

PHARMACY POLICY STATEMENT

Georgia Medicaid

DRUG NAME	Simponi (golimumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Actemra, Enbrel, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz QUANTITY LIMIT— 1 injection per 28 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Simponi (golimumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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 must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia and Cosentyx. Treatment failure requires at least 12 weeks of therapy with each drug.
9. **Dosage allowed:** 50 mg subcutaneously once a month.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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 must have tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla, and Xeljanz. Treatment failure requires at least 12 weeks of therapy with each drug.
7. **Dosage allowed:** 50 mg subcutaneously once a month.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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 with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND
Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. Medication is being given in combination with methotrexate or with another non-biologic DMARD if member is unable to tolerate methotrexate; AND
6. Member must have tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
7. **Dosage allowed:** 50 mg subcutaneously once a month.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. 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 member meets all the reauthorization requirements above, 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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.);
 - a) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.).
5. **Dosage allowed:** 200 mg subcutaneously at week 0, followed by 100 mg at week 2, then 100 mg every 4 weeks thereafter.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Simponi (golimumab) not medically necessary for the treatment of the diseases that are not listed in this document.

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.

UC: Removed all of the different scenarios of UC in #4, replaced with trial options of conventional therapies. Corrected dosing.

References:

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12. Smolen JS, Landewé RBM, Bijlsma JWJ, 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.
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