Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Actemra (tocilizumab) Intravenous***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2016***

Last P & T Committee Approval Date: *December 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

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)

DEFINITIONS

ALT – alanine aminostransferase

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 Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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

PROCEDURE

*****Please Note: When coverage of Actemra is requested through the pharmacy benefit, please refer to policies RX.008.2 Exceptions Due to Medical Necessity and RX.011 Request for Non-Covered Medications. This policy, RX.PA.135.1.E (B), is for requests for Actemra Intravenous on the Medical Benefit only.*****

Initial Authorization Criteria:

1. **PLAN DESIGN SUMMARY**
   Requests for Actemra are subject to the preferred medical drug list program. This program applies to non-preferred autoimmune products used in the treatment of plaque psoriasis, inflammatory joint related conditions, or inflammatory bowel disease. Coverage for these products (those which are non-preferred and not covered for the prescribed indication) is provided based on clinical circumstances that would exclude the use of the preferred product(s) for the indication. Coverage for non-preferred products will continue in situations where the patient is currently receiving treatment.

   Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Disease-modifying antirheumatic drugs for autoimmune conditions

	Products*
Preferred	• Remicade **(infliximab)** • Simponi Aria **(golimumab, intravenous)**
Non-preferred	• Actemra **(tocilizumab)** • Cimzia **(certolizumab pegol)** • Entyvio **(vedolizumab)** • Ilumya **(tildrakizumab-asmn)** • Inflectra **(infliximab-dyyb)** • Renflexis **(infliximab-abda)** • Stelara **(ustekinumab)** • Orencia (**abatacept)**

*If applicable for approved indication

Requests for Actemra on the Medical Benefit must meet one of the following exception criteria in addition to clinical criteria:

1. ***EXCEPTION CRITERIA (Use for Non-Preferred Requests Only)***

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product(s) (as applicable).

Coverage for a non-preferred product is provided when ANY of the following criteria are met:

A. Actemra, Cimzia, Entyvio, Ilumya, Orencia and Stelara
   1. Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs
   2. Member has a documented inadequate response or intolerable adverse event with all of the preferred product(s) indicated for the condition being treated, unless there is a documented clinical reason to avoid TNF inhibitors
      i. History of demyelinating disorder
      ii. History of congestive heart failure
      iii. History of hepatitis B virus infection
      iv. Autoantibody formation/lupus-like syndrome
      v. Risk of lymphoma
   3. Requested product is Cimzia and member is currently pregnant or breastfeeding

B. Inflectra and Renflexis

Member has a documented intolerable adverse event with the preferred product, Remicade

III. CLINICAL CRITERIA (*Use for ALL Drug Requests on the Medical Benefit*)

Must meet criteria for all diagnoses in addition to that 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 currently not be using a tumor necrosis factor (TNF)-blocking agent or other biologic agents in combination with Actemra
- 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 >2000cells/mm3
    - Platelet count >100,000cells/mm3

1. Rheumatoid Arthritis:

- Must be prescribed by 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 with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
    - Members with significant side effects/toxicity or who have a contraindication to methotrexate, must have an adequate trial of at least 3 months of leflunomide, hydroxychloroquine, minocycline, or sulfasalazine with an inadequate response, or significant side effect/toxicity, or have a contraindication to these therapies

2. Juvenile Idiopathic Arthritis with systemic symptoms, includes systemic juvenile idiopathic arthritis (SJIA):

- Must be prescribed by 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 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 4 weeks with a non-steroidal anti-inflammatory drug (NSAID) at an anti-inflammatory dose, with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- Must have an adequate trial (of at least 3 months), of methotrexate or leflunomide with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

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

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 from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and no evidence of infection. Additionally, the member must have the following laboratory values for reauthorization of treatment:

- AST and ALT laboratory values <5x upper limit of normal
- Absolute neutrophil count >500cells/mm3
- Platelet count >50,000cells/mm3

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

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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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
Annual review	*02/16, 02/17, 02/18*
Criteria update	*12/16, 05/18*
Preferred Product Update (effective 4/1/18)	*02/18*
Added procedural clarification	*6/18*
Preferred Product Update (effective 1/1/19)	*12/18*