Simponi Aria® (golimumab)

When requesting Simponi Aria® (golimumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications 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
- Active psoriatic arthritis
- Active polyarticular juvenile idiopathic arthritis
- Adult patients with active ankylosing spondylitis

Coverage Guidelines

Rheumatoid Arthritis

The individual must meet the following criteria for an initial authorization:

- Is 18 years of age or older;
- Meets one of the following:
    - Has had a 3-month trial of at least one other biologic agent for rheumatoid arthritis (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);
- Simponi Aria is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Simponi therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Simponi, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Clinical Disease Activity Index [CDAI], Disease Activity Score [DAS] 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale [PAS]-II, Simplified Disease Activity Index [SDAI], etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain or morning stiffness, or improvement in function or activities of daily living, etc.).

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

The individual must meet the following criteria for an initial authorization:

- Is 2 years of age or older;
- Meets one of the following:
    - Has tried one other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug [NSAID], adalimumab, abatacept, etanercept); OR
    - Has aggressive disease;
- Simponi Aria is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Simponi therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Simponi, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Physician Global Assessment [MD global], Juvenile Arthritis Disease Activity Score [JDAS], Clinical Juvenile Arthritis Disease Activity Score [cJDAS], Juvenile Spondyloarthritis Disease Activity Index [JSpADA], etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain or tenderness, less fatigue, decreased duration of morning stiffness, or improvement in function or activities of daily living).

Ankylosing Spondylitis

The individual must meet both of the following criteria for an initial authorization:

- Is 18 years of age or older;
- Simponi Aria is prescribed by or in consultation with a rheumatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Simponi therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Simponi, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Ankylosing Spondylitis Disease Activity Score [ASDAS], Ankylosing Spondylitis Quality of Life Scale [ASQoL], Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], Bath Ankylosing Spondylitis Functional Index [BASFI], Bath Ankylosing Spondylitis Global Score [BAS-G], etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain or stiffness, or improvement in function or activities of daily living).

Psoriatic Arthritis

The individual must meet both of the following criteria for an initial authorization:

- Is 2 years of age or older;
- Simponi Aria is prescribed by or in consultation with a rheumatologist or dermatologist.

The individual must meet the following criteria for re-authorization:

- Has been established on Simponi therapy for at least 6 months (*Note: A patient who has received < 6 months of therapy, or who is restarting therapy with Simponi, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Disease Activity Index for Psoriatic Arthritis [DAPSA], Composite Psoriatic Disease Activity Index [CPDAI], Psoriatic Arthritis Disease Activity Score [PsA DAS], Grace Index, Minimal Disease Activity [MDA], Psoriatic Arthritis Impact of Disease [PsAID-12], etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain or morning stiffness, less fatigue, or improvement in function or activities of daily living).

Approval duration (initial): 6 months
Approval duration (renewal): 12 months

Dosing Recommendations

Adult patients with Psoriatic Arthritis, Rheumatoid Arthritis, Ankylosing Spondylitis
The recommended dose is 2 mg/kg administered intravenously at weeks 0 and 4, and every 8 weeks thereafter.

Pediatric patients with Psoriatic Arthritis and Polyarticular Juvenile Idiopathic Arthritis
The recommended dose is 80 mg/m^2 administered intravenously at weeks 0 and 4, and every 8 weeks thereafter.

References

1. Simponi Aria® intravenous infusion [prescribing information]. Horsham, PA: Janssen; April 2025.
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.
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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.
9. Onel KB, Horton DB, Lovell DJ, et al. 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 Rheumatol.* 2022 Apr;74(4):553-569.

