DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
FROM THE MAY 2025 MEETING

INFORMATION FOR THE UNIFORM FORMULARY
BENEFICIARY ADVISORY PANEL MEETING DAY #1 PM – refer to the posted Agenda for meetings dates and times at https://health.mil/About-MHS/Federal-Advisory-Committees/BAP

I. UNIFORM FORMULARY REVIEW PROCESS

In accordance with Section 1074g of Title 10, United States Code (USC), as implemented by Section 199.21 of Title 32, Code of Federal Regulations (CFR), the Department of Defense (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. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBS): INTERLEUKIN (IL)-1, IL-6 AND CYTOTOXIC T-LYMPHOCYTE ASSOCIATED ANTIGEN-4 IMMUNOGLOBULIN (CTLA4-IG) SUBCLASSES

P&T Comments

A. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Relative Clinical Effectiveness Conclusion

Background—The Targeted Immunomodulatory Biologics (TIBs) class is comprised of several subclasses, including the tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab [Humira]), non-TNF inhibitors, and miscellaneous interleukin subclasses. The entire TIBs class was last reviewed at the August 2014 P&T Committee meeting and branded adalimumab (Humira) is currently step-preferred for most indications. Since the original review, 18 new drugs with multiple new mechanisms of action have entered the market. These newer agents have strong clinical evidence in specific disease states. Two subclasses were reviewed at the November 2024 meeting, the interleukin (IL)-17s, and the IL-23s.

Biosimilar entrants have now entered the market for the originator tocilizumab (Actemra) formulation and are on the horizon for abatacept (Orencia). The advent of biosimilars is expected to reshape treatment. Therefore, to address the growing complexity of the TIBs class, additional subclasses were created,

the Interleukin-1 inhibitors (IL-1), Interleukin-6 inhibitors (IL-6), and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig).

The drugs in the subclasses include the following:

- IL-1: anakinra (Kineret), rilonacept (Arcalyst)
- IL-6: tocilizumab (Actemra), tocilizumab-aazg (Tyenne, a biosimilar for Actemra), sarilumab (Kevzara), satralizumab (Enspryng)
- CTLA4-Ig: abatacept (Orencia)

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, meta-analyses and systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1 Agents

- **anakinra (Kineret)** is indicated for rheumatoid arthritis (RA), cryopyrin-associated periodic syndromes (CAPS), neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA). There is substantial supporting evidence for off-label utilization for systemic juvenile idiopathic arthritis (sJIA), Adult-Onset Still's Disease (AOSD), familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells Syndrome (MWS), and recurrent pericarditis (RP). Despite carrying the FDA approval, anakinra is not recommended by contemporary guidelines for use in RA. Limitations include frequent dosing intervals, requiring daily injections.
- **rilonacept (Arcalyst)** is indicated for CAPS, DIRA, FCAS, MWS, and RP. Most indications are approved for patients aged 12 and older, with the exception of DIRA which is indicated for use in infants weighing 10 kilograms (kg) or more. Limitations include lack of approval for more common disease states, including RA or JIA.

Interleukin-6 Agents

- **tocilizumab (Actemra, and the biosimilar Tyenne)** is FDA indicated for RA, pJIA, sJIA, giant cell arteritis (GCA), and systemic sclerosis-associated interstitial lung disease (SSc-ILD), which are available as part of the TRICARE pharmacy benefit. Indications available as IV infusions under the medical benefit include treatment of cytokine release syndrome (CRS) and hospitalized patients with COVID-19 (C19). There is substantial off-label evidence for AOSD, neuromyelitis optica spectrum disorder (NMOSD), and polymyalgia rheumatica (PMR). Advantages include evidence to support use in young children, while limitations include multiple uses without formal FDA-approved labeling. Biosimilars are considered identical to the

reference product for efficacy and safety, based on the conclusions from the August 2024 DoD P&T Committee meeting minutes' "Process for Evaluating Biosimilars and Biologics" section.

  - *Biosimilars:* There are currently three FDA-approved biosimilars to the reference tocilizumab (Actemra). These include Tofidence, Tyenne, and Avtozma. Tofidence infusion is available under the TRICARE medical benefit. Tyenne has both a subcutaneous (SC) injection (available under the TRICARE pharmacy benefit) and a vial for infusion (available under the TRICARE medical benefit.) Avtozma is FDA-approved but had not launched at the time of the meeting and was not reviewed for formulary status. *(Refer to the November 2022 and August 2024 DoD P&T Committee meeting minutes for the "Process for Evaluating Biosimilars and Biologics").*

- **sarilumab (Kevzara)** is indicated for RA, pJIA in patients two years of age or older and weighing at least 63 kg and is the only FDA-approved therapy for PMR.
- **satralizumab (Enspryng)** is indicated for treatment of neuromyelitis optica spectrum disorder in adult patients who are aquaporin-4 immunoglobulin G (AQP4-IgG) positive. Advantages include that it is the only FDA-approved outpatient medication for this indication. Disadvantages include approval for adults only and lack of approval or data in AQP4-IgG negative disease.

Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin Agents

- **abatacept (Orencia)** is indicated for RA, pJIA, and psoriatic arthritis (PsA) under the pharmacy benefit and under the medical benefit as an IV infusion for graft versus host disease (GVHD). Advantages include approval for use in pediatrics as young as two years old as well as the risk of causing less immunosuppression than the other TIBs. Disadvantages include a relatively lower level of efficacy per rheumatoid arthritis and psoriatic arthritis guidelines. Orencia additionally carries risk for unique side effects including cytomegalovirus (CMV) and Epstein-Barr virus (EBV), which was primarily seen in the studies for GVHD.
  - *Biosimilars:* Based on patent expiration, abatacept (Orencia) will likely have the next biosimilar within this subclass.

Rheumatoid Arthritis (IL-1s, IL-6s, and CTLA4-Ig)

- After failure of a TNF inhibitor, use of the tocilizumab and sarilumab (Kevzara) are equally recommended in professional treatment guidelines. Abatacept (Orencia) is also recommended after failure of other agents or in patients at very high risk of infections.

- Although anakinra (Kineret) is FDA-approved for rheumatoid arthritis, it is not mentioned or recommended in the RA guidelines from the United States, Europe or France.

Polyarticular Juvenile Idiopathic Arthritis (IL-6, CTLA4-Ig)

- ACR guidelines recommend non-biologics including non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and methotrexate as first-line therapy. A biologic can be considered after failure of a non-biologic disease modifying antirheumatic drug (DMARD). These guidelines indicate a TNF inhibitor is the most commonly used biologic in children, and that all agents approved at the time of publication were equally recommended, including both tocilizumab and Orencia.

Systemic Juvenile Idiopathic Arthritis, Adult-Onset Still's Disease (IL-1, IL-6)

- Literature within the space of systemic juvenile idiopathic arthritis (sJIA) and Adult-Onset Still's Disease (AOSD) is rapidly evolving. Newly published joint guidelines from Europe have combined these two, previously considered distinct, disease states into one disease called Still's Disease. These new guidelines recommend for patients without macrophage activation syndrome (MAS) early treatment with either anakinra (Kineret) or tocilizumab is clinically appropriate. For patients with MAS, the European guidelines indicate treatment with an IL-1 is preferred due to the amount of clinical experience by the guideline committee, specifically in those patients aged 16 years or older.
- Tocilizumab is FDA-approved for treating sJIA, while anakinra (Kineret) is approved by the European Medicines Agency (EMA) for treating Adult-Onset Still's Disease. Based on the published literature and guidelines, it is unclear whether therapy with anakinra or tocilizumab is more safe or efficacious than the other at this time.

Psoriatic Arthritis (CTLA4-Ig)

- Various guidelines for psoriatic arthritis recommend TNF-inhibitors, IL-23 inhibitors (e.g., Tremfya, Skyrizi) and IL-17 inhibitors (e.g., Taltz) as first-line. Contemporary guidelines list abatacept (Orencia) as an option only after failure of one or more other targeted therapies due to limited efficacy.

Neuromyelitis optica spectrum disorder (IL-6)

- Satralizumab (Enspryng) is the only FDA-approved pharmacy benefit drug approved for treating adult patients with AQP4-IgG positive NMOSD. Additionally, tocilizumab has substantial evidence for efficacy and safety in treating AQP4-IgG positive and negative NMOSD, despite lack of formal FDA-approval.
- A systematic review from 2021 concluded that both tocilizumab and satralizumab (Enspryng) were effective at decreasing the annualized

relapse rate in NMOSD. Additionally, tocilizumab, but not Enspryng, significantly improved both pain and fatigue compared to placebo. Adverse events were similar between the two agents.

Polymyalgia Rheumatica (IL-6)

- Guidelines for polymyalgia rheumatica (PMR) are outdated. The British Society of Rheumatology is currently working on an update with an anticipated 2025 release. The scoping document states both tocilizumab and sarilumab (Kevzara) have data in new-onset and refractory PMR. Sarilumab (Kevzara) is the only FDA-approved biologic pharmacy benefit drug for treating patients with PMR.
- Tocilizumab is FDA-approved for treating giant cell arteritis (GCA), which is a condition closely related to PMR.

Recurrent Pericarditis (IL-1)

- Rilonacept (Arcalyst) is the only FDA-approved biologic pharmacy benefit item indicated to treat patients older than 12 with recurrent pericarditis. The 2015 guidelines from the European Society of Cardiology (ESC) recommend the standard of care including NSAIDs, colchicine, and corticosteroids. The ESC guidelines also recommend anakinra (Kineret) as a category IIB level of evidence. It is unknown when the guidelines will be updated to include Arcalyst.
- One published study from the Journal of the American Heart Association 2021) continues to recommend either anakinra (Kineret) or rilonacept (Arcalyst) for the treatment of colchicine-refractory recurrent pericarditis, based on their demonstrated effectiveness in decreasing pericarditis recurrence and increasing time to recurrence.

Safety

- Published clinical practice guidelines do not make a distinction among individual IL-1, IL-6, or CTLA4-Ig agents in terms of safety, with the distinction of abatacept (Orencia) as potentially preferred if the patient has a history of non-tuberculosis mycobacterium infection.
- Noted adverse events for all the products include hypersensitivity risk, increased risk of infections including tuberculosis, injection site reactions, and warnings against concurrent use of live vaccines. IL-6 agents all carry the additional risk for hepatotoxicity and gastrointestinal perforation. Unique safety concerns were discussed with the individual product summaries.
- A review of the package inserts, guidelines, and other published literature of the adverse events with IL-1, IL-6, and CTLA4-Ig found the following:
    - The most common adverse drug reactions across all therapies included injection site reactions, infections,

nasopharyngitis or upper respiratory tract infection, and headaches.

- Overall, agents within this subclass appear well-tolerated with acceptable safety profiles.

Other Factors

- Special populations:
  - The agents are generally considered safe during the pregnancy planning phase but are discontinued once pregnancy is confirmed. There is no compelling evidence that one IL-1, IL-6, or CTLA4-Ig should be preferred over another during pregnancy. TNF inhibitors are also considered safe and effective in pregnancy.
  - All agents are approved for use in the pediatric patient population with the exception of satralizumab (Enspryng), based on FDA-labeling.
- Provider opinion:
  - Military Health System (MHS) rheumatologists voiced that a TNF inhibitor should remain first-line for RA and pJIA, while subsequent therapy with an IL-6, CTLA4-Ig, or a JAK inhibitor is appropriate based on patient characteristics. Pediatric providers are more likely to utilize tocilizumab for pJIA rather than sarilumab (Kevzara), due to the minimum weight requirement with Kevzara. Providers did note that SC administration of abatacept (Orencia) is less effective than other choices.
  - For the treatment of psoriatic arthritis, providers were in agreement that abatacept was less effective than drugs with other mechanisms of action. Providers were supportive of the requirement to utilize an IL-17 prior to use of a CTLA4-Ig for treatment of psoriatic arthritis.
  - For treatment of Still's Disease, encompassing both systemic JIA and AOSD, rheumatologists were highly supportive of increasing access to both the IL-1 anakinra (Kineret) and the IL-6 tocilizumab as first-line agents. The providers agreed that a step requirement was not appropriate due to the multitude of patient factors, including those currently stabilized on therapy.
  - Ophthalmologists and neuroimmunologists relayed opinions on using tocilizumab and satralizumab (Enspryng) for NMOSD and MOGAD. While feedback was mixed on the use of tocilizumab in adults, for the pediatric population there was full support for utilizing tocilizumab as the preferred outpatient therapy for NMOSD as it is useful in

both AQP4-Ig positive and negative disease, as well as MOGAD. Since Enspryng is the only FDA-approved agent for this condition, a step requirement was not recommended.

- MHS rheumatologists were supportive of increasing options for evidence-based treatment of polymyalgia rheumatica. At this time, only sarilumab (Kevzara) carries the FDA-approved labeling for this condition, however other agents, including tocilizumab are used off-label, therefore a step requirement was not recommended.
- For treatment of recurrent pericarditis, providers were in agreement with increasing access to multiple treatment options. Rilonacept (Arcalyst) is the only FDA-approved biologic treatment, however older guidelines and current treatment algorithms recommend therapy with either anakinra (Kineret) or rilonacept (Arcalyst). Due to off label utilization of anakinra, a step requirement was not recommended.

Overall Conclusion

- Based on FDA indication and published guidelines it is reasonable to continue to require a trial of Humira first for many rheumatologic diseases including rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, consistent with the previous class review in 2014.
- Biosimilars are interchangeable to the reference product. Market launch of tocilizumab biosimilars in 2024 provides an opportunity for contracting initiatives with other Federal agencies via a Joint National Contract. Abatacept (Orencia) is the next biosimilar expected to enter the market.
- Within the subclass, when the agents are compared to one another, there are not compelling differences in efficacy and safety. Individual patients may show variability in response to different agents.
- Provider feedback overwhelmingly supported increasing accessibility to several agents, including optimizing PA pathways to allow off-label indications for which these medications are considered standard of care.
- For clinical coverage, at least one IL-1, IL-6, and CTLA4-Ig agent is needed on the formulary to cover each indication of RA, pJIA, and Still's Disease (sJIA, AOSD) to meet the needs of MHS beneficiaries. Additional options should be considered to provide more choices for providers based on individual patient characteristics.

B. TIBs: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Relative Cost Effectiveness Conclusion

The 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 (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1s, Interleukin-6s, Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin

- CMA results showed that the formulary placement of tocilizumab (Tyenne) as UF and step-preferred was cost-effective.
- BIA and sensitivity results showed cost avoidance by designating Tyenne as step-preferred and all the other IL-1s, IL-6s, and CTLA4-Ig as non-step-preferred.

C. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation

The P&T Committee recommended for the IL-1, IL-6s, and CTLA4-Igs (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF and step-preferred
  - IL-6: tocilizumab-aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*
- UF and non-step-preferred
  - IL-1: anakinra (Kineret) *moves from NF non-step-preferred to UF non-step-preferred*
  - IL-6: sarilumab (Kevzara) *moves from NF non-step-preferred to UF non-step-preferred*
- NF and non-step-preferred
  - IL-6: tocilizumab (Actemra)
  - CTLA-4Ig: abatacept (Orencia)
  - IL-1: rilonacept (Arcalyst) *moves from UF no step to NF non-step-preferred*
  - IL-6: satralizumab (Enspryng) *moves from UF no step to NF (no step required)*
- Complete Exclusion: None
- Note, as part of this recommendation, a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, CTLA4-Ig products in all new patients, depending on the clinical indication.

- Enspryng is not subject to the step therapy requirements for its indication of NMOSD.

D. TIBs: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig)—Manual PA Criteria

Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updated manual and step therapy PA criteria for the IL-1, IL-6 and CTLA4-Ig products as outlined below.

- *General Changes*:
  - Updating the step therapy requirements as outlined in the formulary recommendation and adding new indications as necessary.
  - Streamlining the list of medications that should not be used concurrently by drug classes rather than individual agents (new medications, biosimilars).
- *IL-1s:* Current PA criteria for the IL-1s require a trial of Humira first for all overlapping indications. The recommended PA changes for the IL-1s include the following:
  - For Kineret, which is now the UF non-step-preferred IL-1, clarifying that a trial of Tyenne and Humira are both required for rheumatoid arthritis only, unless the patient has had an inadequate response, contraindication or adverse reaction to Humira and Tyenne. Neither Humira nor Tyenne will be required prior to Kineret for non-RA indications. The indications for recurrent pericarditis and chronic infantile neurological cutaneous and articular (CINCA) disease will be added.
  - For Arcalyst, a trial of Kineret is now required first for treatment of deficiency of interleukin receptor 1 antagonist (DIRA). Rheumatologists will also be able to prescribe Arcalyst for recurrent pericarditis, in addition to cardiologists. Kineret is not required prior to use of Arcalyst for recurrent pericarditis.
- *IL-6s*: For the IL-6 agents, currently Humira is required first for all overlapping indications. The recommended PA changes include the following:
  - For Tyenne, which is now UF step-preferred, an automated drug lookback for utilization of either Humira or Actemra will be added. New indications for Still's Disease, polymyalgia rheumatica (PMR), neuromyelitis optica spectrum disorder (NMOSD), and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) were added to the PA form.
  - For Actemra, which is the NF non-step-preferred tocilizumab product, all new and current users will be required to move to Tyenne. The current automated Humira lookback will be removed. A trial of Tyenne will be required for all indications, and a trial of Humira will be required for

appropriate indications. All new and current users of Actemra and the other tocilizumab biosimilars (when they are marketed) will require a trial of Tyenne first.

- For Kevzara, which moves to UF non-step-preferred status, a trial of Tyenne will be added for the conditions of RA and pJIA; the Humira step requirement will remain.
- Enspryng will not be subject to step-therapy requirements as there are currently no overlapping FDA-approved indications with either Humira or Tyenne. Any future indications that may overlap with Humira or Tyenne will require step-therapy. Documentation will now be required to demonstrate aquaporin-4 immunoglobulin G (AQP4-IgG) positivity.

- *CTLA4-Igs*: For the CTLA4-Ig agents, currently Humira is required first for all indications. The recommended PA changes include the following:
  - Orencia will maintain the requirement for a trial of Humira first. A Tyenne step will be added for rheumatoid arthritis and pJIA. A trial of the IL-17 ixekizumab (Taltz) will be added for adult psoriatic arthritis. The automated drug lookback for Humira will be removed. The PA changes will apply to new users.
  - Biosimilars for the CTLA4-Ig Orencia are expected to launch in 2026. This will allow formulary addition of a cost effective abatacept product in a future review.

The Manual PA criteria are as follows.

1. abatacept (Orencia)

Updates from the May 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of abatacept (Orencia).

~~Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), 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,~~ Orencia is approved if all criteria are met:

- **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND**
  - **The patient has had an inadequate response to Tyenne OR**
  - **The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR**
  - **The patient has a contraindication to Tyenne**

    - **A trial of Tyenne is not required for adult or pediatric psoriatic arthritis**
- **Humira is the Department of Defense's preferred targeted biologic agent.** The patient must have tried Humira AND:
    - The patient had an inadequate response to Humira OR
    - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
    - The patient has a contraindication to Humira
- **The patient must have tried Taltz AND:**
    - **The patient had an inadequate response to Taltz OR**
    - **The patient experienced an adverse reaction to Taltz that is not expected to occur with the requested agent OR**
    - **The patient has a contraindication to Taltz**
    - **A trial of Taltz is not required for adult or pediatric psoriatic arthritis**
- Coverage approved for patients 18 years of age or older with one of the following diagnoses/indications:
    - Moderate to severely active rheumatoid arthritis
    - Active psoriatic arthritis
- ~~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.)~~
- Coverage approved for patients 2 to 17 years of age with one of the following diagnoses/indications:
    - Moderately to severely active polyarticular juvenile idiopathic arthritis
    - Active psoriatic arthritis. Note that a trial of non-biologic systemic therapy and Humira is required
- ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~
- ~~May not be used concomitantly with other TIBs agents~~
- **Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, C5 inhibitors, or rituximab**

Non-FDA approved uses are not approved

Prior Authorization does not expire

2. anakinra (Kineret)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of anakinra (Kineret).

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

- **Provider acknowledges the Department of Defense requires a trial of Humira. The patient must have tried Humira AND**
  - **The patient has had an inadequate response to Humira OR**
  - **The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR**
  - **The patient has a contraindication to Humira**
- **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND**
  - **The patient has had an inadequate response to Tyenne OR**
  - **The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR**
  - **The patient has a contraindication to Tyenne AND**
- Patient is 18 years of age or older with:
  - ~~Adult-Onset Still's Disease (AOSD) with active systemic features of moderate to high disease activity (Trial of Humira not required) OR~~
  - Moderate to severe active rheumatoid arthritis ~~AND~~
    - ~~Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications~~
    - ~~The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent~~
    - ~~The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])~~
- **Patients 12 years of age or older with**
  - **Recurrent pericarditis**

- **Prescription has been written by or in consultation with a cardiologist or rheumatologist AND**
- **Patient has a contraindication to colchicine and at least ONE of the following drug classes**
  - **aspirin**
  - **NSAIDs OR**
- **Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes**
  - **aspirin**
  - **NSAIDs**
  - **corticosteroids**

- ~~Pediatries~~ **Patients** (all ages) with:
  - Neonatal-Onset Multisystem Inflammatory Disease (NOMID) ~~a subset of cryopyrin associated periodic syndrome (Trial of Humira not required)~~
  - **Chronic Infantile Neurological Cutaneous and Articular (CINCA) disease**
  - **Cryopyrin-Associated Periodic Syndrome (CAPS)**. ~~(Trial of Humira not required)~~
  - Systemic Juvenile Idiopathic Arthritis (sJIA) ~~(Trial of Humira not required).~~
  - ~~Adult-Onset~~ Still's Disease with active systemic features of moderate to high disease activity
  - Deficiency of Interleukin-1 Receptor Antagonist (DIRA~~) (Trial of Humira not required).~~
- Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: ~~adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER)~~ **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**

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

Prior authorization does not expire

3. rilonacept (Arcalyst)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of rilonacept (Arcalyst)

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

- Patient **is 12 years of age or older with** one of the following diagnoses:
  - Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS)
    - ~~Patient is 12 years of age of older~~
  - Recurrent pericarditis
    - ~~Patient is 12 years of age of older~~
    - Prescription is **written by or in consultation with a cardiologist or rheumatologist**
    - Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR
    - Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids
- **Patients of all ages with**
  - Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
    - The patient weighs at least 10 kg (22 pounds)
    - **Patient has had an inadequate response to anakinra OR**
    - **Patient has experienced an adverse reaction to anakinra that is not expected to occur with the requested agent OR**
    - **Patient has a contraindication to anakinra**
- ~~The patient is not concurrently receiving a TNF-inhibitor (e.g., Humira, Enbrel, Cimzia, and Simponi) due to the increased risk of serious infections.~~
- **Coverage is not provided for concomitant use with other TIBs including, but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**

Non-FDA approved uses are not approved, including rheumatoid arthritis, neonatal-onset multisystemic inflammatory disease (NOMID), cardiovascular disease other than pericarditis (MI, acute coronary

syndrome, atherosclerosis, heart failure, and Kawasaki disease), and gout.

Prior authorization does not expire

4. sarilumab (Kevzara)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Kevzara

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

- Kevzara is prescribed by or in consultation with a rheumatologist
- Provider acknowledges ~~Humira~~ **Tyenne** is the Department of Defense's preferred ~~targeted biologic agent~~ **IL-1, IL-6, CTLA4-Ig agent.** The patient must have tried Humira AND:
  - The patient had an inadequate response to ~~Humira~~ **Tyenne** OR
  - The patient experienced an adverse reaction to ~~Humira~~ **Tyenne** that is not expected to occur with the requested agent OR
  - The patient has a contraindication to ~~Humira~~ **Tyenne**
  - **Note that a trial of Tyenne is not required for Polymyalgia Rheumatica**
- The patient requires a trial of Humira.
  - The patient has had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira
  - **Note that a trial of Humira is not required for Polymyalgia Rheumatica**
- Patient has a diagnosis of:
  - Moderately to severely active rheumatoid arthritis OR ~~AND~~
    - ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~
  - Active polyarticular juvenile idiopathic arthritis (pJIA) and weighs 63 kg or more OR ~~AND~~
    - ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~
  - Polymyalgia Rheumatica (PMR) (Trial of **Tyenne and** Humira is not required) AND
    - Patient has tried and/or failed ONE systemic corticosteroid; OR

- The patient is not a candidate for corticosteroid therapy

- ~~Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR~~
- **Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**

Non-FDA approved uses are not approved

~~PA for non-PMR indications approved indefinitely.~~

PA does not expire for indications other than Polymyalgia Rheumatica

For Polymyalgia Rheumatica, PA expires after 12 months.

- **Renewal Criteria: (initial TRICARE PA approval is required for renewal). Coverage will be approved indefinitely for continuation of therapy if the following criteria are met:**
  - **The patient has had a positive response to therapy**

5. satralizumab (Enspryng)

Updates from May 2025 are in bold and ~~strikethrough~~

Manual PA is required for all new users of Enspryng.

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

- The patient is 18 years of age or older
- The drug is prescribed by or in consultation with a neurologist
- The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
- **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig product is tocilizumab-aazg (Tyenne). Tyenne is available for the treatment of aquaporin-4 (AQP4) seropositive or seronegative NMOSD**
- Patient has aquaporin-4 (AQP4) antibody positive NMOSD; documentation must be submitted
- Patient has clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening

- ~~Patient has laboratory evidence of HBV negative and TB negative~~
- ~~Patient and provider are enrolled in the REMS program~~
- **Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, C5 inhibitors, or rituximab**

Non-FDA approved uses are not approved

PA does not expire

6. tocilizumab-aazg (Tyenne)

Updates from the May 2025 meeting are in bold and strikethrough

Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) or tocilizumab (Actemra) at any MHS pharmacy point of service (MTFs, retail pharmacies, or mail order) during the previous 180 days. AND

Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne), **if automated criteria are not met**

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

- Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira. The patient must have tried Humira AND
  - The patient has had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira AND
- Patient has moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs~~ OR
- Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR
- Patient has a diagnosis for which adalimumab is not approved including
  - Giant cell arteritis **(GCA)**
  - Systemic sclerosis-associated lung disease **(SSc-ILD)**
  - Systemic Juvenile Idiopathic Arthritis (sJIA)

- **Still's Disease with active systemic features of moderate- to high- disease activity**
- **Polymyalgia Rheumatica (PMR) AND**
  - **Patient has tried and failed ONE systemic corticosteroid OR**
  - **Patient is not a candidate for corticosteroid therapy**
- **Neuromyelitis Optica Spectrum Disorder (NMOSD), aquaporin-4 (AQP4) seropositive or seronegative**
- **Myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD)**
- ~~If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~

- Patient is not receiving other targeted immunomodulatory biologics with Tyenne

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

PA does not expire

7. tocilizumab (Actemra)

Updates from the May 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new **and current** users of tocilizumab (Actemra)

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

- Provider acknowledges the Department of Defense~~'s preferred targeted immune biologic is~~ **requires a trial of** Humira. The patient must have tried Humira AND
  - The patient has had an inadequate response to Humira OR
  - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Humira AND
- Provider acknowledges the Department of Defense's preferred ~~tocilizumab~~ **IL-1, IL-6, CTLA4-Ig product** is Tyenne. The patient must have tried Tyenne AND
  - The patient has had an inadequate response to Tyenne OR
  - The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR
  - The patient has a contraindication to Tyenne AND
- Patient has tried Humira **and has a diagnosis of**

- Moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs for example: methotrexate, aminosalicylates [for example, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [for example, azathioprine)~~
- Active polyarticular Juvenile Idiopathic Arthritis (pJIA)

- Patient has not tried Humira and has a diagnosis for which adalimumab is not approved: ~~AND is greater than 18 years of age:~~
  - Giant cell arteritis
  - Systemic sclerosis-associated lung disease
  - Systemic Juvenile Idiopathic Arthritis (sJIA)
  - ~~If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~
- Patient is not receiving other targeted immunomodulatory biologics with ~~tocilizumab~~ the requested agent, included but not limited to the following: **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, rituximab**

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

PA does not expire

E. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF, PA and Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving Enspryng and Arcalyst who will be affected by the formulary status change and to beneficiaries receiving Actemra due to the PA changes affecting both new and current users.

III. UF DRUG CLASS REVIEW—TIBS: INTERLEUKIN (IL)-1, IL-6 AND CYTOTOXIC T-LYMPHOCYTE ASSOCIATED ANTIGEN-4 IMMUNOGLOBULIN (CTLA4-IG) SUBCLASSES

UF BAP Comments

A. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation

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

- UF and step-preferred

    - IL-6: tocilizumab aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*
- UF and non-step-preferred
    - IL-1: anakinra (Kineret) *moves from NF to UF non-step-preferred*
    - IL-6: sarilumab (Kevzara) *moves from NF to UF non-step-preferred*
- NF and non-step-preferred
    - IL-6: tocilizumab (Actemra)
    - CTLA-4Ig: abatacept (Orencia)
    - IL-1: rilonacept (Arcalyst) *moves from UF to NF non-step-preferred*
    - IL-6: satralizumab (Enspryng) *moves from UF to NF (no step required)*
- Complete Exclusion: None
- Note, as part of this recommendation a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, CTLA4-Ig products in all new patients, depending on the clinical indications.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—Manual PA Criteria

The P&T Committee recommended PA criteria in new users of Tyenne, Kineret, Arcalyst, Kevzara, Enspryng and Orencia, and in new and current users of Actemra as outlined above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. TIBS: Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses—UF Recommendation, PA Criteria, and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 90 days after signing of the minutes in all points of service and that DHA will send letters to beneficiaries receiving Enspryng and Arcalyst who will be affected by the formulary status change and to beneficiaries receiving Actemra due to the PA changes affecting both new and current users.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEW—BREAST CANCER AGENTS: CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS SUBCLASS

P&T Comments

A. Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors—Subclass Relative Clinical Effectiveness Conclusion

Background—The P&T Committee evaluated the relative clinical effectiveness of the CDK inhibitor subclass used for advanced or metastatic hormone receptor-positive (HR(+)), human epidermal growth factor receptor 2-negative (HER2(-)) breast cancer. The drugs in the class include abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali). The drugs were last reviewed for formulary status in February 2021. Updates to clinical practice guidelines and FDA-approved indications were reviewed.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 1 abstained, 0 absent) the following:

Efficacy

- A comprehensive review of the evidence shows that each CDK inhibitor offers a statistically and clinically significant advantage in median progression free survival and objective response rate (ORR) relative to the respective controls used in the individual clinical trials.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) both provide a statistically and clinically significant advantage in invasive disease-free survival (iDFS), relative to the respective controls used in the individual clinical trials for early breast cancer treatment. This is a new indication for both agents that was not present in the prior class review.

- There are no high-quality head-to-head trials available directly comparing one CDK inhibitor with another.

Professional Treatment Guidelines

- The National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines recommend abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali) in the treatment of advanced or metastatic HR(+)/HER2(-) breast cancer as preferred first-line, second-line, or subsequent therapy. In the NCCN Guidelines, all agents carry a Category 1 recommendation in specific settings.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) are now also recommended in the setting of early breast cancer. Both agents carry the same level of recommendations in this setting by the NCCN and ESMO Guidelines.
- Other guidelines (e.g., American Society of Clinical Oncology, European Society for Medical Oncology) are in agreement with one another and make no distinction in the choice of a particular agent. Each CDK inhibitor has the same preference and strength of recommendation.

Safety

- There is no one clearly superior CDK inhibitor in terms of safety or tolerability.
- The safety profiles of the CDK inhibitors overlap, however, there are unique adverse events associated with each agent. Hematologic adverse events (e.g., neutropenia, anemia, and thrombocytopenia) are considered class effects.
    - Palbociclib (Ibrance) has the highest rate of thrombocytopenia.
    - Abemaciclib (Verzenio) has a higher relative risk for diarrhea and unique warnings for venous thromboembolism (VTE).
    - Ribociclib (Kisqali) has a higher relative risk for QT interval prolongation.

Overall Clinical Conclusion

- Treatment choice in HR(+)/HER2(-) advanced or metastatic breast cancer depends on several factors, including the safety profile of the individual CDK inhibitor, comorbidities, and disease burden.

B. Breast Cancer Agents: CDK Inhibitors Subclass—Relative Cost Effectiveness Analysis and Conclusion

CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that ribociclib, abemaciclib and palbociclib were all cost-effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating all CDK inhibitors as UF demonstrated significant cost avoidance for the MHS.

C. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following.

- UF
  - abemaciclib (Verzenio)
  - palbociclib (Ibrance)
  - ribociclib (Kisqali)
- NF – none
- Complete Exclusion – none

D. Breast Cancer Agents: CDK Inhibitors Subclass—Manual PA Criteria

Manual PA currently apply to all three CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) streamlining the criteria by removing questions on detailed indication criteria, removing the safety and monitoring questions, and standardizing the verbiage for updates to NCCN criteria, consistent with the actions taken for other oncology drug PA criteria.

The Manual PA criteria are as follows.

1. abemaciclib (Verzenio)

Updates from the May 2025 meeting are in bold and strikethrough.

Manual PA criteria apply to all new users of Verzenio.

Manual PA Criteria: Verzenio is approved if all of the following criteria are met:

- Drug is prescribed by or in consultation with an oncologist
- ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~
- ~~For Verzenio only, the patient has hormone receptor~~

  ~~HR(+)/HER2(-), node(+) early~~ breast cancer ~~at high risk of recurrence as determined by an FDA-approved test.~~

- The patient has advanced or metastatic ~~hormone receptor~~ (HR(+))/(HER2(-)) breast cancer
- ~~If the patient is female, the patient meets one of the following criteria:~~
  - ~~Verzenio will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~
  - ~~Verzenio will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR~~
  - ~~Verzenio will be used as monotherapy following metastatic progression on chemotherapy~~
- ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~
- ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~
- ~~Provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity~~
- ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~
- ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~
- ~~Male patients have been informed of the risk of infertility~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis: _____~~. **To facilitate approval please list the diagnosis, guidelines version and page number**.

  _____

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

Prior authorization does not expire

2. palbociclib (Ibrance)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Ibrance

Manual PA Criteria: Ibrance is approved if all of the following criteria are met:

- Drug is prescribed by or in consultation with an oncologist
- ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~
- The patient has ~~advanced or metastatic~~ ~~hormone receptor~~ ~~(~~HR(+)~~)~~/HER2(-) breast cancer
- ~~If the patient is female, the patient meets one of the following criteria:~~
  - ~~Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~
  - ~~Ibrance will be as first-line or later-line endocrine therapy in combination with fulvestrant~~
- ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~
- ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~
- ~~For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism~~
- ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~
- ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~
- ~~Male patients have been informed of the risk of infertility~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____.~~ **To facilitate approval please list the diagnosis, guidelines version and page number**_____.

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

Prior authorization does not expire

3. ribociclib (Kisqali)

Updates from the May 2025 meeting are in bold and strikethrough

Manual PA criteria apply to all new users of Kisqali

Manual PA Criteria: Kisqali is approved if all of the following criteria are met:

- Drug is prescribed by or in consultation with an oncologist
- ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~
- The patient has ~~advanced or metastatic hormone receptor (~~HR(+)~~)~~/HER2(-) breast cancer
- ~~If the patient is female, the patient meets one of the following criteria:~~
- ~~Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~
- ~~Kisqali will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR~~
- ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~
- ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~
- ~~For Kisqali: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity~~
- ~~Female patients of childbearing age are not pregnant confirmed by (-) HCG~~
- ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~
- ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~
- ~~Male patients have been informed of the risk of infertility~~
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category

1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____~~. **To facilitate approval please list the diagnosis, guidelines version and page number_____.**

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

Prior authorization does not expire

E. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation, PA Criteria, and Implementation Period

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

V. UF DRUG CLASS REVIEW—BREAST CANCER AGENTS: CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS SUBCLASS

UF BAP Comments

A. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation

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

- UF
  - abemaciclib (Verzenio)
  - palbociclib (Ibrance)
  - ribociclib (Kisqali)
- NF – None
- Complete Exclusion – None

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Breast Cancer Agents: CDK Inhibitors Subclass—Manual PA Criteria

The P&T Committee recommended streamlining the Manual PA Criteria as detailed above.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Breast Cancer Agents: CDK Inhibitors Subclass—UF Recommendation, PA Criteria, and Implementation Period

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

UF BAP Comments

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

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

P&T Comments

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

The products were divided into two groups when presented at the DoD P&T Committee meeting. The generic names are included below. Group 1 included Zunveyl, Alhemo, Inzirqo, Xromi, Prevymis, Gomekli, Raldesy, and five ustekinumab biosimilars (Steqeyma, Otulfi, Pyzchiva, Yesintek, and Selarsdi). Group 2 included Journavx, Vykat extended release (XR) and Romvimza.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 16 for, 0 opposed, 1 abstained, and 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 2025 DoD P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations.

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

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

- UF
  - concizumab-mtci (Alhemo) – Antihemophilic Agents
  - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
  - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
  - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection

- mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
- suzetrigine (Journavx) – Pain Agents
- ustekinumab-auuz (Otulfi) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors; biosimilar for Stelara
- ustekinumab-stab (Steqeyma) – TIBs IL-23s; biosimilar for Stelara
- vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor

- NF
  - hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents
  - trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor
  - ustekinumab-ttwe (Pyzchiva) – TIBs IL-23s; biosimilar for Stelara
  - ustekinumab-kfce (Yesintek) – TIBs IL-23s; biosimilar for Stelara
  - ustekinumab-aekn (Selarsdi) – TIBs IL-23s; biosimilar for Stelara
- Completely Excluded:
  - benzgalantamine (Zunveyl) – Alzheimer's Agents
    - Zunveyl was recommended for complete exclusion status as it has little to no clinical benefit relative to the other Alzheimer's Agents, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include galantamine and galantamine ER.

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

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

- Applying manual PA criteria to new users of the UF ustekinumab products Otulfi and Steqeyma, similar to what is required for all non-step-preferred Interleukin-23 inhibitors, where a trial of adalimumab (Humira) will be required first. These products are non-step-preferred.
  - For the NF ustekinumab products Pyzchiva, Yesintek, and Selarsdi, the PA will also apply to new users and require a trial of Humira, plus a trial of all the UF ustekinumab products. These products are non-step-preferred.
- Applying manual PA criteria to new users of Alhemo, similar to the PA requirements for other hemophilia agents.

- Applying manual PA criteria to new users of Zunveyl, until implementation of complete exclusion status.
- Applying manual PA criteria to new users of Vykat XR, Xromi, Gomekli, Inzirqo, Raldesy, and Romvimza.

The Manual PA criteria are as follows:

1. benzgalantamine (Zunveyl)

Manual PA criteria apply to all new users of Zunveyl

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

- Provider acknowledges that Zunveyl will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the DoD P&T Committee meeting minutes by the Director, DHA
- The patient is 18 years of age or older
- The medication is being prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine
- The patient is being treated for mild or moderate dementia of the Alzheimer's type
- Provider must document why the patient cannot use galantamine immediate release and galantamine extended release and donepezil products. (blank write-in)
  - Acceptable responses include the patient has had an adverse reaction to an excipient in galantamine immediate release and galantamine extended-release products that are not likely to occur with benzgalantamine (Zunveyl) or
  - The patient has had an inadequate response, experienced an adverse effect, or has a contraindication to donepezil

Non-FDA approved uses are not approved

PA does not expire until implementation of Complete Exclusion status

2. concizumab-mtci (Alhemo)

Manual PA criteria apply to all new users of Alhemo

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

- Patient is 12 years of age or older
- Prescribed by or in consultation with a hematologist
- Patient has hemophilia A with factor VIII inhibitors or hemophilia B with factor IX inhibitors

- Patient is not concurrently receiving factor VIII or factor IX therapy unless for the treatment of breakthrough bleeding

Non-FDA approved uses are not approved

PA does not expire

3. diazoxide choline (Vykat XR)

Manual PA criteria apply to all new users of diazoxide choline (Vykat XR)

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

- Patient is 4 years of age or older
- Prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome
- Patient has a diagnosis of Prader-Willi Syndrome confirmed by genetic testing
- Patient is being treated for hyperphagia
- Patient weighs between 20 kg and 135 kg

Non-FDA approved uses are not approved

Initial PA expires in 6 months

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

- The patient's hyperphagia has improved and stabilized to warrant continued therapy
- Medication continues to be prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome

4. hydrochlorothiazide 10 mg/mL oral suspension (Inzirqo)

Manual PA criteria apply to all new users of hydrochlorothiazide suspension (Inzirqo) who are over 12 years of age

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:

- Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease
- Provider must write in why the patient requires Inzirqo and cannot take a loop diuretic and a thiazide diuretic in a tablet formulation

- Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience

Non-FDA approved uses are not approved

PA does not expire

5. hydroxyurea 100 mg/mL oral solution (Xromi)

Manual PA criteria apply to all new users of hydroxyurea oral solution (Xromi) who are 18 years of age and older

PA does not apply to patients younger than 18 years of age (age edit)

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

- Patient has sickle cell anemia with recurrent moderate to severe painful crises
- Patient is not using Xromi for malignancy, including chronic myelocytic leukemia or other cancers
- The provider must explain why the patient cannot use the preferred products generic hydroxyurea or Siklos dispersed in water
  - Acceptable responses include the patient has swallowing difficulties, not just for convenience AND patient has sickle cell disease

Non-FDA approved uses are not approved

PA expires after 12 months

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

- Patient continues to have swallowing difficulties that preclude the use of hydroxyurea capsules AND Siklos tablets dispersed in water

6. mirdametinib (Gomekli)

Manual PA criteria apply to all new users of mirdametinib

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

- Patient is 2 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist
- Patient has a diagnosis of neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas
- Patient has tried and had an inadequate response, adverse effect, or has a contraindication to selumetinib (Koselugo)

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

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

PA does not expire

7. trazodone 10 mg/mL oral solution (Raldesy)

Manual PA criteria apply to all new users of trazodone oral solution (Raldesy)

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

- Patient has major depressive disorder (MDD)
- Provider must explain why the patient requires Raldesy and cannot take trazadone tablets
    - Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia) and not due to convenience

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

PA does not expire

8. vimseltinib (Romvimza)

Manual PA criteria apply to all new users of vimseltinib (Romvimza)

Manual PA criteria:

Coverage is approved if all criteria are met:

- Patient is 18 years of age or older
- Prescribed by or in consultation with a hematologist or oncologist
- Patient has symptomatic tenosynovial giant cell tumor
- Tumor is not amenable to treatment with surgery
- Patient has tried and had an inadequate response to pexidartinib (Turalio) OR
- Patient has tried and had an adverse effect to pexidartinib (Turalio) OR
- Patient has a contraindication to use of pexidartinib (Turalio)
- The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category

1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____.

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

PA does not expire

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

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

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

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

UF BAP Comments

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

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

- UF
  - concizumab-mtci (Alhemo) – Antihemophilic Agents
  - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
  - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
  - mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
  - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection
  - suzetrigine (Journavx) – Pain Agents
  - vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor
- NF

- hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents
- trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants And Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor

- Completely Excluded:
  - benzgalantamine (Zunveyl) – Alzheimer's Agents

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

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

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

VIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND IMPLEMENTATION PLAN

P&T Comments

A. New Manual PA Criteria

1) **Anti infectives: Antihelmintics—mebendazole (Emverm)—**Emverm is indicated to treat a variety of parasitic worm infections. The price of Emverm has increased

exponentially in recent years and some commercial health plans require a PA for Emverm. MTF providers support the addition of a PA restricting use to parasitic indications and requiring a step of over-the-counter (OTC) pyrantel pamoate, ivermectin, or albendazole. Off-label uses for indications other than parasitic infections will not be allowed.

The PA criteria are as follows:

mebendazole (Emverm)

Manual PA criteria apply to all new users of Emverm

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

- Patient has a diagnosis of pinworm (*Enterobius vermicularis)*, hookworm (*Ancylostoma duodenale* or *Necator americanus*), roundworm (*Ascaris lumbricoides*), or whipworm (Trichuris trichiura) OR
- Medication is prescribed by an infectious disease specialist for another parasitic infection AND
- For all indications, patient has a failure, contraindication, or intolerance to at least one of the following: OTC pyrantel pamoate, ivermectin, or albendazole

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

PA expires in one month. A new PA is required for each course of therapy

2.) **Miscellaneous Endocrine Agents: Antihyperglycemic-Glucocorticoid Receptor Blocker—mifepristone (Korlym)—**Korlym is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym is more costly than other alternatives used to treat Cushing's syndrome. A manual PA was recommended for Korlym to restrict use to its FDA-approved indication in new and current users, to require prescribing by an endocrinologist, and a trial of at least one other agent for Cushing's syndrome in new users. MTF providers supported establishment of PA criteria.

mifepristone (Korlym)

The PA criteria are as follows:

The following manual PA criteria apply to all new users of Korlym

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

- Patient is 18 years of age or older
- Prescription is written by an endocrinologist
- Patient has a diagnosis of endogenous Cushing's syndrome AND
- Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND
- Patient has failed surgery or is not a candidate for surgery

- Patient has tried and failed one of the following for the treatment of endogenous Cushing's syndrome: ketoconazole tablets, metyrapone capsules, mitotane, pasireotide, osilodrostat, orcabergoline

Non-FDA-approved uses are not approved including type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome

PA expires in 1 year

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

- Patient has had a positive clinical response while on Korlym

The following manual PA criteria apply to all **current** users of Korlym

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

- Patient has a diagnosis of endogenous Cushing's syndrome AND
- Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND
- Patient has failed surgery or is not a candidate for surgery

Non-FDA-approved uses are not approved including type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

PA expires in 1 year

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

- Patient has had a positive clinical response while on Korlym

3.) **Leukotriene Modifying Agents—zileuton (Zyflo), zileuton ER generic—**Zileuton is indicated to treat asthma and is less cost-effective than other agents in the class. Hepatic monitoring is required for zileuton due to liver function test elevations. A manual PA affecting new and current users was recommended requiring a trial of montelukast (generic Singulair) and zafirlukast (generic Accolate) first, due to safety concerns. Zyflo will be added to the Rapid Response/Safety Net program, which will provide additional outreach to beneficiaries who have not received a prescription after an initial PA reject.

zileuton (Zyflo), zileuton ER generic

The PA criteria are as follows:

Manual PA criteria apply to all new and current users

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

- Patient is being treated for asthma
- Patient is 12 years of age or older

- Patient has a contraindication to, intolerability to, or has failed treatment with both of the following:
  - montelukast AND
  - zafirlukast

Non-FDA-approved uses are not approved

PA expires in 1 year

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

- The patient has had a positive response to therapy, as defined by one of the following:
  - a decrease in asthma exacerbations
  - improvements in forced expiratory volume in one second (FEV1) decrease in oral corticosteroid use

B. New Manual PA Criteria and Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Emverm in new users and for Korlym, and zileuton in new and current users. 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 currently receiving Korlym, zileuton IR and zileuton ER.

IX. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended manual PA criteria for Emverm, Korlym and zileuton, as outlined above. 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 currently receiving Korlym, zileuton IR and zileuton ER.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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

Manual PA criteria were recommended for two recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet—Numerous other more cost-effective generic metformin IR and ER tablets are available.

Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet—There are other tramadol formulations available, including tramadol 50 mg tablets, that are more cost-effective than this 100 mg strength.

The Manual PA criteria are as follows:

1. metformin 750 mg IR tablet

Manual PA criteria apply to all new and current users of metformin 750 mg IR tablet.

Manual PA criteria: metformin 750 mg IR Tablet is approved if all criteria are met:

- Provider acknowledges other formulations of metformin are available without prior authorization.
- Provider must explain why the patient requires metformin 750 mg IR Tablet and cannot take the cost-effective generic metformin formulations
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin formulations

Non-FDA approved uses are not approved

Prior authorization does not expire

2. tramadol 100 mg immediate release (IR) tablet

Manual PA criteria apply to all new and current users of tramadol 100 mg tablets

Manual PA criteria: tramadol 100 mg tablets are approved are approved if all criteria are met:

- Provider is aware and acknowledges that tramadol 50 mg tablets are available to DoD beneficiaries without the need of prior

authorization. Providers are encouraged to consider changing the prescription to the preferred tramadol 50 mg.

- Provider must explain why the patient requires tramadol 100 mg tablets and cannot take the cost-effective generic tramadol 50 mg formulations (fill-in the blank)
  - Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg tablets

Non-FDA approved uses are not approved

Prior authorization does not expire

B. New PA Criteria for Drugs Not Subject to 32 CFR 199.21(G)(5) and Implementation Plan

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for metformin 750 mg and tramadol 100 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. 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.

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

UF BAP Comments

The P&T Committee recommended manual PA for metformin 750 mg IR tabs and tramadol 100 mg tablets as stated above; and an effective date the first Wednesday 60 days after signing of the minutes and DHA will send letters to the affected beneficiaries.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Updated PA Criteria for New FDA Approved Indications

The P&T Committee recommended (17 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) **Miscellaneous Metabolic Agents—setmelanotide (Imcivree**)—The manual PA criteria were expanded to include children two years of age and older with certain syndromic or monogenic forms of obesity.

b) **Miscellaneous Immunological Agents: Oral Agents—house dust mite allergen extract (Odactra)**—The manual PA criteria were expanded to include children ages 5 to 11 years of age.

c) **TIBs**: **IL-23 Inhibitor—guselkumab (Tremfya)—**Tremfya is now indicated for the treatment of Crohn's disease in adults. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the ulcerative colitis criteria for this drug.

d) **Leukemia and Lymphoma Agents: BTK Inhibitors—acalabrutinib (Calquence)—**The manual PA criteria were updated to allow for treatment of a subset of previously untreated mantel cell lymphoma patients

e) **Oncological Agents: Lung Cancer —sotorasib (Lumakras)—**Lumakras received a new indication for KRAS G12C-mutated metastatic colorectal cancer. The manual PA form was updated to include this indication and require coadministration with panitumumab in patients who have received prior fluoropyrimidine, oxaliplatin-, and irinotecan-based chemotherapy based on the FDA label. Additionally, edits were made to match the recent changes in other oncology PAs as part of the ongoing oncology standardization process.

f) **Diabetes Non-Insulin: Glucagon-Like Peptide-1 Receptor Agonists (GLP-1RAs)—semaglutide (Ozempic)—**Semaglutide under the trade name Ozempic is now indicated to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, and cardiovascular death in adults with chronic kidney disease and type 2 diabetes. Current treatment guidelines recommend a renin angiotensin system inhibitor (ACE inhibitor or angiotensin receptor blocker) and sodium-glucose co-transporter 2 (SGLT-2) inhibitor. The Ozempic PA criteria were updated to require use of the cost effective guideline-recommended therapies first.

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) implementation for the new PA criteria for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic in new users will be effective the first Wednesday 60 days after the signing of the minutes.

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

UF BAP Comments

Updated PA Criteria for New FDA Approved Indications and Implementation Plan

The P&T Committee recommended updates to the PA criteria due for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic in new users, due to FDA-approved indications and expanded age ranges. Implementation of the new PA criteria will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

P&T Comments

A. Updated PA Criteria for Reasons other than New FDA Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs. The updated PA criteria outlined below will apply to new users.

a) **Corticosteroids-Immune Modulators: Atopic Dermatitis—crisaborole (Eucrisa)—**An age edit was added allowing patients two years of age and younger to bypass the PA as other non-steroid treatments are only approved for children older than age two.

b) **Antigout Agents: Chronic—febuxostat (Uloric)**—An automated lookback for allopurinol 300 mg was added to the Uloric PA. Patients with a prescription claim for allopurinol in the past 180 days will bypass the Uloric PA. In addition, the safety questions were removed.

c) **Oncological Agents—fedratinib (Inrebic), selumetinib (Koselugo), pomalidomide (Pomalyst), ripretinib (Qinlock), midostaurin (Rydapt), capmatinib (Tabrecta), tepotinib (Tepmetko), pexidartinib (Turalio), quizartinib (Vanflyta), larotrectinib (Vitrakvi), dacomitinib (Vizimpro), and gilteritinib (Xospata)**— Updates were made as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for National Cancer Care Network

(NCCN) guideline updates. For more details on oncology PA standardization, please refer to the November 2024 meeting minutes. Additionally, the PA for Pomalyst was updated to add the Kaposi Sarcoma indication.

d) **Metabolic Agents Miscellaneous—odevixibat (Bylvay) and maralixibat (Livmarli)**—Bylvay and Livmarli are FDA-approved to treat pruritus due to progressive familial intrahepatic cholestasis or Alagille syndrome. The drugs treat the pruritic symptoms, but do not change the underlying disease course. Both drugs were reviewed as innovators and were designated as UF with a PA requiring a trial of five other generic, well-established agents first. Bylvay and Livmarli are not yet included in professional treatment guidelines. Based on a review of MHS prescription claims, the PA will expand the options to the six drugs included in the current treatment guidelines, but only require a trial of three products first, prior to Bylvay or Livmarli. Other updates included standardizing the new nomenclature for non-alcoholic fatty liver disease (NAFLD), now known as metabolic dysfunction-associated steatotic liver disease (MASLD).

e.) **Antipsychotic Agents: Parkinson's Psychosis—pimavanserin (Nuplazid)—** Nuplazid will now require a trial of clozapine first, unless the patient has a contraindication, intolerability to, or has failed treatment with clozapine. The reasons for the clozapine step are due to removal of the previous clozapine Risk Evaluation and Mitigation System (REMS) program, network meta-analysis data supporting its use before Nuplazid, and provider feedback supporting using Nuplazid as a later-line agent. Additionally, clozapine is more cost-effective than Nuplazid.

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

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vitrakvi, Vizimpro, Xospata, Bylvay, Livmarli, and Nuplazid in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

XV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA AND IMPLEMENTATION PERIOD FOR REASONS OTHER THAN NEW FDA APPROVED INDICATIONS AND IMPLEMENTATION PLAN

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vitrakvi, Vizimpro, Xospata, Bylvay, Livmarli, and Nuplazid in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. UTILIZATION MANAGEMENT—REMOVAL OF PAs and IMPLEMENTATION PERIOD

P&T Comments

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA for two drugs, with implementation effective the first Wednesday 2 weeks after signing of the minutes.

a) **Multiple Sclerosis Agents: Methyl Fumarate—dimethyl fumarate (Tecfidera)—**Tecfidera is designated as UF. Generic formulations of Tecfidera are now available and dimethyl fumarate is the most cost-effective methyl fumarate agent. The Tecfidera PA will be removed for these reasons.

b) **Alzheimer's Agents—memantine ER (Namenda XR)—**Currently, memantine IR (Namenda) is designated as UF while memantine ER (Namenda XR) is designated as NF with a PA. Namenda XR is administered once daily and is available as a generic. Due to clinical and cost considerations, the PA will be removed for Namenda XR, but Namenda XR will remain as NF.

XVII. UTILIZATION MANAGEMENT—REMOVAL OF PAs and IMPLEMENTATION PERIOD

UF BAP Comments

The P&T Committee recommended updates to the manual PA criteria for Tecfidera and Namenda XR as outlined above, with implementation effective two weeks after signing of the minutes.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVIII. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR SACUBITRIL/VALSARTAN (ENTRESTO)

P&T Comments

Renin-Angiotensin Antihypertensives: Combinations—Sacubitril/valsartan (Entresto) tablets are designated as UF without a 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 Entresto tablets will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. The Tier 1 copay for brand Entresto is recommended.

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) requiring brand Entresto tablets over the generics in 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 Entresto tablets. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics

XIX. UTILIZATION MANAGEMENT—BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR SACUBITRIL/VALSARTAN (ENTRESTO)

UF BAP Comments

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

UF BAP Comments

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

XX. UTILIZATION MANAGEMENT—WEIGHT LOSS DRUGS PAs: COMPREHENSIVE LIFESTYLE INTERVENTION AND IMPLEMENTATION

P&T Comments

The current PA criteria for the weight loss drugs was reviewed. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding to the PA criteria that the patient has had verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of weight management: diet, physical activity, and behavioral changes on both treatment initiation and annual renewal. Implementation will occur the first Wednesday 60 days after signing of the minutes in all three points of service.

XXI. UTILIZATION MANAGEMENT—WEIGHT LOSS DRUGS PAs: COMPREHENSIVE LIFESTYLE INTERVENTION AND IMPLEMENTATION

UF BAP Comments

The P&T Committee recommended adding to the PA criteria that the patient has had verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of weight management: diet, physical activity, and behavioral changes on both initiation and annual renewal. Implementation will occur the first Wednesday 60 days after signing of the minutes in all three points of service.

UF BAP Comments

Concur: Non-Concur: Abstain: Absent: