

Simponi Aria® (golimumab)

When requesting Simponi Aria® (golimumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

Simponi Aria is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Simponi Aria is indicated for the treatment of adult patients with active psoriatic arthritis.

Simponi Aria is indicated for the treatment of adult patients with active ankylosing spondylitis.

Coverage Guidelines

Rheumatoid Arthritis

For an initial authorization, the individual must meet all of the following criteria:

- Has had a 3-month trial of at least one biologic agent (e.g., certolizumab, etanercept, adalimumab, infliximab, abatacept); OR
- Has had a 3-month trial of at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, leflunomide); AND
- Simponi Aria is prescribed by or in consultation with a rheumatologist.

Ankylosing Spondylitis

For an initial authorization, the individual must meet the following criteria:

- Simponi Aria is prescribed by or in consultation with a rheumatologist.

Psoriatic Arthritis

For an initial authorization, the individual must meet the following criteria:

- Simponi Aria is prescribed by or in consultation with a rheumatologist or dermatologist.

For re-authorization (for all indications), the individual must meet the following criteria:

- Has had a response to Simponi Aria therapy (e.g., decreased pain or stiffness, improved function or activities of daily living).

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

Dosing Recommendation

Approve up to 2 mg/kg administered intravenously at weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

References

1. Simponi Aria® injection for intravenous use [prescribing information]. Horsham, PA: Janssen Biotech, Inc; September 2019.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019 Aug 22. [Epub ahead of print].
3. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
5. Simponi injection [prescribing information]. Horsham, PA: Centocor Ortho Biotech Inc; March 2018.
6. Rutgeerts P, Feagan BG, Marano CW, et al. Randomised clinical trial: a placebo-controlled study of intravenous golimumab induction therapy for ulcerative colitis. *Aliment Pharmacol Ther*. 2015;42(5):504-514.