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DRUG POLICY

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, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, and Xeljanz/Xeljanz XR 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), alone or in combination with methotrexate
3. Active ankylosing spondylitis (AS)
4. Moderately to severely active ulcerative colitis (UC) 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, and achieving and sustaining clinical remission in induction responders.

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 (Cosentyx, Enbrel, Humira, Rinvoq, 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

B) Psoriatic 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 (Cosentyx, Enbrel, Humira, Otezla, Rinvoq, Stelara, Tremfya, 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

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, Rinvoq, 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).

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- A) Rheumatoid arthritis (RA)
 - 1. For initial requests:
 - i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
 - ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
 - 2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

- B) Psoriatic arthritis: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

- C) Ankylosing spondylitis (AS) and axial spondyloarthritis:
 - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable). If therapy is not advisable, documentation of clinical reason to avoid therapy.
 - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

- D) Ulcerative colitis (UC)
 - 1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
 - 2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

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. The requested medication 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 meets either of the following criteria:
 - i). Member has been tested for either of the following biomarkers and the test was positive:
 - 1. Rheumatoid factor (RF)
 - 2. Anti-cyclic citrullinated peptide (anti-CCP)
 - ii). Member has been tested for ALL of the following biomarkers:
 - 1. RF
 - 2. Anti-CCP
 - 3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
 - b. Member is prescribed the requested medication in combination with methotrexate or has a clinical reason not to use methotrexate.
 - c. 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 at least 15 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 active axial spondyloarthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis or active axial spondyloarthritis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active 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 when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix C).

Continuation of Therapy

A) Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B) Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

C) Active ankylosing spondylitis (AS) and active axial spondyloarthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

D) Moderately to severely active ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
 - i. Stool frequency
 - ii. Rectal bleeding
 - iii. Urgency of defecation
 - iv. C-reactive protein (CRP)
 - v. Fecal calprotectin (FC)
 - vi. Endoscopic appearance of the mucosa
 - vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

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 associated with an increased risk of TB.

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

For all indications: Member cannot use the requested medication 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 <u>Initiation of therapy:</u> 3 x 100mg syringes or auto-injectors per first 15 days <u>Maintenance:</u> 1 x 100mg syringe or auto-injector per 30 days Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis <u>Initiation of therapy and Maintenance:</u> 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

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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