

Clinical Policy: Golimumab (Simponi)

Reference Number: HIM.PA.SP28

Effective Date: 05/17

Last Review Date:

Line of Business: Health Insurance Marketplace

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Golimumab (Simponi[®]) is a tumor necrosis factor (TNF) blocker.

FDA approved indication

Simponi is indicated:

- For the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- For the treatment of adult patients with active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- For the treatment of adult patients with active ankylosing spondylitis (AS)
- For the treatment of 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

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of moderately to severely active rheumatoid arthritis (RA) and one or more of the following:
 - a. At least five inflamed joints;
 - b. Elevation in the erythrocyte sedimentation rate (ESR) and/or serum C-reactive protein (CRP) concentration;
 - c. Positive rheumatoid factor and/or anticyclic citrullinated peptide (CCP) antibodies;
 - d. Evidence of inflammation on plain radiography of the hands, wrists, or feet, such as osteopenia and/or periarticular swelling;
2. Prescribed by or in consultation with a rheumatologist;
3. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the member has received treatment for latent TB infection;
4. Failure of all of the following therapies (a, b, and c), unless all are contraindicated or clinically significant adverse effects are experienced:
 - a. Humira or Enbrel;

- b. Methotrexate (MTX) for ≥ 3 consecutive months;
- c. If member has contraindication or intolerance to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months;
5. Simponi is prescribed in combination with MTX, or another non-biologic disease-modifying antirheumatic drug (DMARD) if intolerant/contraindicated to MTX;
6. Dose does not exceed 50 mg once monthly.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of active psoriatic arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. 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;
4. Failure of all of the following therapies (a, b, and c), unless all are contraindicated or clinically significant adverse effects are experienced:
 - a. Humira or Enbrel;
 - b. Methotrexate (MTX) for ≥ 3 consecutive months;
 - c. If member has contraindication or intolerance to MTX, failure of sulfasalazine, leflunomide, cyclosporine, or azathioprine for ≥ 3 consecutive months;
5. 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. 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;
4. Failure of all of the following therapies (a and b), unless all are contraindicated or clinically significant adverse effects are experienced:
 - a. Humira or Enbrel;
 - b. At least 2 non-steroidal anti-inflammatory drugs (NSAIDs) at maximum tolerated doses, each trialed for ≥ 4 weeks;
5. Dose does not exceed 50 mg once monthly.

Approval duration: 6 months

D. Ulcerative Colitis (must meet all):

1. Diagnosis of ulcerative colitis (UC);
2. Prescribed by or in consultation with a gastroenterologist;
3. 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;
4. Failure of all of the following therapies (a and b) for ≥ 3 months unless all are contraindicated or clinically significant adverse effects are experienced:
 - a. Humira or Enbrel;
 - b. An immunomodulator (e.g., azathioprine, 6-mercaptopurine), corticosteroid, or aminosalicylate;

5. Dose does not exceed 200 mg at week 0, 100 mg at week 2, then 100 mg every 4 weeks thereafter.

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed the following:
 - a. For RA, PsA, and AS: 50 mg once monthly;
 - b. For UC: 100 mg every 4 weeks.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

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 – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis

CCP: citrullinated peptide

CRP: C-reactive protein

DMARD: disease modifying antirheumatic drug

ESR: erythrocyte sedimentation rate

FDA: Food and Drug Administration

MTX: methotrexate

NSAIDs: non-steroidal anti-inflammatory drugs

PsA: psoriatic arthritis

RA: rheumatoid arthritis

TB: tuberculosis

TNF: tumor necrosis factor

UC: ulcerative colitis

V. References

1. Simponi Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; January 2016. Available at: www.simponi.com. Accessed January 31, 2017.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol* 2016 Jan;68(1):1-26.
3. Gottlieb A, Korman NJ, Gordon KB, Feldman SR, Lebwohl M, Koo JY, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol*. 2008 May;58(5):851-64.
4. 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 & rheumatology* (Hoboken, NJ). 2016;68(2):282-298.
5. Kornbluth A , Sachar DB and The Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, practice parameters committee. *Am J Gastroenterol* 2010;105:501 – 523.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/17	

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.

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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.

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