Clinical Policy: Golimumab (Simponi, Simponi Aria)

Reference Number: CP.PHAR.253
Effective Date: 07/16
Last Review Date: 07/17
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 human IgG1κ monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNFα. This interaction prevents the binding of TNFα to its receptors, thereby inhibiting the biological activity of TNFα (a cytokine protein).

FDA approved indication

Simponi is indicated for the treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Adult patients with active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Adult patients with active ankylosing spondylitis
- 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 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 rheumatoid arthritis in combination with methotrexate.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) 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. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (refer to *Appendix B*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):

a. Failure of methotrexate (MTX) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
b. If intolerance or contraindication to MTX: sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;

5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab.*
6. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed:
   a. Simponi: 50 mg once monthly;
   b. Simponi Aria: 2mg/kg dosed at weeks 0 and 4 then every 8 weeks thereafter.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of active psoriatic arthritis (PsA);
2. Prescribed in consultation with a dermatologist or rheumatologist;
3. Request is for Simponi;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
   a. Failure of methotrexate (MTX) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine, used for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
6. Failure of etanercept *(Enbrel is preferred)* AND adalimumb *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
7. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
8. Dose does not exceed 50 mg once monthly.

Approval duration: 6 months

C. Ankylosing Spondylitis (must meet all)**:**
1. Diagnosis of active ankylosing spondylitis (AS);
2. Prescribed by or in consultation with a rheumatologist;
3. Request is for Simponi;
4. Age ≥ 18 years;
5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effect are experienced;
6. Failure of etanercept *(Enbrel is preferred)* AND adalimumb *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;

Prior authorization is required for etanercept and adalimumab

7. TB test within past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
8. Dose does not exceed 50 mg once monthly.

Approval duration: 6 months

D. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of moderately to severely active ulcerative colitis (UC);
2. Prescribed by or in consultation with a gastroenterologist;
3. Request is for Simponi;
4. Age ≥ 18 years;
5. Failure of a thiopurine (6MP, azathioprine) for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of adalimumb *(Humira is preferred)*, used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   Prior authorization is required for adalimumab
7. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
8. Dose does not exceed 200 mg week 0, 100 mg week 2, then maintenance therapy with 100 mg every 4 weeks.

Approval duration: 6 months

E. Other diagnoses/indications: Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

A. All Indications in Section I: (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Simponi: RA, PsA, AS – 50 mg SC once monthly; UC – 100 mg SC once monthly;
   b. Simponi Aria: RA – 2mg/kg IV infusions every 8 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
CRP: C-reactive protein
DMARD: disease modifying antirheumatic drug
ESR: erythrocyte sedimentation rate
MTX: methotrexate
PsA: psoriatic arthritis
RA: rheumatoid arthritis
SC: subcutaneous
TB: tuberculosis
TNF: tumor necrosis factor
UC: ulcerative colitis

Appendix B: The 2010 ACR Classification Criteria for RA

Add score of categories A through D. A score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint Involvement**	**Score**
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA	2
	High positive RF *or* high positive ACPA	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal CRP and normal ESR	0
	Abnormal CRP or normal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or disease-modifying antirheumatic drug (DMARD) failure

In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count, ≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Simponi	RA, PsA, AS	50 mg SC once monthly	50 mg/month
	UC	200 mg SC at week 0 100 mg SC at week 2 100 mg SC every 4 weeks as maintenance therapy	Maintenance: 100 mg/month

Simponi Aria	RA	2 mg/kg IV at weeks 0 and 4, then every 8 weeks	Maintenance: 2 mg/kg every 8 weeks

VI. Product Availability

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

VII. References

1. Simponi Prescribing Information. Horsham, PA; Janssen Biotech; June 2017. Available at http://simponiaria.com/sites/default/files/prescribing-information.pdf. Accessed June 23, 20176.
2. Simponi Aria Prescribing Information. Horsham, PA; Janssen Biotech; January 2017. Available at http://www.simponi.com/shared/product/simponi/prescribing-information.pdf. Accessed June 23, 2016.
3. Smolen JS, Landewé 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*. 2017; 0: 1-18.
4. Sing JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guidelines for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research* 2015; 68(1):1-26.
5. Schur PH, Cohen S. Initial treatment of moderately to severely active rheumatoid arthritis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at: www.UpToDate.com. Accessed June 2017.
6. Cohen S, Cannella A. Treatment of rheumatoid arthritis in adults resistant to initial nonbiologic DMARD therapy. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at: www.UpToDate.com. Accessed June 2017.
7. Menter A, Korman NJ, Elmets CA, et al. 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(1):137-174.
8. Menter A, Gottlieb A, Feldman SR, et al. Guidelines for the management of psoriasis and psoriatic arthritis. Section 1: Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2008;58(5):826-850.
9. Gladman DD, Ritchlin C. Treatment of psoriatic arthritis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed June 2017.
10. Ward MM, 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 & Rheumatology, 2015. DOI 10.1002/ART.39298.
11. Braun J, van den berg R, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Am Rheu Dis. 2011: 70; 896-904.

12. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol.* 2010;105;501-523.
13. Dassopoulos T, Cohen R, Scherl E, et al. Ulcerative Colitis Clinical Care Pathway. American Gastroenterological Association. 2015. Available at http://campaigns.gastro.org/algorithms/UlcerativeColitis/. Accessed June 23, 2017.

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	Approval Date
Policy split from CP.PHAR.86.ArthritisTreatments, CP.PHAR.85 Psoriasis Treatments, CP.PHAR.87.IBD Treatment_4. RA, PsA, AS, UC: Removed criteria related to HBV, malignant disease, concomitant use with other biologics, and concurrent administration of live vaccines; added dosing limits/details; added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated (just Humira for UC); RA: changed age requirement to 18; modified criteria to require trial of MTX unless contraindicated; added sulfasalazine and hydroxychloroquine as alternatives to MTX if contraindicated; Simponi Aria indication RA only per PI. Re-auth: combined into All Indications; added criteria related to dosing and reasons to discontinue. Modified approval duration to 6 months for initial and 12 months for renewal. Shortened background section.	06/16	07/16
PsA: Preferenced trial of MTX above other DMARDs per CPC feedback. UC: removed option of trial of aminosalicylates per 2015 AGA Clinical Care Pathway.	11/16	
Converted to new template. RA: modified the RA diagnostic criteria from requiring one or more of the following: ≥ 5 inflamed joints, elevation in the ESR and/or CRP concentration; positive rheumatoid factor and/or anticyclic citrullinated peptide) antibodies (present in most patients), evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling, to the ACR diagnostic criteria. Removed requirement for use in combination with MTX.	07/17	07/17

Reviews, Revisions, and Approvals	Date	Approval Date
PsA, AS, UC: clarified request must be for Simponi. For UC, limited accepted first line trials to thiopurine.		

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.