DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE MAY 2022 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING JUNE 30, 2022

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. UF DRUG CLASS REVIEWS—GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs) SUBCLASS

P&T Comments

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Relative Clinical Effectiveness Analysis and Conclusion

Background—The GLP1RAs were most recently reviewed in February 2018 when dulaglutide (Trulicity) replaced albiglutide (Tanzeum) on the formulary, due to market withdrawal. Exenatide once weekly (Bydureon BCise) and Trulicity have been the formulary step-preferred agents since 2018, with the remainder of the products nonformulary and non-step-preferred. This review focused primarily on systematic reviews and meta-analyses of the cardiovascular outcomes trials (CVOTs) with the GLP1As. Oral semaglutide (Rybelsus) was not part of this review, but remains UF.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- Metformin has an established place in therapy and remains first-line in most patients unless there are contraindication for use.

- The previous clinical conclusions from February 2018 remain largely unchanged with regard to GLP1RA effects on glycemic control, lipids, blood pressure, and body weight as well as safety and tolerability in patients with type 2 diabetes (T2DM).

- The GLP1RAs have a comparable range of efficacy across a broad population of patients with T2DM.

- Active comparator studies are available that evaluate the changes in hemoglobin A1c between the once weekly agents, semaglutide (Ozempic), dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise).

    - Ozempic vs. Bydureon: In the open-label, active comparator SUSTAIN-3 study, Ozempic was statistically and clinically superior to Bydureon BCise in glycemic control, as semaglutide lowered A1c by 1.5% from baseline compared to 0.9% with exenatide. Limitations to the SUSTAIN-3 study include its open label, active comparator design; it was not designed to show superiority.

    - Ozempic vs. Trulicity: In the open-label, active comparator SUSTAIN-7 study, semaglutide (Ozempic) was statistically superior to dulaglutide (Trulicity) in glycemic control, as it reduced A1c by 1.5-1.8% from baseline compared to 1.1-1.4% with dulaglutide. However, the differences in change in A1c between semaglutide and dulaglutide were not considered clinically relevant, as the change in A1c between the two drugs was less than 0.5% in respective treatment arms. Additionally, SUSTAIN-7 did not include the highest doses of dulaglutide (3 mg and 4 mg) which are now available.

- One recent systematic review (Giugliano, 2021) included approximately 60,000 patients with T2DM, where approximately 14,800 patients did not have established CV disease.

    - Overall, the results showed the GLP1RAs have a moderate benefit on major adverse cardiovascular events (MACE), including a reduction in hospitalization from heart failure, all-cause mortality, and the incidence of macroalbuminuria.

    - A greater effect was shown in those patients with known cardiovascular (CV) disease compared to those without.

- Individual clinical trials have shown a neutral or beneficial effect of the GLP1RAs in reducing CV events. The package inserts of Victoza, Ozempic, and Trulicity have an additional indication for CV risk reduction in those with established CV disease or who have multiple CV risk factors.

- Ozempic and Trulicity have warnings regarding diabetic retinopathy in their package inserts. However, studies are not powered to adequately assess this adverse effect. Additional studies are needed to definitively determine the long term effects of GLP1RAs on diabetic retinopathy.

Overall Conclusions

- Trulicity and Ozempic have a high degree of therapeutic interchangeability with regard to once weekly administration, cardiovascular benefits, ease of administration, indications, warnings, and adverse reactions.

- Victoza, Adlyxin, Bydureon BCise, and Byetta are less advantageous and have less clinical utility compared to Trulicity and Ozempic, due to such factors as the results of CVOT trials, increased frequency of dosing, or user-friendliness of the device.

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and also conducted a budget impact analysis (BIA). The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- Cost minimization analysis (CMA) results showed that dulaglutide (Trulicity), exenatide (Byetta), exenatide once weekly (Bydureon BCise), liraglutide (Victoza), lixisenatide (Adlyxin), and semaglutide (Ozempic) were all cost effective agents.

- Budget Impact Analysis (BIA) and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Trulicity as UF, and Byetta, Bydureon BCise, Victoza, Adlyxin, and Ozempic as NF demonstrated significant cost avoidance for the MHS.

C. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF Recommendation

The P&T Committee recommended ((15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - dulaglutide (Trulicity)
- NF
  - semaglutide (Ozempic)
  - exenatide once weekly (Bydureon BCise) -*moves from UF to NF*
  - exenatide twice daily (Byetta)
  - liraglutide (Victoza)
  - lixisenatide (Adlyxin)
  - Note that for Bydureon BCise, Byetta, Victoza and Adlyxin, a trial of both Trulicity and Ozempic are required
- Tier 4/Not Covered
  - None

D. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Manual PA Criteria

PA criteria have applied to the GLP1RAs for several years, requiring a trial of metformin first, unless the patient has had an adverse event, inadequate response or a contraindication. Currently a trial of dulaglutide (Trulicity) and exenatide once weekly (Bydureon BCise) are required, prior to use of one of the non-step-preferred products.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the GLP1RA class. Metformin will still be required in all new users of a GLP1RA, consistent with professional treatment guidelines. For semaglutide (Ozempic), a trial of dulaglutide (Trulicity) will no longer be required in new patients.

All new and current users of Bydureon BCise (which is now moving to NF status), Byetta, Victoza, and Adlyxin will now require a trial of both Trulicity and Ozempic. Children as young as 10 years can receive Victoza or Bydureon BCise without a trial of Trulicity and Ozempic, as these two products are the only GLP1RAs approved for children.

The Manual PA criteria is as follows:

dulaglutide (Trulicity) and semaglutide (Ozempic)

The only change from the May 2022 meeting is new patients receiving Ozempic do not require a trial of Trulicity first.

All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.

Manual PA criteria—Trulicity or Ozempic are approved (i.e., a trial of metformin is NOT required) if:

- The patient has a confirmed diagnosis of Type 2 diabetes mellitus.
- The patient has experienced any of the following issues on metformin:
  - impaired renal function precluding treatment with metformin
  - history of lactic acidosis
- The patient has had inadequate response to metformin
- The patient has a contraindication to metformin

Non-FDA-approved uses are not approved.
Prior Authorization does not expire.

exenatide once weekly (Bydureon BCise), exenatide twice daily (Byetta), liraglutide (Victoza) and lixisenatide (Adlyxin)

Changes from the May 2022 meeting are in bold and strikethrough.

All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first.

New and current users of Bydureon BCise, Byetta, Victoza, or Adlyxin, must try ~~Bydureon/Bydureon BCise~~ Trulicity and Ozempic first. *(Note that a trial of Bydureon BCise is no longer required)*

Manual PA criteria—Bydureon BCise, Byetta, Victoza, or Adlyxin is approved (i.e., a trial of metformin is NOT required) if:

- The patient has a confirmed diagnosis of Type 2 diabetes mellitus.
- The patient has experienced any of the following issues on metformin:
    - impaired renal function precluding treatment with metformin
    - history of lactic acidosis
- The patient has had inadequate response to metformin
- The patient has a contraindication to metformin

AND

In addition to the above criteria regarding metformin, the following PA criteria would apply specifically to new and current users of Bydureon BCise, Byetta, Victoza, and Adlyxin:

- The patient has had an inadequate response to Trulicity and **Bydureon BCise** Ozempic OR *(Note that a trial of Bydureon BCIse is no longer required)*
- **For Victoza and Bydureon BCise, patient is age 10 years to < 18 years.**

Non-FDA-approved uses are not approved.
Prior Authorization does not expire.

E. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF, PA and Implementation Period

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service.

III. UF DRUG CLASS REVIEWS—GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP1RAs) SUBCLASS

BAP Comments

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF Recommendations

The P&T Committee recommended the formulary status for the Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass as stated above.

- UF
  - Trulicity
- NF
  - Ozempic
  - Bydureon BCise *moves from UF to NF*
  - Byetta
  - Victoza
  - Adlyxin
- Tier 4/Not Covered
  - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—Manual PA Criteria

The P&T Committee recommended maintaining the PA criteria as stated above.

BAP Comments

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

C. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) Subclass—UF, PA and Implementation Period

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

BAP Comments

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

IV. UF DRUG CLASS REVIEWS—Migraine Agents - Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

P&T Comments

A. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the oral CGRP antagonists. The drugs in the subclass include ubrogepant (Ubrelvy), rimegepant (Nurtec), and atogepant (Qulipta). The CGRP antagonists are available as tablets (Ubrelvy, Qulipta) and as an oral disintegrating tablet (ODT) (Nurtec).

Ubrelvy and Nurtec ODT were reviewed as new drugs during the May 2020 P&T committee meeting, while Qulipta was reviewed in February 2022. The injectable CGRP agents for migraine headache prevention [erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality)] were reviewed for formulary status in February 2019.

The drugs in the subclass differ in their FDA-approved indications. Ubrelvy is approved for the acute treatment of migraine, Qulipta is labeled for prevention of episodic migraine, and Nurtec ODT is approved for both acute treatment of migraine and prevention of episodic migraine.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

Professional Treatment Guidelines

- *Acute treatment:* Medications with established efficacy for acute migraine treatment should be considered prior to initiation of the oral CGRP agents. Specifically, oral CGRP medications may be considered after a trial of two or more oral triptans, or in patients with a contraindication to or intolerability to triptans. These recommendations are based on the 2021 American Headache Society (AHS) consensus statement for integrating new migraine treatments into clinical practice.

- *Preventive treatment*: Medications including antiepileptics (e.g., valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol) and antidepressants (e.g., amitriptyline, nortriptyline), are first-line treatment options for episodic migraine prevention. This is based on the 2012/2015 American Academy of Neurology/American Headache Society migraine prevention guidelines. The 2021 AHS consensus statement for instituting new migraine treatments into clinical practice expands on the use of injectable CGRP antagonists for episodic migraine prevention. However, there is no specific guidance for oral CGRPs, citing the need for additional evidence and data.

Efficacy

- *Acute treatment vs. other therapies*: A 2020 network meta-analysis (NMA) from the Institute for Clinical and Economic Review (ICER) found that the oral CGRP antagonists (Ubrelvy, Nurtec ODT) are less efficacious than triptans when assessing pain freedom at 2 hours post treatment of migraine. A 2020 Cochrane NMA similarly reported that Ubrelvy and Nurtec ODT are less efficacious than sumatriptan, ibuprofen, diclofenac, and acetylsalicylic acid when assessing pain freedom at 2 hours post treatment of migraine.

- *Preventive treatment vs other therapies*: There are no head-to-head trials comparing Nurtec ODT and Qulipta to other standard migraine preventive treatments, or to their injectable CGRPs counterparts. Of note, the injectable CGRPs (Aimovig, Ajovy, Emgality) are only indicated for prevention of migraine, not acute treatment. Clinical trials demonstrate that the oral CGRP antagonists (Nurtec ODT, Qulipta) decrease monthly migraine days (MMD) by 0.7 to 1.7 days from baseline, compared to placebo. A 2018 ICER NMA found that the injectable CGRP antagonists, decreased MMDs by 1.2 to 1.9 days from baseline, compared to placebo.

- *Oral CGRPs vs. Oral CGRPs:* There are no head-to-head trials between the oral CGRP antagonists for either acute treatment or prevention of migraine headache. The high placebo response rate limits the ability to determine if there are

clinically relevant differences in efficacy between Qulipta, Nurtec ODT and Ubrelvy.

Safety

- The oral CGRP agents all have a relatively mild side effect profile. The most frequently reported adverse events for all the products include nausea, nasopharyngitis, urinary tract infection, and upper respiratory tract infection. Constipation and fatigue have been reported with Qulipta.

- There is limited long-term data to understand the risks with chronic CGRP antagonism. CGRP is a known vasodilator; there is a theoretical risk of increased ischemic events with CGRP antagonism. However, the 2021 FDA review for Qulipta states that based on available data, this medication does not require CV restrictions in labeling. The AHS in 2021 states that oral CGRPs (i.e. Nurtec ODT) may have a role in patients with CV contraindications to triptans. Extension studies out to 52 weeks with Ubrelvy report no significant adverse CV outcomes.

Distinguishing Characteristics

- *atogepant (Qulipta)* has multiple strengths available and allows for dosage adjustment in end stage renal disease; however it only carries a single indication (preventive treatment) and has more reported side effects than its competitor, Nurtec ODT.

- *rimegepant (Nurtec ODT)* has dual indications (acute and preventive treatment of migraine). However it only allows for once daily dosing in 24 hours with acute treatment, and must be avoided in patients with renal and hepatic failure. Indirect comparisons suggest Nurtec ODT has fewer reported adverse effects than Qulipta and Ubrelvy. Nurtec ODT has not been associated with rebound headache for acute migraine treatment.

- *ubrogepant (Ubrelvy)* allows for repeat doses for acute migraine treatment, and dosage adjustment in hepatic failure; however it only carries a single indication for use (acute treatment**).** Ubrelvy has not been associated with rebound headache for acute migraine treatment.

Overall Conclusions

- In terms of efficacy, there is a high degree of interchangeability between the oral CGRP antagonists when compared across the same clinical indication. In terms of safety, there is a moderate degree of therapeutic interchangeability, as

each medication carries a few unique adverse events. However, the side effects are mild and the oral agents are considered well tolerated.

- In order to meet the needs of MHS beneficiaries, at least one oral CGRP agent is required for treatment of each indication, acute migraine treatment, and episodic migraine prevention.

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that atogepant (Qulipta) was the most cost-effective oral CGRP antagonist, followed by rimegepant (Nurtec ODT), and then ubrogepant (Ubrelvy).

- BIA was performed to evaluate the potential impact of designating the three oral CGRP agents as UF, NF, or Tier 4 on the formulary. BIA results found that designating Ubrelvy, Nurtec ODT, and Qulipta as UF demonstrated significant cost avoidance for the Military Health System (MHS).

C. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF Recommendation

The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - atogepant (Qulipta) *moves from NF to UF*
  - rimegepant (Nurtec ODT)
  - ubrogepant (Ubrelvy) *moves from NF to UF*
- NF
  - None

- Tier 4/Not Covered
    - None

D. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Manual Prior Authorization Criteria

PA criteria were originally recommended when the individual oral CGRP medications were first evaluated as new drugs. The current PA criteria require a trial of first-line medications for both acute and preventive indications. For Ubrelvy, currently a trial of Nurtec ODT is required.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) minor updates to the current manual PA criteria in new users. The PA criteria and updates reflect the recommendations from the 2021 AHS Consensus Statement regarding candidates for a CGRP and assessment of response. For episodic migraine prevention, a trial of two standard therapies (antiepileptics, beta blockers, or antidepressants) as well as one injectable CGRP agent (Aimovig, Ajovy, or Emgality) will continue to be required first, before an oral CGRP agent. Additionally, for acute migraine treatment, a trial of two triptans are still required. Consultation with or evaluation by a neurologist is also still required for the oral CGRP agents.

For Ubrelvy and Nurtec ODT, the exclusion for patients with underling cardiovascular disease has been removed. Additionally, a trial of Nurtec ODT is no longer required in new patients receiving Ubrelvy. There were no changes made to the PA criteria for Qulipta (the CV exclusion was previously removed at the February 2022 meeting).

The PA Criteria are as follows:

1. atogepant (Qulipta)

There were no changes made at the May 2022 meeting

Manual PA criteria apply to all new users of Qulipta.

- Patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another “gepant”) is not allowed
- Patient has Episodic Migraine as defined by the following:

- 4 to 7 migraine days per month for 3 months AND has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 *OR*
- 8 to 14 migraine days per month for 3 months

- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
  - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
  - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
  - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine

- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents
  - erenumab-aooe (Aimovig)
  - fremanezumab-vfrm (Ajovy)
  - galcanezumab-gnlm (Emgality)

Non-FDA-approved uses are not approved.
Prior Authorization expires after 6 months.

Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

- The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:

- Migraine Disability Assessment (MIDAS)
  - Reduction of ≥ 5 points when baseline score is 11–20
  - Reduction of ≥ 30% when baseline score is > 20
- Headache Impact Test (HIT-6)
  - Reduction of ≥ 5 points
- Migraine Physical Functional Impact Diary (MPFID)
  - Reduction of ≥ 5 points

2. rimegepant (Nurtec ODT)

Updates from the May 2022 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of rimegepant (Nurtec ODT).

- The patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrelvy or another "gepant") is not allowed
- ~~**Not approved for patients who have clinically significant or unstable cardiovascular disease**~~

For Acute Treatment

- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
  - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)

For Prevention of Episodic Migraine

- The patient has episodic migraine as defined by one of the following:
  - Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR

- Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months

- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
  - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
  - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
  - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents
  - erenumab-aooe (Aimovig)
  - fremanezumab-vfrm (Ajovy)
  - galcanezumab-gnlm (Emgality)

Non-FDA-approved uses are NOT approved.
PA expires after 6 months.

Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:

Acute Treatment

- Patient has a documented positive clinical response to therapy

Preventive Treatment

- The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
  - Migraine Disability Assessment (MIDAS)

- Reduction of ≥ 5 points when baseline score is 11–20
- Reduction of ≥ 30% when baseline score is > 20

- Headache Impact Test (HIT-6)
  - Reduction of ≥ 5 points
- Migraine Physical Functional Impact Diary (MPFID)
  - Reduction of ≥ 5 points

3. ubrogepant (Ubrelvy)

Updates from the May 2022 Meeting are in strikethrough.

Manual PA criteria apply to all new users of ubrogepant (Ubrelvy).

- The patient is 18 years of age or older
- Medication is prescribed by or in consultation with neurologist
- Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or another "gepant") is not allowed
- ~~Not approved for patients who have clinically significant or unstable cardiovascular disease~~
- Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications
- sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax)
- ~~Patient has had a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT~~

Non-FDA-approved uses are not approved.
PA expires after 6 months

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

Acute Treatment: Patient has a documented positive clinical response to therapy

E. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEWS—Migraine Agents - Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

BAP Comments

A. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - Qulipta *moves from NF to UF*
  - Nurtec ODT
  - Ubrelvy *moves from NF to UF*
- NF
  - None
- Tier 4/Not Covered
  - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—Manual Prior Authorization

The P&T Committee recommended minor updates to the current manual PA criteria in new users as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass—UF, PA, and Implementation Period

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

BAP 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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent; and Group 2: 16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
  - filgrastim-ayow injection (Releuko) – White Blood Cell Stimulants - filgrastims. Note that as part of this recommendation Releuko will be designated as non-step-preferred.

- mitapivat (Pyrukynd) – Miscellaneous metabolic agent for pyruvate kinase deficiency
- naloxone 5 mg/0.5mL injection (Zimhi) – Narcotic Antagonist
- pacritinib (Vonjo) – Oncologic agent for myelofibrosis

- NF
  - abrocitinib (Cibinqo) – Atopy drug class; oral Janus kinase (JAK) inhibitor for atopic dermatitis
  - baclofen oral suspension (Fleqsuvy) – Skeletal Muscle Relaxant for spasticity associated with multiple sclerosis
  - tenapanor (Ibsrela) – Gastrointestinal-2 Agent for Constipation-Predominant Irritable Bowel Syndrome (IBS-C)
  - tralokinumab-ldrm injection (Adbry) – Atopy drug class; injectable agent for atopic dermatitis

- Tier 4/Not Covered

  The drugs listed below were recommended for Tier 4 status, as they provide little to no additional clinical effectiveness relative to similar agents in their respective drug classes, and the needs of TRICARE beneficiaries are met by available alternative agents.

  - budesonide delayed release (DR) capsules (Tarpeyo) – Miscellaneous nephrology agent; an extended-release formulation of budesonide approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN)
    - Alternatives include prednisone, methylprednisolone, and budesonide DR capsules (Entocort EC, generics).
  - celecoxib/tramadol (Seglentis) – Narcotic Analgesics and Combinations; a fixed-dose combination of celecoxib and tramadol for acute pain
    - Alternatives include tramadol and celecoxib individual components, or tramadol with other NSAIDs

- glycopyrrolate orally disintegrating tablet (Dartisla ODT) – Anti-cholinergic/Antispasmodic Agents; another formulation of glycopyrrolate approved to reduce the symptoms of peptic ulcer as an adjunct to treatment of peptic ulcer

    - Alternatives include glycopyrrolate tablets, glycopyrrolate oral solution (Cuvposa), omeprazole or other PPIs, and famotidine or other H-2 blockers.

- levoketoconazole (Recorlev) – Miscellaneous endocrine agent; a ketoconazole formulation approved to treat Cushing's disease for whom pituitary surgery is not an option or has not been curative

    - Alternatives include ketoconazole (generic), osilodrostat (Isturisa), metyrapone, mitotane, and pasireotide SQ (Signifor LAR injection, available under the medical benefit).

- torsemide 20 mg, 40 mg and 60 mg tablets (Soaanz) – Diuretics; another formulation of torsemide approved to treat patients with heart failure or renal disease with edema who have concerns with excessive urination or hypokalemia

    - Alternatives include torsemide tablets (generic), bumetanide, furosemide, and ethacrynic acid.

- tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twyneo) – Acne Agent; combination of tretinoin and benzoyl peroxide approved for acne vulgaris in 9 years of age and older

    - Alternatives include the individual components of tretinoin and benzoyl peroxide, Epiduo, and Epiduo Forte

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

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

- Releuko will be non-step-preferred, requiring a trial of both Granix and Nivestym prior to use. The same manual PA criteria that currently applies to the non-step-preferred filgrastims, Neupogen and Zarxio, will apply to new users of Releuko.

- Applying manual PA criteria to new users of Adbry and Cibinqo, requiring a trial of topical corticosteroids and topical calcineurin inhibitors (e.g., pimecrolimus, tacrolimus), similar to the requirements for other products approved for atopic dermatitis, including Dupixent, Opzelura cream and Rinvoq (see Utilization Management section).

- Applying manual PA criteria to new users of Fleqsuvy, similar to the current PA for baclofen oral solution (Ozobax).

- Applying manual PA criteria to new users of Ibsrela, similar to the current PA for prucalopride (Motegrity).

- Applying manual PA criteria to new users of Pyrukynd, consistent with the FDA indications and monitoring requirements.

The PA Criteria is as follows:

1. abrocitinib (Cibinqo)

Manual PA criteria apply to all new users of abrocitinib (Cibinqo).

- Patient is 18 years of age or older
- Medication is prescribed by an allergist, dermatologist, or immunologist
- Drug is used to treat moderate to severe atopic dermatitis
- Patient failed, has a contraindication, or intolerability to one medication in EACH of the following two categories:
    - Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND
    - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
- Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy
- Patient has had a negative TB test in the last 12 months (or is adequately managed)

- Patient has no history of venous thromboembolism (VTE)
- Provider is aware of the boxed FDA warnings
- Patient does not have neutropenia (ANC < 1000)
- Patient does not have lymphocytopenia (ALC < 500)
- Patient does not have anemia (Hgb < 8 mg/dL)
- Patient is not taking a concomitant JAK inhibitors (e.g., Rinvoq, Xeljanz), immunosuppressants (e.g., Dupixent), or biologic immunomodulators (e.g., Humira)

Non-FDA-approved uses are not approved.

PA expires in 1 year.

Renewal criteria: (Note that initial TRICARE PA approval is required for renewal). The PA will be approved indefinitely if the patient's disease severity has improved and stabilized to warrant continued therapy

2. **baclofen oral suspension (Fleqsuvy)**

Manual PA criteria apply to all new users of baclofen oral suspension (Fleqsuvy).

- Baclofen will be used for spasticity
- Patient requires baclofen and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

3. **filgrastim-ayow injection (Releuko)**

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

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

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

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

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

Non-FDA-approved uses are not approved.
Prior authorization does not expire.

4. tenapanor (Ibsrela)

Manual PA criteria apply to all new users of Ibsrela.

- Patient is 18 years of age or older

- Patient has diagnosis of IBS-C

- Patient has had documented symptoms for ≥ 3 months

- Patient has tried and failed all formulary agents including Linzess, Amitiza, and Trulance

- Patient does not have GI obstruction

- Patient has documentation of failure of an increase in dietary fiber/dietary modification

- Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes defined as:

    - osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)
    - bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids;

- stool softener (e.g., docusate)
- stimulant laxative (e.g., bisacodyl, sennosides)

- Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Trulance, Zelnorm, Motegrity, Symproic, Relistor, or Movantik)

Non-FDA-approved uses are not approved including opioid-induced constipation (OIC), chronic idiopathic constipation (CIC), and hyperphosphatemia.

Prior authorization expires in 1 year.

Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved for an additional year if both of the following applies:

- Patient has had improvement in constipation symptoms
- Patient is not taking any of these agents concomitantly Amitiza, Linzess, Trulance, Motegrity, Zelnorm, Symproic, Relistor, or Movantik

5. tralokinumab-ldrm injection (Adbry)

Manual PA criteria apply to all new users of Adbry.

- Patient is 18 years of age or older
- The drug is prescribed by a dermatologist, allergist, or immunologist
- The patient has moderate to severe atopic dermatitis
- The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:
  - Topical Corticosteroids: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) AND
  - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)

- The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy

Non-FDA-approved uses are not approved.

PA expires in 1 year

Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:

- The patient's disease severity has improved and stabilized to warrant continued therapy.

6. mitapivat (Pyrukynd)

Manual PA criteria apply to all new users of Pyrukynd.

- Patient is 18 years of age or older
- Patient has a documented diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency
- Patient has a documented presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, at least one of which is a missense variant
- Patient has a hemoglobin less than or equal to 10 g/dL
- Patient and provider are aware that abrupt discontinuation may lead to acute hemolysis

Non-FDA-approved uses are not approved including patients who were homozygous for the c.1436G>A (p.R479H) variant or had 2 non-missense variants (without the presence of another missense variant) in the PKLR gene.

Prior authorization expires in 6 months.

Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies:

- Patient has experienced a ≥ 1.5 g/dL sustained increase in Hgb from baseline after 24 weeks of therapy.

- Patient must demonstrate significant improvement in pruritus symptoms.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, Tier 4/Not Covered, and PA Implementation Plan

The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 1 absent) and for group 2: (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF or 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 Tier 4 Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation.

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

BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF/Tier 4 Recommendation

The P&T Committee recommended the formulary status for the newly approved drugs as stated above:

- UF
  - Releuko
  - Pyrukynd
  - Zimhi
  - Vonjo

- NF
  - Cibinqo
  - Fleqsuvy
  - Ibsrela
  - Adbry
- Tier 4/Not Covered
  - Tarpeyo
  - Seglentis
  - Dartisla ODT
  - Recorlev
  - Soaanz
  - Twyneo

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 above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, Tier 4/Not Covered and PA Implementation Plan

The P&T Committee recommended the following implementation plans as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. Utilization Management--New Manual PA Criteria Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for several recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. 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 within the Newly Approved Drug process. These drugs all have numerous cost-effective formulary alternatives available that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users, requiring a trial of cost effective generic formulary medications first.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for citalopram 30 mg capsule, lanreotide 120 mg injection, ketoprofen 25 mg capsule, and meclizine 25 mg chewable tablet (Antivert) in new and current users, due to the significant cost differences compared with numerous available alternative agents.

1) **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 new 25 mg chewable tablet has come to market manufactured by a single company which requires a prescription prior to dispensing.

   Manual PA criteria:

- Provider is aware and acknowledges that meclizine 25 mg tablet is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred meclizine 25 mg tablet

- The provider must explain why the patient requires meclizine 25 mg chewable tablet (Antivert) and cannot take the cost-effective meclizine 25 mg tablet (fill-in blank)

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

2) Endocrine Agents Miscellaneous—lanreotide 120 mg injection

Lanreotide 120 mg injection is a new Somatuline Depot formulation only available in this one dosage strength. Somatuline Depot is more cost-effective than the lanreotide 120 mg injection made by a sole manufacturer.

Manual PA criteria:

- Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization.
- Provider must explain why the patient cannot use the 120 mg Somatuline Depot brand.

Non-FDA-approved uses are not approved.
Prior authorization does not expire.

3) Selective Serotonin Reuptake Inhibitors (SSRIs)—citalopram 30 mg capsule

Citalopram 30 mg capsules are manufactured by a single company and are markedly not cost-effective relative to other generic SSRIs. All other formulations of citalopram and various other SSRIs are included on the TRICARE pharmacy benefit and do not require prior authorization criteria.

Manual PA criteria:

- Provider acknowledges other strengths of citalopram and other formulary SSRIs are available without prior authorization.

- Provider must explain why the patient cannot take a combination of lower strengths to achieve the desired dose.

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

4) Pain Agents: NSAIDs—ketoprofen 25 mg capsule

Ketoprofen 25 mg capsule is manufactured by a single company, which requires a prescription prior to dispensing. Numerous cost-effective ketoprofen formulations are available without prior authorization in addition to other formulary cost-effective NSAIDs.

Manual PA criteria:

- Provider acknowledges that other strengths of ketoprofen and other formulary NSAIDs are available without the need of prior authorization.
- The provider must explain why the patient requires ketoprofen 25 mg capsule and cannot take the cost-effective generic ketoprofen or other formulary NSAIDs (fill-in blank)

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

B. Utilization Management--New Manual PA Criteria Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an implementation plan of the first Wednesday 60 days after signing of the minutes for the manual PA criteria for citalopram 30 mg capsule, lanreotide 120 mg injection, ketoprofen 25 mg capsule, and meclizine 25 mg chewable tablet (Antivert). DHA will send letters to affected patients.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. Utilization Management--New Manual PA Criteria Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

The P&T Committee recommended new manual PA criteria for citalopram capsule, lanreotide injection, ketoprofen capsule, and meclizine chewable tablet (Antivert), as listed above.

BAP Comments

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

B. Utilization Management--New Manual PA Criteria Implementation Plan

The P&T Committee recommended PAs criteria for citalopram capsule, lanreotide injection, ketoprofen capsule, and meclizine chewable tablet (Antivert) become effective the first Wednesday 60 days after signing of the minutes, and DHQ will send letters.

BAP Comments

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

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

P&T Comments

A. Utilization Management—Updated Manual PA Criteria for New FDA-Approved Indications The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 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. The most current PA criteria is found on the TRICARE Formulary Search Tool at: **www.esrx.com/tform.**

1. **Anticonvulsants-Antimania Agents—fenfluramine oral solution (Fintepla).** The manual PA criteria were updated to expand use for Lennox-Gastaut syndrome.
2. **Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)—**The manual PA criteria were updated to expand use for adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.

3. **Targeted Immunomodulatory Biologics (TIBs)**

   a) **ustekinumab (Stelara) -** The manual PA criteria were updated to expand use for moderate to severe ulcerative colitis (UC). Patients must first try adalimumab (Humira) before use of Stelara for UC. Alternatively, the medical benefit drug infliximab (Remicade) may be used first in lieu of Humira.

   b) **upadacitinib (Rinvoq) -** The manual PA criteria were updated for Rinvoq to expand use for atopic dermatitis (AD) and moderately to severely active ulcerative colitis (UC). For AD, patients must first try a high potency topical corticosteroid and a topical calcineurin inhibitor similar to other agents approved for AD. For UC, patients must first try adalimumab (Humira) before use of Rinvoq. Additionally, other non-biologics (e.g., azathioprine, sulfasalazine) are well established therapies for UC, and are more cost effective than Rinvoq.

B. Utilization Management—Updated Manual PA Criteria Implementation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an implementation date of the first Wednesday 60 days after signing of the minutes for Lynparza, Fintepla, Stelara, and Rinvoq in new users.

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

BAP Comments

A. Utilization Management—Updated Manual PA Criteria for New FDA-Approved Indications The P&T Committee recommended updates to the PA criteria for Lynparza, Fintepla, Stelara, and Rinvoq in new users drugs, as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Utilization Management—Updated Manual PA Criteria Implementation Plan The implementation will be effective the first Wednesday 60 days after signing of the minutes for the updates to the drugs stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL of INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

Oncological Agents: idelalisib (Zydelig)—Zydelig was reviewed as a newly approved drug in November 2019. PA criteria was implemented at that time. Recently the FDA determined that two previously-approved indications were no longer merited, including relapsed follicular B-cell non-Hodgkin lymphoma (FL) and relapsed small lymphocytic lymphoma (SLL). The indication of chronic lymphocytic leukemia (CLL) will remain.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) to remove the FL and SLL indications for new users but will allow current users to consult their provider as to whether continued treatment is clinically appropriate. The other FDA-approved indication for CLL for Zydelig is not affected and will remain on the PA. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL of INDICATIONS AND IMPLEMENTATION PLAN

BAP Comments

The P&T Committee recommended updates to the PA for Zydelig to remove the indications of FL and SLL, with an implementation plan of 60 days, as stated above,

BAP Comments

Concur: Non-Concur: Abstain: Absent

XIV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW FDA INDICATIONS

P&T Comments

A. Utilization Management—Updated PA Criteria for Reasons other than new FDA Indications

a) **Neurological Agents Miscellaneous: amifampridine (Firdapse)**—Manual PA criteria for Firdapse for treating Lambert-Eaton myasthenic syndrome (LEMS) were first recommended in May 2019. Ruzurgi is another amifampridine formulation approved for ALS. In May 2019, manual PA criteria for Firdapse required a trial of the cost-effective amifampridine agent Ruzurgi first in new patients. The FDA deemed Ruzurgi's license in pediatric patients as no longer valid in February 2022 therefore the manual PA criteria for Firdapse was updated to allow use for LEMS without a trial of Ruzurgi.

b) **Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy—testosterone cypionate and testosterone enanthate—**PA criteria were recommended for the injectable testosterone products at the February 2022 meeting. Based on current policies and guidelines for treating gender dysphoria, the Committee recommended removal of the requirement of 3 months of real life experience (RLE) and/or 3 months of psychotherapy prior to PA approval.

c) **Anti-Inflammatory Immunomodulatory Ophthalmic Agents: cenegermin-bkbj ophthalmic solution (Oxervate)**—Oxervate was reviewed as a new drug in February 2019 and is FDA-approved to treat neurotrophic keratitis. Manual PA criteria currently allow for an indefinite duration of use. PA Criteria were updated to expire after 6 months to ensure an appropriate duration of therapy, consistent with the product labeling for Oxervate.

d) **Miscellaneous Insulin Devices: Omnipod, Omnipod DASH**—Manual PA criteria were recommended for Omnipod Classic (generation 3) and Omnipod DASH (generation 4) in November 2021. These devices may be used for up to 72 hours but could be changed every 48 hours. The renewal PA criteria were updated to remove the previously listed limit for duration of use.

B. Utilization Management—Updated PA Criteria for Reasons other than new FDA Indications Implementation

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the PA for Firdapse, IM testosterone products, Oxervate and the Omnipod products. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW FDA INDICATIONS

BAP Comments

A. Utilization Management—Updated PA Criteria for Reasons other than new FDA Indications

The P&T Committee recommended manual PA criteria for Firdapse, IM testosterone products, Oxervate and the Omnipod products as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Utilization Management--Updated PA Criteria for Reasons other than new FDA Indications Implementation Plan

The P&T Committee recommended the updated PAs will become effective the first Wednesday 60 days after the signing of the minutes.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. BRAND OVER GENERIC AUTHORIZATION FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE DOSE VIALS (RESTASIS), TIER 1 COPAY and IMPLEMENTATION PLAN

P&T Comments

Background—The Ophthalmic Immunomodulatory Agents subclass was reviewed in February 2018. This class includes cyclosporine 0.05% ophthalmic emulsion (Restasis) and lifitegrast 5% ophthalmic solution (Xiidra). Since then, generic formulations of Restasis have come to market however these generics are less cost-effective compared to brand Restasis at the MTFs and Mail Order.

Brand Restasis will now be required prior to receiving generic cyclosporine 0.05% ophthalmic emulsion at the MTFs and Mail Order. This brand over generic PA will not apply at the retail point of service. Additionally, the requirement only applies to the Restasis single dose formulation, and not the multi-dose formulation. The Tier 1 copay for brand Restasis single dose is also recommended.

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) requiring brand Restasis over generic cyclosporine 0.05% ophthalmic emulsion in all new and current users at MTF and mail, based on cost effectiveness. The prescriber will provide patient-specific justification as to why brand Restasis cannot be used. The Tier 1 (generic) copayment will also apply to brand Restasis. The effective date will be two weeks after signing of the minutes at MTF and mail. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3): When a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

XVII. BRAND OVER GENERIC AUTHORIZATION FOR CYCLOSPORINE 0.05% OPHTHALMIC EMULSION SINGLE DOSE VIALS (RESTASIS), TIER 1 COPAY and IMPLEMENTATION PLAN

BAP Comments

The P&T Committee recommended brand over generic authorization for Brand Restasis and the Tier 1 copay, with a 2 week implementation, as stated above.

BAP Comments

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

XVIII. INFORMATIONAL ITEM—BENEFICIARY IMPACT (MAY 2022 DoD P&T COMMITTEE MEETING)

Table of Implementation Status of UF Recommendations/Decisions Summary and Affected Unique Utilizers

Date	DoD PEC Drug Class	Type of Action	UF Medications	Nonformulary Medications	Implement Date	Notes and Unique Users Affected
May 2022	**Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) Subclass**	UF Class Review Class previously reviewed Nov 2010 Nov 2012 Aug 2015 Feb 2018	▪ dulaglutide (Trulicity)	▪ exenatide once weekly Bydureon BCise) – *moves from UF to NF* ▪ exenatide twice daily (Byetta) ▪ liraglutide (Victoza) ▪ lixisenatide (Adlyxin) ▪ semaglutide (Ozempic) – *trial of Trulicity no longer required*	60 days	▪ Metformin required first in new users of any GLP1RA unless a contraindicated ▪ Ozempic remains NF; a trial of Trulicity is no longer required for new users. ▪ Manual PA criteria required for all new and current users of Bydureon BCise, Byetta, Victoza, and Adlyxin. Must try Trulicity and Ozempic first. ▪ No patients currently receiving Adlyxin <u>Unique Users Affected</u> Affected by NF status: 15,275 Affected by PA: Mail 10,354 MTF 7,439 <u>Retail 928</u> Total 18,721
May 2022	**Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass**	UF Class review Class not previously reviewed; drugs individually reviewed as innovators	<u>UF</u> ▪ atogepant (Qulipta) - *moves from NF to UF* ▪ rimegepant (Nurtec ODT) ▪ ubrogepant (Ubrelvy) - *moves from NF to UF*	▪ None	30 days	▪ PA criteria in place since 2020; only minor updates made. ▪ For episodic migraine prevention (Nurtec ODT, Qulipta) a trial of an injectable CGRP is required first, and other preventive treatments ▪ For acute treatment of migraine headache (Nurtec ODT, Ubrelvy), a trial of two oral triptans is required first. ▪ For Ubrelvy a trial of Nurtec ODT is no longer required in new patients. ▪ Unique Users Affected – N/A (no NF drugs)

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

Drug	
budesonide delayed release (DR) capsules (Tarpeyo)	4
celecoxib/tramadol (Seglentis)	10
glycopyrrolate orally disintegrating tablet (Dartisla ODT)	2
levoketoconazole (Recorlev)	Zero
torsemide 20 mg and 60 mg tablets (Soaanz)	37
tretinoin 0.1%/benzoyl peroxide 3% topical cream (Twyneo)	39

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
meclizine 25 mg chewable tablets (Antivert)	0	0	3	0
lanreotide 120 mg injection	0	0	3	3
citalopram 30 mg capsules	0	0	2	2
ketoprofen 25 mg capsules	0	0	28	28