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

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING APRIL 6, 2022

I. UNIFORM FORMULARY REVIEW PROCESS

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

II. UF DRUG CLASS REVIEWS—Oncological Agents: Subclasses for the following:

- **Renal Cell Carcinoma (RCC)**
- **Epidermal Growth Factor Receptor (EGFR) + Non-Small Cell Lung Cancer (NSCLC)**
- **Non-Bruton Tyrosine Kinase Inhibitors (Non-BTKIs) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**
- **Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors for BRCA+ Cancers (PARPIs)**
- **Janus Kinase Inhibitors for Myelofibrosis (MF)**

P&T Comments

A. Oncological Agents —Relative Clinical Effectiveness Analysis and Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness for five oncology subclasses. The Committee reviewed a distillation of the evidence including attention to guideline recommended use, the strength of those recommendations, the levels of evidence supporting those recommendations, and, where applicable, comparative judgments about the qualitative differences in clinical effectiveness between agents. A safety evaluation of each subclass's agents included comparative quantitative as well as qualitative assessments. There are a total of 23 drugs in the subclasses, with only two products available in generic formulations (everolimus and erlotinib).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

Renal Cell Carcinoma (RCC)

- Nine agents comprise the RCC subclass: axitinib (Inlyta), cabozantinib (Cabometyx), cabozantinib (Cometriq), everolimus (Afinitor, generic), lenvatinib (Lenvima), pazopanib (Votrient), sorafenib (Nexavar), sunitinib (Sutent), and tivozanib (Fotivda).
- Cumulatively, the 9 RCC agents are FDA-approved and/or guideline recommended to treat 14 different disease states including RCC, hepatocellular carcinoma, various forms of thyroid carcinoma, endometrial carcinoma, soft tissue sarcoma, gastrointestinal stromal tumors, pancreatic neuroendocrine tumors, melanoma, non-small cell lung cancer, acute myeloid leukemia, myelofibrosis, cutaneous T-cell lymphoma, bone cancers, and adenoid cystic carcinoma. With the exception of tivozanib (Fotivda) and everolimus (Afinitor) that are used exclusively in RCC, no two agents have perfectly overlapping usage in the exact same disease states.
- Where mutually indicated and/or guideline supported, comparisons can be drawn between agents for a particular disease context in a particular disease state, with some comparisons showing agents are largely qualitatively similar with similar overall clinical effectiveness, strengths of recommendation, and supporting levels of evidence. Meanwhile, other comparisons show a hierarchy of superiority. However, even where such comparisons are possible, it is difficult if not impossible to draw global conclusions about the relative clinical effectiveness of agents because a comparative conclusion among agents for one disease context of a specific disease state may differ from conclusions for another disease context or state.
- A review of safety shows that certain adverse events are class effects associated with mechanism of action, while others are unique to the specific agent. No two agents had identical safety profiles. However, overall the agents have similar tolerability.
- The RCC review concludes that the 9 subclass agents are significantly different from one another, and all the agents are necessary inclusions to the benefit.

Epidermal Growth Factor Receptor-Mutant Non-Small Cell Lung Cancer (EGFR+ NSCLC)

- Five agents comprise the EGFR+ NSCLC subclass: afatinib (Gilotrif), dacomitinib (Vizimpro), erlotinib (Tarceva, generic), gefitinib (Iressa) and osimertinib (Tagrisso).

- The 5 EGFR+ NSCLC agents are FDA-approved and/or guideline recommended to treat NSCLC and erlotinib is also approved in pancreatic carcinoma. Osimertinib uniquely can be sequenced with the other EGFR+ NSCLC agents.
- The only disease context where all 5 agents are mutually comparable is frontline therapy for metastatic EGFR+ NSCLC. Osimertinib is the preferred frontline therapy. The remaining four agents have weaker strengths of recommendation supporting their use, with evidence showing qualitatively inferior outcomes relative to osimertinib but relatively equivalent between themselves. Only osimertinib and axitinib are guideline-recommended in the relapsed/refractory setting [and axitinib only in combination with the medical benefit drug cetuximab (Erbitux)]. Osimertinib is the only subclass agent recommended in the adjuvant setting.
- A review of safety shows that rate of severe adverse events was similar between all EGFR+ NSCLC agents.
- The EGFR+ NSCLC review concludes that agents are only comparable in the treatment-naïve setting and that osimertinib and erlotinib are not true comparators to the remaining agents because of their alternative usages.

Non-Bruton Tyrosine Kinase Inhibitors for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (non-BTKI for CLL/SLL)

- Three agents comprise the non-BTKI for CLL/SLL subclass: duvelisib (Copiktra), idelalisib (Zydelig), and venetoclax (Venclexta).
- The three subclass agents mutually treat CLL/SLL with and without del7p/TP53 mutation. However, their other indications and guideline-supported use in Non-Hodgkin Lymphomas and Acute Myeloid Leukemia (for venetoclax) do not overlap.
- Venetoclax is guideline recommended for CLL/SLL in both the treatment-naïve and relapse-refractory settings. Duvelisib and idelalisib are only used in the relapsed/refractory setting. In the relapsed/refractory setting, venetoclax is the preferred regimen over duvelisib and idelalisib regardless of del17p/TP53 status and patient risk category. While duvelisib and idelalisib have the same strength of recommendation and levels of evidence supporting their use, idelalisib has qualitatively superior overall clinical effectiveness across the disease contexts in which both agents are used.
- A review of safety shows qualitatively and quantitatively unique safety profiles for each agent. Venetoclax has the least number of severe events that resulted in warnings/precautions on the label and has no black box warnings.

Duvelisib and idelalisib have a greater number of warnings relative to venetoclax. Duvelisib and idelalisib also have overlapping but non-identical black box warnings.

- The non-BTKIs for CLL/SLL review concludes that mechanism of action categorizes the agents by usage, guideline support, and safety profiles. Agents are only comparable in the relapsed/refractory context of CLL/SLL and such a comparison shows a clear hierarchy of overall clinical effectiveness with venetoclax superior to idelalisib and both venetoclax and idelalisib superior to duvelisib.

Poly (Adenosine Diphosphate-Ribose) Polymerase Inhibitors for BRCA+ Cancers (PARPI)

- Four agents comprise the PARPI subclass: niraparib (Zejula), olaparib (Lynparza), rucaparib (Rubraca), and talazoparib (Talzenna).
- The four PARPI agents have overlapping but non-identical FDA-approved indications: olaparib is approved for ovarian cancer, breast cancer, pancreatic cancer, and prostate cancer. Niraparib is only indicated for ovarian cancer. Rucaparib is indicated for ovarian cancer and prostate cancer. Talazoparib is indicated only for breast cancer.
- Where mutually indicated and/or guideline supported, comparisons can be drawn between agents showing that the PARPI products are largely qualitatively similar with similar overall clinical effectiveness, strengths of recommendation, and supporting levels of evidence. However, the absence of evidence supporting the use of certain agents in particular disease states limits the ability to draw comparative conclusions of global efficacy across the various disease states. Rather only indirect comparisons can be drawn using olaparib as a reference point.
- The PARPI products show statistically significant differences in rates of severe adverse events, with olaparib and talazoparib showing lower rates than niraparib and rucaparib. No statistically significant difference is observed between olaparib and talazoparib, nor between niraparib and rucaparib.
- The PARPI review concludes that the products are not broadly comparable because of the difference in approved indications, but where mutually used, the agents have qualitatively similar overall clinical effectiveness. However, olaparib and talazoparib demonstrate quantitative superior safety in terms of reduced rates of severe adverse events.

Janus Kinase Inhibitors for Myelofibrosis (MF)

- Only two agents comprise the MF subclass: fedratinib (Inrebic) and ruxolitinib (Jakafi).
- Ruxolitinib is used in a variety of hematopoietic disorders including myelofibrosis, polycythemia vera, essential thrombocythemia, and graft vs. host disease. Fedratinib is only indicated and guideline supported for treating myelofibrosis.
- Ruxolitinib and fedratinib have overlapping but non-identical guideline supported use in myelofibrosis; only ruxolitinib is recommended in low-risk patients. The comparative conclusion between the two agents depends on the disease context. For example, in high-risk non-transplant candidates with treatment-naïve disease, ruxolitinib has superior overall qualitative clinical effectiveness. However, in the relapsed/refractory setting, fedratinib shows qualitatively superior efficacy. Another difference is that in the relapsed/refractory setting, fedratinib can be used in ruxolitinib refractory disease (but not vice-a-versa; ruxolitinib was not tested in fedratinib-refractory disease).
- Ruxolitinib and fedratinib have significantly different rates of adverse events with fedratinib showing greater rates of hematologic and gastrointestinal adverse events. Fedratinib also uniquely increases the risk of Wernicke's encephalopathy due to an indirect thiamine deficiency from malnutrition related to its poor gastrointestinal tolerability.
- The MF review concludes that fedratinib and ruxolitinib are not true comparators given the difference in usage, context of use within the same disease state, and clinically significant difference in adverse event profiles.

Overall Conclusions

- Comparative clinical statements between members within all five subclasses are confounded by differences between agents based on usage, guidelines, and safety profiles.
- Where agents are comparable, comparisons are often limited to either a subset of agents, a subset of disease states and/or disease contexts, or a combination of the two.

B. Oncological Agents—Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion— The Committee reviewed the solicited bids and also conducted a budget impact analysis (BIA). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following*:*

- BIA was performed to evaluate the projected spend and cost avoidance after considering the solicited bids. BIA results showed that designating all of the 24 drugs in the 5 subclasses as UF demonstrated the greatest cost avoidance for the MHS.

C. Oncological Agents —UF/Tier 4/Not Covered Recommendation

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

- UF
  - Renal Cell Carcinoma (RCC)
    - axitinib (Inlyta)
    - cabozantinib (Cabometyx)
    - cabozantinib (Cometriq)
    - everolimus (Afinitor tab and disperz tab; generic)
    - lenvatinib (Lenvima)
    - pazopanib (Votrient)
    - sorafenib (Nexavar)
    - sunitinib (Sutent)
    - tivozanib (Fotivda)
  - Epidermal Growth Factor Receptor (EGFR) plus Non-Small Cell Lung Cancer (NSCLC)
    - afatinib (Gilotrif)
    - dacomitinib (Vizimpro)
    - erlotinib (Tarceva; generic)
    - gefitinib (Iressa)
    - osimertinib (Tagrisso)
  - Non-Bruton's Tyrosine Kinase Inhibitor (Non-BTKI) for Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
    - duvelisib (Copiktra)

        - idelalisib (Zydelig)
        - venetoclax (Venclexta)
    - Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors
        - olaparib (Lynparza)
        - niraparib (Zejula)
        - rucaparib (Rubraca)
        - talazoparib (Talzenna)
    - JAK Kinase inhibitors for Myelofibrosis
        - ruxolitinib (Jakafi)
        - fedratinib (Inrebic)
- NF
    - None
- Tier 4/Not Covered
    - None

D. Oncological Agents —Manual PA Criteria

PA criteria currently apply to 10 drugs. Newer products that have been reviewed as innovators generally have PA criteria. PAs are in place based on NCCN guideline recommendations suggesting step therapy (e.g., RCC – Fotivda) or for safety issues or poor tolerability (e.g., Myelofibrosis: Inrebic; EGFR+NCSLC: Vizimpro). PAs are in place for all the drugs in the class for the PARPIs and the non-BTKIs for CLL/SL subclass.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) to maintain the current PAs for the drugs listed below. The most current PA criteria is found on the TRICARE Formulary Search Tool at: https://www.express-scripts.com/frontend/open-enrollment/tricare/fst/#/.

- RCC: Fotivda
- EGFR+NCLC: Vizimpro
- Non-BTKI for CLL/SL: Copiktra, Zydelig, Venclexta
    - For Copiktra, refer to the Utilization Management section on pp. 31-32 for the removal of the indication for relapsed or refractory follicular zone lymphoma
- PARPs: Lynparza, Zejula, Rubraca, Talzenna
- Myelofibrosis: Inrebic

E. Oncological Agents —UF, PA and Implementation Period

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) an effective date upon signing of the minutes in all points of service.

III. UF DRUG CLASS REVIEWS-Oncological Agents

BAP Comments

A. Oncological Agents —UF Recommendations

The P&T Committee recommended the formulary status for the Oncological Agents in the five subclasses as discussed above.

- UF: All 23 agents
- NF - None
- Tier 4/Not Covered - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Oncological Agents —Manual PA Criteria

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Oncological Agents—UF, PA and Implementation Plan

The P&T Committee recommended the implementation plan upon signing of the minutes in all points of service.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEWS—Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products

P&T Comments

A. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Relative Clinical Effectiveness Analysis and Conclusion

Background— The P&T Committee evaluated the relative clinical effectiveness of the hypoglycemia agents used for treating severe hypoglycemia in diabetic patients. The drugs in the class all contain glucagon as the active ingredient, and there are three new branded products marketed, glucagon nasal (Baqsimi), glucagon subcutaneous (SC) injection (Gvoke), and dasiglucagon SC injection (Zegalogue). This class has not been previously reviewed, but the products were already reviewed as innovators. Baqsimi and Gvoke were reviewed and made UF in November 2019 and Zegalogue was reviewed and made UF in August 2021.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Professional treatment guidelines from the American Diabetes Association and Diabetes Canada recommend using glucagon to treat severe hypoglycemia events. Diabetic patients at increased risk for hypoglycemia should have access to a glucagon product. However, the guidelines do not give a preference for any one agent over another.
- Older formulations of glucagon (e.g., Glucagon emergency kit, GlucaGen Hypokit) have been available for several years in intramuscular (IM) formulations that require reconstitution prior to administration.
- Three ready-to-use formulations are now available that offer significant advantages over existing agents in emergency situations due to their ease of use. Gvoke and Zegalogue are available as SC injections not requiring reconstitution, while Baqsimi is administered nasally.
- Specific clinical considerations for the products are as follows:
    - *Zegalogue* is available in a prefilled syringe and autoinjector, and is approved in patients as young as 6 years of age. It has an approximately 3 minute slower onset of action compared to glucagon IM. Common adverse events include injection site reactions. Disadvantages include that Zegalogue should not be used in patients with latex allergy, as the grey cap contains latex. Once removed from the refrigerator, Zegalogue has a shelf life of 12 months at room temperature, compared to 2 years at room temperature with Baqsimi and Gvoke.
    - *Baqsim*i nasal spray advantages include it is the only non-injectable glucagon formulation, and is easy for both patient and caregiver administration. Its onset of action is approximately 3 minutes slower

compared to glucagon IM. It is approved for patients as young as 4 years of age. Unique adverse events with Baqsimi include localized upper respiratory tract irritation due to the nasal administration route.

- *Gvoke* advantages include FDA-approval in children as young as 2 years of age. The available formulations include a prefilled syringe and autoinjector for SC use. The onset of action is approximately 4 minutes slower compared to glucagon IM. The adverse event profile is similar to Zegalogue.

- Overall, there is a high degree of therapeutic interchangeability between the newer products, with treatment success approaching 100%.
- The P&T Committee recognizes that the newer glucagon preparations (nasal and autoinjectors) offer a significant advantages in terms of ease of administration.

B. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Relative Cost Effectiveness Analysis and Conclusion

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Baqsimi, Gvoke and Zegalogue were all cost effective agents.

- BIA was performed to evaluate the potential impact of designating the three newer glucagon agent as UF, NF, or Tier 4 on the formulary. BIA results showed that designating all the products as UF demonstrated the greatest cost avoidance for the MHS.

C. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF Recommendation The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF
  - glucagon nasal (Baqsimi)
  - glucagon prefilled syringe, autoinjector, and kit (Gvoke, Gvoke Hypopen, Gvoke PFS)
  - dasiglucagon prefilled syringe and autoinjector (Zegalogue)
- NF
  - None

- Tier 4/Not Covered
  - None

  Note that the older IM product (Glucagon emergency kit, GlucaGen Hypokit, GluGen Diagnostic) will remain on the formulary

D. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Baqsimi Tier 1 Status

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) lowering the current Tier 2 cost-share for Baqsimi 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 Baqsimi will provide a greater incentive for beneficiaries to use the most cost-effective glucagon, in the purchased care points of service.

E. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF, Tier 1 Copay and Implementation Plan

The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service (POS).

V. UF DRUG CLASS REVIEWS-Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products

BAP Comments

A. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF Recommendation

The P&T Committee recommended the formulary status for the glucagon products cas discussed above:

- UF
  - Baqsimi
  - Gvoke
  - Zegalogue

- NF – None
- Tier 4/Not Covered - None

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —Baqsimi Tier 1 Status

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Binders-Chelators-Antidotes-Overdose Agents for Severe Hypoglycemia – Glucagon products —UF, Tier 1 Copay and Implementation Plan

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1 and Group 2: 17 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/Tier 4/Not Covered Recommendation

The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 0 abstained, 0 absent); celecoxib oral solution (Elyxyb): (15 for, 1 opposed, 0 abstained, 1 absent)the following:

- UF:
  - asciminib (Scemblix) – Oncological Agent for chronic myelogenous leukemia (CML)
  - avacopan (Tavneos) – Hematological Agent for microscopic polyangiitis and granulomatosis with polyangiitis
  - marabavir (Livtencity) – Antiviral for CMV infection/disease
  - topiramate oral solution (Eprontia) – Anticonvulsant-Antimania Agent for Epilepsy, migraine headache, and Lennox-Gastaut syndrome
  - vosoritide injection (Voxzogo) – Miscellaneous Growth Stimulating Agent for pediatric achondroplasia
- NF:
  - atogepant (Qulipta) – Migraine agent for acute treatment of migraines
  - carbidopa/levodopa IR scored tab (Dhivy) – a scored immediate-release tablet formulation of carbidopa and levodopa for Parkinson's disease
  - lonapegsomatropin-tcgd injection (Skytrofa) – Growth stimulating Agent
  - maralixibat (Livmarli) – Miscellaneous Metabolic Agent for treatment of cholestatic pruritus in Alagille syndrome +
  - ropeginterferon alfa-2b-njft injection (Besremi) – Hematological Agent for polycythemia vera
  - varenicline nasal solution (Tyrvaya) –Dry Eye Disease agent
- Tier 4 (Not covered):
  - celecoxib oral solution (Elyxyb) – NSAIDs: another formulation of celecoxib as an oral solution approved for acute treatment of migraines
    - Elyxyb was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to NSAIDs, and the needs of TRICARE beneficiaries are met by available alternative agents. Formulary alternatives include ibuprofen, naproxen, diclofenac, and numerous other NSAIDs or combo products.

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

The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Oncologic drugs: Applying manual PA criteria to new users of Scemblix.
- Growth Stimulating Agents: Applying manual PA criteria to new users of Skytrofa. A trial of Norditropin, the step-preferred product is required first.
- Migraine Agents: Applying manual PA criteria to new users of Qulipta, similar to the other oral migraine agents.
- Applying manual PA criteria to new users of Besremi, Dhivy, Eprontia, Livmarli, Skytrofa, Tavneos, Tyrvaya, and Voxzogo.

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

1. asciminib (Scemblix)

Manual PA criteria apply to all new users of Scemblix

- Patient is 18 years of age and older
- Scemblix is prescribed by or in consultation with a hematologist/oncologist
- The patient has Philadelphia chromosome-positive CML (Ph+ CML) in chronic phase (CP) and was previously treated with two or more tyrosine kinase inhibitors
- The provider will monitor for myelosuppression, pancreatitis, hypertension, hypersensitivity, and cardiovascular toxicity
- 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 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 except as noted above.

Prior authorization does not expire.

2. avacopan (Tavneos)

Manual PA criteria apply to all new users of Tavneos

- Patient is 18 years of age or older
- Tavneos is prescribed by or in consultation with a rheumatologist
- Patient has a documented diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's), microscopic polyangiitis (MPA)
- Patient meets one of the following criteria (either a or b):
  a. Positive ELISA test for anti-proteinase-3 (PR-3)
  b. Positive ELISA test for anti-myeloperoxidase (MPO)
- Patient has documentation of baseline Birmingham vasculitis activity score (BVAS), with at least one of the following criteria (at least a, b, or c):
  c. At least 1 major item (i.e. gangrene, scleritis/episcleritis, hearing loss, massive hemoptysis/alveolar, hemorrhage, respiratory failure, Ischemic abdominal pain, rise/fall in serum creatinine, meningitis, CVA);
  d. At least 3 non-major items;
  e. At least the 2 renal items of proteinuria and hematuria
- Patient has experienced or has a high probability to experience significant adverse effect from prednisone
- Tavneos is prescribed in combination with cyclophosphamide or rituximab, unless clinically significant adverse effects are experienced or both are contraindicate

Non-FDA-approved uses are not approved, including Immunoglobulin A nephropathy, Hidradenitis suppurativa, acne inversa, and C3 Glomerulopathy (C3G).

Prior authorization expires after 6 months. Tavneos will be approved indefinitely if the following criteria are met:

- Patient has responded positively to therapy as evidenced by at least a 50% reduction in BVAS from baseline or remission (BVAS of zero) AND
- If request is for a dose increase, new dose does not exceed 60 mg (2 tabs) per day

3. atogepant (Qulipta)

Manual PA criteria apply to all new users of Qulipta.

- Patient is 18 years of age or older
- Qulipta is prescribed by or in consultation with a neurologist
- Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed
- Patient has Episodic Migraine as defined by the following:
    - 4 to 7 migraine days per month for 3 months AND has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR
    - 8 to 14 migraine days per month for 3 months
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
    - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
    - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol
    - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine
- Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents?
    - erenumab-aooe (Aimovig)
    - fremanezumab-vfrm (Ajovy)
    - galcanezumab-gnlm (Emgality)

Non-FDA approved uses are not approved
Prior authorization expires in 6 months.

Qulipta will be approved indefinitely if one of the following criteria are met:

- The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR
- The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:
    - Migraine Disability Assessment (MIDAS)
        - Reduction of ≥ 5 points when baseline score is 11–20
        - Reduction of ≥ 30% when baseline score is > 20
    - Headache Impact Test (HIT-6) - Reduction of ≥ 5 points
    - Migraine Physical Functional Impact Diary (MPFID) Reduction of ≥ 5 points

4. carbidopa/levodopa IR scored tab (Dhivy)

Manual PA criteria apply to all new users of Dhivy

- Provider acknowledges that generic immediate-release carbidopa/levodopa is available without a PA (e.g. generic Sinemet)
- The patient has tried and failed a generic immediate-release formulation of carbidopa/levodopa OR
- The patient cannot achieve the required dose with generic immediate-release carbidopa/levodopa (e.g. generic Sinemet)

Non-FDA-approved uses are not approved.

Prior authorization does not expire.

5. lonapegsomatropin-tcgd injection (Skytrofa)

Manual PA criteria apply to all new users of Skytrofa

- Patient is a pediatric patient at least one year of age and older who weights at least 11.5 kg

- Skytrofa is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients
- Skytrofa is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment?
- Patient has one or more of the following:
    - Patient has a contraindication to Norditropin OR
    - Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with an Skytrofa
        - Note that patient preference for a particular device is insufficient grounds for approval of an NF agent

AND

- Patient requires a less than daily dosing regimen due to needle intolerance or aversion

Non-FDA-approved uses are not approved including Idiopathic Short Stature, normal aging process, obesity, and depression.

Coverage not approved for concomitant use of multiple somatropin agents.

Prior authorization expires in 1 year; provider must fill out a new PA.

6. maralixibat (Livmarli)

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

- Patient is 1 year of age or older
- Patient has diagnosed Alagille syndrome 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), non-alcoholic fatty liver disease (NAFLD), progressive familial intrahepatic cholestasis (PFIC), biliary atresia and other cholestatic disease are not approved.

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

- Patient must demonstrate significant improvement in pruritus symptoms.

7. ropeginterferon alfa-2b-njft injection (Besremi)

Manual PA criteria apply to all new users of Besemri.

- Provider acknowledges that another pegylated interferon (Pegasys) is available at the formulary copay and without requiring prior authorization
- Patient is 18 years of age or older
- Drug is prescribed by or in consultation with a hematologist/oncologist
- Patient has a confirmed diagnosis of polycythemia vera (PV)
- Patient is high-risk (age >60 years and/or prior history of thrombosis)
- Patient is currently taking aspirin 81-100mg daily and regular phlebotomy (to maintain hematocrit < 45%)
- Patient must try and fail or be intolerant or resistant to (showing phlebotomy-dependence and/or progressive splenomegaly) hydroxyurea OR
- The patient has a contraindication to hydoxyurea (e.g., pregnancy)

Non-FDA-approved uses are not approved including myeloproliferative neoplasms, essential thrombocythemia (ET), or adult T-cell leukemia (ATL).

Prior authorization does expires after 1 year**.** Besremi will be approved for an additional year if the following criteria are met:

- Patient has a documented improvement in symptoms.

8. topiramate oral solution (Eprontia)

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

- PA does not apply to patients less than 12 years of age (age edit)
- Eprontia is prescribed by or in consultation with an adult or pediatric neurologist
- Patient has a diagnosis of one of the following:
  - For epilepsy monotherapy: Partial onset seizure or primary generalized tonic-clonic seizures in patients 2 years or age or older
  - For epilepsy adjunctive therapy: Partial onset seizure or primary \ generalized tonic-clonic seizures or seizures associated with Lennox Gastaut syndrome in patients 2 years of age or older
  - For Migraine: preventive treatment in patients 12 years of age or older
- Patient requires a liquid formulation due to swallowing difficulty or has a feeding tube and cannot use topiramate (sprinkles)

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

9. varenicline nasal solution (Tyrvaya)

Manual PA criteria apply to all new users of Tryvaya

- Patient is 18 years of age or older
- Tyrvaya is prescribed by an ophthalmologist or optometrist
- Patient has a diagnosis of dry eye disease as supported by both of the criteria below:
  - Positive symptomology screening for dry eye disease from an appropriate measure

        - At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
    - Patient must try and fail the following:
        - At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systame, Lacrilube])
        - Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol)
    - If the patient has moderate to severe Dry Eye Disease
        - Patient has tried and failed an adequate course (at least 6 weeks) of treatment of lifitegrast or cyclosporine treatment

Non-FDA-approved uses are NOT approved

Prior authorization expires after 1 year. Tyrvaya will be approved indefinitely if the following criteria are met:

- The drug is prescribed by an ophthalmologist or optometrist.
- The patient must have documented improvement in ocular discomfort.
- The patient must have documented improvement in signs of dry eye disease.

10. vosoritide injection (Voxzogo)

- Patient is 5 years of age or older
- Voxzogo is prescribed by or in consultation with a pediatric endocrinologist
- Patient has a documented diagnosis of achondroplasia with open epiphyses
- Patient/Caregiver and provider acknowledge that Voxzogo was FDA approved in an accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials

- Patient/Caregiver and provider acknowledge that a clinical benefit with Voxzogo has not been proven
- Patient/Caregiver have been instructed on how to properly use, store, and administer Voxzogo
- Provider agrees to monitor growth and adjust dose according to body weight
- Provider agrees to permanently discontinue Voxzogo upon closure of epiphyses

Non-FDA-approved uses are not approved.

Prior Authorization expires after 1 year; provider must fill out a new PA.

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

The P&T Committee recommended for group 1: (16 for, 0 opposed, 0 abstained, 1 absent); group 2: (17 for, 0 opposed, 0 abstained, 0 absent); and celecoxib oral solution (Elyxyb): (15 for, 1 opposed, 0 abstained, 1 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:**
  - Scemblix
  - Tavneos
  - Livtencity
  - Eprontia
  - Livtencity
  - Voxzogo

- **NF:**
  - Qulipta
  - Dhivy
  - Skytrofa
  - Livmarli
  - Besremi
  - Tyrvaya

- **Tier 4/Not Covered:**
  - Elyxyb

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

P&T Comments

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

Manual PA criteria were recommended for several recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. 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 (15 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Neonatal Plus (regardless of the woman's age), Fenoglide, and Indocin suppositories in new and current users, due to the significant cost differences compared with numerous available alternative agents.

1) **Anti lipidemics-2: Fenofibrates – fenofibrate 120 mg (Fenoglide)—** Fenoglide is a new fenofibrate formulation available in 120 mg strengths. There are several formulations of fibric acid derivatives currently available, including gemfibrozil (Lopid, generics), generic fenofibrate micronized/nonmicronized formulations (including Lofibra), and fenofibrate nanocrystallized (Tricor). Fenoglide is made by a sole manufacturer and is not cost-effective relative to other fibric acid derivatives.

   Manual PA criteria applies to new and current users of fenofibrate 120 mg tablets (Fenoglide)

- The provider is aware and acknowledges that other formulations of fenofibrate, including Tricor, Trilipix and Lofibra are available to DoD beneficiaries without the need of prior authorization
- The provider must explain why the patient t cannot take one generic fenofibrate 134 mg capsule or two fenofibrate 54 mg tablets or another formulation of fenofibrate *(fill-in blank)*

Non-FDA approved uses are NOT approved.

Prior Authorization does not expire.

2) **Pain Agents: NSAIDs—indomethacin 50 mg suppositories (Indocin):** The indomethacin suppositories are markedly not cost-effective. All other formulations of indomethacin (suspension and capsules) and various other NSAIDs (generic meloxicam, ibuprofen suspension, diclofenac potassium, and naproxen) 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 indomethacin suppositories

   - The provider acknowledges that several other indomethacin formulations, including generic indomethacin suspension and capsules are available to TRICARE beneficiaries without requiring prior authorization
   - Provider acknowledges that several other NSAIDs are available to TRICARE beneficiaries without requiring prior authorization including generic meloxicam, ibuprofen suspension, diclofenac potassium, and naproxen
   - The provider must explain why the patient requires Indocin suppositories and cannot take generic indomethacin suspension, indomethacin capsules, or other formulary NSAIDs (fill-in blank)

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

3) **Vitamins: Prenatal—prenatal MVI (Neonatal Plus):** Neonatal Plus is a prenatal dietary supplement manufactured by a single company which requires a prescription prior to dispensing. The primary ingredients of Neonatal Plus are similar to that found in Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, and Neonatal Complete, 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 Plus

- 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.

B. New Manual PA Criteria—Androgens-Anabolic Steroids: Intramuscular (IM) Testosterone Replacement Therapy testosterone cypionate and testosterone enanthate:

The Testosterone Replacement Therapy (TRT) class was reviewed for formulary placement in August 2012, with PA criteria required for the gel and topical formulations. The IM injectable products were not included in the review, due to low utilization and cost at that time. They remain Uniform Formulary "by default" (since not previously reviewed) with no Prior Authorization requirements. A DHA provider workgroup requested that the DoD P&T Committee evaluate the need for a PA for the injectable formulations of testosterone.

There has been a notable increase in utilization of the injectable products, while use of the topicals has declined across all age groups. Several commercial health plans have PAs in place for the injectable TRT formulations.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing PA criteria for testosterone cypionate and testosterone enanthate IM in new users, to ensure appropriate clinical use. The Committee also recommended updating the existing PA criteria for the topicals and all other brand and generic TRT formulations (e.g., Fortesta, Androgel, Testim Xyosted etc), to ensure that the provider has investigated the etiology of low

testosterone levels, as several clinical conditions (e.g., untreated DM) can lower testosterone levels. This criteria will not apply when the TRTs are used for the indication of gender dysphoria.

The PA criteria is as follows, with updates shown in bold

Manual PA criteria applies to new users of testosterone cypionate or testosterone enanthate IM injections.

- Coverage approved for male patients if:
  - Patient is male over the age of 17 years AND
  - Patient has diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND
  - **Provider has investigated the etiology of the low testosterone levels and acknowledges that testosterone therapy is clinically appropriate and needed AND**
  - The patient does not have prostate cancer AND
  - The patient is experiencing symptoms usually associated with hypogonadism

OR

- Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:
  - Patient has diagnosis of gender dysphoria made by a TRICARE authorized mental health provider according to most current edition of the DSM
  - Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2 AND
  - Patient has no signs of breast cancer AND
  - For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding AND
  - Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g. unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) AND
  - Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous

psychotherapy addressing gender transition as an intervention for gender dysphoria

Non-FDA approved uses are NOT approved.
Not approved for concomitant use with other testosterone products.
Prior Authorization does not expire.

C New Manual PA Criteria Implementation Plan

The P&T Committee recommended the following implementation periods:

- The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the manual PA criteria for Fenoglide, Indocin suppositories, and Neonatal Plus (regardless of the woman's age), become effective the first Wednesday 90 days after the signing of the minutes, and DHA will send letters to affected patients.
- The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the new PA criteria for IM testosterone cypionate and testosterone enanthate will become effective the first Wednesday 90 days after the signing of the minutes.

IX. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA

BAP Comments

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

The P&T Committee recommended new manual PA criteria for the 3 products listed above that contain active ingredients that are widely available in cost effective generic formulations: Fenoglide 120 mg tablets, Indocin 50 mg suppositories and Neonatal Plus, as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. New Manual PA Criteria for Testosterone Replacement Therapies: IM testosterone cypionate and testosterone enanthate

The P&T Committee recommended new manual PA criteria for IM testosterone cypionate and testosterone enanthate as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. New Manual PA Criteria Implementation Plan

The P&T Committee recommended the new PA criteria for Fenoglide, Indocin suppositories Neonatal plus and IM testosterone cypionate and testosterone enanthate become effective the first Wednesday 90 days after signing of the minutes.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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.) **Respiratory Interleukins–dupilumab (Dupixent)—**The manual PA criteria were updated to expand use in children as young as 6 years of age for add-on maintenance therapy for moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

2.) **Hepatitis C Agents: Direct Acting Agents–elbasvir/grazoprevir (Zepatier)**—The manual PA criteria were updated for Zepatier, allowing use in children as young as 12 years of age or weighing 30 kg or more for chronic hepatitis C virus (HCV) genotype 1 or 4 infection.

3.) Atypical Antipsychotic Agents

- **brexpiprazole (Rexulti)—**The manual PA criteria were updated to allow use in children as young as 13 years of age for schizophrenia (Rexulti was previously only approved for adults)
- **lumateperone (Caplyta)**—Includes the new indication for depressive episodes associated with bipolar disorder I or II in adults, as monotherapy or as adjunct to lithium or valproate.

4.) Targeted Immunomodulatory Biologics (TIBs)

- **risankizumab-rzaa (Skyrizi)**—Includes the new indication for active PsA in adults.
- **secukinumab (Cosentyx)—**Includes the new indication for active enthesitis-related arthritis (ERA) in patients 4 years of age and older. The manual PA criteria were also updated allowing use in children as young as 2 years of age for PsA. Note that for the ERA indication a trial of a non-biologic (e.g., methotrexate, sulfasalazine, mesalamine steroids or azathioprine) is not required.
- **tofacitinib (Xeljanz/Xeljanz XR)—**Includes the new indication for active ankylosing spondylitis in adults who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) blockers. Note that for the ankylosing spondylitis indication, a trial of a non-biologic (e.g., methotrexate, sulfasalazine, mesalamine steroids or azathioprine) is not required. The PA update also includes the new safety warnings for the drug class (See the November 2021 meeting minutes for the safety updates made for Rinvoq and Olumiant)
- **upadacitinib (Rinvoq ER)—**Includes the new indication for active psoriatic arthritis (PsA) in adults who have had an inadequate response or intolerance to one or more TNF blockers. Note that the Atopic Dermatitis indication will be discussed at the May 2022 P&T meeting in more detail, and thus is not included in this PA update

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 Dupixent, Zepatier, Rexulti, Caplyta, Skyrizi, Cosentyx, Xeljanz and Rinvoq ER as discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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 Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL OF AN INDICATION

P&T Comments

A. Updated PA Criteria for Removal of an indication

Oncological Agents: Non-Brutons Tyrosine Kinase Inhibitor (Non-BTKI) for Chronic Lymphocytic Leukemia— duvelisib (Copiktra)

In December 2021, the manufacturer of Copiktra voluntarily withdrew the indication for Copiktra use in patients with relapsed or refractory follicular lymphoma following at least 2 previous systemic therapies. The manufacturer determined this indication was no longer merited, based on the current treatment landscape for follicular lymphoma in the U.S. and the logistics, cost, and timing

of the post-marketing requirements for the drug. This indication was originally approved by the FDA in September 2018 via accelerated pathway and was contingent upon the manufacturer completing confirmatory trials to receive full approval.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing the follicular lymphoma indication for new users; current users will be able to consult their provider as to whether continued treatment is clinically appropriate. The other FDA-approved indications for Copiktra are not affected and will remain on the PA (e.g., relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL),

B. Updated PA Criteria for Safety Information Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an implementation of the first Wednesday 60 days after signing of the minutes for Copiktra.

XIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REMOVAL OF AN INDICATION

BAP Comments

A. Updated PA Criteria for Safety Information

The P&T Committee recommended updates to the PA criteria for Copiktra as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Updated PA Criteria for Safety - Implementation Plan

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. REMOVAL OF AN INDICATION REMOVAL OF BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE/SALMETEROL DRY POWDER INHALER (ADVAIR DISKUS)

P&T Comments

A. Fluticasone/salmeterol dry powder inhaler (Advair Diskus) removal of brand over generic authorization

Brand over generic PA requirements and a Tier 1 (generic) co-payment have applied to fluticasone/salmeterol dry powder inhaler (Advair Diskus DPI) since May 2019, due to cost effectiveness compared to AB-rated generics (e.g. Wixela). The branded agent, Advair Diskus is no longer the most cost effective inhaled corticosteroid/long-acting beta agonist (LABA/ICS) dry powder inhaler at MTF and Mail Order points of service. Generic prices of fluticasone/salmeterol DPI will continually be monitored.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing the Advair Diskus brand over generic PA requirement. As a result, the current PA criteria for the generic fluticasone/salmeterol DPI will be removed. The branded Advair Diskus will remain available at the Tier 1 (generic) co-payment at the Mail Order and the Retail network pharmacies, until further direction from the P&T Committee.

XV. REMOVAL OF AN INDICATION REMOVAL OF BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE/SALMETEROL DRY POWDER INHALER (ADVAIR DISKUS)

BAP Comments

A. Fluticasone/salmeterol dry powder inhaler (Advair Diskus) removal of brand over generic authorization

The P&T Committee recommended removing the Advair Diskus brand over generic authorization, as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. INFORMATIONAL ITEM—BENEFICIARY IMPACT (FEBRUARY 2022 DoD P&T COMMITTEE MEETING)

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

Drug	Total
celecoxib oral solution (Elyxyb)	0

Drugs with New Prior Authorization Criteria—Unique Utilizers Affected

Drug	MTF	Mail Order	Retail	Total
Fenofibrate 120 mg tablets	22	90	50	162
Indomethacin suppositories	0	3	6	9
prenatal vitamin Neonatal Plus	0	0	0	0