Effective Date **4/1/2023**
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Coverage Policy Number **IP0238**

Golimumab Intravenous

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for golimumab intravenous (Simponi Aria®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Golimumab intravenous (Simponi Aria) is considered medically necessary when ONE of the following is met:

1. **Ankylosing Spondylitis.** Individual meets **BOTH** of the following criteria (A and B):
   A. Documentation of **ONE** of the following (i or ii):
      i. Failure, contraindication, or intolerance to **ONE** non-steroidal anti-inflammatory drug (NSAID)
      ii. Already tried a biologic or targeted synthetic DMARD for Ankylosing Spondylitis

B. Medication is being prescribed by, or in consultation with, a rheumatologist

Dosing for Ankylosing Spondylitis. Individual meets the following regimen:
A. Up to 2 mg/kg intravenous infusion at Weeks 0 and 4, then once every 8 weeks

2. **Polyarticular Juvenile Idiopathic Arthritis (includes Juvenile Rheumatoid Arthritis, Juvenile Spondyloarthropathy/Active Sacroiliac Arthritis).** Individual meets **BOTH** of the following criteria (A and B):
   A. 2 years of age or older
   B. Medication is prescribed by, or in consultation with, a rheumatologist

   Dosing for Polyarticular Juvenile Idiopathic Arthritis. Individual meets the following regimen:
   A. Up to 80 mg/m^2 intravenous infusion at Weeks 0 and 4, then once every 8 weeks

3. **Psoriatic Arthritis.** Individual meets the following criterion:
   A. Medication is prescribed by, or in consultation with, a rheumatologist or dermatologist

   Dosing for Psoriatic Arthritis. Individual meets **ONE** of the following regimens (A or B):
   A. 18 years of age or older, up to 2 mg/kg intravenous infusion at Weeks 0 and 4, then once every 8 weeks
   B. Less than 18 years of age, up to 80 mg/m^2 intravenous infusion at Weeks 0 and 4, then once every 8 weeks

4. **Rheumatoid Arthritis.** Individual meets **BOTH** of the following criteria (A and B):
   A. Documentation of **ONE** of the following (i or ii):
      i. Failure to **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD), unless contraindicated or intolerant
      ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Rheumatoid Arthritis
   B. Medication is prescribed by, or in consultation with, a rheumatologist

   Dosing for Rheumatoid Arthritis. Individual meets the following regimen:
   A. Up to 2 mg/kg intravenous infusion at Weeks 0 and 4, then once every 8 weeks

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Golimumab intravenous (Simponi Aria) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Golimumab intravenous (Simponi Aria) is considered experimental, investigational or unproven for **ANY** other use including the following (this list may not be all inclusive):

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. 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.

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.[5] 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.[6] Appropriate dosing of Simponi Aria in ulcerative colitis is unclear.

Coding

This list of codes may not be all-inclusive.
Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1602	Injection, golimumab, 1 mg, for intravenous use

Background

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

- **Ankylosing spondylitis**, in adults with active disease.
- **Polyarticular juvenile idiopathic arthritis**, in patients ≥ 2 years of age with active disease.
- **Psoriatic arthritis**, in patients ≥ 2 years of age with active disease.
- **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):** Simponi (golimumab, route not specified) is among the TNFis recommended in the American College of Rheumatology (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. Actemra® (tocilizumab intravenous, tocilizumab subcutaneous) and Orencia® (abatacept intravenous, abatacept subcutaneous) are also among the biologics recommended for polyarthritis. 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.

Dosage and Administration
Adult patients with Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis:
- 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter

Pediatric patients with polyarticular Juvenile Idiopathic Arthritis and Psoriatic Arthritis:
- 80 mg/m2 intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter

Dosage Forms and Strengths
Injection: 50 mg/4 mL (12.5 mg/mL) solution in a single-dose vial

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.

APPENDIX

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Humira	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitor; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology				Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
	Janus Kinases Inhibitors					
Olumiant	√	--	--	--	--	--
Rinvoq	√	--	√	√	--	√
Xeljanz tablets	√	√#	√	√	--	√
Xeljanz oral solution	--	√#	--	--	--	--
Xeljanz XR	√	--	√	√	--	√
Phosphodiesterase Type 4 Inhibitor						
Otezla	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator						
Zeposia	--	--	--	--	--	√

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.