

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.

Approved Off-Label Compendial Use(s)

None

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have an active infection including localized infection
- Simponi Aria (golimumab) will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor, T-cell costimulation modulator)
- Is at least 18 years of age
- For an initial authorization request, an individual has been screened for latent tuberculosis (TB). For positive latent TB, an individual has started/completed or will be treated for TB prior to starting Simponi Aria (golimumab)
- For a re-authorization request, an individual's condition has improved or stabilized with Simponi Aria (golimumab) therapy

For rheumatoid arthritis:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Has moderately to severely active disease AND
- Had an inadequate response to at least 3 months of methotrexate therapy unless contraindicated or intolerant to methotrexate OR
- Had an inadequate response to at least 3 months of leflunomide or sulfasalazine unless contraindicated or intolerant to leflunomide or sulfasalazine

For psoriatic arthritis:

1. Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Had an inadequate response to methotrexate unless contraindicated or intolerant to methotrexate

For ankylosing spondylitis:

- Had an inadequate response or intolerance to prior biologic agent OR
- Had an inadequate response or intolerance to at least 2 different non-steroidal anti-inflammatory drugs (NSAIDs) unless contraindicated

Approval duration (initial and renewal): 12 months

Dosing Recommendations

The recommended dose is 2 mg/kg administered intravenously over 30 minutes at weeks 0 and 4, then every 8 weeks

References

1. Simponi Aria prescribing information. Horsham, PA; Janssen Biotech, Inc. February 2018.
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3. Smolen JS, Landewe R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis* Published Online First: [March 6, 2017] doi:10.1136/annrheumdis-2016-210715
4. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008;58:851-864.
5. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol* 2011;65:137-174.
6. van der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis* Published Online First: [January 13, 2017] doi:10.1136/annrheumdis-2016-210770.
7. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of American/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. 2015 *Arthritis & Rheumatology*.