RX.PA.048.CCH ACTEMRA (TOCILIZUMAB) INTRAVENOUS

The purpose of this policy is to define the prior authorization process for Actemra® (tocilizumab) intravenous.

Actemra® (tocilizumab) intravenous is indicated for the treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs
- Patients 2 years of age or older with active polyarticular juvenile idiopathic arthritis
- Patients 2 years of age or older with active systemic juvenile idiopathic arthritis
- Patients 2 years of age or older with Chimeric Antigen Receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
- Adult patients with giant cell arteritis
- Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

DEFINITIONS

ALT – alanine aminotransferase

AST – aspartate aminotransferase

DMARDs – Disease-Modifying Anti-Rheumatic Drugs

TNF – Tumor Necrosis Factor

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Actemra® (tocilizumab) intravenous, is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:
Must meet all of the criteria listed under the respective diagnosis:

For all diagnoses:

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.TB test (T-Spot)]
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD [such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast)]
- Must have no evidence of infection
- Must have the following laboratory values:
    - AST and ALT laboratory values <1.5x upper limit of normal
    - Absolute neutrophil count >2,000cells/mm^3
    - Platelet count >100,000cells/mm^3
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling.

1. Rheumatoid Arthritis:

- Must be prescribed by or in consultation with a rheumatologist
- Must be age 18 years or older
- Must have a diagnosis of moderate to severely active rheumatoid arthritis
- Must have an adequate trial (of at least 3 months) of methotrexate to a therapeutic dose of 15mg per week with an inadequate response
    - Members with significant side effects/toxicity or who have a contraindication to methotrexate, must have an adequate trial of at least 3 months of a different conventional DMARD (such as leflunomide, hydroxychloroquine, or sulfasalazine) with an inadequate response, or significant side effect/toxicity, or have a contraindication to these therapies (see Appendix 1)
- Must have an adequate trial (of at least 3 months) of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with an inadequate response, or significant side effects/toxicities, or have a contraindication to these therapies
    - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

2. **Juvenile Idiopathic Arthritis with systemic symptoms, includes systemic juvenile idiopathic arthritis (SJIA):**
   - Must be prescribed by or in consultation with a pediatric rheumatologist
   - Must be age 2 years or older
   - Must have a diagnosis of active systemic juvenile idiopathic arthritis. Chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other diagnoses must be provided.
   - Chart documentation must demonstrate ALL of the following:
     - History of fever for at least 2-week duration
     - History of at least 1 of the following:
       - Evanescent rash (a macular salmon-colored rash on trunk and extremities that is transient)
       - History of arthritis in 1 or more joints
       - Generalized lymph node enlargement
       - Hepatomegaly or splenomegaly
       - Pericarditis, pleuritis, or peritonitis

3. **Juvenile Idiopathic Arthritis without systemic symptoms, includes polyarticular juvenile idiopathic arthritis (PJIA):**
   - Must be prescribed by or in consultation with a pediatric rheumatologist
   - Must be age 2 years or older
   - Must have a diagnosis of moderately to severely active juvenile idiopathic arthritis
   - Must have an adequate trial (of at least 3 months) of methotrexate or a different conventional DMARD (such as leflunomide or sulfasalazine) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies (see Appendix 1)
     - If no response is observed after at least 6 weeks of therapy on a conventional DMARD, member does not need to complete the 3-month trial before either changing to monotherapy or adding on therapy with a biologic
   - Must have an adequate trial (of at least 3 months) of at least 2 preferred biologic or targeted synthetic DMARDs (such as TNF-alpha inhibitors or JAK inhibitors) with an inadequate response, or significant side effects/toxicity, or have a contraindication to these therapies
     - Preferred alternatives covered through the pharmacy benefit may be found via https://countycare.com/formulary-tool/

4. **Chimeric Antigen Receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)**
   - Must be age 2 years or older
   - Must have received CAR T-cell treatment
   - Must be prescribed by or in consultation with an oncologist or hematologist

5. **Giant Cell Arteritis (GCA)**
   - Must be age 18 years or older
   - Must be prescribed by or in consultation with a rheumatologist
   - Must have a diagnosis of Giant Cell Arteritis
   - Must have an adequate trial of a systemic corticosteroid with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

6. **Systemic Sclerosis – Associated Interstitial Lung Disease (SSc-ILD)**
   - Must be age 18 years or older
   - Must be prescribed by or in consultation with a pulmonologist or a rheumatologist
   - Must have a diagnosis of Systemic Sclerosis – Associated Interstitial Lung Disease
   - Must have an adequate trial (of at least 3 months) of mycophenolate mofetil or cyclophosphamide with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

Reauthorization Criteria:

All prior authorization renewals for diagnoses other than CRS are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation of the following:

- Must have the following laboratory values:
  - AST and ALT laboratory values <5x upper limit of normal
  - Absolute neutrophil count >500cells/mm^3
  - Platelet count >50,000cells/mm^3
- The member's condition has improved based upon the prescriber's assessment while on therapy
- Member must be prescribed a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must not be used in combination with a biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD [such as Xeljanz (tofacitinib), Olumiant (baracitinib), or Otezla (apremilast)]

Requests for CRS re-authorization may be extended based upon chart documentation from the prescriber supporting the rationale for continued treatment.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	CRS: Up to 1 month All other diagnoses: Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
IV solution	800 mg (40 mL) per 28 days

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

APPENDIX 1

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin
• Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease • Breastfeeding • Drug interaction • Cannot be used due to risk of treatment-related toxicity (e.g., true allergy, severe side effects that cannot be resolved with dosage or administration modification) • Pregnancy or currently planning pregnancy • Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, renal impairment)

HCPCS CODE(S)

HCPCS Code	Description
J3262	INJECTION TOCILIZUMAB 1 MG

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial review	3/22