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Department of Origin: Pharmacy	**Effective Date:** 12/06/2023
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	**Date Approved:** 12/06/2023
Pharmacy Clinical Policy Document: Actemra Infusion Prior Authorization	**Replaces Effective Policy Dated:** 5/24/2023
Reference #: PC/A012	**Page** 1 of 4

PURPOSE:
The intent of the Actemra Infusion Prior Authorization Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit documentation for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certification of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must be tried, and the most cost-effective alternative must be requested for coverage consideration.

Self-administered formulations are taken into consideration as the most cost-effective alternative for any provider-administered medication request and may result in a requirement to use the self-administered formulation for that particular medication when applicable.

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I or II

Table 1: Actemra (tocilizumab) infusion

Biologic	Route of Administration	Biosimilar?	Molecule	Drug Class
Actemra	Intravenous infusion	No	Tocilizumab	IL-6 receptor inhibitor
Tofidence	Intravenous infusion	Yes	Tocilizumab	IL-6 receptor inhibitor

I. Initial request for tocilizumab infusion – must satisfy any of the following: A or B*.
   A. Must satisfy all of the following: 1-3
      1. Must satisfy ONE of the following: a – b
         a. Diagnosis of moderate to severe active rheumatoid arthritis in a member equal to or greater than 18 years of age; or
         b. Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA) or systemic juvenile idiopathic arthritis (SJIA) in a member equal to or greater than 2 years of age; and

      2. Prescribed by or in consultation with a rheumatologist; and

      3. Member has not responded to, is intolerant to, responds to but cannot taper off without recurrent symptoms, or is a poor candidate for two self-administered biologic drugs with different mechanisms of action (ie from different drug classes) (Tables 2 &3).

   B. Must be used to treat ONE of the following: 1 – 3

1. Chimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome; or
2. Giant Cell Arteritis that is refractory/unresponsive to glucocorticoids in a member equal to or greater than 18 years of age; or
3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) in a member equal to or greater than 18 years of age.

II. Continuation request – allow up to 12 months.

Table 2: Self-Administered Biologic Drugs for JIRA/JRA*

Drug	Generic/ Molecule Name	Is this a Biosimilar?	Generic Available	Route of Administration	Recommended Age	Drug Class
Actemra	tocilizumab	N	N	subcutaneous injection	age 2 and older	IL-6 receptor inhibitor
Enbrel	etanercept	N	N	subcutaneous injection	age 2 and older	TNFα blocker
Humira	adalimumab	N	N	subcutaneous injection	age 2 and older	TNFα blocker
Ilaris	canakinumab	N	N	subcutaneous injection	age 2 and older	IL-1α receptor antagonist
Orencia	abatacept	N	N	subcutaneous injection	age 2 and older	T lymphocyte inhibitor
Xeljanz/XR	tofacitinib	N	N	oral	age 2 and older	JAK inhibitor

* This list of drugs is not exhaustive, nor does it ensure coverage. Please check member's prescription benefit.

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Table 3: Self-Administered Biologic Drugs for Rheumatoid Arthritis*

Drug	Generic/ Molecule Name	Is this a Biosimilar?	Generic Available	Route of Administration	Recommended Age	Drug Class
Actemra	tocilizumab	N	N	subcutaneous injection	adult	IL- 6 antagonist
Cimzia	certolizumab	N	N	subcutaneous injection	adult	TNFα blocker
Enbrel	etanercept	N	N	subcutaneous injection	not age specific	TNFα blocker
Humira	adalimumab	N	N	subcutaneous injection	adult	TNFα blocker
Kevzara	sarilumab	N	N	subcutaneous injection	adult	IL-6 antagonist
Kineret	anakinra	N	N	subcutaneous injection	adult	IL-1 antagonist
Olumiant	baricitinib	N	N	oral	adult	JAK inhibitor
Orencia	abatacept	N	N	subcutaneous injection	adult	T lymphocyte inhibitor
Rinvoq	upadacitinib	N	N	oral	adult	JAK inhibitor
Simponi	golimumab	N	N	subcutaneous injection	adult	TNFα blocker
Xeljanz/XR	tofacitinib	N	N	oral	adult	JAK inhibitor

* This list of drugs is not exhaustive, nor does it ensure coverage. Please check member's prescription benefit.

DEFINITIONS:

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Biologic/biological: biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

BACKGROUND:
This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications and dosing, expert consensus opinion and/or available reliable evidence.
Prior authorization: Yes, per network provider agreement – up to 12 months. This is subject to the member's contract benefits.

CODING:
HCPCS – 2023
J3262 Injection, tocilizumab, 1mg (Actemra)

REFERENCES:

1. Actemra [package insert]. South San Francisco, CA. Genentech. Inc.; 2022.
2. Agency for Healthcare Research and Quality. Drug Therapy for Early Rheumatoid Arthritis in Adults – An Update. 2017. Retrieved from https://effectivehealthcare.ahrq.gov/products/rheumatoid-arthritis-medicine-update/research-protocol Accessed 10-25-23.
3. Kimura, Y. Systemic juvenile idiopathic arthritis: Treatment. (Topic 6400 Version 35.0; last updated 1/30/23) In: TePas, ed. *UpToDate.* Waltham, Mass.: UpToDate; 2023. www.uptodate.com. Accessed 10-12-23.
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6. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
7. Medical Policy: MP/C009 Coverage Determination Guidelines
8. Pharmacy Clinical Policy: PP/O001 Off-label Drug Use
9. Pharmacy Clinical Policy: PP/O002 Off-label Drug Use for Business Process Outsourced Clients
10. Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence

DOCUMENT HISTORY

Created Date: 04/16/2021
Reviewed Date: 4/7/2022, 3/7/2023, 10/12/2023
Revised Date:

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PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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Minneapolis, MN 55459-0212
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Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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