Clinical Policy: Golimumab (Simponi, Simponi Aria)

Reference Number: IN.PHAR.253
Effective Date: 07.16
Last Review Date: 10.22
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Golimumab (Simponi®, Simponi Aria®) is a tumor necrosis (TNF) blocker.

FDA Approved Indication(s)

Simponi is indicated for the treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX)
- Adult patients with active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine (6-MP) for:
  - inducing and maintaining clinical response
  - improving endoscopic appearance of the mucosa during induction
  - inducing clinical remission
  - achieving and sustaining clinical remission in induction responders

Simponi Aria is indicated for the treatment of:

- Adult patients with moderately to severely active RA in combination with methotrexate
- Active PsA in patients 2 years of age and older
- Adult patients with active AS
- Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Simponi and Simponi Aria are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all)**:**

1. Diagnosis of AS;
2. Dose does not exceed one of the following (a or b):
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

B. Polyarticular Juvenile Idiopathic Arthritis (must meet all)**:**
1. Diagnosis of pJIA
2. Request is for Simponi Aria;
   **Prior authorization may be required for Enbrel and Xeljanz*
3. Dose does not exceed 80 mg/m^2 IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

C. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of PsA;
2. Dose does not exceed one of the following (a or b):
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria:
      i. Adults: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*);
      ii. Pediatrics: 80 mg/m^2 IV at weeks 0 and 4, followed by maintenance dose of 80 mg/m^2 every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

D. Rheumatoid Arthritis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Failure of a ? 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a ? 3 consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
2. Failure of at least one of the following, used for ? 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Kevzara®, Xeljanz®/Xeljanz XR®;
   **Prior authorization may be required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR*
3. Dose does not exceed one of the following (a or b):
   a. Simponi: 50 mg SC once monthly;
   b. Simponi Aria: 2 mg/kg IV at weeks 0 and 4, followed by maintenance dose of 2 mg/kg every 8 weeks (*see Appendix F for dose rounding guidelines*).

Approval duration: 12 months

E. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of UC;
2. Request is for Simponi (SC formulation);
3. Dose does not exceed 200 mg at week 0, 100 mg at week 2, followed by maintenance dose of 100 mg every 4 weeks.

Approval duration: 12 months

F. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy (must meet all)**:**

A. History of the requested agent within the past 90 days
B. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, or d):
   a. RA, PsA, AS (Simponi): 50 mg SC once monthly;
   b. UC (Simponi): 100 mg SC every 4 weeks;
   c. AS, PsA, RA (Simponi Aria) Adults: 2 mg/kg IV every 8 weeks;*
   d. PJIA, PsA (Simponi Aria) Pediatrics: 80 mg/m^2 IV every 8 weeks.*
   **see Appendix F for dose rounding guidelines*

Approval duration: 12 months

A. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6MP: 6-mercaptopurine
AS: ankylosing spondylitis
CDAI: clinical disease activity index
cJADAS: clinical juvenile arthritis disease activity score
DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
MTX: methotrexate
NSAID: non-steroidal anti-inflammatory drug
PJIA: polyarticular juvenile idiopathic arthritis
PsA: psoriatic arthritis
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan®, Imuran®)	**RA** 1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
corticosteroids	**UC** budesonide (Uceris®) 9 mg PO QD	Varies
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg PO QD Maintenance dose: 200 – 400 mg PO QD	600 mg/day
leflunomide (Arava®)	**RA** 100 mg PO QD for 3 days, then 20 mg PO QD **pJIA*** Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
methotrexate (Rheumatrex®)	**RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **UC*** 15 – 25 mg/week IM or SC **pJIA*** 10 – 20 mg/m^2/week PO, SC, or IM	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS** Varies	Varies
sulfasalazine (Azulfidine®)	**RA** 2 gm/day PO in divided doses **pJIA*** 30-50 mg/kg/day PO divided BID	RA: 3 g/day pJIA: 2 g/day
Enbrel® (etanercept)	**AS** 50 mg SC once weekly **RA**	50 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	25 mg SC twice weekly or 50 mg SC once weekly **pJIA** Weight < 63 kg: 0.8 mg/kg SC once weekly Weight ≥ 63 kg: 50 mg SC once weekly	
Cimzia® (certolizumab)	**AS** Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Kevzara® (sarilumab)	**RA** 200 mg SC once every two weeks	200 mg/2 weeks
Taltz® (ixekizumab)	**AS** Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks
Xeljanz® (tofacitinib)	**PsA, RA** 5 mg PO BID **UC** 10 mg PO BID for 8 weeks; then 5 mg PO BID **pJIA** • 10 kg ≤ body weight < 20 kg: 3.2 mg (3.2 mL oral solution) PO BID • 20 kg ≤ body weight < 40 kg: 4 mg (4 mL oral solution) PO BID • Body weight ≥ 40 kg: 5 mg PO BID	PJIA, PsA, RA: 10 mg/day UC maintenance: 10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**PsA, RA** 11 mg PO QD **UC** 22 mg PO QD for 8 weeks; then 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): serious infections and malignancy

Appendix D: General Information

- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

Appendix E: Dose Rounding Guidelines

Weight-based Dose Range	Vial Quantity Recommendation
≤ 52.49 mg	1 vial of 50 mg/4 mL
52.5 to 104.99 mg	2 vials of 50 mg/4 mL
105 to 157.49 mg	3 vials of 50 mg/4 mL
157.5 to 209.99 mg	4 vials of 50 mg/4 mL
210 to 262.49 mg	5 vials of 50 mg/4 mL

IV. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Golimumab (Simponi)	AS PsA RA	50 mg SC once monthly	50 mg/month
	UC	Initial dose: 200 mg SC at week 0, then 100 mg SC at week 2 Maintenance dose: 100 mg SC every 4 weeks	100 mg every 4 weeks
Golimumab (Simponi Aria)	AS PsA RA	Adults: Initial dose (AS, PsA, RA): 2 mg/kg IV at weeks 0 and 4 Adults: Maintenance dose (AS, PsA, RA): 2 mg/kg IV every 8 weeks	Adults (AS, PsA, RA): 2 mg/kg every 8 weeks

Drug Name	Indication	Dosing Regimen	Maximum Dose
	PJIA	Pediatrics: Initial dose (PsA, PJIA): 80 mg/m^2 IV at weeks 0 and 4 Pediatrics: Maintenance dose (PsA, PJIA): 80 mg/m^2 IV every 8 weeks	Pediatrics (PsA, PJIA): 80 mg/m^2 every 8 weeks

V. Product Availability

Drug Name	Availability
Golimumab (Simponi)	Single-dose prefilled SmartJect® autoinjector: 50 mg/0.5 mL, 100 mg/1 mL Single-dose prefilled syringe: 50 mg/0.5 mL, 100 mg/1 mL
Golimumab (Simponi Aria)	Single-use vial: 50 mg/4 mL

VI. References

1. Simponi Prescribing Information. Horsham, PA; Janssen Biotech; September 2019. Available at http://www.simponi.com/shared/product/simponi/prescribing-information.pdf. Accessed January 15, 2021.
2. Simponi Aria Prescribing Information. Horsham, PA; Janssen Biotech; September 2020. Available at http://simponiaria.com/sites/default/files/prescribing-information.pdf. Accessed January 15, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Created for IN Medicaid PA Alignment.	08.21	OMPP approved
Annual Review. No changes	10.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.