamine ER chew tab (Dyanavel XR)
    - dextroamphetamine transdermal system (Xelstrym)
    - lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)
    - mixed amphetamine salts ER capsules triphasic release (Mydayis)
    - methylphenidate ER (Relexxi)
    - methylphenidate transdermal system
    - methylphenidate ER chew tab (Quillichew ER)
    - methylphenidate XR-ODT (Cotempla XR ODT)
- Complete Exclusion – None
- For the products that were discontinued from the market, Evekeo ODT, Adzenys ER oral suspension and Adhansia XR if they return to market they will retain the previous formulary and PA status.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. ADHD: Stimulants Subclass—Manual PA Criteria

The P&T Committee recommended the new PA criteria for Adzenys ODT in new users; updated manual PA criteria for Azstarys, and Jornay PM and maintaining the current manual PA criteria for Arynta, Cotempla XR ODT, Jornay PM, Mydayis, Relexxi, Vyvanse, and Xelstrym.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. ADHD: Stimulants Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended an implementation plan of 60 days 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 products were divided into two groups when presented at the P&T Committee meeting. The generic names are included below. Group 1 included Saphnelo, Atoncy, Baxfendy, Zolymbus, Idvynso, duloxetine, Filkri, Xtoro, Quiofic, Lynavoy, Bysanti, Lifyorli, Widaplik, Nereus and Veppanu, and Group 2 included Hepcludex and Xocova.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 18 for, 0 opposed, 0 abstained, 1 absent and Group 2: 17 for, 0 opposed, 0 abstained, and 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 Recommendation

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 1 absent and Group 2: 17 for, 0 opposed, 0 abstained, and 2 absent) the following

- UF
  - anifrolimab-fnia injection (Saphnelo) - Immunosuppressive for Systemic Lupus Erythematosus (SLE)
  - bulevirtide-gmod injection (Hepcludex) - Hepatitis D Agents
  - doravirine/islatravir (Idvynso) - Antiretrovirals for HIV
  - ensitrelvir fumarate (Xocova) - Antivirals for COVID
  - relacorilant (Lifyorli) - Oncological Agents for Ovarian Cancer
  - telmisartan/amlodipine/indapamide (Widaplik) - Renin-Angiotensin Antihypertensives (RAAs)
  - vepdegestrant (Veppanu) -Breast Cancer Agents
- NF

- atomoxetine 4 mg/mL oral solution (Atoncy) – ADHD Agents: Non-Stimulants
- baxdrostat (Baxfendy) – Diuretics
- bimatoprost 0.01% ophthalmic gel (Zolymbus) – Glaucoma drugs
- duloxetine 80-, 90-, 120 mg delayed release (DR) capsules (no brand name) - Antidepressants and Non-Opioid Pain Syndrome
- finafloxacin 0.3% otic suspension (Xtoro) - Antibiotics for acute otitis externa
- linerixibat (Lynavoy) - GI-2 Agent for pruritus from primary biliary cholangitis
- milsaperidone (Bysanti) - Antipsychotic Agents
- tradipitant (Nereus) - Antiemetic-Antivertigo Agents

- Complete Exclusion
  - filgrastim-laha injection (Filkri) - White Blood Cell Stimulants biosimilar for Neupogen
    - Filkri was recommended for complete exclusion status as it has little to no clinical benefit relative to the other filgrastim formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio).
  - folic acid 0.2 mg/mL oral solution (Quiofic and authorized generic) – Vitamins
    - Quiofic oral solution was recommended for complete exclusion status as it has little to no clinical benefit relative to the folic acid tablets, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include folic acid tablets.

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 1 absent and Group 2: 17 for, 0 opposed, 0 abstained, and 2 absent) the following PA criteria:

- Applying manual PA criteria to new users of Bysanti, requiring a trial of at least two formulary atypical antipsychotics, similar to other antipsychotics (e.g., Vraylar, Caplyta, Rexulti). Accordingly, new PA criteria were recommended for new users of iloperidone (Fanapt) to ensure clinical consistency across the bioequivalent agents. See the utilization management section on page 42.

- Applying manual PA criteria to new users of duloxetine, Xtoro otic suspension, Nereus, Saphnelo, and Lynavoy, requiring a trial of other formulary agents first.
- Applying manual PA criteria to new users of Hepcludex, Lifyorli and Veppanu, consistent with what is in place for other drugs for hepatitis virus (Hepcludex) and for other oncology drugs (Lifyorli and Veppanu).
- Applying manual PA criteria to new users of Atoncy and its authorized generic, atomoxetine solution, similar to the PA criteria currently in place for other ADHD non-stimulants.
- Applying manual PA criteria to new users of Zolymbus, requiring a trial of generic formulary agents, similar to what is in place for the other preservative-free ocular prostaglandin, latanoprost 0.005% ophthalmic solution (Iyuzeh). Updates were also made to the PA criteria for Iyuzeh. See the utilization management section on page 43.
- Applying manual PA criteria to new users of Baxfendy, requiring use of at least two standard hypertensive agents, one of which must be a diuretic, and a trial of spironolactone, in alignment with treatment guidelines for resistant hypertension. Accordingly, updates were made to aprocitentan (Tryvio), which is also indicated in resistant hypertension. See the utilization management section on page 43.
- Applying temporary PA criteria to new users of Filkri, Quiofic, and the folic acid solution authorized generic, until implementation of Complete Exclusion status.

The Manual PA criteria are as follows:

1. anifrolimab-fnia injection (Saphnelo)

Manual PA criteria apply to all new users of anifrolimab-fnia (Saphnelo)

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 a rheumatologist
- Patient has a diagnosis of systemic lupus erythematosus (SLE) that is autoantibody-positive as defined by at least one of the following: antinuclear antibodies (ANA), anti-double-strand DNA (anti-dsDNA) antibodies, anti-Smith (anti-Sm) antibodies
- Patient had an adequate trial (at least 3 months) of the following with an inadequate response, adverse effect, or contraindication to at least two of the four therapies; hydroxychloroquine, azathioprine, methotrexate, mycophenolate
- Patient is concurrently taking standard therapy (e.g., hydroxychloroquine, antimalarials, systemic corticosteroids and/or immunosuppressives either

alone or in combination) and will remain on standard therapy with Saphnelo

- Patient does not have severe active lupus nephritis or severe active central nervous system lupus
- The patient is not taking concurrent rituximab, belimumab, or other biologics including but not limited to, TNF inhibitors, interleukins, JAK inhibitors

Non-FDA approved uses are not approved

PA expires in 12 months

Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be approved for an additional 12 months if the following applies:

- Patient has shown documented clinical benefit (i.e. improvement in number/frequency of flares, improvement in in Safety of Estrogen in Lupus Erythematosus National Assessment - SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.)
- Patient is concurrently taking standard therapy (e.g., hydroxychloroquine, antimalarials, systemic corticosteroids and/or immunosuppressives either alone or in combination) and will remain on standard therapy with Saphnelo
- Patient does not have severe active lupus nephritis or severe active central nervous system lupus
- The patient is not taking concurrent rituximab, belimumab, or other biologics including but not limited to, TNF inhibitors, interleukins, JAK inhibitors

2. atomoxetine 4 mg/mL oral solution (Atoncy and authorized generic)

Manual PA criteria apply to all new users of Atoncy

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

- Patient is 6 years or older
- Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
- For patients younger than 12, must have tried and failed, had an inadequate response, OR contraindication to one stimulant medication (either amphetamine or methylphenidate product)
- For patients 12 and older, must have tried and failed, had an inadequate response, intolerance OR contraindication to all of the following:
  - amphetamine XR salts (Adderall XR, generics) or other long- acting amphetamines and their derivatives AND

- methylphenidate OROS and other (Concerta, generic) or other long-acting methylphenidate or derivative drug AND
- The patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, autism spectrum disorder, etc.), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

3. baxdrostat (Baxfendy)

Manual PA criteria apply to all new users of baxdrostat (Baxfendy)

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

- Patient is 18 years of age or older
- The drug is prescribed by a hypertension specialist (for example: internal medicine, cardiologist, nephrologist or prescriber with certification from the American Society of Hypertension)
- The patient has documented evidence of resistant hypertension by all the following:
  - Systolic blood pressure (SBP)/diastolic blood pressure (DBP) ≥ 130/80
  - Patient is currently taking maximal tolerable doses of 3 or more antihypertensive medications of which one must be a diuretic taken at maximally tolerated dose
    - diuretics
    - renin-angiotensin system blockers (e.g., ACE inhibitor or ARB blocker)
    - calcium channel blockers
    - mineralocorticoid receptor blockers (e.g., spironolactone)
- The patient has a contraindication to or has failed spironolactone as defined by:
  - potassium (K) level > 5 mmol/mL
  - estimated glomerular filtration rate (eGFR) <30 mL/minute
  - failure to control blood pressure to ≤ 130/80 with spironolactone
- If unable to take spironolactone:
  - The patient has a contraindication to amiloride, beta blocker, Alpha-2 Agonist, or vasodilator OR
  - The patient is unable to achieve blood pressure control with a fourth line agent
- Provider is aware of sodium and potassium monitoring requirements

Non-FDA approved uses are not approved

PA expires in one year

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

- Baxfendy treatment has controlled blood pressure within goal range

4. bimatoprost 0.01% ophthalmic gel (Zolymbus)

Manual PA criteria apply to all new users of bimatoprost 0.01% ophthalmic gel (Zolymbus)

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

- Patient is 16 years of age or older
- Patient has elevated intraocular pressure (IOP) due to open angle glaucoma or ocular hypertension
- Prescriber is an ophthalmologist or an optometrist
- Patient has tried two different formulary options, from any of the following glaucoma drug classes, in combination or separately at an appropriate duration of therapy
    - prostaglandin analogs (e.g., Lumigan, Travatan, Xalatan)
    - beta blockers (e.g., Timoptic)
    - alpha2-adrenergic agonists (e.g., Alphagan P)
    - topical carbonic anhydrase inhibitors (e.g., Azopt, Trusopt, Cosopt) OR
- Patient is currently taking bimatoprost and requires a preservative-free formulation because they are experiencing significant adverse events OR
- Patient is taking three or more different ocular medications that contain preservatives and accumulation of preservatives is a concern. Must document the drug and date of therapy
    - Drug Name_____ Date_____
    - Drug Name_____ Date_____
    - Drug Name_____ Date_____

Non-FDA approved uses are not approved

PA does not expire

5. bulevirtide-gmod injection (Hepcludex)

Manual PA criteria apply to all new users of bulevirtide-gmod (Hepcludex)

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

- Provider acknowledges that severe acute exacerbations of hepatitis D and hepatitis B may occur after Hepcludex is discontinued, especially in

patients with cirrhosis, who may be at increased risk of more severe flares or progression to hepatic decompensation. Refer to Hepcludex package labeling on monitoring recommendations.

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist or a liver transplant physician
- Patient has laboratory evidence of chronic active hepatitis D virus infection
- Patient either does not have cirrhosis or has compensated cirrhosis

Non-FDA approved uses are not approved

PA expires in 12-months

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for an additional 12 months of therapy if all the criteria are met

- Patient has evidence of positive response to treatment defined as achieving a virologic response (undetectable HDV RNA OR a ≥ 2 log10 decline in HDV RNA from baseline)
- Provider continues to monitor alanine aminotransferase levels as part of the assessment of ongoing clinical benefit

6. duloxetine 80-, 90-, 120 mg DR capsules (no brand name)

Manual PA criteria apply to all new users of duloxetine 80-, 90-, 120 mg delayed release capsules

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

- Provider acknowledges other formulations of duloxetine are available without prior authorization
- Patient is 7 years of age or older and has a diagnosis of generalized anxiety disorder OR
- Patient is 18 years of age or older and has a diagnosis of major depression AND
- The patient cannot take multiples or a combination of existing duloxetine generic product dosage strengths (e.g.40 mg or 60 mg) _____(write-in)
  - Acceptable reasons include the patient has an allergy to an inactive ingredient in generic duloxetine that is not contained in higher dose strength product

Non-FDA approved uses are not approved

PA does not expire

7. filgrastim-laha injection (Filkri)

Manual PA criteria apply to all new users of Filkri

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

- Provider acknowledges that Filkri will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T meeting minutes by the Director, DHA
- Tbo-filgrastim (Granix) and filgrastim-aafi (Nivestym) 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 Network 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), filgrastim-ayow (Releuko), filgrastim-txid (Nypozi), filgrastim-sndz (Zarxio), or filgrastim-laha (Filkri)

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

8. finafloxacin 0.3% otic suspension (Xtoro)

Manual PA criteria apply to all new users of finafloxacin 0.3% otic suspension (Xtoro)

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

- Patient has a diagnosis of acute otitis externa caused by susceptible strains of *Pseudomonas aeruginosa* and *Staphylococcus aureus*.
- Patient has tried and failed, experienced an adverse reaction, or has a contraindication to two other medications used to treat acute otitis externa (e.g., ciprofloxacin, ofloxacin, ciprofloxacin/dexamethasone, neomycin-polymyxin-hydrocortisone)

Non-FDA approved uses are not approved

PA expires after each course of therapy. PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA

9. folic acid 0.2 mg/mL (Quiofic and authorized generic)

Manual PA criteria apply to all new users of Quiofic and authorized generic

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

- Provider acknowledges that Quiofic will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T meeting minutes by the Director, DHA

- Patient has a diagnosis of megaloblastic anemia due to folic acid deficiency
- Provider must document why the patient cannot take folic acid tablets (Write-in) _____
  - Acceptable responses include: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Non-FDA approved uses are not approved

PA does not expire until after implementation of complete exclusion status

10. linerixibat (Lynavoy)

Manual PA criteria apply to all new users of linerixibat (Lynavoy)

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

- Patient is 18 years of age or older
- The drug is prescribed by a gastroenterologist, hepatologist, or liver transplant specialist
- Patient has Primary Biliary Cholangitis (PBC) with severe refractory pruritus
- Diagnosis of PBC has been confirmed by at least TWO of the following:
  - Alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values
  - Positive anti-mitochondrial antibodies (AMAs) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100)
  - Histologic evidence of PBC from a liver biopsy
- Patient been evaluated for possible orthotopic liver transplant (OLT)
- Patient is currently receiving or has an intolerance to ursodiol therapy
- Patient tried and failed or had intolerance to two of the following:
  - cholestyramine
  - rifampin
  - naltrexone
  - ONE antihistamine (for example, Atarax, Benadryl, etc.)
- Provider acknowledges use of this agent with seladelpar (Livdelzi) or elafibranor (Iqirvo) has not been studied

Non-FDA approved uses are not approved, including progressive familial intrahepatic cholestasis, Alagille syndrome, metabolic dysfunction-associated steatohepatitis (MASH), metabolic dysfunction-associated liver disease (MASLD), primary sclerosing cholangitis, and other cholestatic diseases

PA expires in 6 months

Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional 6 months if all the criteria are met

- Patient demonstrated significant improvement in pruritus symptoms

11. milsaperidone (Bysanti)

Manual PA criteria apply to all new users of milsaperidone (Bysanti)

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

- Patient is 18 years of age or older
- Provider acknowledgers that Bysanti is the active metabolite of Fanapt. FDA approval was based on pharmacokinetic data with Fanapt and no clinical trials were conducted with Bysanti.
- Prescribed by a psychiatrist

Patient has an established, primary diagnosis of schizophrenia AND

- Patient has failed to respond to at least TWO atypical antipsychotics at maximally tolerated doses (ex. iloperidone (Fanapt), risperidone, quetiapine, aripiprazole, olanzapine, olanzapine/fluoxetine, ziprasidone, paliperidone, lurasidone) OR

Patient has a diagnosis of acute treatment of manic or mixed episodes associated with bipolar I disorder in adults AND

- Patient has tried and failed two formulary atypical antipsychotics (e.g., risperidone, aripiprazole, lurasidone, quetiapine)

Non-FDA approved uses are not approved

PA does not expire

12. relacorilant (Lifyorli)

Manual PA criteria apply to all new users of relacorilant (Lifyorli)

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 a hematologist or oncologist
- Patient has platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Patient will be receiving the requested medication in combination with nab-paclitaxel
- Patient has tried one to three prior systemic therapies; where one of which is bevacizumab
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A,

or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____

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

PA does not expire

13. tradipitant (Nereus)

Manual PA criteria apply to all new users of tradipitant (Nereus)

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

- Provider acknowledges that scopolamine patch is available without the need of prior authorization
- Provider acknowledges that dimenhydrinate and meclizine are readily available over the counter and are effective for prevention of motion sickness
- The patient has tried and failed dimenhydrinate, meclizine and scopolamine in the past or had experienced significant adverse effects with these medications
- Provider acknowledges safety has not been established for usage exceeding 90 doses

Non-FDA approved uses are not approved

PA does not expire

14. vepdegestrant (Veppanu)

Manual PA criteria apply to all new users

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 a hematologist or oncologist
- Patient has ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer
- Patient had disease progression following at least one prior line of endocrine therapy (for example, letrozole, fulvestrant)
- Patient had disease progression following at least one CDK4/6 inhibitor (palbociclib, ribociclib, or abemaciclib)
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the

diagnosis, guideline version and page number _____.

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

Prior authorization does not expire

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

The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 1 absent and Group 2: 17 for, 0 opposed, 0 abstained, and 2 absent) an effective date of the following:

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

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

UF BAP Comments

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

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

- UF
  - anifrolimab-fnia injection (Saphnelo)
  - bulevirtide-gmod injection (Hepcludex)
  - doravirine/islatravir (Idvynso)
  - ensitrelvir fumarate (Xocova)
  - relacorilant (Lifyorli)
  - telmisartan/amlodipine/indapamide (Widaplik)
  - vepdegestrant (Veppanu)
- NF
  - atomoxetine 4 mg/mL oral solution (Atoncy)
  - baxdrostat (Baxfendy)
  - bimatoprost 0.01% ophthalmic gel (Zolymbus)

- duloxetine 80-, 90-, 120 mg delayed release (DR) capsules (no brand name)
- finafloxacin 0.3% otic suspension (Xtoro)
- linerixibat (Lynavoy)
- milsaperidone (Bysanti)
- tradipitant (Nereus)

- Complete Exclusion
  - filgrastim-laha injection (Filkri)
  - folic acid 0.2 mg/mL oral solution (Quiofic and authorized generic)

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) 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 two 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. All of the below PAs will require a provider to write-in clinical rationale explaining the need for the medication.

a) **Antidepressants and Non-Opioid Pain Syndrome Agents: Gamma-aminobutyric Acid Analogs—gabapentin (Relgaabi) 200 mg, 300 mg, and 400 mg capsules—**There are a plethora of generic gabapentin capsules that can meet the beneficiaries' need at a more cost-effective price than these Relgaabi capsules.

b) **Antianxiety Agents—buspirone 2.5 mg and 12.5 mg tablet**—Buspirone is readily available in cost-effective 5 mg and 7.5 mg tablets that can be split to achieve the same doses as in this product.

The Manual PA criteria are as follows:

1. **solution gabapentin (Relgaabi) capsules**

   Manual PA criteria apply to all new and current users of Relgaabi

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

   - Provider is aware and acknowledges that other formulations of gabapentin are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.
   - Provider must explain why the patient requires Relgaabi and cannot take the cost-effective formulations (blank write in)
     - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available gabapentin capsules

   Non-FDA approved uses are not approved

   PA does not expire

2. **buspirone 2.5 mg and 12.5 mg tablets (no brand name)**

   Manual PA criteria apply to all new and current users of buspirone 2.5 mg and 12.5 mg tablets

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

- Provider acknowledges other buspirone formulations, including the 5 mg and 7.5 mg tablets are available without requiring prior authorization.
- The provider must explain why the patient requires buspirone 2.5 mg and 12.5 mg tablets and cannot take cost effective alternative buspirone formulations. (blank write-in)
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available buspirone tablets

Non-FDA approved uses are not approved

PA 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 gabapentin (Relgaabi) capsules and buspirone 2.5 mg and 12.5 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. The new PAs 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 criteria for gabapentin (Relgaabi) capsules and buspirone 2.5 mg and 12.5 mg tablets in new and current users as stated above; and an effective date the first Wednesday 60 days after signing of the minutes. DHA will send letters to the affected beneficiaries.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

X. UTILIZATION MANAGEMENT—NEW PA CRITERIA

P&T Comments

A. New PA Criteria

The P&T Committee recommended new PA criteria for one drug.

Antibiotics: Tetracyclines—omadacycline (Nuzyra)—Nuzyra is a tetracycline antibiotic with a broad spectrum of activity indicated for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and soft tissue infections (ABSSI). Nuzyra was reviewed as an innovator at the February 2019 meeting and designated as non-formulary; currently there is not a PA.

Guidelines do not recommend first-line use of Nuzyra for any indications. In support of antimicrobial stewardship, Nuzyra is reserved for patients unable to use first-line agents. Review of MHS data shows increasing utilization and spend, and signs of inappropriate prescribing. Many commercial health plans require a PA for Nuzyra. Provider outreach determined it was reasonable to require a PA and allow infectious disease (ID) physicians and pulmonologists to bypass the PA, as these specialists commonly treat multidrug resistant infections.

The P&T committee recommended PA criteria in new users for Nuzyra, restricting use to the FDA-approved indication and one off-label use for non-tuberculous mycobacteria. Patients must have had an inadequate response, intolerance, contraindication or documented resistance to other antibiotics. ID physicians and pulmonologists will be allowed to bypass the PA. Nuzyra will be added to the Rapid Response/Safety Net Program.

The Manual PA criteria are as follows:

1. **omadacycline (Nuzyra)**

   Manual PA criteria apply to all new users of omadacycline (Nuzyra)

   Automated PA criteria: When prescribed by an infectious disease physician or a pulmonologist, prior authorization is not required.

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

   - Patient is 18 years of age or older
   - Patient has a diagnosis of community-acquired bacterial pneumonia (CABP), acute bacterial skin and soft tissue infection (ABSSTI), or non-tuberculous mycobacteria (NTM) AND
     - Patient has documented bacterial culture results showing one of the susceptible organisms from the package insert that is resistant to all other oral antibiotics, including doxycycline OR
     - Patient has experienced inadequate treatment response, intolerance, or contraindication to at least two first-line therapies for each approved diagnosis (e.g. CABP—macrolide, doxycycline, amoxicillin, levofloxacin; ABSSTI-vancomycin, linezolid, clindamycin, cephalexin, trimethoprim/sulfa, piperacillin-tazobactam) OR

- Patient is receiving omadacycline for a documented NTM/*Mycobacterium abscessus* infection in consultation with an NTM specialist

Other indications are not approved unless prescribed by an ID physician or pulmonologist.

PA does not expire for NTM indication. For all other indications, PA expires in 14 days.

No renewal allowed. A new prescription will require a new PA to be submitted.

B. New PA Criteria Implementation Plan

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for Nuzyra in new users, due to provider feedback, clinical guidelines, and the significant cost differences compared with generic alternatives. Nuzyra will be added to the Rapid Response/Safety Net program. The new PA will become effective the first Wednesday 60 days after the signing of the minutes

XI. UTILIZATION MANAGEMENT—NEW PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended new PA criteria for Nuzyra as outlined above, in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

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

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (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) **Antidepressants and Non-Opioid Pain Syndrome Agents—dextromethorphan/ bupropion (Auvelity)—**The manual PA criteria for Auvelity were updated for the new indication for agitation associated with Alzheimer's disease. The criteria mirror existing criteria for Rexulti for this indication, except for the removal of the requirement for prescribing by or in consultation with a specialist. Provider feedback recommended allowing primary care physicians to prescribe Auvelity, given the lack of a black-box warning for use in the elderly.

b) **Antihemophilic Agents: Non-Factor Agents—marstacimab-hncq (Hympavzi)—**The manual PA criteria for Hympavzi were updated to allow for the new hemophilia A and B with inhibitors indication and for the expanded age indication down to age six years.

c) **Antilipidemics-2 Agents—olezarsen (Tryngolza)—**Tryngolza received a new indication for use as adjunct to diet to decrease triglycerides and the risk of acute pancreatitis in adults with severe hypertriglyceridemia. The manual PA criteria were updated to reflect this new indication and to remove the Redemplo preference in the PA, as these two agents are now similarly priced. Additionally, PA language was added to prevent the concurrent use with Redemplo.

d) **Atopy: IL-13, IL-31—dupilumab (Dupixent)—**Dupixent received an expanded indication for chronic spontaneous urticaria in patients two years and older. Additionally, the prurigo nodularis indication was updated for clarity and to align with the commercial standard for this indication.

e) **Breast Cancer Agents: PIK3CA—capivasertib (Truqap)—**The manual PA criteria for Truqap were updated to allow for a new metastatic prostate cancer indication. In addition, the NCCN guideline question was updated to reflect the wording used in other oncology PAs.

f) **Metabolic Agents: Miscellaneous—setmelanotide (Imcivree)—**The manual PA criteria for Imcivree were updated to allow for the new indication for acquired hypothalamic obesity in patients 4 years of age and older.

g) **Nephrology Agents Miscellaneous—sparsentan (Filspari)—**The manual PA criteria for Filspari were updated for the new focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome indication.

h) **Neurologic Agents Miscellaneous—efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)—**The FDA updated the labeling for Vyvgart Hytrulo to no longer limit the myasthenia gravis indication to patients with anti-acetylcholine receptor (AChR) antibody positive disease. Therefore, this previous requirement was removed from the PA requirements.

i) **Pain Agents: Pain Topical—diclofenac epolamine 1.3% patch (Licart)—**The manual PA criteria for Licart were updated to include patients six years of age or older with acute pain.

j) **TIBs: IL-17s—secukinumab (Cosentyx)—**The manual PA criteria for Cosentyx were updated to allow use for hidradenitis suppurativa and ankylosing spondylitis in patients aged 12 and older.

k) **TIBs: IL-23s—risankizumab (Skyrizi) pens and syringes—**The manual PA criteria for Skyrizi pens and syringes were updated to allow use for plaque psoriasis and psoriatic arthritis in patients aged 6 and older. Note that the PA for Skyrizi On-Body- Injector (OBI) is only approved for adults.

l) **TIBs: IL-23s—ustekinumab-aauz (unbranded), ustekinumab-hmny (Starjemza), ustekinumab-srlf (Imuldosa), ustekinumab-ttwe (Pyzchiva), ustekinumab-aekn (Selarsdi), ustekinumab (Stelara), ustekinumab (unbranded Stelara), ustekinumab-stba (Steqeyma), ustekinumab-auub (Wezlana), ustekinumab-kfce (Yesintek)—**The manual PA criteria for the UF non-step preferred and NF non-step preferred ustekinumab products were updated to reflect the expanded age indication for pediatric Crohn's disease, now approved in patients as young as two years old. Of note, the PA for the preferred Otulfi product was not updated as there is no age restriction on this PA.

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

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the PA updates for Auvelity, Hympavzi, Tryngolza, Dupixent, Truqap, Imcivree, Filspari, Vyvgart Hytrulo, Licart patch, Cosentyx, Skyrizi, and the ustekinumab products (not including Otulfi), in new users. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes in all points of service.

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

UF BAP Comments

Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended the PA updates for Auvelity, Hympavzi, Tryngolza, Dupixent, Truqap, Imcivree, Filspari, Vyvgart Hytrulo, Licart patch, Cosentyx, Skyrizi, and the ustekinumab products in new users. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—UPDATED AND NEW PA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes.

a) **Antiemetic/Antivertigo Agents—meclizine 25 mg chewable tablet (Antivert)—**Meclizine is an older antiemetic widely available in 12.5 mg and 25 mg tablets in prescription and over-the-counter (OTC) formulations. A PA requiring documentation of a trial of generic meclizine tablets has been in place since May 2022 for the prescription chewable tablets. The "write-in" PA criteria were amended to require both a trial of the meclizine 25 mg tablet and the meclizine 25 mg OTC chewable tablet for the branded prescription Antivert 25 mg chewable tablet.

b) **Antilipidemics-2 Agents—plozasiran (Redemplo)—**The Redemplo PA was updated to prevent concurrent use with Tryngolza.

c) **Antipsychotic Agents—iloperidone (Fanapt)—**New PA criteria will apply to new users of Fanapt, requiring a trial of at least two second-generation antipsychotics, based on clinical practice guidelines and provider feedback. The PA will align with the PA criteria for Bysanti. Fanapt was also added to the Rapid Response/Safety Net program. (See the new drugs section on page 24.)

   The PA criteria is as follows:

   iloperidone (Fanapt)

   Manual PA criteria apply to all new users of iloperidone (Fanapt)

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

   - Patient is 18 years of age or older
   - Prescribed by a psychiatrist
   - Patient has an established, primary diagnosis of schizophrenia and has tried and failed two formulary atypical antipsychotics OR
   - Patient has a diagnosis of acute treatment of manic or mixed episodes associated with bipolar I disorder and has tried and failed two formulary atypical antipsychotics

   Non-FDA approved uses are not approved

   PA does not expire

d) **Atopy: IL-13, 31—nemolizumab (Nemluvio)—**The prurigo nodularis indication was updated for clarity, to match the changes made to the Dupixent PA.

e) **Breast Cancer Agents: Polyadenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors—niraparib (Zejula)—**The manual PA criteria for Zejula were updated to improve the PA flow and to remove the current homologous recombination deficiency (HRD) requirement, to align with NCCN comments on the value of HRD testing.

f) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation (CIC) and Constipation-Predominant Irritable Bowel Syndrome (IBS-C)—prucalopride (Motegrity), plecanatide (Trulance), tenapanor (Ibsrela)—**All PAs were updated to change the concomitant use wording to reflect the agents' mechanisms of actions. The renewal criteria were updated to require one renewal and then allow for indefinite approval.

g) **Gastrointestinal-2 Agents: Opioid Induced Constipation (OIC)--naloxegol (Movantik), naldemedine (Symproic), methylnaltrexone (Relistor)--**All PAs were updated to change the concomitant use wording to reflect the agents' mechanisms of action.

h) **Glaucoma Drugs—latanoprost 0.005% ophthalmic solution (Iyuzeh)—**The recent approval of Zolymbus (see new drugs section on page 25) prompted an update to the manual PA criteria for Iyuzeh, in new users. The three preservative-containing therapies previously trialed must be documented, along with the trial dates.

i) **Hematological Agents—ropeginterferon alfa-2b-njft (Besremi)—**An MTF oncologist requested a review of the Besremi MN criteria to allow for providers to select contraindications as a reason for MN approval. This change was added to the criteria, in addition to existing criteria which allow use in the setting of significant adverse effects or therapeutic failure to one previous agent.

j) **Oncological Agents: Multiple Myeloma—selinexor (Xpovio)—**Xpovio's indication for diffuse large B-cell lymphoma was FDA approved via accelerated approval in 2020. The manufacturer did not complete the required phase 3 study and instead requested to voluntarily withdraw this indication. The withdrawn indication was removed from the PA.

k) **Pulmonary Arterial Hypertension (PAH)—sotatercept (Winrevair)—**The manual PA criteria for Winrevair were updated to expand access to World Health (WHO) Functional Class IV PAH. Additionally, automated specialist bypass was added for pulmonologists, cardiologists, cardiac transplant surgeons, and cardiothoracic transplant surgeons if the patient is 18 years of age or older.

l) **Renin-Angiotensin Antihypertensives—aprocitentan (Tryvio)—**The manual PA criteria for Tryvio was updated in new users due to the recent approval of baxdrostat (Baxfendy), (see new drugs section on page 25.) A trial of three antihypertensive drugs will be required, of which one must be spironolactone. The contraindications for spironolactone were also added to the criteria.

XV. UTILIZATION MANAGEMENT—UPDATED and NEW PA FOR REASONS OTHER THAN NEW INDICATIONS AND IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended updates to the PA criteria for Antivert 25 mg chewable tablets, Redemplo, Nemluvio, Zejula, Motegrity, Trulance, Ibsrela, Movantik, Symproic,

Relistor, Besremi, Xpovio Winrevair, Iyuzeh and Tryvio, and the new PA criteria for Fanapt, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

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

XVI. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATIONS AND TIER 1 COPAYS – ADDITIONS AND REMOVALS AND IMPLEMENTATION PLAN

P&T Comments

- **Additions**
  - Leukemia and Lymphoma Agents: Breakpoint cluster (BCR)-Ableson (ABL) Tyrosine Kinase Inhibitors (TKIs)—bosutinib (Bosulif) tablets
  - Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) inhibitors—sitagliptin (Januvia) tablets
  - TIBS: Miscellaneous—tofacitinib (Xeljanz) IR and ER tablets

  Generic formulations are now marketed for Bosulif tablets, Januvia tablets, and Xeljanz immediate release (IR) and ER tablets; however, these generics are less cost-effective compared to the branded agents. Therefore, the branded agents will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. Accordingly, the Tier 1 (generic) copay for brand Bosulif tablets, Januvia tablets, and Xeljanz IR and ER tablets is recommended.

- **Removals**
  - Leukemia and Lymphoma Agents: BCR-ABL TKIs—nilotinib (Tasigna)

  Tasigna capsules were recommended for brand over generic status at the November 2025 P&T meeting. Generic nilotinib capsules are now more cost effective than the branded agent. The brand over generic criteria for the Tasigna capsules will be removed, and the Tier 2 copay will apply.

- **Implementation Plan**

  The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) adding brand over generic criteria for Bosulif tablets, Januvia, and Xeljanz IR and

ER tablets, plus the removal of brand over generic requirements for Tasigna. Implementation will occur the first Wednesday 60-days after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XVII. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATIONS AND TIER 1 COPAYS – ADDITIONS AND REMOVALS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended addition the brand over generic criteria for Bosulif tablets, Januvia, Xeljanz IR and Xeljanz XR, and removal of the brand over generic requirements for Tasigna, as outlined above.

UF BAP Comments

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

XVIII. OVER-THE-COUNTER (OTC) DRUG BENEFIT—ACETAMINOPHEN 325 MG TABLETS AND ORAL SUSPENSION AND ASPIRIN 81 MG TABLETS AND IMPLEMENTATION PLAN

P&T Comments

Background: In accordance with 10 U.S.C. 1074g(a)(2)(F), implemented by 32 CFR 199.21(h)(5)(i), an OTC drug may be included on the UF upon the recommendation of the P&T Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared to other drugs in the same therapeutic class of pharmaceutical agents. OTC drugs placed on the UF, in general, will be treated the same as generic drugs on the UF for purposes of availability in the MTF pharmacies, retail pharmacies, and TMOP. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the requirement for the prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under 32 CFR 199.21 (i)(2)(xii) for OTC drugs specifically used in certain emergency care treatment situations. Copayments for OTC drugs may be waived at Retail pharmacies, but not at TMOP.

Acetaminophen and aspirin were evaluated for clinical effectiveness and cost effectiveness for inclusion on the UF. Formulary inclusion would also result in dispensed prescriptions being noted on the patient's medication profile.

- ***acetaminophen 325 mg tablets and oral suspension*:** All single-ingredient oral formulations of acetaminophen are solely available as OTC products, therefore formulary inclusion would provide an additional non-opioid pain agent on the

UF. The suspension formulation is commonly used to treat fever and pain in the pediatric population.

Multiple professional organizations and clinical practice guidelines support the use of acetaminophen, including the American Academy of Pediatrics (AAP), WHO Pain Ladder, American Academy of Orthopaedic Surgeons (AAOS), and the Department of Veterans Affairs (VA)/DoW clinical practice guidelines on osteoarthritis and headache. The safety profile of acetaminophen differs from that of other pain agents, e.g., NSAIDs risk of adverse GI effect.

The cost of acetaminophen tablets and suspension is generally comparable to or lower than generically available legend pain agents (e.g., diclofenac, celecoxib, meloxicam, ibuprofen suspension) and both formulations are clinically preferred in some populations and situations due to adverse effect considerations.

- ***aspirin 81 mg*:** Clinical evidence supporting aspirin use was reviewed. The US Preventive Services Task Force (USPSTF) recommends aspirin as a preventive medication after 12 weeks of gestation in persons who are at high risk for preeclampsia. (Category B Recommendation). Private health insurers are required to cover (without cost sharing) medications with a USPSTF Category A or Category B recommendation. Guidelines from the American College of Cardiology/American Heart Association also recommend aspirin for secondary prevention of atherosclerotic cardiovascular disease.

  The cost analysis concluded that low-dose aspirin in general occupies a unique clinical niche and is cost-effective relative to legend medications used for cardiovascular prevention.

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- Adding acetaminophen 325 mg tablets to the UF (GCN 16964)
  - Maintaining the copay
- Adding acetaminophen 160 mg/5 mL oral suspension to the UF (GCN 26911)
  - Waiving the copay (emergency use)
- Adding aspirin 81 mg delayed release (DR) tab to the UF (GCN 00161)
  - Maintaining the copay
- Implementation will occur the first Wednesday 30 days after signing of the minutes by the Director, DHA

XIX. OVER-THE-COUNTER (OTC) DRUG BENEFIT—ACETAMINOPHEN 325 MG TABLETS AND ORAL SUSPENSION AND ASPIRIN 81 MG TABLETS AND IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended adding OTC acetaminophen 325 mg tablets and oral suspension and aspirin 81 mg tablets to the UF, with an implementation plan as noted above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XX. DRUGS DESIGNATED WITH COMPETE EXCLUSION: ANNUAL REVIEW AND FORMULARY RECOMMENDATIONS AND IMPLEMENTATION PLAN

P&T Comments

Background—P&T Committee reviewed all drugs designated with complete exclusion from the TRICARE pharmacy benefit program under 32 CFR 199.21(e)(3), which allows the P&T Committee to recommend special Uniform Formulary actions "to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD.

Drugs designated with complete exclusion are not available at the MTFs or TMOP points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail pharmacies. The Committee plans to review complete exclusion status drugs on an annual basis.

The P&T Committee reviewed all the drugs currently designated with complete exclusion status. The P&T Committee found no significant new clinical data, guidelines, or indications for the majority of the products that would change the previous conclusion that the drug offers little or no clinical effectiveness relative to similar agents. The Committee also found that all the complete exclusion drugs remain substantially more costly than similar agents, although prices have decreased for a few generically available products, which will continue to be monitored.

One drug was discussed in detail.

- ***Antihypertensive Agents—clonidine hydrochloride (HCl) 0.02 mg/mL oral solution (Javadin)*:** Javadin was recommended for complete exclusion status at the February 2026 P&T Committee meeting, with implementation slated for December 2, 2026. This drug is the first liquid oral immediate-release formulation of clonidine. No new clinical studies were conducted; FDA-approval was granted via the 505(b)(2) pathway using data from clonidine tablets (Catapres). While Javadin is solely approved for adults with hypertension, MTFs utilize liquid formulations to meet specific dosing needs. The FDA approval letter stated the product did not represent a meaningful therapeutic benefit over existing therapies for pediatric patients.

  Feedback from the MTFs requested formulary inclusion for Javadin, due to operational issues. Javadin's IR formulation and concentration of 0.02 mg/mL allow for smaller dosing increments than the other liquid clonidine formulation, Onyda

XR, a 0.1 mg/mL extended-release preparation solely approved for ADHD. Since Javadin is now commercially available as a clonidine liquid preparation, compound clonidine is no longer allowed.

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent)

- **Javadin:**
  - Moving Javadin from complete exclusion status back to NF.
  - The Javadin PA criteria originally recommended at the February 2026 meeting were updated to include an age edit for pediatric patients younger than 12 years of age. The updated PA criteria will apply to new users.

    The PA criteria are as follows:

    clonidine HCl 0.02 mg/ml oral solution (Javadin)

    Updates to the August meeting are in bold and strikethrough

    Age edit: PA not required if patient is age 12 years or younger

    Manual PA criteria apply to all new users of clonidine oral solution (Javadin)

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

    - ~~Patient is 18 years of age or older~~
    - ~~Patient has hypertension~~
    - Provider must document why the patient cannot take clonidine tablets and transdermal system. (write-in)
      - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis) AND
      - The patient has had significant irritation with the clonidine transdermal system OR the clonidine transdermal system is inappropriate for the indication

    ~~Non-FDA approved uses are not approved~~

    PA does not expire
  - The original recommendation for complete exclusion status from the February 2026 P&T Committee meeting will not be implemented.
  - Due to operational concerns, the updated PA criteria will be implemented no later than August 26, 2026.
- **Remainder of the drugs currently designated with complete exclusion status:** No changes were recommended to the other drugs currently designated with complete exclusion status, as the products have little to no clinical benefit relative to other drugs in their respective classes, and the needs of TRICARE beneficiaries are met by alternative agents.

XXI. DRUGS DESIGNATED WITH COMPETE EXCLUSION: ANNUAL REVIEW AND FORMULARY RECOMMENDATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended moving Javadin to NF status, with updated PA criteria, as outlined above. The implementation periods will be no later than August 26, 2026, due to operational issues.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent: