Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Simponi under the patient's prescription drug benefit.

Description:

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.

A. FDA-Approved Indications
   1. Moderately to severely active rheumatoid arthritis (RA) in adults, in combination with methotrexate.
   2. Active psoriatic arthritis (PsA) in adults, alone or in combination with methotrexate.
   3. Active ankylosing spondylitis (AS) in adults.
   4. Moderately to severely active ulcerative colitis (UC) in adults who have demonstrated corticosteroid dependance or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.

B. Compendial Use
   1. Non-radiographic axial spondyloarthritis
   2. Immune checkpoint inhibitor-related toxicities - inflammatory arthritis

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

Applicable Drug List:

Non-preferred: Simponi

Policy/Guideline:

The patient is unable to take a preferred adalimumab product AND Enbrel and ONE additional preferred product (a preferred ustekinumab product, Kevzara, Otezla or Rinvoq), where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. **Rheumatoid arthritis (RA)**
   1. 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. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. **Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA) and immune checkpoint inhibitor-related toxicity**
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.

C. **Ulcerative colitis (UC)**
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialty:
This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Ulcerative colitis: gastroenterologist
D. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Criteria for Initial Approval:
A. Rheumatoid arthritis (RA)
1. 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. 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 A).

2. 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:
   i. Member meets either of the following criteria:
      a. 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)
      b. 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)
   ii. 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 A).
   iii. Member meets either of the following criteria:
      a. 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).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Psoriatic arthritis (PsA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when any of the following criteria is met:
   i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

D. Ulcerative colitis (UC)

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

E. Immune checkpoint inhibitor-related toxicity

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:

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

Continuation of Therapy:

A. Rheumatoid arthritis (RA)

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.

B. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

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 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)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all (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)

E. 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 Criteria:
or 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 or Leflunomide
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding

6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Approval: Initial and Renewal Approval: 12 months

Quantity Level Limit:

Medication	Standard Limit	Exception Limit *	FDA-recommended dosing
Simponi (golimumab) 50 mg per 0.5 mL single-dose pre-filled syringe/autoinjector	1 syringe/ autoinjector per 28 days	N/A	**RA/PsA/AS** • 50 mg every month **UC** • Loading doses: 200 mg at week 0, followed by 100 mg at week 2 • Maintenance dose: 100 mg every 4 weeks
Simponi (golimumab) 100 mg per 1 mL single-dose pre-filled syringe/autoinjector	1 syringe/ autoinjector per 28 days	3 syringes/ autoinjectors per 14 days	

*Coverage up to the exception limits may be provided with prior authorization

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