Simponi
(golimumab for subcutaneous injection)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Simponi drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Humira, Enbrel, Cosentyx, Xeljanz/Xeljanz XR, Otezla and Stelara are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
2. Active psoriatic arthritis (PsA)
3. Active ankylosing spondylitis (AS)
4. Moderately to severely active ulcerative colitis (UC)

Compendial Use

1. Axial spondyloarthritis

POLICY

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

A) Ankylosing Spondylitis

1. Criteria for initial approval for ankylosing spondylitis will only apply when at least ONE of the following criteria are met:
   a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Humira, Enbrel and Cosentyx)
   b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

B) Psoriatis arthritis

1. Criteria for initial approval for psoriatic arthritis will only apply when at least ONE of the following criteria are met:
   a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Costentyx, Enbrel, Humira, Otezla and Stelara)
   b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

C) Rheumatoid Arthritis

1. Criteria for initial approval for rheumatoid arthritis will only apply when at least ONE of the following criteria are met:
   a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Humira, Enbrel and Xeljanz/Xeljanz XR)
   b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

D) Ulcerative Colitis

1. Criteria for initial approval for ulcerative colitis will only apply when at least ONE of the following criteria are met:
   a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Humira, Stelara and Xeljanz/Xeljanz XR)
   b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

Criteria for Initial Approval

A) Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis. Simponi must be prescribed in combination with

methotrexate unless the member has a clinical reason not to use methotrexate (see Appendix A).

2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
   a. Member is prescribed Simponi in combination with methotrexate or has a clinical reason not to use methotrexate.
   b. Member meets any of the following criteria:
      i). Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
      ii). Member has an intolerance or contraindication to methotrexate (see Appendix A).

B) Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA).

C) Active ankylosing spondylitis (AS) and axial spondyloarthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis or axial spondyloarthritis.
2. Authorizations of 12 months may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when any of the following criteria is met:
   a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   b. Member has an intolerance or contraindication to two or more NSAIDs (see Appendix B).

D) Moderately to severely active ulcerative colitis (UC)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis.
2. Authorization of 12 months may be granted for the treatment of moderately to severely active UC for members who had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix C).

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who are using Simponi for an indication outlined in the Criteria for Initial Approval and who achieve or maintain positive clinical response with Simponi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs (e.g., Xeljanz), and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer golimumab to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of golimumab.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Simponi concomitantly with any other biologic DMARD or targeted synthetic DMARD.

Simponi is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Trade Name	Generic Name	Quantity Limit
Simponi®	golimumab	**Ulcerative Colitis** Initiation of therapy: 3 x 100mg syringes or auto-injectors per first 15 days Maintenance: 1 x 100mg syringe or auto-injector per 30 days **Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis** Initiation of therapy and Maintenance: 1 x 50mg syringe or auto-injector every 30 days

Appendix

Appendix A: Examples of Contraindications to Methotrexate

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Contraindications to the Use of NSAIDs

1. Allergic-type reaction following aspirin or other NSAID administration
2. Asthma
3. Gastrointestinal bleeding
4. History of intolerance or adverse event
5. Significant drug interaction
6. Urticaria

Appendix C: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
   a.) Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
   b.) Rectal mesalamine (e.g., Canasa, Rowasa)
   c.) Rectal hydrocortisone (e.g., Colocort, Cortifoam)
   d.) Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
   a.) Oral mesalamine, balsalazide, olsalazine, rectal mesalamine

b.) Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a.) Prednisone, hydrocortisone IV, methylprednisolone IV
   b.) Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   a.) Azathioprine, mercaptopurine
   b.) Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
   a.) Alternative: rectal mesalamine

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

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POLICY HISTORY

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