

## 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*

- Had a 3-month trial of at least one biologic agent (e.g., certolizumab, etanercept, adalimumab, infliximab, abatacept) OR
- 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

#### **Psoriatic Arthritis and Ankylosing Spondylitis:**

##### *For an initial authorization*

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

##### ***For a re-authorization (for all indications)***

- An individual is responding 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

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® injection for intravenous use [prescribing information]. Horsham, PA: Janssen Biotech, Inc; May 2018.
  2. Weinblatt ME, Bingham CO 3rd, Mendelsohn AM, et al. Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GO-FURTHER trial. *Ann Rheum Dis*. 2013;72(3):381-389.
  3. 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.
  4. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
  5. 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.
  6. Smolen JS, Aletaha D, Bijlsma JW, et al; T2T Expert Committee. Treating rheumatoid arthritis to target: recommendations of an international task force. *Ann Rheum Dis*. 2010;69:631-637.
  7. Singh JA, Cameron DR. Summary of AHRQ's comparative effectiveness review of drug therapy for rheumatoid arthritis (RA) in adults--an update. *J Manag Care Pharm*. 2012;18(4 Suppl C):S1-18.
  8. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2016;68(2):282-298.
  9. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
- Coates LC, Kavanaugh A, Mease PJ, et al. Group for research and assessment of psoriasis and psoriatic arthritis: treatment recommendations for psoriatic arthritis 2015. *Arthritis Rheumatol*. 2016;68(5):1060-1071.