Effective Date:02/01/2022
Reviewed: 12/2021, 7/2022, 12/2022, 8/2023, 02/2024 Scope: Medicaid

Simponi (golimumab)
Subcutaneous Injection

POLICY

I. CRITERIA FOR INTIAL AND CONTINUATION OF THERAPY

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication

II. 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 (PsA): For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ulcerative colitis
   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. Chart notes or medical record documentation of hospitalization due to acute, severe ulcerative colitis (if applicable)
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. CRITERIA FOR APPROVAL

An authorization may be granted when the following criteria are met:

- Patient is ≥18 years of age; AND
- Simponi will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Stelara (ustekinumab), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Velsipity (etrasimod), etc.); AND

Rheumatoid Arthritis (RA)

- Therapy must be initiated or recommended by a rheumatologist; AND
- Patient has a diagnosis of moderate to severe active rheumatoid arthritis; AND
- Patient meets either of the following criteria:
    - 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 all of the following:
    - 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); OR Member has an intolerance or contraindication to methotrexate (see Appendix A); AND
    - Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.; AND
    - Patient is unable to tolerate the intravenous formulation of golimumab (Simponi Aria) and medical rationale has been provided

Psoriatic Arthritis (PsA)

- Therapy must be initiated or recommended by a rheumatologist or dermatologist; AND
- Patient has a diagnosis of psoriatic arthritis; AND
- Patient member meets either of the following criteria:
    - If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
    - If member has peripheral arthritis, member has experienced an inadequate response to at least a 3 month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, or sulfasalazine, unless intolerance experienced; AND
- Member has had an inadequate response, intolerance, or contraindication to a 3 month trial of adalimumab at maximum tolerated doses.; AND

- Patient is unable to tolerate the intravenous formulation of golimumab (Simponi Aria) and medical rationale has been provided

Ankylosing Spondylitis (AS)

- Therapy must be initiated or recommended by a rheumatologist; AND
- Patient has a diagnosis of active Ankylosing Spondylitis; AND
- Patient failed or has a contraindication to TWO (2) NSAIDs; AND
- Member has had an inadequate response, intolerance, or contraindication to a 3-month trial of adalimumab at maximum tolerated doses.; AND
- Patient is unable to tolerate the intravenous formulation of golimumab (Simponi Aria) and medical rationale has been provided

Ulcerative Colitis (UC)

- Therapy must be initiated or recommended by a gastroenterologist; AND
- Patient has a diagnosis of ulcerative colitis; AND
- Patient has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of one conventional therapy option (e.g., mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine) at maximum tolerated doses; AND
- Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

IV. CONTINUATION OF THERAPY

Rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis

- Patient has a diagnosis of rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis; AND
- Therapy must be initiated or recommended by a rheumatologist or dermatologist; AND
- Patient demonstrated a clinical response to therapy (i.e., improvement in physical function, control of the progression of joint damage, and/or pain reduction); AND

Ulcerative colitis

- Member has a diagnosis of ulcerative colitis; AND
- Therapy must be initiated or recommended by a gastroenterologist; AND
- Patient demonstrated a clinical response to therapy (i.e., decrease in symptoms, decreased hospitalizations, improvement in fistula occurrence/healing); AND

V. QUANTITY LIMIT

Initial therapy:

- Rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis:
  - One(1) 50mg/0.5mL syringe per 30 days for 12 months
- Ulcerative colitis:
  - Three (3) 100mg/1mL syringe for the first month, followed by One (1) 100mg/1mL syringe per 30 days for the following 11 months

Continuation of therapy:

- Rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis:
  - One (1) 50mg/0.5mL syringe per 30 days for 12 months
- Ulcerative colitis:
  - One (1) 100mg/1mL syringe per 30 days for 12 months

VI. COVERAGE DURATION

- 12 months

VII. APPENDIX

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, 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 planning pregnancy
10. Renal impairment
11. Significant drug interaction

VIII. REFERENCES

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