

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 active psoriatic arthritis.

Simponi Aria is indicated for the treatment of active polyarticular juvenile idiopathic 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, hydroxychloroquine, and sulfasalazine); AND
- Simponi Aria is prescribed by or in consultation with a rheumatologist.

Juvenile Idiopathic Arthritis or Juvenile Rheumatoid Arthritis including juvenile spondyloarthritis/active sacroiliac arthritis

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

- Has tried one other medication for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug [NSAID], adalimumab, abatacept, etanercept); OR
- Has aggressive disease; 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

Psoriatic Arthritis (18 years of age or older), Rheumatoid Arthritis, Ankylosing Spondylitis

The recommended dose is 2 mg/kg administered intravenously at weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

Psoriatic Arthritis (less than 18 years of age), Juvenile Idiopathic Arthritis

The recommended dose is 80 mg/m² administered intravenously at weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

References

1. Simponi Aria® intravenous infusion [prescribing information]. Horsham, PA: Janssen; February 2021.
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;71(10):1599-1613.
3. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
4. 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;65(10):2499-2512.
5. 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.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol.* 2021;73(7):1108-1123.
7. Simponi injection [prescribing information]. Horsham, PA: Centocor Ortho Biotech; September 2019.
8. 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.