CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Simponi (golimumab)
BENEFIT TYPE	Pharmacy
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.

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 AS; AND
4. Member shows at least **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has tried and failed **TWO** preferred biologic DMARDs for at least 3 months each, one of which must be a TNF inhibitor; AND
7. Member has had a negative tuberculosis test within the past 12 months.
   Dosage allowed/Quantity limit: 50 mg subcutaneously once a month. Quantity limit: 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 such as 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 PsA; AND

4. 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).
5. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each, one of which must be another TNF inhibitor; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 50 mg subcutaneously once a month. Quantity limit: 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 such as 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 3 months;
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
5. Provider attests that Simponi will be given in combination with methotrexate or another conventional DMARD if member is unable to tolerate methotrexate; AND
6. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each, one of which must be another TNF inhibitor; 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. Quantity limit: 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 such as 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. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member must have a documented trial and inadequate response with **ONE** of the following:
   a) 6-mercaptopurine or azathioprine;
   b) Corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
4. Member has had a negative tuberculosis test within the past 12 months.
5. **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 such 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. AS: Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. PsA: 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.). RA: 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. UC: 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.

06/27/2024	Added/removed references. AS: changed trial of each NSAID from 4 weeks to 2 weeks for a total of 4 weeks of treatment per EULAR 22 guidelines; reduced initial authorization length from 12 months to 6 months; removed criteria requiring back pain for 3 or more months before the age of 50 and inflammation of one or both of the sacroiliac joints and added that member must have elevated CRP or sacroiliitis on MRI per EULAR 22 guidelines RA: added provider attestation that Simponi will be used with methotrexate or another conventional DMARD if methotrexate is not tolerated
07/23/2025	UC: Removed duration from drug trial. Added references.

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