MVP Health Care Medical Policy

Medicare Part B: Tocilizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**11/01/2023**
Approval Date:	**02/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	**Abatacept, Certolizumab, Golimumab, Infliximab, Risankizumab, Ustekinumab**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

Drugs Requiring Prior Authorization under the medical benefit

J3262 tocilizumab, 1mg injection (Actemra injection)

Overview/Summary of Evidence

Tocilizumab is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody produced in mammalian (Chinese hamster ovary) cells. It is FDA approved to treat moderate to severe rheumatoid arthritis (RA), polyarticular and systemic juvenile idiopathic arthritis (pJIA and sJIA), giant cell arteritis (GCA or temporal arteritis), systemic sclerosis-associated interstitial lung disease (SSc-ILD), and cytokine release syndrome (CRS). Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, Tocilizumab IV (Actemra) may be considered for **medical** coverage when:
   - Must be prescribed for an FDA approved indication **AND**
   - Must be ordered by or with consult from a rheumatologist/immunologist **AND**
   - Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy

B. **Giant Cell Arteritis**

   Tocilizumab may be considered for coverage for Giant Cell Arteritis when the above criteria is met **AND**:
   - Treatment must be directed by or in consultation with a Rheumatologist or Immunologist
   - Member has received high-dose glucocorticoids (prednisone 40mg to 60mg) but is unable to taper without disease flare **OR**
   - The member has a contraindication to the use of glucocorticoids

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Juvenile Idiopathic Arthritis**

   Tocilizumab to treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy **AND** there is medical necessity for use of the IV formulation instead of a self-administered formulation.
Extension requests where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Rheumatoid Arthritis**

Tocilizumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

Documentation identifies failure of nonbiologic disease modifying anti-rheumatic drugs (DMARDs) and NSAIDs if indicated

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy.
Extension requests where Tocilizumab IV (Actemra) did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

The use of Tocilizumab will not be covered for the following situations:

- Dosing, age, and/or frequency outside of the FDA approved package labeling
- Combination therapy that is not supported by current clinical guidelines

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References

1. Clinical Pharmacology. Tocilizumab (Actemra). Revised 12/22/2022. Accessed 01/04/2023
2. Fraenkel et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research Vol. 73, No. 7, July 2021, pp 924–939 DOI 10.1002/acr.24596. Available at: 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis (contentstack.io).
3. Actemra (tocilizumab) injection, for intravenous or subcutaneous use. Genentech, Inc. San Francisco, CA. Revised December 2022.
4. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis and Rheumatology. Vol 74 No. 4 April 2022, pp553-569. Available at: https://www.rheumatology.org/Portals/0/Files/ACR-JIA%20Guideline-Oligo-TMJ-sJIA-EarlyView.pdf