

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE FEBRUARY 2024 MEETING**

**INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING APRIL 3, 2024**

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with 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 complete exclusion status, prior authorizations (PAs), pre-authorizations, and the effective date for a pharmaceutical agent's change from formulary to nonformulary (NF) or to complete exclusion status are received from the Uniform Formulary Beneficiary Advisory Panel (UF BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEW—GROWTH-STIMULATING HORMONE AGENTS

P&T Comments

A. Growth-Stimulating Hormone Agents—Relative Clinical Effectiveness Conclusion

The P&T Committee evaluated the relative clinical effectiveness of the growth hormone-stimulating agents which are used for treating growth hormone deficiency and other conditions in children, including small for gestational age, chronic renal insufficiency, Prader Willi syndrome, Turner Syndrome, Noonan's Syndrome, and ShoX Homeobox Mutation. Additional FDA-labeled uses for adults include treating AIDS/HIV wasting cachexia and short bowel syndrome were also considered. The class was last reviewed for formulary status in May 2018. Since then, three long-acting agents entered the market, which were originally reviewed as innovator drugs. PA has applied to the class since 2007.

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

Products

- The short-acting drugs all contain recombinant human growth hormone (somatropin) and are injected once daily. The long-acting products lonapegsomatropin (Skytrofa), somapacitan (Sogroya), and somatrogen (Ngenla) are injected once weekly.

- There is no change from the 2018 conclusion that although products differ in terms of storage requirements, preservatives, available quantities, delivery devices, smallest delivery increment, reconstitution and assembly steps prior to delivery, and FDA indications, these differences do not impact treatment outcome.

Clinical Practice Guidelines

- Guidelines from the Pediatric Endocrine Society (2016), the Growth Hormone Research Society (2019), and the American Association of Clinical Endocrinology (2019) all recommend recombinant human growth hormone for the treatment of growth hormone deficiency, but do not recommend one product over another.
- For the long-acting products, guidelines mention a potential for improved adherence, and that early studies demonstrate comparable safety and efficacy to the short-acting growth hormone agents. However, there is no preference for the long-acting preparations over the short-acting products.

Efficacy

- All short-acting recombinant human growth hormone agents are bioidentical and therapeutically interchangeable.
- Systematic reviews and meta-analyses show the long-acting products are similar in efficacy and safety compared to the short-acting products, although limited head-to-head data is available.

Safety

- There is considerable overlap in terms of commonly reported adverse effects, however, specific differences between products are related to the different preservatives used and not due to differences in the active ingredient.

Individual Product Characteristics

- Short-Acting Agents
 - *Genotropin* is available in a vial formulation as well as a pre-filled reusable pen option. Genotropin can be stored at room-temperature and also provides a preservative-free option.
 - *Humatrope* is available in a vial formulation as well as a pre-filled cartridge and disposable pen option. It requires refrigeration and contains metacresol as a preservative as well as glycerin.
 - *Norditropin* is available in a pre-filled, pre-mixed multi-dose disposable pen and uses a non-benzyl alcohol preservative. It is stable at room temperature for up to 3 weeks.
 - *Nutropin* is available in a pre-filled, pre-mixed multi-dose disposable pen that requires refrigeration and contains phenol as a preservative.

- *Saizen* is available in a vial formulation and can be stored at room-temperature prior to reconstitution. Benzyl alcohol is used as a preservative. Additionally, it can be used with a needle-free device.
- *Serostim* is unique as it is labeled only for growth hormone deficiency due to HIV wasting and short bowel syndrome. It is packaged in individual vials and requires higher doses than the other preparations. Availability solely in vials is a limitation for use in terms of patient convenience.
- *Zomacton* is available in a vial formulation and can be used with a needle-free delivery device. It contains either benzyl alcohol or metacresol as a preservative. The needle-free device is associated with bruising.
- Long-acting Agents
 - *sompacitan-beco (Sogroya)* is available as a pre-filled, pre-mixed, multi-dose disposable pen. It requires refrigeration and has a phenol preservative.
 - *lonapegsomatropin-tcgd (Skytrofa)* is available as a pre-filled dual chamber cartridge that requires reconstitution prior to being loaded into the single-dose reusable chargeable pen device. Prior to reconstitution, cartridges can be stored at room-temperature for up to 6-months. Skytrofa does not contain a preservative.
 - *somatrogon-ghla (Ngenla)* is available as a pre-filled, pre-mixed, multi-dose disposable pen. It requires refrigeration and contains the preservative metacresol.

Other Factors

- MHS providers agreed that a prefilled device is preferred over a vial and diluent that requires reconstitution, in terms of patient ease of use.

Overall Clinical Conclusion

- The products offering a pre-filled, pre-mixed multi-dose pen delivery systems for ease of use include Norditropin, Omnitrope, Sogroya and Ngenla.
- The growth hormone-stimulating agents are highly therapeutically interchangeable.
- In order to meet the needs of MHS patients, both a short-acting and long-acting agent are required on the formulary, to allow for a variety of preservatives and preservative-free options, different devices, and to allow for potential manufacturer shortages.

B. Growth-Stimulating Hormone Agents—Relative Cost Effectiveness Analysis and Conclusion

The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that somatropin (Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Saizen-Prep, Serostim, Zomacton), lonapegsomatropin-tcgd (Skytrofa), somapacitan-beco (Sogroya), and somatrogon-ghla (Ngenla) were all cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the growth stimulating hormone agents in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

C. Growth-Stimulating Hormone Agents—UF Recommendation

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

- UF and step-preferred
 - Short-acting agents
 - somatropin (Norditropin)
 - somatropin (Genotropin) – *moves from NF non-step-preferred to UF and step preferred*
 - somatropin (Zomacton) - *moves from UF non-step-preferred to UF and step preferred*
 - somatropin (Omnitrope) - *moves from UF non-step-preferred to UF and step preferred*
 - Long-acting agents
 - somatrogon-ghla (Ngenla) – *moves from NF non-step-preferred to UF and step preferred*
 - somapacitan-beco (Sogroya) – *moves from NF non-step-preferred to UF and step preferred*
- NF and non-step-preferred
 - Short-acting agents
 - somatropin (Humatrope)
 - somatropin (Nutropin)
 - somatropin (Serostim)

- somatropin (Saizen, Saizen Prep)
- Long-acting agents
 - lonapegsomatropin-tcgd (Skytrofa)
- Complete exclusion
 - None
- Note that as part of this recommendation, a trial of two short-acting step-preferred drugs and two long-acting step-preferred products will be required prior to use of the non-step-preferred products in new and current users.

D. Growth-Stimulating Hormone Agents—Manual PA Criteria

PA criteria have applied to the class since 2007, and PA was applied to the long-acting agents when they were reviewed individually as innovator drugs.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the existing PA for the new step therapy. A trial of two short-acting agents and two long-acting agents is required in all new and current users of the non-step-preferred products (Humatrope, Nutropin, Serostim, Saizen, Saizen Prep and Skytrofa), unless the patient has a contraindication to or has experienced an adverse event from the step-preferred products. For the step-preferred products, criteria will apply to new users.

A growth hormone-stimulating agent is not allowed for use in idiopathic short stature, the normal ageing process, obesity, depression, or for other off-label uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment, etc.). Concomitant use of multiple growth hormone products is not allowed. Annual PA renewal is required, to ensure appropriate use.

The Manual PA criteria is as follows:

1. Step-preferred products

Short-acting: somatropin (Genotropin), somatropin (Norditropin), somatropin (Omnitrope), somatropin (Zomacton)

Long-acting: somatrogen-ghla (Ngenla), somapacitan-beco (Sogroya)

February 2024 changes are in bold and ~~strikethrough~~

Manual PA criteria apply to all new users of Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla and Sogroya

~~Norditropin FlexPro is the preferred Growth Stimulating Agent.~~

~~All new and current users of the non-step preferred Growth Stimulating Agents must try Norditropin FlexPro first.~~

Manual PA Criteria: Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla or Sogroya are approved if:

For Pediatric patients:

- The patient is younger than 18 years of age and has one of the following indications:
 - Growth hormone deficiency
 - Small for gestational age
 - Chronic renal insufficiency associated with growth failure
 - Prader-Willi Syndrome (in patients with a negative sleep study for obstructive sleep apnea)
 - Turner Syndrome
 - Noonan's Syndrome
 - Short stature homeobox (ShoX) gene mutation
- ~~• For patients younger than 18 years of age who do not have one of the indications above, document the diagnosis below:~~

- For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment

For Adult patients:

- The patient is 18 years of age or older and has one of the following indications:
 - Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood
 - HIV/AIDS wasting/cachexia
 - Short Bowel Syndrome
- For patients older than 18 years of age, the prescription is written by or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist)

AND

~~For Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim and Zomacton: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton:~~

- ~~• The patient has a contraindication to Norditropin FlexPro OR~~
- ~~• The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with the non-step-preferred product (e.g., because of different preservative)~~

~~Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim or Zomacton.~~

For Pediatric and Adult patients:

- Use of a Growth Hormone-Stimulating Agent is not approved for idiopathic short stature, the normal ageing process, obesity, or depression
- Use of a Growth Hormone-Stimulating Agent is not approved for other non-FDA-approved uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment)
- Concomitant use of multiple Growth Stimulating Agents is not approved

Prior authorization expires in one year. A new PA must be submitted yearly

2. Non-step-preferred products

Short-acting: somatropin (Humatrope), somatropin (Nutropin), somatropin (Serostim), somatropin (Saizen, Saizen Prep)

Long-acting: lonapegsomatropin-tcgd (Skytrofa)

February 2024 changes are in bold and ~~strikethrough~~

Manual PA criteria apply to all new and current users of Humatrope, Nutropin, Serostim, Saizen, Saizen Prep, or Skytrofa

~~Norditropin FlexPro is the preferred Growth Stimulating Agent.~~

~~All new and current users of the non-step-preferred Growth Stimulating Agents must try Norditropin FlexPro first.~~

Manual PA Criteria: Humatrope, Nutropin, Serostim, Saizen, Saizen-Prep, or Skytrofa are approved if:

For Pediatric patients:

- **The provider acknowledges that Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla and Sogroya are DoD's preferred growth hormone-stimulating agents**
- The patient is younger than 18 years of age and has one of the following indications:
 - Growth hormone deficiency
 - Small for gestational age
 - Chronic renal insufficiency associated with growth failure
 - Prader-Willi Syndrome (in patients with a negative sleep study for obstructive sleep apnea)
 - Turner Syndrome
 - Noonan's Syndrome
 - Short stature homeobox (ShoX) gene mutation

- ~~For patients younger than 18 years of age who do not have one of the indications above, document the diagnosis below:~~

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- For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment

For Adult patients:

- **The provider acknowledges that Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla and Sogroya are DoD's preferred growth hormone-stimulating agents**
- The patient is 18 years of age or older and has one of the following indications:
 - Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood
 - HIV/AIDS wasting/cachexia
 - Short Bowel Syndrome
- For patients older than 18 years of age, the prescription is written by or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist)

AND

~~For Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim and Zomacton: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton:~~

- ~~The patient has a contraindication to Norditropin FlexPro OR~~
- ~~The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with the non-step preferred product (e.g., because of different preservative)~~

~~Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim or Zomacton.~~

For Pediatric and Adult patients:

- **Patient has a contraindication (e.g., due to hypersensitivity to a preservative or other inactive ingredient) to the following:**
 - **two short acting agents including Norditropin, Genotropin, Omnitrope, or Zomacton AND**
 - **two long-acting agents including Sogroya and Ngenla**
- **Patient has experienced an adverse event (e.g., due to a preservative or other inactive ingredient) to the following:**

- two short acting agents including Norditropin, Genotropin, Omnitrope, or Zomacton AND
- two long-acting agents including Sogroya and Ngenla
- Note that patient preference for a particular device is insufficient grounds for approval of Humatrope, Nutropin, Serostim, Saizen, Saizen Prep, or Skytrofa
- Serostim is only approved for HIV cachexia and is not allowed for other indications
- Use of a Growth Hormone-Stimulating Agent is not approved for idiopathic short stature, the normal ageing process, obesity, or depression
- Use of a Growth Hormone-Stimulating Agent is not approved for other non-FDA-approved uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment)
- Concomitant use of multiple Growth Stimulating Agents is not approved

Prior authorization expires in one year. A new PA must be submitted yearly

E. Growth-Stimulating Hormone Agents—Removal of Tier 1 Copay for Norditropin

Norditropin currently has a Tier 1 copay, implemented at the previous 2018 class review. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the Tier 1 copay for Norditropin, as it is no longer the sole step-preferred growth-stimulating hormone agent. Norditropin will move to the Tier 2 copay.

F. Growth-Stimulating Hormone Agents—UF, PA, Tier 1 Copay Removal, and Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) An effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) that DHA will send letters to beneficiaries affected by the NF, non-step-preferred recommendation and to those patients affected by the change in copay for Norditropin.

III. UF DRUG CLASS REVIEW—GROWTH-STIMULATING HORMONE AGENTS

UF BAP Comments

A. Growth-Stimulating Hormone Agents—UF Recommendation

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

- UF and step-preferred
 - Short-acting agents
 - Norditropin
 - Genotropin
 - Zomacton
 - Omnitrope
 - Long-acting agents
 - Ngenla
 - Sogroya
- NF and non-step-preferred
 - Short-acting agents
 - Humatrope
 - Nutropin
 - Serostim
 - Saizen, Saizen Prep
 - Long-acting agents
 - Skytrofa
- Complete exclusion
 - None
- Note that as part of this recommendation, a trial of two short-acting step-preferred drugs and two long-acting step-preferred products will be required prior to use of the non-step-preferred products in new and current users.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Growth-Stimulating Agents—Manual PA Criteria

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Growth-Stimulating Agents—Removal of Tier 1 Copay for Norditropin

The P&T Committee recommended removal of Tier 1 copay for Norditropin as discussed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

D. Growth-Stimulating Agents—UF, PA, Tier 1 Copay Removal, and Implementation Period

The P&T Committee recommended an effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and that DHA send letters to beneficiaries affected by the NF, non-step-preferred recommendation and to those patients affected by the change in copay for Norditropin.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

The products were divided into two groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Abrilada, Augtyro, Bimzelx, Cabtreo, Coxanto, Fruzaqla, Jesduvroq, Jylamvo, Likmez, Motpoly XR, Ogsiveo, Ojjaara, Truqap, Velsipity, Xalkori pellets, Xphozah and Zepbound, while Group 2 included Entyvio, Omvoh, Voquezna and Zurzuvae.

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

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

- UF
 - capivasertib (Truqap) – Oncological Agents for breast cancer
 - crizotinib oral pellets (Xalkori) – Oncological Agents; a new formulation for non-small cell lung cancer (NSCLC), anaplastic large cell lymphoma (ALCL) and inflammatory myofibroblastic tumors (IMT)
 - etrasimod (Velsipity) – Sphingosine-1 phosphate (S1p) receptor modulators for ulcerative colitis
 - fruquintinib (Fruzaqla) – Oncological Agents for colorectal cancer
 - methotrexate oral solution (Jylamvo) – Antirheumatics; new formulation of methotrexate
 - metronidazole oral suspension (Likmez) – Gastrointestinal-2 Agents; new formulation of metronidazole
 - mirikizumab-mrkz (Omvoh) – Targeted Immunomodulatory Biologics (TIBs) for ulcerative colitis
 - momelotinib (Ojjaara) – Oncological Agents for myelofibrosis
 - nirogacestat (Ogsiveo) – Oncological Agents for desmoid tumors
 - repotrectinib (Augtyro)– Oncological Agents for NSCLC
 - tirzepatide (Zepbound) – Weight Loss Agents
 - vedolizumab (Entyvio) – TIBs for ulcerative colitis
 - zuranolone (Zurzuvae) – Antidepressants and Non-Opioid Pain Syndrome Agents for postpartum depression
- NF
 - adalimumab-afzb (Abrilada) – TIBs; Humira biosimilar
 - bimekizumab-bkzx (Bimzelx) – TIBs for plaque psoriasis
 - daprodustat (Jesduvroq) – Hematological Agents
 - lacosamide extended release (Motpoly XR) – Anticonvulsants-Antimania Agents
 - tenapanor (Xphozah) – Electrolyte Depleting Agents; phosphate absorption inhibitor for chronic kidney disease

- vonoprazan (Voquezna) – Proton Pump Inhibitors: Potassium-Competitive Acid Blockers
- Complete Exclusion:
 - clindamycin 1.2%, adapalene 0.15%, and benzoyl peroxide 3.1% topical gel (Cabtreo) – Acne Agents: Topical Acne and Rosacea
 - Cabtreo was recommended for complete exclusion as it has little to no clinical benefit relative to other drugs for acne, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include clindamycin/benzoyl peroxide gel, adapalene gel, and tretinoin cream.
 - oxaprozin 300 mg capsules (Coxanto) – Pain Agents: NSAIDs
 - Coxanto was recommended for complete exclusion as it has little to no clinical benefit relative to other pain agents, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include meloxicam, oxaprozin 600 mg tablets, and naproxen ER (Naprelen ER).

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

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

- Applying manual PA criteria to new users of the oncology drugs Truqap, Xalkori, Fruzaqla, Ojjaara, Ogsiveo and Augtyro; and for new users of Jesduvroq, Motpoly XR, Jylamvo, Likmez, Voquezna and Zurzuvae.
- Applying manual PA criteria to new and current users of the Humira biosimilar Abrilada, similar to what is in place for the other Humira biosimilars. A trial of the Humira branded product is required first as per the February 2023 P&T Committee meeting minutes.
- Applying manual PA criteria to new users of Bimzelx, requiring a trial of Humira, Stelara and Cosentyx, similar to what is in place for the other TIBs approved for treating plaque psoriasis.
- Applying manual PA criteria to new users of Velsipity and Omvoh, requiring a trial of Humira first, and for new users of Entyvio, requiring a trial of Humira or infliximab first, similar to what is in place for the other TIBs approved for treating ulcerative colitis.
- Applying manual PA criteria to new and current users of Xphozah, requiring a trial of two traditional phosphate binders first.
- Applying manual PA criteria to new users of Zepbound, requiring a trial of generic phentermine, Qsymia (or its generic components) and Contrave (or its generic components), similar to what is in place for the weight loss agents Saxenda and Wegovy.

- Applying interim manual PA criteria in new and current users for Cabtreo and Coxanto prior to the complete exclusion implementation.

The Manual PA criteria is as follows:

1. adalimumab-afzb (Abrilada)

Manual PA criteria apply to all new and current users of the Humira biosimilar

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

- Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations
- Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient
 - Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Humira biosimilar
- If patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease
 - If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older
 - If indication is moderate to severe Crohn's disease patient must be 6 years of age or older AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease
- If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa
 - If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease

- If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months
- Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira
- Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed)
- Patient is not receiving other targeted immunomodulatory biologics with Humira, including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER)

Non-FDA approved uses are NOT approved, except if indication is approved for Humira, it is approved for a biosimilar

PA does not expire

2. **bimekizumab-bkzx (Bimzelx)**

Manual PA criteria apply to all new users of bimekizumab-bkzx (Bimzelx)

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

- The provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent and the patient must try Humira first
- Patient had inadequate response to Humira OR
- Patient had adverse reaction to Humira that is not expected to occur with the requested agent OR
- Patient has a contraindication to Humira AND
- Patient had inadequate response to Stelara OR
- Patient had adverse reaction to Stelara that is not expected to occur with the requested agent OR
- Patient has a contraindication to Stelara AND
- Patient had inadequate response to Cosentyx OR
- Patient had adverse reaction to Cosentyx that is not expected to occur with the requested agent OR
- Patient has a contraindication to Cosentyx AND

- Patient is 18 years of age or older
- Patient has moderate to severe plaque psoriasis
- Patient is a candidate for systemic therapy or phototherapy
- Patient had inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.)
- Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)
- Patient will not be receiving any other targeted immunomodulatory biologics with bimekizumab, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR

Non-FDA approved uses are NOT approved

PA does not expire

3. **capivasertib (Truqap)**

Manual PA criteria apply to all new users of capivasertib (Truqap)

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

- Patient is 18 years of age or older
- The drug is prescribed or in consultation with hematologist or oncologist
- Patient has advanced or metastatic HR-positive, HER2-negative breast cancer
- Patient has PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test
- Patient has tried and failed, or is not a candidate for, adjuvant or neoadjuvant chemotherapy
- Patient had disease progression while on or after endocrine therapy
- Patient will be receiving fulvestrant injection (Faslodex) therapy along with capivasertib (Truqap)
- 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. The diagnosis must be listed.
- Provider is aware of all monitoring requirements and screening precautions

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

PA does not expire

4. **clindamycin, benzoyl peroxide topical gel (Cabtreo)**

Interim Manual PA criteria apply to all new users of clindamycin phosphate, adapalene, and benzoyl peroxide topical gel (Cabtreo)

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

- This agent has been identified as having cost-effective alternatives including adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, and gel). These agents are available without a PA. Please consider changing the prescription to one of these agents
- Patient has Acne Vulgaris
- Please explain why this agent is required and patient cannot take formulary alternatives
 - Acceptable responses include the following: the patient has tried and failed at least three step-preferred (e.g., generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, tazarotene cream, or adapalene) topical acne products, including different retinoids (e.g., adapalene, tazarotene cream, and tretinoin) or other topical agents, OR
 - The patient has experienced an adverse reaction with formulary, step-preferred topical tretinoin and adapalene agents that is not expected to occur with Cabtreo

Non-FDA approved uses are NOT approved

PA does not expire (until complete exclusion implementation)

5. **crizotinib (Xalkori) oral pellets**

Manual PA criteria apply to all new users of crizotinib oral pellets (Xalkori)

Age edit: PA does not apply to children 12 year of age and younger

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

- Prescribed by or in consultation with a hematologist/oncologist
- Patient has metastatic non-small cell lung cancer (NSCLC) AND
 - The NSCLC tumor is anaplastic lymphoma kinase (ALK) positive or ROS1-positive (as detected by an FDA-approved test) OR
- Patient has relapsed or refractory systemic anaplastic large cell lymphoma (ALK positive) AND
 - Patient is 1 year of age and older or a young adult (Note - limitation of use: safety and efficacy of Xalkori have not been established in older adults with refractory or refractory systemic ALK-positive anaplastic large cell lymphoma) OR

- Patient has unresectable, recurrent, or refractory inflammatory myofibroblastic tumor
 - Patient is 1 year of age or older
 - Tumor is anaplastic lymphoma kinase (ALK) positive
- 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. The diagnosis must be listed.
- Provider must explain why the patient cannot take Xalkori tablets.
 - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience

Other non-FDA approved uses are NOT approved except as noted above
PA does not expire

6. daprodustat (Jesduvroq)

Manual PA criteria apply to all new users of daprodustat (Jesduvroq)

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

- Provider acknowledges that epoetin alfa-epbx (Retacrit) is the preferred erythropoietin stimulating agent for TRICARE and is available without prior authorization
- Patient has experienced an inadequate response or adverse reaction to Retacrit
- Patient is 18 years of age or older
- Prescribed by or in consultation with a nephrologist
- Patient has diagnosis of anemia due to chronic kidney disease
- Patient has been receiving dialysis for at least 4 months
- Provider is aware of the warnings, screening, and monitoring precautions for Jesduvroq

Non-FDA approved uses are not approved

PA expires in 6 months

Renewal Criteria: Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. Continued use of Jesduvroq will be approved indefinitely for the following:

- The patient has had a positive response to therapy as shown by an increase or stabilization in hemoglobin levels or a reduction or absence in red blood cell transfusions.

7. etrasimod (Velsipity)

Manual PA criteria apply to all new users of Velsipity

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

- Patient has a diagnosis of moderately to severely active ulcerative colitis
- The patient is 18 years of age or older
- The provider acknowledges that Humira is the Department of Defense's preferred targeted immunomodulatory biologic agent for ulcerative colitis.
- The patient must have tried Humira AND:
 - Had an inadequate response to Humira OR
 - Experienced an adverse reaction to Humira that is not expected to occur with Velsipity OR
 - Has a contraindication to Humira
- Provider is aware of all assessments, warnings, screening, and monitoring precautions for Velsipity.
- The patient is not receiving oral immunomodulatory or biologic therapies concomitantly
- The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g., azathioprine], etc.)

Non-FDA-approved uses are not approved

Prior authorization does not expire

8. fruquintinib (Fruzaqla)

Manual PA criteria apply to all new users of fruquintinib (Fruzaqla)

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

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with hematologist or oncologist
- Patient has a diagnosis of metastatic colorectal cancer
- Patient has had progression following treatment with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy
- Patient must have had progression following anti-VEGF therapy (e.g., bevacizumab, Zaltrap, Cyramza)

- If RAS wild-type, patient must have had progression following treatment with anti-EGFR therapy (e.g., cetuximab, panitumumab)
- 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. The diagnosis must be listed.
- Provider is aware of all monitoring requirements and screening precautions

Other non-FDA approved uses are NOT approved except as noted above
PA does not expire

9. **lacosamide ER (Motpoly XR)**

Manual PA criteria apply to all new users of lacosamide ER capsule (Motpoly XR)

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

- Patient has a diagnosis of partial-onset seizures
- Patient weighs at least 50 kg
- The drug is prescribed by a neurologist
- Provider is aware of the warnings, screening, and monitoring precautions for Motpoly XR
- The provider must explain why the patient requires Motpoly XR and cannot take the generic formulary alternative, lacosamide tablet
 - Acceptable responses include: the patient is having adherence problem with twice daily lacosamide tablet dosing or that the patient has had an adverse reaction to an excipient in lacosamide tablets that would not be likely to occur with Motpoly XR capsules.

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

10. **methotrexate (Jylamvo) oral solution**

Manual PA criteria apply to all new users of methotrexate oral solution (Jylamvo)

Age edit: PA criteria does not apply to children 12 years of age and younger

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

- Patient has acute lymphoblastic leukemia (ALL), mycosis fungoides, relapsed or refractory non-Hodgkin lymphoma, rheumatoid arthritis, severe psoriasis, or active polyarticular juvenile idiopathic arthritis
- Patient has a history of difficulty swallowing tablets or has a medical condition that is characterized by difficulty swallowing or inability to swallow
- 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. The diagnosis must be listed.

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

PA does not expire

11. **metronidazole (Likmez) oral suspension**

Manual PA criteria apply to all new users of metronidazole oral suspension (Likmez)

PA does not apply to patients 12 years of age and younger (Age edit)

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

- Provider acknowledges that metronidazole tablets are available without a PA
- Patient requires metronidazole and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience

PA expires after 6 months

New PA required to continue therapy

12. **mirikizumab-mrkz (Omvoh)**

Manual PA criteria apply to all new users of mirikizumab-mrkz

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

- Patient is 18 years of age or older
- Patient has moderately to severely active ulcerative colitis
- The provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis
- Patient had inadequate response to Humira
- Patient had adverse reaction to Humira that is not expected to occur with the requested agent
- Patient has a contraindication to Humira
- Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g.,

sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc.

- Patient has negative TB test result in past 12 months (or TB is adequately managed)
- Patient will not be receiving any other targeted immunomodulatory biologics with mirikizumab including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), upadacitinib (Rinvoq ER), or vedolizumab (Entyvio)

Non-FDA approved uses are NOT approved

PA does not expire

13. momelotinib (Ojjaara)

Manual PA criteria apply to all new users of momelotinib (Ojjaara)

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

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with hematologist/oncologist
- Patient has diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with anemia
- If the patient is female, she is not pregnant or planning to become pregnant
- Females of reproductive potential will use effective contraception during treatment and for 1 week after the last dose
- Female patients will not breastfeed during treatment and for at least 1 week after discontinuation
- Provider is aware of the warnings, screening and monitoring precautions for Ojjaara
- 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. The diagnosis must be listed.

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

PA does not expire

14. nirogacestat (Ogsiveo)

Manual PA criteria apply to all new users of nirogacestat (Ogsiveo)

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

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with hematologist or oncologist
- Patient has a diagnosis of progressing desmoid tumor or aggressive fibromatosis which requires systemic treatment
- 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. The diagnosis must be listed.
- Provider is aware of the warnings, screening, and monitoring precautions for Ogsiveo

Other non-FDA approved uses are NOT approved except as noted above
PA does not expire

15. Oxaprozin (Coxanto)

Interim Manual PA criteria apply to all new users of oxaprozin capsules (Coxanto)

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

- Multiple formulary NSAIDs are available for DoD beneficiaries without a prior authorization including celecoxib, diclofenac potassium, diclofenac sodium, ibuprofen, indomethacin, meloxicam, naproxen, and oxaprozin. Please consider changing the prescription to one of these formulary NSAIDs.
- Please provide the clinical rationale as to why the patient cannot take any of the formulary NSAIDs.
 - Acceptable responses include the following: patient has an allergy to an excipient in oxaprozin caplets AND has tried and failed at least 3 other formulary NSAIDs

Non-FDA approved uses are NOT approved

PA does not expire (until complete exclusion implementation)

16. repotrectinib (Augtyro)

Manual PA criteria apply to all new users of repotrectinib (Augtyro)

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

- Patient is 18 years of age or older

- The drug is prescribed by or in consultation with hematologist or oncologist
- Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC)
- Patient has NSCLC that is ROS1-positive
- 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. The diagnosis must be listed.
- Provider is aware of all warning, screening and monitoring precautions for Augtyro

Other non-FDA approved uses are NOT approved except as noted above
PA does not expire

17. **tenapanor (Xphozah)**

Manual PA criteria apply to all new and current users of tenapanor tablets (Xphozah)

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

- Patient is 18 years of age or older
- The drug is prescribed by or in consultation with a nephrologist
- Patient has a diagnosis of hyperphosphatemia in chronic kidney disease (CKD)
- Patient has been receiving maintenance dialysis for at least 3 months
- Serum phosphate level is >5.5. mg/dL and <10 mg/dL
- Patient has tried and had an inadequate response to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenol), ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate) OR
- Patient has tried and been unable to tolerate at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenol), ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate) OR
- Patient has a contraindication to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenol), ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro), calcium carbonate, or calcium acetate. Contraindications to phosphate binders includes bowel obstruction, iron overload, or hypercalcemia OR
- Patient has had intolerance to any dose of phosphate binder therapy.

Non-FDA approved uses are NOT approved, including constipation-predominant irritable bowel syndrome (IBS-C)

PA does not expire

18. tirzepatide (Zepbound)

Manual PA criteria apply to all new users of tirzepatide (Zepbound)

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

- Patient is 18 years of age or older
- Patient has a BMI greater than or equal to 30 OR BMI greater than or equal to 27 with risk factors in addition to obesity (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease)
- Patient has tried and failed or has a contraindication to all of the following agents: generic phentermine, Qsymia (or its generic components) and Contrave (or its generic components)
 - Date and duration of use or contraindication for each medication must be provided
- If patient has type 2 diabetes, they must they tried and failed metformin and the preferred glucagon-like peptide-1 receptor agonist (GLP1RA) (Trulicity)
- Medication will not be used with another GLP1RA (for example, Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy)
- Patient must not have a history or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2
- Patient was engaged in a trial of behavioral modification and dietary restriction or at least 6 months and failed to achieve desired weight loss and will remain engaged throughout the course of therapy
- Patient must not be pregnant

Non-FDA approved uses are not approved

PA expires in 6 months and then annually

Renewal Criteria: Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. PA will be approved for 12 months if the following:

- Patient is currently engaged in behavioral modification and on a reduced calorie diet
- Patient lost greater than or equal to 5 percent of baseline body weight since starting medication

19. vedolizumab (Entyvio)

Manual PA criteria apply to all new users of vedolizumab

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

- Patient is 18 years of age or older
- Patient has moderate to severely active ulcerative colitis
- Provider acknowledges that Humira is the Department of Defense’s preferred targeted biologic agent for ulcerative colitis
- Patient had an inadequate response to Humira OR
- Patient had an adverse reaction to Humira that is not expected to occur with the requested agent OR
- Patient has a contraindication to Humira OR
- Patient tried and failed or had an inadequate response to infliximab (Remicade)
- Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc.
- Patient has received induction dosing with two intravenous doses of vedolizumab (Entyvio) OR patient has been receiving intravenous vedolizumab (Entyvio) and achieved clinical response or remission beyond week 6
- Patient will not be receiving any other targeted immunomodulatory biologics with vedolizumab including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi) or upadacitinib (Rinvoq ER)

Non-FDA approved uses are NOT approved

PA does not expire

20. vonoprazan (Voquezna)

Manual PA criteria apply to all new users of vonoprazan (Voquezna)

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

- Prescriber acknowledges that omeprazole capsules and pantoprazole tablets are the Department of Defense’s preferred Proton Pump Inhibitors (PPIs) and are available without a prior authorization
- Patient is 18 years of age or older

- Prescription is written by or in consultation with a gastroenterologist or infectious disease specialist
- Patient has a diagnosis of erosive esophagitis or *Helicobacter pylori* (*H. pylori*) infection
- Voquezna will not be used concomitantly with a PPI
- For erosive esophagitis:
 - Patient has Los Angeles Grade C or D esophagitis
 - Patient has had an inadequate response after an adequate 8-week trial (high-dose, twice daily dosing, administered 30-60 minutes before meals) or adverse reaction to at least TWO of the following formulary PPIs: ONE must be omeprazole, pantoprazole, esomeprazole, or lansoprazole and the OTHER must be rabeprazole
 - Please write in date, drug name, strength, and frequency of PPI trials below:
 - Date ____ Drug name _____ Strength ____ Frequency ____
 - Date ____ Drug name _____ Strength ____ Frequency ____
 - OR patient has a contraindication to ALL of the following: omeprazole, pantoprazole, rabeprazole, esomeprazole, and lansoprazole
- For *H. pylori*:
 - Patient has tried and failed two 14-day trials with a guideline-recommended first-line treatment regimen. Appropriate treatment combinations for *H. pylori* include PPIs, amoxicillin, rifabutin, clarithromycin, bismuth subsalicylate, metronidazole, tetracycline, and levofloxacin

Non-FDA approved uses are NOT approved

PA expires in 6 months for initial approval, then annually

Renewal Criteria: Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. PA will be approved for 12 months if the following:

- Provider acknowledges that current FDA labeling recommends up to 6-months of maintenance therapy with Voquezna
- Patient has not had serious adverse events with Voquezna
- Provider has considered step-down therapy

21. zuranolone (Zurzuvae)

Manual PA criteria apply to all new users of zuranolone (Zurzuvae)

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

- Patient is 18 years of age or older
- Patient has postpartum depression (PPD)
- Patient is 12 months or less postpartum
- Patient has a contraindication to, intolerance to, or has failed a trial of ONE formulary antidepressant medication (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose) OR
- Patient is currently stable on an antidepressant medication and is experiencing breakthrough symptoms OR
- Patient is classified as having severe postpartum depression and/or is at significant risk for harm to self or others as determined by their provider and requires prompt symptom control OR
- Patient is continuing therapy that was initiated during an inpatient hospital stay
- The patient has not had previous treatment course with zuranolone during the current postpartum period
- Females of reproductive potential will use effective contraception during treatment and for one week after the final dose
- Provider acknowledges the risk of fetal harm associated with zuranolone exposure in pregnancy and has counseled patient to avoid conception for the duration of use and one week after final dose

Non-FDA approved uses are NOT approved

PA expires after 9 months. Provider must fill out a new PA

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

The P&T Committee recommended (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 15 for, 0 opposed, 1 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 Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion recommendation at 30 days and 60 days prior to implementation.

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

UF BAP Comments

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

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

- UF
 - Truqap
 - Xalkori pellets
 - Velsipity
 - Fruzaqla
 - Jylamvo
 - Likmez
 - Omvoh
 - Ojjaara
 - Ogsiveo
 - Augtyro
 - Zepbound
 - Entyvio
 - Zurzuvae
- NF
 - Abrilada
 - Bimzelx
 - Jesduvroq
 - Motpoly XR
 - Xphozah
 - Voquezna
- Complete Exclusion
 - Cabtreo
 - Coxanto

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VI. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—POTASSIUM CHLORIDE (KCl) 10 mEq PACKET (POKONZA) AND LIDOCAINE 5% PATCH (DERMACINRX, LIDOCAN, LIDOCAN II, LIDOCAN III)

P&T Comments

A. New Manual PA Criteria—potassium Chloride (KCl) 10 mEq Packet (Pokonza) and Lidocaine 5% Patch (DermacinRx, Lidocan, Lidocan II, Lidocan III)

- a) **Electrolyte-Mineral-Trace Element Replacement—potassium chloride (KCl) 10 mEq packet (Pokonza)**—Pokonza was identified as a high-cost potassium product in a class with many cost-effective alternatives, including alternate dosage formulations (liquid and packets). Many commercial health plans have chosen to not cover Pokonza or require a PA. PA criteria were recommended requiring providers to explain why the cost-effective alternatives cannot be used instead.

- b) Pain Agents: Pain Topical**—lidocaine 5% patch (DermacinRx, Lidocan, Lidocan II, Lidocan III)—Lidocan patches are manufactured by a single manufacturer and are not cost-effective compared to numerous other lidocaine patches produced by generic manufacturers. PA criteria were recommended for these brands.

The New Manual PA criteria is as follows:

1. potassium chloride 10 mEq packet (Pokonza)

Manual PA criteria apply to all new and current users of potassium chloride 10 mEq packet (Pokonza).

Manual PA criteria: Potassium chloride 10 mEq packet (Pokonza) is approved if all criteria are met:

- Provider acknowledges other strengths and formulations of potassium chloride are available without prior authorization.
- Provider must explain why the patient requires Pokonza and cannot take the cost-effective generic potassium chloride formulations. Acceptable responses include the following:
 - The patient has failed a trial of preferred potassium chloride capsules or tablets OR has documented swallowing difficulties (not due to convenience)
 - AND The patient has failed a trial of potassium chloride liquid AND potassium chloride 20 mEq packets, examples of failure include a documented allergy to an inactive ingredient

Non-FDA-approved uses are not approved

Prior authorization does not expire

2. lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III)

Manual PA criteria apply to all new and current users of lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III).

Manual PA criteria: lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III) is approved if all criteria are met:

- Provider acknowledges other formulations of lidocaine 5% patch are available without prior authorization.
- Provider must explain why the patient requires DermacinRx Lidocan, Lidocan II, or Lidocan III and cannot take the cost-effective generic lidocaine 5% formulations.
 - Acceptable responses include that the patient has failed a trial of at least 3 other preferred generic lidocaine 5% patches; examples of failure include a documented allergy to an inactive ingredient or the patch not adhering to skin.

Non-FDA-approved uses are not approved

Prior authorization does not expire

B. New Manual PA Criteria and Implementation Period—potassium Chloride (KCl) 10 mEq Packet (Pokonza) and Lidocaine 5% Patch (DermacinRx, Lidocan, Lidocan II, Lidocan III)

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria in new and current users of Pokonza, DermacinRx, Lidocan, Lidocan II, and Lidocan III. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

VII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—POTASSIUM CHLORIDE (KCl) 10 mEq PACKET (POKONZA) AND LIDOCAINE 5% PATCH (DERMACINRX, LIDOCAN, LIDOCAN II, LIDOCAN III)

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Pokonza and Lidocaine 5% Patch as outlined above, with an implementation date the first Wednesday 60 days after the signing of the minutes as stated above. DHA will send letters to patients affected by the PA criteria.

UF BAP Comments

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

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

P&T Comments

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

Manual PA criteria were recommended for three 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 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.

- a) **Diabetes Non-Insulin Drugs: Sulfonylureas—glipizide 2.5 mg immediate release (IR) tablet**—Numerous other glipizide IR (5 mg and 10 mg) and extended release (ER) (2.5 mg, 5 mg and 10 mg) formulations are more cost-effective than this 2.5 mg IR formulation made by a sole manufacturer.
- b) **Corticosteroids-Immune Modulators: High-Potency Corticosteroids—amcinonide 0.1% ointment**—There are multiple topical steroids of similar potency and an amcinonide cream that is cost-effective relative to this amcinonide 0.1% ointment.
- c) **Binders-Chelators-Antidotes-Overdose Agents—trientine 500 mg capsule**—Trientine is already available as a cost-effective 250 mg capsule. Patients requiring trientine 500 mg can take two capsules of the 250 mg formulation instead.

The Manual PA criteria is as follows:

1. glipizide 2.5 mg IR tablet

Manual PA criteria apply to all new and current users of glipizide 2.5 mg IR tablets.

Manual PA criteria: glipizide 2.5 mg IR tablets are approved if all criteria are met:

- Provider acknowledges other formulations of glipizide are available without prior authorization.
- Provider must explain why the patient requires glipizide 2.5 mg IR tablets and cannot take the cost-effective generic glipizide formulations.
 - Acceptable responses include that the patient has failed a trial of preferred glipizide 5 mg split in half AND glipizide ER 2.5 mg

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

2. amcinonide 0.1% ointment

Manual PA criteria apply to all new and current users of amcinonide 0.1% ointment.

Manual PA criteria: amcinonide 0.1% ointment is approved if all criteria are met:

- Provider acknowledges this drug has been identified as having cost-effective alternatives including clobetasol 0.05% and fluocinonide 0.05% ointments. These agents do not require a PA.

- Patient has tried for at least 2 weeks and failed, has a contraindication to, or has had an adverse reaction to fluocinonide 0.05%, desoximetasone 0.25% AND betamethasone dipropionate 0.05% ointments.
- Provider must explain why the patient requires this product and cannot take one of the cost-effective alternatives.
 - Acceptable responses include that the patient has had a past hypersensitivity to both desoximetasone AND betamethasone dipropionate (in any forms/concentrations) AND intolerance to carrier/vehicle of fluocinonide 0.05% ointment (specifically).

Non-FDA-approved uses are not approved

Prior authorization does not expire

3. trientine 500 mg capsule

Manual PA criteria apply to all new and current users of trientine 500 mg capsules.

Manual PA criteria: trientine 500 mg capsules are approved if all criteria are met:

- Provider acknowledges other strengths of trientine capsules are available without prior authorization.
- Provider must explain why the patient requires trientine 500 mg capsules and cannot take the cost-effective generic trientine formulations.
 - Acceptable responses include if the patient has failed a trial of the preferred trientine 250 mg capsules (taking 2 capsules of the 250 mg to get to 500 mg)

Non-FDA-approved uses are not approved

Prior authorization does not expire

B. Manual PA Criteria and Implementation Period for Newly Approved Drugs Not Subject To 32 CFR 199.21(G)(5)

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for glipizide 2.5 mg IR tablets, amcinonide 0.1% ointment, and trientine 500 mg capsules in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

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

UF BAP Comments

Manual PA Criteria and Implementation Period for Newly Approved Drugs not Subject to 32 CFR 199.21(G)(5)

The P&T Committee recommended manual PA criteria for glipizide 2.5 mg IR tablets, amcinonide 0.1% ointment, and trientine 500 mg capsules in new and current users with an implementation date effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients.

UF BAP Comments

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

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (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.

- a) **Oncological Agents: Ovarian Cancer—olaparib (Lynparza)**—Lynparza’s indication for the maintenance treatment of recurrent ovarian cancer is now restricted to those patients with a germline breast cancer (BRCA) mutation only. The manual PA criteria were updated accordingly.
- b) **Oncological Agents—encorafenib (Braftovi) and binimetinib (Mektovi)**—The manual PA criteria for Braftovi and Mektovi were updated to allow for the treatment of metastatic NSCLC.
- c) **Oncological Agents: Lung Cancer—entrectinib (Rozlytrek)**—The solid tumor indication for Rozlytrek was expanded to include children older than 1 month of age. The manual PA criteria were updated to remove age cutoff criteria.
- d) **Oncological Agents: Prostate Cancer 2nd Generation Antiandrogens—enzalutamide (Xtandi)**—The manual PA criteria for Xtandi were updated to

allow for the treatment of non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis.

- e) **Oncological Agents—pirtobrutinib (Jaypirca)**—The manual PA criteria were updated to allow for the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) in adults who have received two or more prior lines of therapy, including a bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma- 2 (BCL-2) inhibitor.
- f) **Oncological Agents: Acute Myelogenous Leukemia (AML) ivosidenib (Tibsovo)**—The manual PA criteria were updated to allow for the treatment of relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
- g) **Oncological Agents—belzutifan (Welireg)**—The PA was updated to allow for the new indication of advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). Additionally, due to updated (NCCN guidelines that allow use in metastatic disease, the previous exclusion for metastatic disease was removed.
- h) **Oncological Agents: Non-Bruton Tyrosine Kinase (BTK) Inhibitors for (CLL)—venetoclax (Venclexta)**—The PA was updated to allow for dose modification when Venclexta is used with a CYP3A inhibitor, based on updated FDA-labeling regarding drug interactions.
- i) **Growth Stimulating Agents: Miscellaneous—vosoritide (Voxzogo)**—The age cutoff for Voxzogo was removed from the PA due to a recent FDA label update. In addition, minor edits were made to standardize wording in the safety section.
- j) **Psoriasis Agents—roflumilast 0.3% cream (Zoryve)**—The manual PA criteria were updated to reflect the new expanded indication in children as young as 6 years old with plaque psoriasis.
- k) **Atopy Agents—tralokinumab-ldrm (Adbry)**—The manual PA criteria were updated to reflect the new expanded indication for atopic dermatitis in children as young as 12 years old. The PA criteria for children mirrors that of adults except it allows pediatric patients to use any topical steroid (as opposed to a high potency steroid as required for adults).
- l) **TIBs—etanercept (Enbrel) and abatacept (Orencia)**—Enbrel and Orencia are both now approved for pediatric patients 2 years of age and older with psoriatic arthritis. A trial of non-biologic systemic therapy and Humira will be required before the patient can try Enbrel or Orencia.
- m) **Targeted Immunomodulatory Biologics: Non-TNF Inhibitors—secukinumab (Cosentyx)**—The manual PA criteria were updated to allow for the treatment of moderate to severe hidradenitis suppurativa in adults.

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

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Lynparza, Braftovi, Mektovi, Rozlytrek, Venclexta, Xtandi, Jaypirca, Tibsovo, Welireg, Voxzogo, Zoryve, Adbry, Enbrel, Orencia, and Cosentyx in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

Updated PA Criteria and Implementation Period for New FDA Approved Indications

The P&T Committee recommended updates to the manual PA criteria for drugs listed above in new users an implementation effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

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

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

P&T Comments

A. Updated PA Criteria for Reasons other than New Indications

- a) **Pulmonary 1-Agents: Inhaled Corticosteroids—NF, non-step-preferred products (QVAR, Pulmicort, Arnuity Ellipta, Alvesco, Aerospan, and Asmanex)**—The Flovent HFA and Diskus branded agents were discontinued from the market in late 2023. Language in the PA criteria for the non-step-preferred inhaled corticosteroids was updated to require a trial of fluticasone propionate first, rather than Flovent HFA or Flovent Diskus.
- b) **Oncological Agents: Prostate Cancer 2nd Generation Antiandrogens—darolutamide (Nubeqa)**—At the November 2022 P&T Committee meeting, the Nubeqa PA was updated to allow for a new indication for the treatment of metastatic hormone-sensitive prostate cancer. The renewal criteria for Nubeqa was removed, as previously limited treatment to patients with non-metastatic disease, which no longer applies.

- c) **Oncological Agents: Prostate Cancer CYP-17 Inhibitors—abiraterone acetate 500 mg (Zytiga)**—Step-therapy in the subclass currently requires a trial of micronized abiraterone (Yonsa) and generic abiraterone acetate 250 mg (Zytiga) prior to use of branded Zytiga 500 mg. Due to changes in pricing, the Zytiga 250 mg and Yonsa steps were removed from the Zytiga 500 mg PA.
- d) **Hematological Agents—ropeginterferon alfa-2b-njft (Besremi)**—Besremi was reviewed at the February 2022 meeting and designated NF requiring PA. The PA currently restricts use to high-risk polycythemia vera (PV) patients and requires a trial of hydroxyurea first, unless there is therapeutic failure, intolerance or a contraindication. In December 2023, updated NCCN guidelines now list Besremi as a preferred treatment regimen for low-risk PV patients. Other options for low-risk PV patients including hydroxyurea are no longer preferred regimens. For high-risk PV patients, hydroxyurea and Besremi are now both listed as preferred regimens. Provider feedback and a review of other commercial healthcare plans support allowing Besremi use in low-risk PV patients and removing the hydroxyurea requirement. Additional updates to the PA were made based on provider feedback.
- e) **Sphingosine-1 phosphate (S1-P) receptor modulators for ulcerative colitis—ozanimod (Zeposia)**—Zeposia was originally approved for treating multiple sclerosis in 2020 but gained an indication for ulcerative colitis (UC) in August 2021. The PA currently requires a trial of Humira first, consistent with the requirements for other drugs classes used for UC, including the TIBs. The PA for Zeposia was updated to also require a trial of Velsipity first, in addition to Humira, unless the patient has a contraindication to or has had an adverse reaction to Velsipity.
- f) **Gastrointestinal-2 Agents: Constipation -predominant Irritable Bowel Syndrome (IBS-C)—tenapanor (Ibsrela)**—Ibsrela and Xphozah both contain the same active ingredient, tenapanor, and are marketed by the same manufacturer, but have different indications. Ibsrela is indicated for IBS-C, while Xphozah is approved for hyperphosphatemia in patients with CKD. The current Ibsrela PA excludes use for hyperphosphatemia. The Ibsrela PA was updated to allow use in hyperphosphatemia, due to the evidence supporting tenapanor use for this indication.

B. Updated PA Criteria and Implementation Period for Reasons other than New Indications

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) criteria updates to the manual PA criteria for Nubeqa, the non-step-preferred inhaled corticosteroids, Zytiga 500 mg, Besremi, Zeposia and Ibsrela. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XIII. UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS

UF BAP Comments

The P&T Committee recommended criteria updates to the manual PA criteria for Nubeqa, the non-step-preferred inhaled corticosteroids, Zytiga 500 mg, Besremi, Zeposia and Ibsrela, with implementation effective the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. REMOVAL OF PA AND IMPLEMENTATION PLAN FOR CONTRACEPTIVES

P&T Comments

At the November 2023 meeting, seven contraceptive agents, including two chewable tablet formulations and two extended cycle products were moved from NF to UF due to availability of cost-effective generic formulations. The PAs for these contraceptive agents will be removed, to support expanded access for these cost-effective contraceptives.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for the seven contraceptives listed below. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (chew tab) (e.g., Charlotte 24 Fe, Finzala, Mibelas 24 Fe) – Generic Code Number (GCN) 34725
- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (e.g., Aurovela 24 Fe, Blisovi 24 Fe, Hailey 24 Fe, Junel Fe 24, Larin 24 Fe, Microgestin 24 Fe, Tarina 24 Fe) – GCN 26629
- norethindrone 0.8mg/ethinyl estradiol 25 mcg (chew tab) (e.g., Kaitlib Fe, Layolis Fe) – GCN 29719
- norethindrone 0.4mg/ethinyl estradiol 35 mcg (e.g., Balziva, Briellyn, Philith, Vyfemla) – GCN 11470
- norethindrone 0.4mg/ethinyl estradiol 35 mcg/iron (chew tab) (e.g., Wymzya Fe) – GCN 97167
- levonorgestrel 0.15 mg/ethinyl estradiol 30 mcg 3-month dose pack (e.g., Amethia, Ashlyna, Camrese, Daysee, Jaimiess, Simpesse) – GCN 27096
- levonorgestrel 0.1 mg/ethinyl estradiol 20 mcg 3-month dose pack (e.g., Camrese Lo, Lojaimiess) – GCN 18167

XV. CONTRACEPTIVES—REMOVAL OF PA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended removing the PA criteria for the seven contraceptives listed above, with an implementation effective the first Wednesday 2 weeks after signing of the minutes

UF BAP Comments

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

XVI. CONTINUOUS GLUCOSE MONITORING SYSTEMS (CGMS) PA CRITERIA AND IMPLEMENTATION PERIOD

P&T Comments

A. CGMS—PA Criteria

The therapeutic CGMS were added to the TRICARE pharmacy benefit at the November 2021 P&T Committee meeting, with implementation in February 2022. A summary of the utilization trends and cost of the CGMS were presented during the February 2024 meeting. The Committee also reviewed the 2024 American Diabetes Association (ADA), 2023 DoD/VA Clinical Practice Guideline for Type 2 Diabetes, and 2021 American Association of Clinical Endocrinologists (AAACE) treatment guidelines for CGMS. Based on this, several changes to the CGMS PA criteria for FreeStyle Libre and Dexcom were recommended. The changes for the manual PA criteria included removing the requirements for specialist prescribing and for multiple daily insulin injections. New automated criteria were also recommended which will look back 180 days and if there is a prescription for any insulin product, the PA will be approved without requiring the manual PA (automated look-back).

The New Manual PA criteria is as follows:

1. FreeStyle Libre 2 and 3, Dexcom G6 and G7

Updates from the February 2024 meeting are in bold and strikethrough

Automated and manual PA criteria applies to all new users of Abbott FreeStyle Libre 2 and 3 and Dexcom G6 and G7.

Automated PA criteria: The patient has filled a prescription for insulin (including basal or rapid acting insulin) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND

Manual PA criteria: **If automated criteria are not met, coverage is approved coverage is approved for FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6 and Dexcom G7 if all criteria are met:**

- *Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria*
- Patient has a diagnosis of diabetes
- **Patient is currently being treated with insulin. Please document the following:**
 - **Insulin product: _____**
 - **Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days.**
- ~~Patient is using basal and prandial insulin injections; OR patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR patient is on insulin therapy with a history of severe hypoglycemia episodes requiring medical intervention (grade 2 or higher)~~
- ~~Device is prescribed by an endocrinologist or diabetes management expert~~
 - ~~Diabetes management expert is defined as: licensed independent practitioner experienced in the management of insulin dependent diabetes requiring basal and bolus dosing or a pump and familiar with the operation and reports necessary for proper management of continuous glucose monitoring systems. This is a self-certification.~~
- ~~Documentation is required of all the following:~~
 - ~~Diagnosis~~
 - ~~Medication history~~
 - ~~Completion of a comprehensive diabetes education program~~
 - ~~Patient agrees to wear CGM as directed~~
 - ~~Patient agrees to share device readings with managing healthcare professional for overall diabetes management~~
- ~~Patient meets the age requirement (≥ two years if Dexcom G6 and Dexcom G7, ≥ two years if FreeStyle Libre 2, or FreeStyle Libre 3)~~
- ~~Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips with the goal of minimizing/discontinuing use~~

Initial PA Expiration: annual

Renewal expiration: annual for the manual PA

Annual manual PA renewal criteria:

- ~~Confirm patient has seen endocrinologist or diabetes specialist within past year~~
- Patient has utilized CGM daily
- Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) at every visit with the goal of minimizing/discontinuing use
- Patients with T2DM continue to require basal ~~or and~~ prandial insulin injections daily
- Patient continues to share data with managing healthcare professional for the purposes of clinical decision making
- **Patient continues to be treated with insulin. Please document the following:**
 - **Insulin product:** _____
 - **Date last filled:** _____ **Note the patient must have filled an insulin prescription within the past 180 days.**

B. GMS—Implementation Period

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updates to the CGMS criteria, with an implementation of the first Wednesday 60 days after signing of the minutes at all points of service. The PA changes will increase beneficiary access under the TRICARE pharmacy benefit, reduce provider administrative time, and align DoD with clinical practice guidelines.

XVII. CONTINUOUS GLUCOSE MONITORING SYSTEMS (CGMS)—PA CRITERIA AND IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended updates to the PA criteria as discussed above, with an implementation of the first Wednesday 60 days after signing of the minutes.

UF BAP Comments

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

XVIII. BRAND OVER GENERIC PA AUTHORIZATION AND TIER 1 COPAY FOR TERIPARATIDE (FORTEO) INJECTION

P&T Comments

Teriparatide (Forteo) is designated as UF and requires PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, the branded Forteo injection will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 copay for brand Forteo is recommended.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) requiring brand Forteo over the generic in all new users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Forteo injections. The effective date will be no later than 60 days after the signing of the minutes. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

XIX. BRAND OVER GENERIC PA AUTHORIZATION AND TIER 1 COPAY FOR TERIPARATIDE (FORTEO) INJECTION

UF BAP Comments

The P&T Committee recommended the above in all new users at all points of service, based on cost effectiveness, with an effective date no later than 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XX. RE-EVALUATION OF NF GENERICS: ANDROGENS-ANABOLIC STEROIDS: TESTOSTERONE REPLACEMENT THERAPY FORMULARY STATUS AND IMPLEMENTATION PERIOD

P&T Comments

A. Testosterone Agents Formulary Status

The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF/Tier 3 drugs that are now available in generic formulations need to be readdressed. Refer to the May 2007, November 2012, and November 2022 P&T Committee minutes for additional information regarding established procedures for returning generic NF agents to formulary status.

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30 days, for the current NF transdermal/nasal testosterone products. The class was most recently reviewed in February 2023.

Currently the step-preferred products include 2% testosterone gel multi-dose pump (MDP) (generic Fortesta), which is also designated as BCF, and 1% testosterone gel (generic AndroGel) MDP and gel packets. The 1.62% testosterone gel MDP and gel packets (AndroGel 1.62%) and 2% solution MDP (Axiron, generics) are currently designated as NF and non-step-preferred.

The P&T Committee noted that brand Fortesta (2% gel MDP) and cost effective generics have been discontinued. Generics for 1.62% testosterone gel (generic AndroGel 1,62%) and 2% solution (Axiron) have dropped in price and are now the most cost-effective options. Several changes in formulary status and step-therapy preference were recommended for the class, which would increase access as the class has recently encountered shortages; align the benefit with product cost; and eliminate NF/Tier 3 copays for the topical/nasal testosterone agents.

B. Testosterone Agents Formulary Status and Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) making the following changes to formulary status, step therapy status, and prior authorization criteria, effective the first Wednesday 30 days after signing of the minutes.

- Move 2% gel MDP (the remaining Fortesta generic, GCN 98317) to UF non-step preferred status
- Return the following generically available products to UF and step-preferred status:
 - 1.62% MDP (AndroGel, generic; GCN 29905); 1.62% (25 mg, 50 mg) gel packets (AndroGel, generic; GCNs 33452, 33453)
 - 2% solution (Axiron, generic: GCN 29647)
 - 1% gel MDP and gel packets (generic AndroGel 1%) (GCN 23141, 47851, 47852)
- Move 1% gel unit dose tubes (Testim, Vogelxo, generics; GCN 97089) to UF step-preferred status
- Retain UF non-preferred status (no change) for:
 - brand Vogelxo 1% gel MDP (GCN 23141) and gel packet (GCN 47852)
 - Androderm 2 mg and 4 mg patch (GCNs 29171, 30796)
 - Natesto nasal gel (GCN 38079)
- Modify PA language to require use of preferred agents prior to receiving non-preferred agents

- Make no changes to other testosterone products
- Branded products with generic equivalents (e.g., Androgel) are subject to mandatory generic policy
- New users of all testosterone products must meet manual prior authorization criteria, based on intended use

As a result, the updated formulary status for the Androgens Anabolic Steroid: Testosterone Replacement Therapy subclass is as follows:

- UF and step-preferred: 1% and 1.62% testosterone gel MDP and gel packets (Androgel, generics); 2% solution MDP (Axiron, generics); 1% gel in unit-dose tubes (Testim, Vogelxo, generics)
- UF and non-step-preferred (requires trial of preferred agents): 2% testosterone gel multi-dose pump (MDP) (Fortesta generic); brand-only Vogelxo 1% gel MDP and gel packets; Androderm patch, Natesto nasal gel; Xyosted auto-injector
- NF and non-step-preferred (requires trial of preferred agents): oral Jatenzo, Tlando, and Kyzatrex
- UF and not subject to step therapy: testosterone cypionate IM, testosterone enanthate IM, and oral methyltestosterone

XXI. RE-EVALUATION OF NF GENERICS: ANDROGENS-ANABOLIC STEROIDS: TESTOSTERONE REPLACEMENT THERAPY FORMULARY STATUS AND IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended making the changes to formulary status as discussed above, effective the first Wednesday 30 days after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XXII. OVER-THE-COUNTER (OTC) DRUG BENEFIT—NALOXONE 3 mg NASAL SPRAY OTC (RIVIVE)—UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT, AND IMPLEMENTATION PERIOD

P&T Comments

Pursuant to 32 CFR 199.21(h)(5)(i), an OTC drug may be included on the UF upon the recommendation of the P&T Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. OTC drugs placed on the UF, in general, will be treated the same as generic drugs on the UF for purposes of availability in the MTF pharmacies, retail pharmacies, and the Mail Order pharmacy program and other requirements. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the requirement for the prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under 32 CFR 199.21 (i)(2)(xii) for OTC drugs specifically used in certain emergency care treatment situations.

OTC Naloxone Nasal Spray 3 mg (RiVive): The P&T Committee evaluated the clinical and cost-effectiveness for the addition of OTC nasal naloxone 3 mg/0.1 mL (RiVive) to the UF. Other prescription naloxone formulations are available on the UF (Narcan 4 mg/0.1 mL, Kloxxado, Zimhi).

Multiple references, including guidance from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, and the 2022 DoD/VA Guideline for the Use of Opioids in Management of Chronic Pain, as well as input from DoD pain management specialists, support the use of intranasal naloxone for the emergency treatment of known or suspected opioid overdose. Based on clinical effectiveness and ease of access, OTC naloxone nasal 3 mg/0.1 mL (RiVive) was recommended for addition to the UF.

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

- adding OTC naloxone 3 mg/0.1 mL (RiVive) nasal spray to the UF
- waiving the copay requirement
- waiving the prescription requirement
- implementation plan of two weeks after signing of the minutes all points of service

The P&T Committee voted to waive the prescription and copay requirements. While the P&T Committee voted to waive the requirement for a prescription at all points of service, there may be state or operational limitations that require some provider input for processing. As an example, some states allow pharmacists who have National Provider Identifier (NPI) numbers to prescribe but the pharmacy claims adjudication systems may require a valid prescription. According to National Council for Prescription Drug Programs (NCPDP) rules, a provider NPI is required for claims to process.

Regarding copay, 32 CFR 199.21(i)(2)(xii) states as a general rule, OTC drugs placed on the UF will have copayments equal to those for generic drugs on the UF. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the copayment may be established at \$0.00 for any particular OTC drug in the retail pharmacy network. The P&T Committee recommended the copay for OTC naloxone be zero at retail and the Tier 1 generic copay at mail.

Note that additional considerations of dispensing OTC naloxone (e.g., distribution to first responders, availability in exchanges/commissaries), while encouraged, fall outside the scope of P&T Committee.

XXIII. OVER-THE-COUNTER (OTC) DRUG BENEFIT—NALOXONE 3 mg NASAL SPRAY OTC (RIVIVE)—UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT, AND IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended adding OTC naloxone 3 mg/0.1 mL nasal spray (RiVive) to the UF, with an implementation effective 2 weeks after signing of the minutes as listed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent: