Effective Date:02/01/2022
Reviewed: 12/2021, 7/2022, 12/2022, 8/2023, 02/2024, 1/2025 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. 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), ustekinumab (e.g., Stelara, Wezlana, etc.) (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 has documentation that 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)
- Patient has documentation that meets all of the following:
    - Patient 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
    - Patient 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

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Psoriatic Arthritis (PsA)

- Therapy must be initiated or recommended by a rheumatologist or dermatologist; AND
- Patient has a documented diagnosis of psoriatic arthritis; AND
- Patient has documentation that meets either of the following criteria:
    - If patient 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 patient 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
- Documentation that the patient has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab and at least a 6-month trial of ustekinumab 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 documented diagnosis of active Ankylosing Spondylitis; AND
- Patient has documentation of a failure or has a contraindication to TWO (2) NSAIDs; AND
- Patient has documentation of 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
- Documentation that the patient has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses; AND
- Patient has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab at maximum tolerated doses

III. 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

- Patient 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

IV. 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

V. COVERAGE DURATION

- 12 months

VI. 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

VII. REFERENCES

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