P&T Committee Meeting Minutes
Commercial, Exchange, & CHIP
August 2022 e-vote

Fast Facts

ACTEMRA IV (tocilizumab)

Clinical Summary: Actemra IV is now clinically indicated for the treatment of Giant Cell Arteritis in adult patients. Previously, it was indicated for the treatment of Rheumatoid Arthritis in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease Modifying Anti-Rheumatic Drugs (DMARDS), Polyarticular Juvenile Idiopathic Arthritis in patients 2 years and older, Systemic Juvenile Idiopathic Arthritis in patients 2 years and older and Cytokine Release Syndrome in patients 2 years and older.

Current formulary status: Actemra is a medical benefit requiring prior authorization.

Recommendation: There are no changes to formulary status or quantity limits at this time. Update policy to include indication for GCA.

OR

For the treatment of Giant Cell Arteritis:

1. Medical record documentation of a diagnosis of Giant Cell Arteritis **AND**
2. Prescription written by a rheumatologist **AND**
3. Patient is 18 years of age or older **AND**
4. Medical record documentation that Actemra is not being used concurrently with a TNF blocker or other biologic agent

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

BREYANZI (lisocabtagene maraleucel)

Updated indication: Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy now indicated for the treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:

- Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy.
- Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age.

Previously, Breyanzi was indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma

(DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Current formulary status: Medical benefit requiring prior authorization.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Breyanzi. It is recommended that the following prior authorization criteria be changed for Medical Benefit Policy 228.0 to incorporate the new indication:

- Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy **AND**
- Medical record documentation of one of the following diagnoses:
    - High-grade B-cell lymphoma **OR**
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) **OR**
    - Primary mediastinal large B-cell lymphoma **OR**
    - Follicular lymphoma grade 3B

AND

- **One** of the following:
    - Medical record documentation of two or more lines of prior systemic therapy ~~**AND**~~ **OR**
- ~~Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy~~
    - Medical record documentation of refractory disease to first-line chemoimmunotherapy **OR**
    - Medical record documentation of relapse within 12 months of first-line chemoimmunotherapy **OR**
    - Medical record documentation of relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

KYMRIAH (tisagenlecleucel)

Clinical Summary: Kymriah is a CD19-direct genetically modified autologous T-cell immunotherapy that is now indicated for the treatment of adults with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy. This indication was approved under accelerated approval which was based on the response rate and duration of response, but continued approval may be contingent on proving clinical benefit through confirmatory trials. Previously, Kymriah was only indicated for the treatment of adults with relapsed or refractory (r/r) large B cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL from follicular lymphoma, and for the treatment of refractory, second relapse, or later relapse of B-cell precursor acute lymphoblastic leukemia (ALL) in patients up to age 25.

Current formulary status: Medical benefit requiring prior authorization.

Recommendation: No changes are recommended to the formulary placement or authorization duration of Kymriah. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy to incorporate the new indication:

Follicular Lymphoma, Relapsed or Refractory (r/r FL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

KYPROLIS (carfilzomib)

Clinical Summary: Kyprolis is now indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with Isatuximab and dexamethasone. Previously, Kyprolis was approved for use in combination with lenalidomide and dexamethasone; or dexamethasone; or daratumumab and dexamethasone; or daratumumab and hyaluronidase-fihj and dexamethasone. It is also indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one of more lines of therapy.

Current formulary status: Medical benefit, requiring a prior authorization; When processed at a specialty pharmacy: Specialty tier or brand non-preferred tier.

Recommendation: There are no changes recommended to the formulary placement or auth duration for Kyprolis. The following changes are recommended to the prior authorization criteria in Medical Benefit Policy 97.0.

- Must be prescribed by hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of prior treatment with at least one therapy **AND**
- Medical record documentation that Kyprolis will be used:
    - As monotherapy **OR**
    - In combination with dexamethasone **OR**
    - In combination with dexamethasone and lenalidomide **OR**
    - In combination with daratumumab (Darzalex) and dexamethasone **OR**
    - In combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro) and dexamethasone
    - In combination with Isatuximab and dexamethasone

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

TAFINLAR (dabrafenib) AND MEKINIST (trametinib)

Clinical Summary: Tafinlar and Mekinist are now indicated in combination for the treatment BRAF V600E mutation positive unresectable or metastatic solid tumors in patients 6 years of age and older who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial or trials. The combination of Tafinlar and Mekinist was previously indicated for the following:

- treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
- adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection
- treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
- treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options

Current formulary status: Tafinlar and Mekinist are pharmacy benefits on the oral oncology brand non preferred tier requiring a prior authorization with a quantity limit.

Recommendation: No changes recommended to the formulary placement of Tafinlar & Mekinist at this time. However, it is recommended to update policy 304.0 Tafinlar and Mekinist to include the following criteria:

Unresectable or Metastatic Solid Tumors

- Medical record documentation that Tafinlar and Mekinist are prescribed by a hematologist or oncologist AND
- Medical record documentation of unresectable or metastatic solid tumors AND
- Medical record documentation that Mekinist and Tafinlar will be used in combination AND
- Medical record documentation of BRAF V600E mutation AND
- Medical record documentation of a previous treatment resulting in disease progression

Discussion: No comments or questions

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ULTOMIRIS (ravulizumab-cwvz)

Clinical Summary: Ultomiris is now FDA approved for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody–positive. This is the only long-acting component 5 (C5) complement inhibitor approved for the treatment of gMG. Previously, Ultomiris was approved for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH) and Atypical Hemolytic Uremic Syndrome (aHUS).

Current formulary status: Medical benefit, requires prior authorization

Recommendation: There are no changes recommended to the formulary placement for Ultomiris. The following changes are recommended to the prior authorization criteria and authorization duration criteria in Medical Benefit Policy 196.0 to incorporate the changes to the myasthenia gravis indication.

For the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH): There are no changes to formulary status or quantity limits at this time.

For the treatment of Atypical Hemolytic Uremia: There are no changes to formulary status or quantity limits at this time.

For the treatment of Myasthenia Gravis:

- Medical record documentation supporting a confirmed diagnosis of anti-acetylcholine receptor (AchR) antibody positive myasthenia gravis AND
- Prescribed by or in consultation with a neuromuscular specialist AND
- Medical record documentation of medical team recommending meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations AND
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV AND
- Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline AND
- Medical record documentation of age > 18 years AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) AND
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG)
- Medical record documentation of failure on, intolerance to, or contraindication to Vyvgart.

AUTHORIZATION DURATION: Initial approval will be given for six months. Subsequent approvals will be for an additional six months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression AND
- Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score.

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note:

Class I myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid) and no other evidence of muscle weakness elsewhere, Class II to IV include muscle weakness in areas of the body beyond the eye.

Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

Additional Recommendations: Based on available literature[4,5], *removal* of the following criteria is recommended from the Soliris policy:

- ~~Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar AND~~
- ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors~~

The following criteria is recommended to be *added* to the Soliris policy:

- Medical record documentation of medical team recommending meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations AND
- Medical record documentation of failure on, intolerance to, or contraindication to Vyvgart.

The following criteria is recommended for *removal* from the Vyvgart policy:

- ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors AND~~
- ~~• Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar~~

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

VEKLURY (remdesivir)

Clinical Summary: Veklury is now indicated for pediatric patients (infants 28 days of age and older and weighing at least 3 kg) who have positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are hospitalized OR not hospitalized, but have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

Current Formulary Status: Medical benefit; no prior authorization required.

Recommendation: There are no changes recommended to formulary placement of Veklury at this time.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

XALKORI (crizotinib)

Clinical Summary: Xalkori is now indicated in adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is anaplastic lymphoma kinase (ALK)-positive. Xalkori is also indicated for the treatment of patients with metastatic non-small cell lung cancer whose tumors are ALK or ROS1-positive and the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is ALK-positive.

Current formulary status: Xalkori is a pharmacy benefit and is currently at the Oral Oncology Brand NP tier. Xalkori requires a prior authorization.

Recommendation: There are no changes to formulary status, authorization duration, or quantity limits recommended at this time. However, it is recommended to add the following criteria to the current policy to reflect the updated indication. It is also recommended to update the FDA approved test note in the policy to match the FDA approved labeling.

Inflammatory Myofibroblastic Tumor

- Medical record documentation that Xalkori is prescribed by an oncologist AND
- Medical record documentation of age greater than or equal to 1 year of age AND
- Medical record documentation of a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is anaplastic lymphoma kinase (ALK) positive

NOTE: The FDA approved test can be found at https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

XIGDUO XR (dapagliflozin and metformin)

Clinical Summary:
Xigduo XR, a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, is now indicated to reduce:

- the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors
- the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction
- the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Previously Xigduo XR was indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Current formulary status: Non Formulary (2022). Brand preferred (2023)

Recommendation: No changes to the formulary status are recommended – PA will be removed in 2023. The following updates to the Xigduo XR policy should be made (highlighted) to match the Farxiga policy for the new indications:

Diabetes

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance in combination with metformin, Synjardy, or Synjardy XR **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana in combination with metformin, Invokamet, or Invokamet XR

Heart Failure

- Medical record documentation of a diagnosis of New York Heart Association (NYHA) class II-IV heart failure **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of reduced ejection fraction (left ventricular ejection fraction (LVEF) of less than or equal to 40%) **AND**
- Medical record documentation that the member is on optimized pharmacological therapy (e.g. combination of renin-angiotensin system inhibitor (ACEi/ARB/angiotensin receptor-neprilysin inhibitor), evidence based beta-blocker (metoprolol succinate/carvedilol/bisoprolol), and a mineralocorticoid receptor antagonist, diuretic) unless contraindication or not tolerated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance

Chronic Kidney Disease:

- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of chronic kidney disease **AND**
- Medical record documentation that Farxiga will be used in combination with angiotensin-converting enzyme/ angiotensin II receptor blocker (ACEi/ARB) unless contraindicated or not tolerated

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ZERBAXA (ceftolozane and tazobactam)

Clinical Summary: Zerbaxa is now indicated for use in combination with metronidazole for the treatment of adult and pediatric patients (birth to less than 18 years old) with complicated intra-abdominal infections (cIAI) caused by the following susceptible Gram-negative and Gram-positive microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, and Streptococcus salivarius*.

Zerbaxa is now indicated for the treatment of adult and pediatric patients (birth to less than 18 years old) with complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa*.

Current formulary status: Zerbaxa is currently covered as a medical benefit medication with the following prior authorization criteria:

Recommendation: There are no changes to formulary status, authorization duration, or quantity limits recommended at this time. However, it is recommended to add the following criteria to the current policy to reflect the updated indication:

- Medical record documentation that the member is greater than or equal to 18 years of age for the indication of Diagnosis of Hospital-acquired Bacterial Pneumonia or Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa,* or *Serratia marcescens*.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ZULRESSO (brexanolone)

Clinical Summary: Zulresso is now indicated for the treatment of postpartum depression (PPD) in patients 15 years and older. Previously, it was approved for treatment of PPD in adult patients.

Current formulary status: Medical benefit requiring prior authorization.

Recommendation: There are no changes recommended to the formulary placement or auth duration of Zulresso. The following changes are recommended to the prior authorization criteria in Medical Benefit Policy 201.0 to incorporate the change regarding age.

- Prescribed by (or in consultation with) a psychiatrist **AND**
- Medical record documentation of age greater than or equal to 15 years **AND**
- Medical record documentation of a diagnosis postpartum depression (PPD) as defined by ALL of the following:
  - Patient has a diagnosis of a major depressive episode **AND**
  - Patient experienced onset of symptoms within the third trimester or within 4 weeks of delivery

  AND
- Medical record documentation that patient is less than or equal to 6 months postpartum **AND**
- Medical record documentation that current depressive episode is moderate to severe based on a standardized and validated questionnaire/scale (e.g. a score of greater than 10 on the Patient Health Questionnaire (PHQ-9), a score of greater than or equal to 17 on the Hamilton Depression Rating Scale (HAM-D), etc.)

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

UPDATES

PRETOMANID

The CDC recently revised their definition of drug-resistant tuberculosis to:

- MDR TB: caused by an organism that is resistant to at least isoniazid and rifampin
- Pre-XDR TB: caused by an organism that is resistant to isoniazid, rifampin, and a fluroquinolone OR by an organism that is resistant to isoniazid, rifampin, and a second-line injectable (amikacin, capreomycin, and kanamycin)
- **XDR TB: caused by an organism that is resistant to isoniazid, rifampin, a fluroquinolone, and a second-line injectable (amikacin, capreomycin, and kanamycin) OR by an organism that is resistant to isoniazid, rifampin, a fluroquinolone, and bedaquiline or linezolid**

It is recommended to update the "Note to Reviewer" to match the CDC's definition of XDR-TB to:

- TI/NR MDR-TB (Treatment-Intolerant or Nonresponsive Multi-Drug Resistant TB). MDR-TB organisms are resistant to rifampin and isoniazid and possibly additional agents.
- XDR-TB (Extensively Drug Resistant TB). These organisms are resistant to isoniazid, rifampin, ~~and fluoroquinolones as well as either aminoglycosides and/or capreomycin~~ a fluroquinolone, and a second-line injectable (amikacin, capreomycin, and kanamycin) OR are resistant to isoniazid, rifampin, a fluroquinolone, and bedaquiline or linezolid

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Voting responses were received from 27 of 47 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on September 20th, 2022 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.