

POLICY: Simponi Aria® (golimumab injection, for intravenous [IV] infusion)

EFFECTIVE DATE: 1/1/2021

LAST REVISION DATE: 12/20/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Simponi Aria, a tumor necrosis factor inhibitor (TNFi), is indicated for the following conditions:¹

1. **Ankylosing spondylitis**, in adults with active disease.
2. **Polyarticular juvenile idiopathic arthritis**, in patients ≥ 2 years of age with active disease.
3. **Psoriatic arthritis**, in patients ≥ 2 years of age with active disease.
4. **Rheumatoid arthritis**, in combination with methotrexate for treatment of adults with moderately to severely active disease.

Simponi Aria is administered by intravenous infusion by a healthcare professional. Efficacy has not been established for patients switching between the Simponi Aria and Simponi subcutaneous.

Guidelines

TNFis feature prominently in guidelines for treatment of inflammatory conditions.

- **Juvenile Idiopathic Arthritis (JIA):** There are guidelines from American College of Rheumatology (ACR) and the Arthritis Foundation for the treatment of JIA (2021) which address oligoarthritis and temporomandibular joint (TMJ) arthritis. For oligoarthritis, a biologic is recommended following a trial of a conventional synthetic DMARD.⁹ In patients with TMJ arthritis, scheduled nonsteroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids are recommended first-line. A biologic is a therapeutic option if there is an inadequate response or intolerance. Additionally, rapid escalation to a biologic \pm conventional synthetic DMARD (methotrexate preferred) is often appropriate given the impact and destructive nature of TMJ arthritis. In these guidelines, there is not a preferred biologic that should be initiated for JIA. Simponi (golimumab, route not specified) is among the TNFis recommended in the ACR/Arthritis Foundation guidelines for the treatment of JIA (2019) specific to juvenile non-systemic polyarthritis, sacroiliitis, and enthesitis.⁴ TNFis are the biologics recommended for polyarthritis, sacroiliitis, enthesitis. Biologics are recommended following other therapies (e.g., following a conventional synthetic disease-modifying antirheumatic drug [DMARD] for active polyarthritis or following a nonsteroidal anti-inflammatory drug [NSAID] for active JIA with sacroiliitis or enthesitis). However, there are situations where initial therapy with a biologic may be preferred over other conventional therapies (e.g., if there is involvement of high-risk joints such as the cervical spine, wrist, or hip; high disease activity; and/or those judged to be at high risk of disabling joint damage).
- **Psoriatic Arthritis:** Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with psoriatic arthritis, and in those who were previously treated with an oral therapy.⁵
- **Rheumatoid Arthritis:** Guidelines from the ACR (2021) recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.⁶
- **Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the ACR/Spondylitis Association of America/Spondyloarthritis

Research and Treatment Network (2019).² Following primary nonresponse to a TNFi, an interleukin (IL)-17 blocker is recommended; however, if the patient is a secondary nonresponder, a second TNFi is recommended over switching out of the class. In patients with a contraindication to a TNFi, use of an IL-17 blocker is recommended over traditional oral agents such as methotrexate or sulfasalazine.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Simponi Aria. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration listed below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Simponi Aria as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Simponi Aria to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Simponi Aria is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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- 1. Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 6 months if prescribed by or in consultation with a rheumatologist.
 - B) Patient is Currently Receiving Simponi Aria or Subcutaneous.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i.** Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).
 - ii.** Patient meets at least one of the following (a or b):
 1. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi Aria or subcutaneous); OR
Note: Examples of objective measures include 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), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 2. Compared with baseline (prior to initiating Simponi Aria or subcutaneous), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Dosing. Approve up to 2 mg/kg as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

2. Juvenile Idiopathic Arthritis (JIA). Approve for the duration noted if the patient meets ONE of the following (A or B):

Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthritis/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):

i. Patient meets ONE of the following conditions (a or b):

a) Patient has tried one other medication for this condition; OR

Note: Examples of other medications for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of a biologic other than the requested medication also counts as a trial of one medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for JIA.

b) Patient has aggressive disease, as determined by the prescriber; AND

ii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi Aria or subcutaneous); OR

Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating Simponi Aria or subcutaneous), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living.

Dosing. Approve up to 80 mg/m² as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

3. Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or dermatologist.

B) Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least one of the following (a or b):

- a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi Aria or subcutaneous); OR
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
- b) Compared with baseline (prior to initiating Simponi Aria or subcutaneous), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

Dosing. Approve ONE of the following regimens (A or B):

- A) Patient is \geq 18 years of age: Approve up to 2 mg/kg as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter; OR
- B) Patient is $<$ 18 years of age: Approve up to 80 mg/m² as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

4. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
 - i. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to “step back” and try a conventional synthetic DMARD.
 - ii. The medication is prescribed by or in consultation with a rheumatologist.
- B) Patient is Currently Receiving Simponi Aria or Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received $<$ 6 months of therapy or who is restarting therapy with Simponi Aria or subcutaneous is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
 - b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

Dosing. Approve up to 2 mg/kg as an intravenous infusion at Weeks 0 and 4, then not more frequently than once every 8 weeks thereafter.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Simponi Aria is not recommended in the following situations:

- 1. Concurrent Use with Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Data are lacking evaluating concomitant use of Simponi Aria in combination with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse events with combinations and lack controlled trial data in support of additive efficacy. **Note:** This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Simponi Aria.
- 2. Ulcerative Colitis.** Simponi subcutaneous injection is indicated for treatment of ulcerative colitis.⁷ A single-dose induction study in patients with ulcerative colitis (n = 176) evaluated doses of 1 mg/kg, 2 mg/kg, and 4 mg/kg; however, enrollment was stopped due to lower than expected efficacy in the dose-ranging Phase II portion of the study.⁸ Appropriate dosing of Simponi Aria in ulcerative colitis is unclear.
- 3.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.
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.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|---|-------------|
| Annual Revision | <p>Ankylosing Spondylitis: Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving Simponi Aria or subcutaneous, it was clarified that this applies to a patient who has received the product for ≥ 6 months. A requirement was added for a patient who is currently receiving Simponi Aria or subcutaneous to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Juvenile Idiopathic Arthritis: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to at least one biologic other than the requested drug. For a patient currently receiving Simponi Aria or subcutaneous, it was clarified that this applies to a patient who has received the product for ≥ 6 months. A requirement was added for a patient who is currently receiving Simponi Aria or subcutaneous to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Psoriatic Arthritis: Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving Simponi Aria or subcutaneous, it was clarified that this applies to a patient who has received the product for ≥ 6 months. A requirement was added for a patient who is currently receiving Simponi Aria or subcutaneous to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Rheumatoid Arthritis: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to at least one biologic other than the requested drug. For a patient currently receiving Simponi Aria or subcutaneous, it was clarified that this applies to a patient who has received the product for ≥ 6 months. A requirement was added for a patient who is currently receiving Simponi Aria or subcutaneous to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.</p> | 11/30/2022 |
| Annual Revision | No criteria changes. | 12/20/2023 |

APPENDIX

| | Mechanism of Action | Examples of Inflammatory Indications* |
|--|----------------------------------|--|
| Biologics | | |
| Adalimumab SC Products (Humira [®] , biosimilars) | Inhibition of TNF | AS, CD, JIA, PsO, PsA, RA, UC |
| Cimzia[®] (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, nr-axSpA, PsO, PsA, RA |
| Etanercept SC Products (Enbrel [®] , biosimilars) | Inhibition of TNF | AS, JIA, PsO, PsA |
| Zymfentra[®] (infliximab-dyyb SC injection) | Inhibition of TNF | CD, UC |
| Infliximab IV Products (Remicade [®] , biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC |
| Simponi[®], Simponi[®] Aria[™] (golimumab SC injection, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA |
| Actemra[®] (tocilizumab IV infusion, tocilizumab SC injection) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA |
| Kezara[®] (sarilumab SC injection) | Inhibition of IL-6 | RA, PMR |
| Orencia[®] (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA |
| Rituximab IV Products (Rituxan [®] , biosimilars) | CD20-directed cytolytic antibody | RA |
| Kineret[®] (anakinra SC injection) | Inhibition of IL-1 | JIA [^] , RA |
| Stelara[®] (ustekinumab SC injection, ustekinumab IV infusion) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC |
| Siliq[™] (brodalumab SC injection) | Inhibition of IL-17RA | PsO |
| Bimzelx[®] (bimekizumab-bkzx SC injection) | Inhibition of IL-17A and IL-17F | PsO |
| Cosentyx[®] (secukinumab SC injection, secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA IV formulation: AS, nr-axSpA, PsA |
| Taltz[®] (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA |
| Ilumya[™] (tildrakizumab-asnm SC injection) | Inhibition of IL-23 | PsO |
| Skyrizi[®] (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO IV formulation: CD |
| Tremfya[™] (guselkumab SC injection) | Inhibition of IL-23 | PsO |
| Entyvio[™] (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | SC formulation: UC IV formulation: CD, UC |
| Oral Therapies/Targeted Synthetic DMARDs | | |
| Otezla[®] (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| Cibinqo[™] (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| Olumiant[®] (baricitinib tablets) | Inhibition of JAK pathways | RA |
| Rinvoq[®] (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, nr-axSpA, RA, PsA, UC |
| Sotyktu[™] (deucravacitinib tablets) | Inhibition of TYK2 | PsO |
| Xeljanz[®] (tofacitinib tablets) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| Xeljanz[®] XR (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC |

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; PMR – Polymyalgia rheumatic; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; TYK2 – Tyrosine kinase 2.