Reference number(s)
2014-A

Specialty Guideline Management
Simponi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Simponi	golimumab

Indications

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 adults, in combination with methotrexate
- Active psoriatic arthritis (PsA) in adults, alone or in combination with methotrexate
- Active ankylosing spondylitis (AS) in adults
- Moderately to severely active ulcerative colitis (UC) in adults and pediatric patients weighing at least 15 kilograms (kg)

Compendial Uses

- Non-radiographic axial spondyloarthritis[2]
- Immune checkpoint inhibitor-related toxicities - inflammatory arthritis[21]

All other indications are considered experimental/investigational and not medically necessary.

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2014-A

Documentation

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

Rheumatoid Arthritis (RA)

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.
- 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).

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), Psoriatic Arthritis (PsA), and Immune Checkpoint Inhibitor-Related Toxicity

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.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Ulcerative Colitis (UC)

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Ulcerative colitis: gastroenterologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid Arthritis (RA)[1,3-5,16,18,19]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis within the past 120 days. The requested medication must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
    - Member has been tested for either of the following biomarkers and the test was positive:
        - Rheumatoid factor (RF)
        - Anti-cyclic citrullinated peptide (anti-CCP)
    - Member has been tested for ALL of the following biomarkers:
        - RF
        - Anti-CCP
        - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
    - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
        - Member has had a documented inadequate response to MTX in combination with or at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
        - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
        - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
        - Member has moderate to high disease activity.
    - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:

    - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
    - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
    - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.
  - Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
    - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
    - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
    - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderate to high disease activity.
- Member is prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Psoriatic Arthritis (PsA)[1,6-9,14]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
  - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
  - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
  - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)[1,2,10,11]

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Ulcerative Colitis (UC)[1,12,15,17]

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Immune Checkpoint Inhibitor-Related Toxicity[21]

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

Rheumatoid Arthritis (RA)[1,3-5,16,18,19]

Authorization of 12 months may be granted for all adult 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.

Psoriatic Arthritis (PsA)[1,6-9,14]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for 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:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)[1,2,10,11]

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis 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:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Ulcerative Colitis (UC)[1,12,15,17]

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.

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:

- Stool frequency
- Rectal bleeding
- Urgency of defecation

- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis 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.

Other[1,13]

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs 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 (e.g., chest x-ray). 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 drug or targeted synthetic drug for the same indication.

Dosage and Administration

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

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide[20]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease

- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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