

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Simponi (golimumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Simponi is a tumor necrosis factor (TNF) alpha-inhibitor initially approved by the FDA in 2009 for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Since that time, Simponi has also been approved for Ulcerative colitis. This medication is given as a subcutaneous injection.

Simponi (golimumab) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis (AS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active ankylosing spondylitis (AS); AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints (sacroiliitis); AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response; AND
8. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi, see Appendix).
Dosage allowed/Quantity limit: 50 mg subcutaneously once a month (4 syringes or autoinjectors per 28 days; 2 mL per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND

4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
 - a) Non-biologic DMARD is not required for:
 - i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
 - b) NSAID and non-biologic DMARD are not required for:
 - i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life).
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi, see Appendix).
7. **Dosage allowed/Quantity limit:** 50 mg subcutaneously once a month (4 syringes or autoinjectors per 28 days; 2 mL per 28 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis (RA)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;
Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Simponi will be given in combination with methotrexate or with another conventional DMARD if member is unable to tolerate methotrexate; AND
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi, see Appendix); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** 50 mg subcutaneously once a month.
(4 syringes or autoinjectors per 28 days; 2 mL per 28 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Member has had a negative tuberculosis test within the past 12 months; AND
3. Medication must be prescribed by or in consultation with a gastroenterologist; AND
4. Member must have a documented trial and inadequate response with **one** of the following:
 - a) 3 months of 6-mercaptopurine or azathioprine;
 - b) 30 days of corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
 - c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.);
 AND
5. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi, see Appendix).
6. **Dosage allowed/Quantity limit:** 200 mg subcutaneously at week 0, followed by 100 mg at week 2, then 100 mg every 4 weeks thereafter.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Simponi (golimumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Simponi created. Policies SRx-0041 and SRx-0042 archived. For diagnoses of AS and RA: trial of Humira and Enbrel was added. For UC: trial of Humira required. List of diagnoses considered not medically necessary was added.
02/26/2019	Humira was removed from criteria; Actemra, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
11/23/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. <u>AS</u> : Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. <u>PsA</u> : Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). <u>RA</u> : Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors. <u>UC</u> : Removed all of the different scenarios of UC in #4, replaced with trial options of conventional therapies. Corrected dosing.
01/24/2022	Transferred to new template. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. Removed Xeljanz, Olumiant from try first options per recent JAK inhibitor label changes; also

	changed from other specific drug names to say 2 preferred biologics one of which is a TNF inhibitor. Added preferred biologic trial with TNFi and Clarified reauth criteria for PsA and AS.
04/01/2022	Added preferred product appendix

References:

1. Simponi [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: September 2019.
2. Sieper J, et al. A randomized, double-blind, placebo-controlled, sixteen-week study of subcutaneous golimumab in patients with active nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2015 Oct;67(10):2702-12.
3. Inman RD, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: results of a randomized, double-blind, placebo-controlled, phase III trial. *Arthritis Rheum.* 2008 Nov;58(11):3402-12.
4. Callhoff J, et al. Efficacy of TNF α blockers in patients with ankylosing spondylitis and non-radiographic axial spondyloarthritis: a meta-analysis. *Ann Rheum Dis.* 2015; 74:1241.
5. 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 Oct;71(10):1599-1613. doi: 10.1002/art.41042. Epub 2019 Aug 22.
6. Akgul O, Ozgocmen S. Classification criteria for spondyloarthropathies. *World J Orthop.* 2011;2(12):107-115. doi:10.5312/wjo.v2.i12.07.
7. Yu DT, Tubergen AV. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc.
8. Michelson MA, et al. Role of golimumab, a TNF-alpha inhibitor, in the treatment of the psoriatic arthritis. *Clin Cosmet Investig Dermatol.* 2010;3:79-84.
9. Kavanaugh A, et al. Golimumab in psoriatic arthritis: one-year clinical efficacy, radiographic, and safety results from a phase III, randomized, placebo-controlled trial. *Arthritis Rheum.* 2012 Aug;64(8):2504-17.
10. Smolen JS. Insights into the efficacy of golimumab plus methotrexate in patients with active rheumatoid arthritis who discontinued prior anti-tumour necrosis factor therapy: post-hoc analyses from the GO-AFTER study. *Ann Rheum Dis.* 2014 Oct;73(10):1811-8.
11. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1):1-26.
12. Smolen JS, Landewé RBM, Bijlsma JWW, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79(6):685-699.
13. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114(3):384-413.
14. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology.* 2020;158(5):1450-1461.
15. 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. doi:10.1002/art.41752

Effective date: 04/01/2022

Revised date: 01/24/2022

Appendix: Preferred Biologic Products

Approved for Rheumatoid Arthritis	<ul style="list-style-type: none"> • Actemra (<i>requires step through Humira</i>) • Enbrel • Humira
Approved for Juvenile Idiopathic Arthritis	<ul style="list-style-type: none"> • Actemra (<i>requires step through Humira</i>) • Enbrel • Humira
Approved for Ankylosing Spondylitis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Humira • Rinvoq
Approved for Non-radiographic Axial	<ul style="list-style-type: none"> • Cimzia • Cosentyx
Approved for Atopic Dermatitis	<ul style="list-style-type: none"> • Rinvoq
Approved for Psoriatic Arthritis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	<ul style="list-style-type: none"> • Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	<ul style="list-style-type: none"> • Humira • Stelara
Approved for Ulcerative Colitis	<ul style="list-style-type: none"> • Humira • Stelara • Rinvoq