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

Simponi (golimumab)
Subcutaneous Injection

POLICY

I. 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.

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.

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.

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 gastroenterologis;t 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

II. 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

III. 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

IV. COVERAGE DURATION

- 12 months