MVP Health Care Medical Policy

Medicare Part B: Golimumab

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, Infliximab, Risankizumab, Tocilizumab, 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

J1602 Simponi Aria (injection, golimumab)

Overview/Summary of Evidence

Golimumab is a TNF-alpha blocker (TNF blocker) available in both intravenous and subcutaneous formulations. It is FDA approved to treat moderately to severely active rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), and polyarticular juvenile idiopathic arthritis (pJIA). Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. For all indications, Simponi Aria (injection, golimumab) 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. **Rheumatoid Arthritis**
Golimumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:
    - Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
    - Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.
        - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
        - If the member has a contraindication or significant intolerance to methotrexate
            - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

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 Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Ankylosing Spondylitis**
Golimumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:
    - Member has a diagnosis of moderate to severe AS
    - Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal

pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis
    - **For members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

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 Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriatic Arthritis**
Golimumab may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:
- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.
    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

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 Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Juvenile Idiopathic Arthritis**
Golimumab 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
Extension requests where Simponi did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

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Exclusions

The use of Golimumab 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
- Diagnosis of Multiple Sclerosis

References

1. Clinical Pharmacology: Golimumab. Revised 09/30/2022. Accessed 01/05/2023.
2. Simponi ARIA (golimumab) injection. Prescribing information. Janssen Biotech, Inc. Horsham, PA. Revised February 2021.
3. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology Vol. 71, No. 1, January 2019, pp 5–32 DOI 10.1002/art.40726. 2018 American College of Rheumatology/ National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis
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

5. 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).
6. Ward Michael, Atul Deodhar et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondylosrthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. Vol 71 (No. 10). October 2019, pp 1599-1613. Available at: https://www.rheumatology.org/Portals/0/Files/AxialSpA-Guideline-2019.pdf