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

Simponi (golimumab)
Subcutaneous Injection

POLICY

I. CRITERIA FOR INTIAL AND CONTINUATION OF THERAPY

For all indications:

- Prior Authorization Request is submitted by the Provider's office; AND
- Prior Authorization Request is not submitted by a pharmacy or another third party; AND
- 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:

Rheumatoid Arthritis

- Patient is ≥18 years of age; AND
- Therapy must be initiated or recommended by a rheumatologist; AND
- Patient has a diagnosis of moderate to severe active rheumatoid arthritis; AND
- Patient must be intolerant or failed a trial of at least one (1) of the following: a DMARD (i.e., methotrexate, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine, leflunomide); AND
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent; AND
- Patient is unable to tolerate the intravenous formulation of golimumab (Simponi Aria) and medical rationale has been provided; AND
- Member has had an inadequate response or intolerance to at least one of the following: Enbrel, Humira, Kevzara, or Rinvoq

Psoriatic Arthritis

- Patient is ≥18 years of age; AND
- Therapy must be initiated or recommended by a rheumatologist or dermatologist; AND
- Patient has a diagnosis of psoriatic arthritis; AND
- Patient must be intolerant or failed a trial of at least one (1) of the following: a DMARD (i.e., methotrexate, sulfasalazine, hydroxychloroquine, azathioprine, cyclosporine, leflunomide); AND
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent; AND
- Patient is unable to tolerate the intravenous formulation of golimumab (Simponi Aria) and medical rationale has been provided; AND
- Member has had an inadequate response or intolerance to at least one of the following: Cosentyx, Enbrel, Humira, Otezla, Skyrizi or Rinvoq

Ankylosing Spondylitis

- Patient is ≥18 years of age; AND
- 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
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent; AND
- Patient is unable to tolerate the intravenous formulation of golimumab (Simponi Aria) and medical rationale has been provided; AND
- Member has had an inadequate response or intolerance to at least one of the following: Cosentyx, Enbrel, Humira, or Rinvoq

Ulcerative Colitis

- Patient is ≥18 years of age; AND
- Patient has a diagnosis of ulcerative colitis; AND
- Therapy must be initiated or recommended by a gastroenterologist; AND
- Patient meets one of the following:
    - The patient is corticosteroid dependent; OR

  - Patient must be intolerant or failed trial of at least one (1) of the following immunosuppressants: azathioprine, 6-mercaptopurine, oral corticosteroids, or oral aminosalicylates; AND
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent; AND
- Member has had an inadequate response or intolerance to at least one of the following: Humira, or Rinvoq

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
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent

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
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent

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

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