Clinical Policy: Tocilizumab (Actemra)
Reference Number: HIM.PA.SP32
Effective Date: 05/17
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tocilizumab (Actemra®) is an interleukin-6 (IL-6) receptor antagonist.

FDA approved indication
Actemra 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 disease-modifying anti-rheumatic drugs (DMARDs)
- For the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
- For the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Rheumatoid Arthritis (RA) (must meet all)**:**

1. Diagnosis of RA and at least one of the following:
   a. At least five inflamed joints;
   b. Elevation in the erythrocyte sedimentation rate (ESR) and/or serum C-reactive protein (CRP) concentration;
   c. Positive rheumatoid factor and/or anticyclic citrullinated peptide (CCP) antibodies;
   d. Evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling;
2. Prescribed by or in consultation with a rheumatologist;
3. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
4. Failure of all of the following therapies (a, b, and c), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Humira or Enbrel;
   b. Methotrexate for ≥ 3 consecutive months;
   c. If methotrexate is contraindicated, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months;
5. Dose does not exceed the following:
   a. Intravenous (IV): 800 mg every 4 weeks;

b. Subcutaneous (SC): 162 mg every week.

Approval duration: 6 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA);
2. Prescribed by or in consultation with a rheumatologist;
3. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
4. Failure of one of the following therapies (a, and b, and c), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Humira;
   b. Methotrexate for ≥ 3 consecutive months;
   c. If methotrexate is contraindicated, failure of sulfasalazine or leflunomide for ≥ 3 consecutive months;
5. Prescribed route of administration is IV infusion;
6. Prescribed frequency is once every 4 weeks.

Approval duration: 6 months

C. Systemic Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of systemic juvenile idiopathic arthritis (SJIA);
2. Prescribed by or in consultation with a rheumatologist;
3. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
4. Failure of one of the following therapies (a and b), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. A non-steroidal anti-inflammatory drug (NSAID) for 1 month and a corticosteroid for 2 weeks;
   b. Methotrexate or leflunomide for ≥ 3 consecutive months;
5. Prescribed route of administration is IV infusion;
6. Prescribed frequency is once every 2 weeks.

Approval duration: 6 months

D. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a, b, or c):
   a. For RA (i or ii) :
      i. IV: 800 mg every 4 weeks;
      ii. SC: 162 mg every week;
   b. For PJIA: once every 4 weeks;

c. For SJIA: once every 2 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CCP: citrullinated peptide
CRP: C-reactive protein
DMARDs: disease-modifying antirheumatic drugs
ESR: erythrocyte sedimentation rate
FDA: Food and Drug Administration
IL: interleukin
IV: intravenous
NSAID: non-steroidal anti-inflammatory drug
PJIA: polyarticular juvenile idiopathic arthritis
RA: rheumatoid arthritis
SC: subcutaneous
SJIA: systemic juvenile idiopathic arthritis

V. References

1. Actemra Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2016. Available at: https://www.actemra.com/. Accessed January 30, 2017.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol 2016 Jan;68(1):1-26.
3. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis care & research. 2011;63(4):465-482.
4. Stoll and Cron: Treatment of juvenile idiopathic arthritis: a revolution in care. Pediatric Rheumatology 2014 12:13.
5. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic

arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013 Oct;65(10):2499-512.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01/17	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.