DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE NOVEMBER 2021 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

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—Continuous Glucose Monitoring Systems (CGMs)

P&T Comments

A. Continuous Glucose Monitoring Systems (CGMs)—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the CGMs. CGMs are minimally-invasive medical devices that continuously monitor and provide real-time results and recording of glucose levels. This allows the patient and provider to have immediate feedback for making treatment decisions.

The devices consist of a subcutaneously placed sensor, an external receiver/reader, and/or an external transmitter. Therapeutic CGMs or integrated CGMs (iCGMs) are part of an integrated system with other compatible medical devices and are designed to replace traditional finger sticks. Two devices currently meet the definition of a therapeutic or iCGMs: Dexcom G6 and Abbott FreeStyle Libre 2.

CGMs were not previously covered under the TRICARE pharmacy benefit. They have been available through the TRICARE medical benefit as durable medical equipment (DME). Medical devices are not part of the TRICARE pharmacy benefit, with limited exceptions, such as some diabetic supplies including self-monitoring blood glucose (SMBG) test strips and lancets. Commercial health care plans have shown a movement toward pharmacy benefit coverage of the CGMs to improve access for patients. As a result of this class review, Dexcom G6 and FreeStyle Libre 2 will be available under the TRICARE pharmacy benefit, and may continue to have coverage under the medical benefit.

The clinical and cost effectiveness review focused on the safety and efficacy of Dexcom G6 and FreeStyle Libre 2. The literature review centered on professional clinical practice guidelines (CPGs) and clinical trial data conducted in patients with type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), and gestational diabetes. Information from manufacturer-provided dossiers was also analyzed. Reviewed studies included those reporting outcomes of hemoglobin A1c (A1c), glucose time in range, hypoglycemia events, or maternal and fetal endpoints. Data evaluating earlier versions of Dexcom or FreeStyle Libre were also included in the review.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

Clinical Practice Guidelines (CPGs)

- Several CPGs from professional organizations in the US, Canada, the UK and Europe were evaluated. Overall, the guidelines support use of CGMs for different patient populations, including T1DM and T2DM, however there were varying levels of evidence to support the recommendations.

Efficacy and Safety

- *T1DM:* The majority of available clinical evidence supporting CGMs use is in patients with T1DM.
    - A systematic review *(Benkhadra 2017)* and data from several individual randomized controlled trials (RCTs) with Dexcom or FreeStyle Libre systems reported significant decreases in A1c.
    - In several randomized controlled trials, use of CGMs produced a significant decrease in the number of hypoglycemic events or time spent below-glucose levels of <70 mg/dL.
- *T2DM:* For patients with T2DM using CGMs, the majority of the evidence is in patients receiving multiple daily insulin injections.
    - Overall, there are fewer studies and more variable results reported in terms of A1c reductions or glucose time in range, compared to the data in patients with T1DM. For the T2DM patient population, higher baseline A1c values may predict better response to CGMs use.
    - There is minimal safety data to guide use in T2DM populations.
    - Further research in T2DM patients is needed, particularly in those patients receiving solely oral medications or those on basal insulin alone.
- *Gestational Diabetes:* Several professional diabetes societies endorse CGMs for pregnant patients. Guidelines from the UK National Institute for Health

and Care Excellence *(NICE 2020)* recommend real-time-CGMs for all pregnant women with T1DM. Studies in this patient population show that a 5% increase in the glucose time in range can significantly reduce adverse outcomes such as large-for-gestational age (LGA) infants, neonatal intensive care unit admissions, and neonatal hypoglycemia episodes.

  - The UK NICE pregnancy guidelines also state that real-time CGMs can be considered in pregnant women with T2DM receiving insulin therapy who have problematic hypoglycemia or unstable blood glucose levels. However, randomized controlled trial data is inconclusive in this area.

Dexcom G6 vs. FreeStyle Libre 2

- There were no head-to-head trials available evaluating outcomes to assess whether there are clinically relevant differences in efficacy or safety between the Dexcom G6 or FreeStyle Libre 2 CGMs.
- Similarities between the Dexcom G6 and FreeStyle Libre 2 include that both devices have programmable voluntary additional alerts for a variety of high or low readings; both allow healthcare provider access to patient data to aid in treatment decisions; finger stick calibration is not required with either system; and both allow self-insertion and removal of the sensor.
- *Dexcom G6*: The Dexcom G6 provides real-time data sharing, as it updates results continuously every 5 minutes via Bluetooth capability. The sensors must be replaced every 10 days, and require a 2 hour warm-up time. Dexcom G6 is approved for patients as young as 2 years of age. This system has a mandatory alarm, the "urgent low soon," which detects downward trends in glucose; this alert cannot be adjusted or disabled. Several insulin pumps are compatible with the Dexcom G6 system.
- *FreeStyle Libre 2*: The FreeStyle Libre 2 is an intermittently scanned system, since scanning of the sensor is required every 8 hours. The data is updated every 15 minutes via RFID or Bluetooth. The sensors are replaced every 14 days, with the sensors requiring a 1 hour warm-up time. FreeStyle Libre 2 is approved for use in children as young as 4 years of age. All alarms are optional. The FreeStyle Libre 2 is currently not compatible with any insulin pump. The receiver has a built-in glucometer for finger sticks.

Other Factors

- Since the iCGMs are intended to replace the need for finger sticks, they ideally will result in a corresponding reduction in overall MHS utilization and subsequent cost of self-monitoring blood glucose test (SMBG) strips.

- The Committee agreed that any newly FDA-approved iCGMs platforms would first be evaluated as to whether they would be included on the TRICARE pharmacy benefit, prior to reviewing them as part of the innovator program.

B. Continuous Glucose Monitoring Systems (CGMs)—Relative Cost Effectiveness Analysis and Conclusion

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

- CMA results showed that the Dexcom G6 and FreeStyle Libre 2 were comparable in cost.
- BIA and a sensitivity analysis were performed to evaluate the potential impact of designating the two iCGMs as UF, NF, or Tier 4 on the formulary. BIA results showed that designating both Dexcom G6 and FreeStyle Libre 2 as UF and included as part of the TRICARE pharmacy benefit demonstrated significant cost avoidance to the MHS, when compared to their costs under the TRICARE medical benefit.

C. Continuous Glucose Monitoring Systems (CGMs)—UF/Tier 4/Not Covered Recommendation

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

- UF
  - Dexcom G6
  - Abbott FreeStyle Libre 2
- NF
  - None
- Tier 4/Not Covered
  - None

D. Continuous Glucose Monitoring Systems (CGMs)—Manual PA Criteria

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) PA criteria for Dexcom G6 and Freestyle Libre 2. All patients currently receiving Dexcom G6 or FreeStyle Libre 2 under the TRICARE medical benefit will require PA to receive coverage under the pharmacy benefit. Coverage for both Type 1 and Type 2 diabetes is allowed, provided that the patient is receiving basal and prandial insulin, or

if the patient is using an insulin pump. There is no requirement for a minimal number of SMBG test strips to be used daily, in order to receive Dexcom G6 or Freestyle Libre 2.

The PA criteria are as follows:

Manual PA criteria apply to all new and current users of Dexcom G6 or Abbott FreeStyle Libre 2 and is approved if all criteria are met.

Note: other CGM systems are not part of the TRICARE pharmacy benefit but may be covered through the TRICARE DME process.

- The patient has a diagnosis of Type 1 diabetes mellitus OR Type 2 diabetes mellitus
- One of the following situations applies:
    - Patient is using basal and prandial insulin injections; OR
    - Patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR
    - Patient has Type 2 diabetes mellitus and is receiving insulin therapy and has a history of severe hypoglycemia episodes requiring medical intervention
- Dexcom G6 or FreeStyle Libre 2 is prescribed by an endocrinologist or diabetes specialist
- Documentation from the patient record must be submitted with all of the following:
    - Diagnosis
    - Medication history, including use of insulin
    - Completion of a comprehensive diabetes education program for the patient
    - Patient agrees to wear CGM as directed
    - Patient agrees to share device readings with managing healthcare professional for overall diabetes management
- Patient meets the following age requirements
    - Dexcom G6: Patient is 2 years of age or older
    - FreeStyle Libre 2: Patient is 4 years of age or older
- Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips, with the goal of minimizing/discontinuing use

Initial prior authorization expires in 1 year

PA renewal will be required annually

Renewal criteria: Coverage will be approved on a yearly basis if all of the following apply (Note that initial TRICARE PA approval is required for renewal)

- Confirmation that the patient has seen an endocrinologist or diabetes specialist at least once within the past year
- Confirmation that the patient has utilized CGM daily
- Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips at every visit, with the goal of minimizing/discontinuing use
- Patients with T2DM continue to require daily basal and prandial insulin injections
- Patient continues to agree to share data with managing healthcare professional for the purposes of clinical decision making

E. Continuous Glucose Monitoring Systems (CGMs)—UF, PA and Implementation Plan

The P&T Committee recommended (15 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 (POS).

III. UF DRUG CLASS REVIEWS-Continuous Glucose Monitoring Systems (CGMs)

BAP Comments

A. Continuous Glucose Monitoring Systems (CGMs)—UF Recommendations

The P&T Committee recommended the formulary status for the Continuous Glucose Monitoring Systems (CGMs) as discussed above.

- UF
  - Dexcom G6
  - Abbott FreeStyle Libre 2
- NF - None
- Tier 4/Not Covered - None

BAP Comment: ☐ Concur ☐ Non-concur

B. Continuous Glucose Monitoring Systems (CGMs)—Manual PA Criteria

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

BAP Comment: ☐ Concur ☐ Non-concur

C. Continuous Glucose Monitoring Systems (CGMs)—UF, PA and Implementation Plan

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

BAP Comment: ☐ Concur ☐ Non-concur

IV. UF DRUG CLASS REVIEWS—Subcutaneous Immunoglobulins (SCIG)

P&T Comments

A. Subcutaneous Immunoglobulins (SCIG)—Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the immunoglobulin replacement agents used for treating a variety of primary immunodeficiency disorders and other conditions. They are used to prevent serious bacterial infection and modulate immune function. The products in the class all contain polyvalent immunoglobulin G (IgG) obtained from pooled donors. Differences between agents are due to variances in the manufacturing process, IgG concentration, stabilizer, and vehicle, and are not due to the active IgG ingredient.

Eight products are available as part of the TRICARE pharmacy benefit, however three agents, Gammaked, Gammagard Liquid and Gamunex can be administered either intravenously (IV) or subcutaneously (SC). The five exclusively SC administered products include Cutaquig, Cuvitru, Hizentra, Hyqvia, and Xembify. The exclusively SC administered formulations provide an option for patients with poor vascular access and those with numerous reactions to the intravenous infusions. Subcutaneous preparations with concentrations higher than 10% or which contain hyaluronidase cannot be given IV.

The exclusively IV administered products (e.g., Gammaplex, Octagam) are part of the TRICARE medical benefit and were not included in the formulary review.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 3 absent) the following:

Efficacy

- Professional treatment guidelines from the Immune Deficiency Foundation Diagnostic and Clinical Care Guidelines (3rd edition) do not make any distinction between an individual SCIG product, manufacturer, concentration, formulation, stabilizer, or quality control method in their recommendations.
- A comprehensive evidence review shows that efficacy of the SCIG products is a function of dose (which correlates to IgG serum levels), rather than a specific SCIG preparation or administration route.
- No one SCIG product is superior (or inferior) to any other. Practical considerations may limit use of one preparation over another, (e.g., patient body size vs. volume to be administered).

Safety

- Safety is a class effect for the SCIG formulations. Common adverse reactions include local infusion site reactions, headache, fever, diarrhea, dermatitis, nausea, vomiting, fatigue and pyrexia.
- SCIG products administered by IV routes have higher rates of systemic adverse events, including systemic hypersensitivity reactions. In contrast products administered by the SC routes have higher rates of local administration site reactions.

- Unique factors of the individual SCIG products may apply to specific patient populations. Lower concentration products can preclude use in patients with minimal subcutaneous tissue (e.g. small children or cachectic patients). Additionally, patients with IgA hypersensitivity should not use preparations with higher thresholds of IgA. Patients at risk of volume overload should avoid higher sodium-containing and higher osmolality products.

Products

- *Gammagard Liquid, Gammaked, and Gamunex-C* have concentrations of 10% and when administered IV can treat conditions requiring greater quantities of IgG. These products are administered once per four weeks. Gammagard 10% is an IgA depleted product. There is currently high utilization of Gamunex-C in the MHS.
- *Cutaquig 16.5%* contains maltose as a stabilizer and could potentially interfere with blood glucose monitoring in diabetic patients, due to the risk of falsely elevated blood glucose readings. Since Cutaquig has the highest threshold concentration of IgA, it should be avoided in patients with IgA hypersensitivity. It also is a high osmolality product and should be avoided in patients with renal dysfunction or heart failure. It is administered weekly.
- *Cuvitru 20%* requires weekly administration.
- *Hizentra 20%* is administered weekly. Patients with hyperprolinemia should avoid Hizentra due to the proline stabilizer. It is also a high osmolality product and is administered weekly. It is an IgA depleted product.
- *Hyqvia 10%* contains hyaluronidase which allows for less frequent administration; it is given every 4 weeks. Patients with hypersensitivity or antibodies to hyaluronidase should avoid Hyqvia. Hyqvia is an IgA depleted product.
- *Xembify 20%* requires weekly administration and has a risk of venous thromboembolism.

Overall Clinical Conclusion

- The SCIG products are highly therapeutically interchangeable, after accounting for differences in dosing and concentrations. There may be niche patient populations where individual preparations are relatively contraindicated.
- In order to meet the needs of MHS patients, at least three SCIG products are required on the formulary, including one formulation that can be given both by the IV and SC routes, and a product which is IgA depleted. Potential manufacturer shortages preclude having only one SCIG agent on the formulary.

B. Subcutaneous Immunoglobulins (SCIG)—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 3 absent) the following:

- CMA results showed that Hyqvia, Cuvitru, Gammagard Liquid, Hizentra, Cutaquig, Gammaked, Gamunex-C, and Xembify were all cost effective agents.

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF, or Tier 4. BIA results showed that designating Cutaquig and Gamunex-C as UF and step-preferred, with Cuvitru, Gammagard Liquid, Gammaked, Hizentra, Hyqvia, and Xembify as UF non-step-preferred demonstrated the greatest cost avoidance for the MHS.

C. Subcutaneous Immunoglobulins (SCIG)—UF Recommendation The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 3 absent) the following:

- **UF Step-preferred**
  - Cutaquig
  - Gamunex-C
- **UF non-step-preferred**
  - Gammagard Liquid
  - Gammaked
  - Cuvitru
  - Hizentra
  - Hyqvia
  - Xembify
  - Note that as part of the recommendation, a trial of either Cutaquig or Gamunex-C is required in new patients, before patients can try Gammagard, Gammaked, Cuvitru, Hizentra, Hyqvia, or Xembify.
- NF
  - None
- Tier 4/Not Covered
  - None

D. Subcutaneous Immunoglobulins (SCIG)—Manual PA Criteria—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for the non-step preferred products, Gammagard Liquid, Gammaked, Cuvitru, Hizentra, Hyqvia, and Xembify. Patients with clinical factors such as a contraindication, intolerance to, or an adverse reaction to the step-preferred SCIG products Gamunex-C or Cutaquig can receive one of the non-step-preferred products.

The PA criteria are as follows:

Manual PA that apply to all new users of Gammagard Liquid, Gammaked, Xembify, Hizentra, Cuvitru, and Hyqvia and is approved if all of the following criteria are met:

- The provider acknowledges that Cutaquig and Gamunex-C do not require a PA.
- Patient is 2 years of age or older
- One of the following situations applies:
    - Patient has primary immunodeficiency disease (any)
    - Patient has a chronic inflammatory demyelinating polyneuropathy (any)
    - Patient has another diagnosis not listed above for which chronic immunoglobulin replacement therapy is a guideline-recommended therapeutic option

      Name of Guideline:_____

      Guideline Recommendation Strength:_____
- Patient has not tolerated, has had an adverse reaction to, and/or has a contraindication to Gamunex-C that is not anticipated with the chosen product (to include intolerance to increased volumes associated with subcutaneous delivery)
- Patient has not tolerated, has had an adverse reaction to, or has a contraindication to Cutaquig that is not anticipated with the chosen product (to include known or increased risk for IgA hypersensitivity, inability to accurately monitor blood sugars, and/or increased risk from a higher osmolality product)
- If immunoglobulin replacement therapy will be administered subcutaneously, and this is the first time this product will be used, provider has followed package label directions for converting from intravenous dose (by mass)
- Patient agrees to be monitored at indicated intervals to establish therapeutic immunoglobulin levels

Other Non-FDA-approved uses are NOT approved

Prior authorization does not expire.

E. Subcutaneous Immunoglobulins (SCIG)—Cutaquig Tier 1 Status

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) lowering the current Tier 2 cost-share for Cutaquig to the generic Tier 1 cost-share.

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

F. Subcutaneous Immunoglobulins (SCIG) Manual PA Criteria—UF, PA, Tier 1 Copay and Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday 90 days from signing of the minutes in all POS.

V. UF DRUG CLASS REVIEWS- Subcutaneous Immunoglobulins (SCIG)

BAP Comments

A. Subcutaneous Immunoglobulins (SCIG)—UF Recommendation

The P&T Committee recommended the formulary status for the Subcutaneous Immunoglobulins (SCIG) as discussed above:

- **UF Step-preferred**
  - Cutaquig
  - Gamunex-C
- **UF non-step-preferred**
  - Gammagard Liquid
  - Gammaked
  - Cuvitru
  - Hizentra
  - Hyqvia
  - Xembify
- NF – None

- Tier 4/Not Covered - None

BAP Comment: ☐ Concur ☐ Non-concur

B. Subcutaneous Immunoglobulins (SCIG)—Manual PA Criteria

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

BAP Comment: ☐ Concur ☐ Non-concur

C. Subcutaneous Immunoglobulins (SCIG)—Cutaquig Tier 1 Status

The P&T Committee recommended lowering the current Tier 2 cost-share for Cutaquig to the generic Tier 1 cost-share as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

D. Subcutaneous Immunoglobulins (SCIG)—UF, PA, Tier 1 Copay and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 90 days after signing of the minutes in all points of service.

BAP Comment: ☐ Concur ☐ Non-concur

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, 2 absent; group 2: 14 for, 0 opposed, 0 abstain, 3 absent; and for Loreev XR 15 for, 0 opposed, 0 abstained, 2 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5).

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

The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent) and group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and for lorazepam ER capsules (Loreev XR) (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF:
    - belumosudil (Rezurock) – Immunosuppressive for chronic graft-vs-host disease
    - belzutifan (Welireg) – Oncological agent for von Hippel Lindau disease
    - mobocertinib (Exkivity) – Oncological agent for non-small cell lung cancer (NSCLC)
    - naloxone nasal 8 mg (Kloxxado) – Narcotic antagonist for opioid overdose
    - serdexmethylphenidate/dexmethylphenidate (Azstarys) – Stimulant ADHD agent

- NF:
    - finerenone (Kerendia) – Miscellaneous cardiovascular agent for chronic kidney disease associated with diabetes
    - ibrexafungerp (Brexafemme) – Antifungal for vulvovaginal candidiasis
    - mirabegron extended release granules for oral suspension (Myrbetriq Granules) – Overactive bladder agent for neurogenic detrusor overactivity (NDO)
    - odevixibat (Bylvay) – Miscellaneous metabolic agent for progressive familial intrahepatic cholestasis (PFIC)
    - olanzapine/samidorphan (Lybalvi) – Combination atypical antipsychotic for schizophrenia and bipolar I disorder
    - ruxolitinib 1.5% cream (Opzelura) – Topical corticosteroid immune modulator for atopic dermatitis
- Tier 4 (Not covered):
    - lorazepam extended-release capsule (Loreev XR) – Antianxiety Agent – benzodiazepines - extended release lorazepam capsules for anxiety in adults already stabilized on three times a day dosing of lorazepam tablets
        - Loreev XR was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other lorazepam formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives to Loreev XR include lorazepam immediate-release tablets and alprazolam IR and XR tablets.
    - dihydroergotamine mesylate nasal spray (Trudhesa) – Migraine drugs - another DHE nasal spray for acute treatment of migraine in adults with or without aura
        - Trudhesa was recommended for Tier 4 as it has little to no clinical benefit relative to other DHE products, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include DHE nasal spray, sumatriptan nasal and oral, and other triptans, including rizatriptan, zolmitriptan, and eletriptan.

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, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent) the following:

- Oncologic drugs: Applying manual PA criteria to new users of Exkivity and Welireg.
- Applying manual PA criteria to new users of Azstarys, Lybalvi, Myrbetriq Granules, and Rezurock.
- Applying manual PA criteria to new and current users of Opzelura, Kerendia, and Bylvay.

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

1. **belumosudil (Rezurock)**

   Manual PA criteria apply to all new users of Rezurock

   - Patient is 12 years of age and older
   - Rezurock is prescribed by or in consultation with a hematologist/oncologist
   - Patient has chronic graft-versus-host disease (cGVHD) and has failed treatment with steroids alone and at least two prior lines of systemic therapy
   - Female patients of childbearing age are not pregnant confirmed by (-) HCG
   - Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment
   - Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.
   - The diagnosis IS NOT listed above but IS cited in a nationally accredited guideline with a moderate strength or higher recommendation. If so, the guideline society is _____, the strength of recommendation is _____, and the diagnosis is: _____.

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

   Prior authorization does not expire.

2. **belzutifan (Welireg)**

   Manual PA criteria apply to all new users of Welireg

   - Patient is 18 years of age or older
   - Welireg is prescribed by or in consultation with an oncologist
   - The patient has von Hippel-Landau disease and requires therapy for associated renal cell carcinoma (RCC), CNS hemangioblastomas or pancreatic neuroendocrine tumors (pNET) not requiring surgery
   - Patient does not have metastatic disease
   - Female patients of childbearing age are not pregnant, confirmed by (-) HCG
   - Female patients will not breast feed during treatment and for at least 3 weeks after the cessation of treatment
   - Both male and female patients of childbearing potential agree to use effective non-hormonal contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male
   - Male patients have been informed of the risk of infertility
   - 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

   Non-FDA-approved uses are not approved, other than noted above

   Prior authorization does not expire.

3. **finerenone (Kerendia)**

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

   - Patient is 18 years of age or older
   - Kerendia is prescribed by or in consultation with a nephrologist
   - The patient has a diagnosis of type 2 diabetes mellitus (T2DM)
   - The patient has documented diabetic kidney disease with albuminuria, defined as one of the following
     - An estimated glomerular filtration rate (eGFR) of 25-75 with albuminuria >300mg/g OR
     - eGFR 25-60 with albuminuria > 30mg/g plus diabetic retinopathy

- Patient has been taking max-dose ACE inhibitor or ARB for at least 4 weeks
- Patient tried DoDs preferred sodium-glucose-co-transporter 2 (SGLT-2) inhibitor empagliflozin (Jardiance)
- The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease
- Patient does not have uncontrolled hypertension (>170/110 mmHg) at initiation of Kerendia therapy
- Patient does not have renal artery stenosis
- Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc)
- Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception

Non-FDA approved uses are not approved including patients renal transplants
Prior authorization does not expire.

4. mirabegron extended release granules for oral suspension (Myrbetriq Granules)

Manual PA criteria apply to all new users of Myrbetriq Granules

Note that the previous automation for Myrbetriq granules and tablets is removed

- Myrbetriq granules for oral suspension are prescribed by or in consultation with a urologist or nephrologist
- The prescription is written for neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele, and not for overactive bladder
- Provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization
- Patient has tried and failed or has a contraindication to oxybutynin
- Patient requires Myrbetriq granules for oral suspension for one of the following reasons:

- The patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, etc) and not convenience. OR
- The patient weighs less than 35 kg

- Provider acknowledges that Myrbetriq granules for suspension are not bioequivalent to and cannot be substituted on a mg to mg basis to the Myrbetriq tablets
- Provider acknowledges that Myrbetriq granules for suspension and the Myrbetriq tablets will not be combined to achieve a specific dose
- Provider acknowledges the detailed renal and hepatic dosing adjustments in the package labeling and agrees to consult this before prescribing the granules in these special populations

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

5. mobocertinib (Exkivity)

Manual PA criteria apply to all new users of Exkivity

- Patient is 18 years of age or older
- Exkivity is prescribed by or in consultation with a hematologist/oncologist
- Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy
- The patient will be monitored for QTc prolongation, interstitial lung disease, pneumonitis, decreased cardiac function, and diarrhea
- If the patient develops diarrhea, he/she will be prescribed an anti-diarrheal agent
- Female patients of childbearing age are not pregnant, confirmed by (-) HCG
- Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment
- Both male and female patients of childbearing potential will use effective non-hormonal contraception during treatment and for

one month after cessation of therapy if female, and for one week after cessation of therapy if male

- The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.

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

Prior authorization does not expire.

6. odevixibat (Bylvay)

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

- Patient is 3 months of age or older and weighs 5 kg or greater
- Patient has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus
- The prescription is written by a pediatric gastroenterologist, or pediatric hepatology transplant specialist
- Patient has been evaluated for possible orthotopic liver transplant (OLT)
- Patient has previously tried and failed all of the following:
  - ursodiol
  - cholestyramine
  - rifampin
  - naltrexone
  - At least one antihistamine (e.g. Atarax, Benadryl, etc.)

Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), progressive familial intrahepatic cholestasis (PFIC2), Alagille syndrome, Biliary atresia are not approved.

Prior authorization expires after 6 months. Bylvay will be approved for an additional 6 months if the following criteria are met:

Renewal criteria (initial TRICARE PA approval is required for renewal) AND
Patient must demonstrate significant improvement in pruritus symptoms.

7. olanzapine/ samidorphan (Lybalvi)

Manual PA criteria apply to all new users of Lybalvi.

- Patient is 18 years of age or older
- Patient has a documented diagnosis of schizophrenia or bipolar 1 disorder
- Patient has tried for at least 6 months and had an adverse event to at least 2 antipsychotic agents
- Provider must indicate the drug, date of initiation, duration of therapy, and whether the patient had an adverse reaction or failure to therapy of other therapies tried
  - Drug: Date_____ Duration of therapy _____

    Adverse Reaction _____ Therapeutic Failure _____
  - Drug: Date_____ Duration of therapy _____

    Adverse Reaction _____ Therapeutic Failure _____

Non-FDA-approved uses are not approved including major depressive disorder, fibromyalgia, or other mood disorders.

Prior authorization does not expire**.**

8. ruxolitinib 1.5% cream (Opzelura)

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

- Patient is 12 years of age and older
- Opzelura is prescribed by a dermatologist, allergist, or immunologist
- The patient has mild to moderate uncontrolled 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:
    - For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)
    - For patients 12 to 17 years of age: any topical corticosteroid

AND

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

- The patient is not using other immuno-biologics (e.g., Humira, Stelara, etc), other JAK inhibitors (e.g., Xeljanz, Olumiant, Rinvoq), or potent immunosuppressants such as azathioprine or cyclosporine

Non-FDA-approved uses are not approved.
Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely.

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

- The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear
- The patient's disease severity has improved and stabilized to warrant continued therapy

9. serdexmethylphenidate/ dexmethylphenidate (Azstarys)

Manual PA criteria apply to all new users of Azstarys

- 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 MPH (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)*

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

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Tier 1 Co-Pay for Naloxone 8 mg nasal (Kloxxado)

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) lowering the current Tier 2 cost-share for Kloxxado to the generic Tier 1 cost-share, with an effective date of the first Wednesday two weeks after signing of the minutes at all points of service. Lowering the cost-share for Kloxxado will provide a greater incentive for beneficiaries to use a cost-effective naloxone formulation in the purchased care points of service.

E. 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, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and for Loreev XR (15 for, 0 opposed, 0 abstained, 2 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 discussed above:

- **UF:**
  - Rezurock
  - Welireg

- Exkivity
- Kloxxado
- Azstarys

- **NF:**
  - Kerendia
  - Brexafemme
  - Myrbetriq Granules
  - Bylvay
  - Lybalvi
  - Opzelura

- **Tier 4/Not Covered:**
  - Loreev XR
  - Trudhesa

BAP Comment:	☐ Concur	☐ Non-concur

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.

BAP Comment:	☐ Concur	☐ Non-concur

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Tier 1 Co-Pay for Naloxone 8 mg nasal (Kloxxado)

The P&T Committee recommended lowering the current Tier 2 cost-share for Kloxxado to the generic Tier 1 cost-share, with an effective date of the first Wednesday two weeks after signing of the minutes, as discussed above.

BAP Comment: ☐ Concur ☐ Non-concur

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 the following implementation plans as described above.

BAP Comment: ☐ Concur ☐ Non-concur

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

A. New Manual PA Criteria

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. These drugs all have numerous cost effective formulary alternatives 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 medication first.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for the following products:

1.) **Antihistamine-1: First Generation and Combinations—clemastine 0.5 mg/ml syrup:** Clemastine syrup is manufactured by a single company and requires a prescription prior to dispensing. Clemastine tablets and other antihistamines are available via prescription that do not require prior authorization criteria or are available over-the-counter (OTC).

Manual PA criteria applies to new and current users of clemastine syrup.

- The provider is aware and acknowledges that clemastine tablets and other antihistamines (i.e., chlorpheniramine, cyproheptadine, diphenhydramine or the 2nd generation antihistamines – loratadine, fexofenadine, cetirizine) are available to DoD beneficiaries without the need of prior authorization
- The provider must explain why the patient must take clemastine 0.5 mg/mL syrup as opposed to available alternatives: *(fill-in blank)*

Non-FDA approved uses are NOT approved.

Prior Authorization does not expire.

2.) **Pain Agents: NSAID—diclofenac potassium 25 mg tablet (Lofena):** A new diclofenac 25 mg tablet that is manufactured by a single company is markedly not cost-effective relative to other formulary NSAIDs. All other strengths of diclofenac potassium, diclofenac sodium, and various other NSAIDs are included on the TRICARE pharmacy benefit and do not require prior authorization criteria. OTC NSAIDs are also widely available.

Manual PA criteria applies to new and current users of diclofenac potassium 25 mg tablet.

- The provider acknowledges that other strengths of diclofenac potassium, generic diclofenac sodium, or other formulary NSAIDs are available to DoD beneficiaries without the need of prior authorization
- The provider must explain why the patient requires diclofenac potassium 25 mg tablet and cannot take the cost-effective generic diclofenac potassium, generic diclofenac sodium, or other formulary NSAIDs (fill-in blank)

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

3.) **Anti-Emetic/Anti-Vertigo Agents—meclizine 50 mg tablet (Antivert):** Meclizine is an older antiemetic widely available in 12.5 mg and 25 mg tablets in prescription and over-the-counter formulations. A new expensive 50 mg tablet has come to market manufactured by a single company which requires a prescription prior to dispensing.

Manual PA criteria applies to new and current users of meclizine 50 mg tablet (Antivert).

- The 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 50 mg 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.

4.) **Antilipidemics-1—niacin 500 mg tablet:** Niacin is available in several formulations, including Niaspan 500 mg, 750 mg and 1,000 mg ER tablets, and Niacor 500 mg tablets. Niacin 500 mg by a sole manufacturer is not cost-effective relative to other niacin formulations.

Manual PA criteria applies to new and current users of Niacin 500 mg tablet.

- The provider acknowledges that other formulations of niacin, including Niaspan and Niacor, are available to DoD beneficiaries without the need of prior authorization
- The patient has tried AND cannot take at least two other prescription or over-the-counter (OTC) niacin-containing products due to a significant allergy to an inactive ingredient (for example dyes, fillers, etc.) or due to significant adverse reactions to the other niacin-containing products
- The provider must explain what differences are in the inactive ingredient(s) which leads to an allergy to the other niacin-containing products or provide what serious adverse reactions to the other niacin-containing products are of concern *(fill-in blank)*

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

5.) **Vitamins: Prenatal—prenatal MVI (Neonatal Complete):** Neonatal Complete is a prenatal dietary supplement manufactured by a single company which requires a prescription prior to dispensing. The primary ingredients of Neonatal Complete are similar to that found in Azesco, Zalvit, Trinaz, Neonatal-DHA, and Neonatal FE, which require manual PA and are very expensive. Several cost-effective prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria.

Manual PA criteria applies to new and current users of prenatal Neonatal Complete

- The provider acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, and Neonatal Complete and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant. Please consider changing the prescription to one of these agents

- The provider must explain why the patient requires Neonatal Complete and cannot take one of the cost effective formulary alternatives. (fill-in blank)

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

6.) **Antidepressant and Non-Opioid Pain Syndrome Agents: SSRIs—sertraline 150 mg and 200 mg capsules:** Sertraline 25 mg, 50 mg and 100 mg tablets have been on the UF long-term, and do not require prior authorization. A new sertraline capsule formulated in 150 mg and 200 mg is not cost effective relative to the other sertraline formulations and other formulary SSRIs.

Manual PA criteria applies to new and current users of sertraline 150 mg and 200 mg capsules.

- The provider acknowledges that other strengths of sertraline and other formulary SSRIs are available to DoD beneficiaries without the need of prior authorization

- The provider must explain why the patient cannot take a combination of lower sertraline strengths to achieve the desired dose: (fill-in blank)

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

7.) **Skeletal Muscle Relaxants and Combinations Tizanidine 2 mg, 4 mg and 6 mg capsules (Zanaflex, generics):** Tizanidine is an alpha2-adrenergic agonist indicated to treat spasticity and is available in tablet and capsule formulations. The 2 mg, 4 mg and 6 mg capsule formulations (available from several manufacturers) are significantly more costly than the tablets. Manual PA criteria were recommended for all new users of tizanidine capsules, to require a trial of the cost-effective tizanidine tablet formulation and other formulary muscle relaxants first.

Manual PA criteria applies to new users of tizanidine capsules (Zanaflex).

- The provider is aware and acknowledges that tizanidine tablets and other formulary muscle relaxants are available to DoD beneficiaries without the need of prior authorization
- The provider must explain why the patient requires tizanidine capsules and cannot take tizanidine tablets or one of the other cost effective formulary alternatives.

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

B. New Manual PA Criteria Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an implementation plan of the first Wednesday 90 days after signing of the minutes, and that DHA will send letters to patients affected by the new PA for clemastine syrup, Lofena, Antivert 50 mg, niacin 500 mg, Neonatal Complete, and sertraline 150 and 200 mg capsules.

The P&T Committee also recommended (14 for, 0 opposed, 0 abstained, 3 absent) an implementation plan of the first Wednesday 60 days after signing of the minutes for the new PA criteria for tizanidine capsules.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

A. New Manual PA Criteria

The P&T Committee recommended new manual PA criteria for the 7 products listed above that contain active ingredients that are widely available in cost effective generic formulations: clemastine syrup, Lofena, Antivert 50 mg, niacin 500 mg, Neonatal Complete, sertraline 150 mg and 200 mg capsules, and tizanidine capsules.

BAP Comment: ☐ Concur ☐ Non-concur

B. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the new PA criteria for become effective the first Wednesday 60 days after signing of the minutes for the tizanidine capsules, and on the first Wednesday 90 days after signing of the minutes for the remaining products, as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

X. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS, AND EXPANDED AGE RANGES

P&T Comments

A. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 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.

Note that since these types of updates expand the patient population eligible for the drug, only a summary of the PA criteria is provided here; the current full PA criteria can be found on the TRICARE Formulary Search Tool at https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/.

1.) **Antilipidemic-1: PCSK9–inhibitors: evolocumab (Repatha)—**The manual PA criteria were updated for Repatha, allowing use in children as young as 10 years of age with homozygous- or heterozygous familial hypercholesterolemia. Additionally, for patients with atherosclerotic cardiovascular disease (ASCVD), the qualifying LDL for treatment is now lowered to less than 70 mg/dL, rather than 100 mg/dL, corresponding with data from the FOURIER outcomes trial and the updated American Heart Association/America College of Cardiology/National Lipid Association guidelines.

2.) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors–zanubrutinib (Brukinsa)—**Includes the new indication for adult patients with the following: Waldenström's macroglobulinemia (WM), a rare non-Hodgkin lymphoma; and relapsed or refractory marginal zone lymphoma (MZL) in patients who have received at least 1 anti-CD20-based regimen.

3.) **Oncological Agents: Acute Myelogenous Leukemia–ivosidenib (Tibsovo)—**Includes the new indication for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a FDA-approved test.

4.) **Respiratory Interleukins–mepolizumab injection (Nucala)—**Includes the new indication for adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) as add-on maintenance therapy who have had an inadequate response to nasal corticosteroids.

5.) **Sleep Disorders: Wakefulness Promoting Agents–sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)**—Includes the new indication for adult patients with idiopathic hypersomnia.

6.) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor Inhibitors–adalimumab (Humira)—**New guidelines from the American College of Rheumatology recommend a trial of Humira first, before small molecule immunomodulators, in patients with psoriatic arthritis. The current Humira PA requires a trial of methotrexate, aminosalicylates (sulfasalazine, mesalamine), corticosteroids, or immunosuppressants (azathioprine) prior to allowing Humira. Manual PA criteria was updated to allow Humira as first-line therapy in patients for psoriatic arthritis, and not require prior non-biologic systemic therapy.

B. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges - Implementation plan:

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) implementation of the first Wednesday 60 days after signing of the minutes for the updated PAs discussed above.

XI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS AND EXPANDED AGE RANGES

BAP Comments

A. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges:

The P&T Committee recommended updates to the PA criteria for Repatha, Brukinsa, Tibsovo, Nucala, Xywav and Humira as discussed above.

BAP Comment: ☐ Concur ☐ Non-concur

B. Updated PA Criteria for New FDA-Approved Indications and Expanded Age Ranges - Implementation Plan

The updated PA criteria for the drugs discussed above will become effective the first Wednesday 60 days after the signing of the minutes.

BAP Comment: ☐ Concur ☐ Non-concur

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR SAFETY INFORMATION

P&T Comments

A. Updated PA Criteria for Safety Information

Targeted Immunomodulatory Biologics (TIBs): Janus Kinase (JAK) inhibitors: baricitinib (Olumiant) and upadacitinib (Rinvoq)—In September 2021, the FDA published results of a large RCT with the oral JAK inhibitor tofacitinib (Xeljanz and Xeljanz XR). Xeljanz and Xeljanz XR were associated with an increased risk of serious cardiovascular-related events, cancer,

thrombosis, and death; subsequently there were revisions to the product labeling. Since Olumiant and Rinvoq have a similar mechanism of action, the FDA also required updates to the package inserts for these products, due to the potential for similar risks as Xeljanz. The revised labeling cautions providers to evaluate the risk vs. benefit of the JAK inhibitors, and to use these products as 2nd line therapy.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria for Olumiant and Rinvoq, requiring provider acknowledgment of the safety alerts and boxed warnings.

B. Updated PA Criteria for Safety Information Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an implementation of the first Wednesday 30 days after signing of the minutes for the safety updates for the JAK inhibitors.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR SAFETY INFORMATION

BAP Comments

A. Updated PA Criteria for Safety Information

The P&T Committee recommended updates to the PA criteria for Olumiant and Rinvoq, as outlined above.

BAP Comment: ☐ Concur ☐ Non-concur

B. Updated PA Criteria for Safety - Implementation Plan

The updated PA criteria for the JAK inhibitors Olumiant and Rinvoq will become effective the first Wednesday 30 days after the signing of the minutes as discussed above.

BAP Comment: ☐ Concur ☐ Non-concur

XIV. INFORMATIONAL ITEM—SUMMARY OF RECOMMENDATIONS AND BENEFICIARY IMPACT (NOVEMBER 2021 DoD P&T COMMITTEE MEETING)

Table of Implementation Status of UF Recommendations/Decisions Summary

DoD PEC Drug Class	UF Drugs	NF Drugs	Tier 4/Not Covered Drugs	Implement Date	Notes and Unique Users Affected
Continuous Glucose Monitoring Systems	▪ Dexcom G6 ▪ Abbott FreeStyle Libre 2	▪ None	▪ None	Pending signing of the minutes /60 days	▪ Note that PA will be required for both CGMs. ▪ Any patients currently receiving one of the CGMs under the Medical Benefit will be required to fulfill PA requirements to obtain a CGM under the Pharmacy benefit. ▪ UUs affected: not applicable, not currently part of the pharmacy benefit and both products designated as UF.
Subcutaneous Immuno-globulins (SCIG)	**UF step-preferred** ▪ Cutaquig ▪ Gamunex-C **UF non-step-preferred** ▪ Gammagard Liquid ▪ Gammaked ▪ Cuvitru ▪ Hizentra ▪ Hyqvia ▪ Xembify	▪ None	▪ None	Pending signing of the minutes /90 days	▪ New PAs required for new users. ▪ A trial of Cutaquig and Gamunex-C is required first before the non-step preferred SCIG products. ▪ UUs affected: not applicable – all products are UF and PAs only affect new users.

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

Drug	Total
dihydroergotamine mesylate nasal spray (Trudhesa)	6
lorazepam extended release capsules (Loreev XR)	1

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
clemastine 0.5 mg/mL oral syrup	0	0	5	5
diclofenac potassium 25 mg tablets	0	0	0	0
meclizine 50 mg tablets	0	0	2	2
niacin 500 mg tablets	0	0	0	0
prenatal vitamin Neonatal Complete	0	0	0	0
sertraline 150 mg and 200 mg capsules	0	0	0	0