Commercial PA Criteria

Effective: January 1, 2019

Prior Authorization: Simponi

Products Affected: Simponi (golimumab) subcutaneous solution

Medication Description: Golimumab is a human monoclonal antibody that binds to both soluble and transmembrane bioactive forms of human tumor necrosis factor alfa (TNF alfa; a cytokine protein), resulting in inhibition of TNF alfa biological activity by preventing the binding of TNF alfa to its receptors. Elevated TNF alfa levels may be associated with several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis as TNF alfa is a mediator of the articular inflammation characteristic of these diseases. The exact mechanism for the action of golimumab in ulcerative colitis is unknown

Covered Uses:

1. Treatment of moderate to severe rheumatoid arthritis
2. Treatment of psoriatic arthritis
3. Treatment of ankylosing spondylitis
4. Treatment of moderate to severe ulcerative colitis

Exclusion Criteria:

1. Concurrent Use with a Biologic or with DMARD
2. Plaque psoriasis without psoriatic arthritis

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions:

Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis: prescribed by, or in consultation with, a rheumatologist
Ulcerative colitis: prescribed by, or in consultation with, a gastroenterologist

Coverage Duration:

Initiation: 6 month
Continuation: 1 year

Other Criteria:

1. **Ankylosing Spondylitis**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has clinically diagnosed ankylosing spondylitis **AND**
   B. Prescribed by or in consultation with a rheumatologist **AND**
   C. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications

Ankylosing Spondylitis
Enbrel
Adalimumab Product
Taltz
Rinvoq
Xeljanz/XR

2. Psoriatic Arthritis

Initial Therapy: Approve if the patient meets the following criteria

A. Patient has clinically diagnosed psoriatic arthritis AND
B. Prescribed by or in consultation with a rheumatologist or dermatologist **AND**
C. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications

Psoriatic Arthritis
Enbrel
Adalimumab product
Otezla
Stelara SC
Taltz
Tremfya
Skyrizi
Rinvoq
Xeljanz/XR

3. Rheumatoid Arthritis

Initial Therapy: Approve if the patient meets the following criteria:

A. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; **AND**

Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional

synthetic DMARD can be made if the patient has already had a 3-month trial with at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

B. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications

Rheumatoid Arthritis
Enbrel
Adalimumab product
Actemra SC
Rinvoq
Xeljanz/XR

4. Ulcerative Colitis

Initial Therapy: Approve if the patient meets the following criteria

a. Patient meets ONE of the following (i **OR** ii):

i. Patient has tried one systemic therapy; **OR**
Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.

ii. Patient meets BOTH of the following (a **AND** b):

a. Patient has pouchitis; **AND**

b. Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; **AND**
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

b. Documented failure of or intolerance to an Adalimumab product

Continuation

A. Patient meets all initial authorization criteria; **AND**

B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Simponi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Simponi® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; September 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Continuation Update to 3 years	07/01/2019
3	Update	Removal of DMARD use for Ankylosing Spondylitis	Other Criteria	07/19/2019
4	Policy Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019
5	Policy Update	Added Dosing Limitations according to FDA label	Other Criteria	5/6/2020
6	Policy Update	Added Otezla as a preferred option for PsA diagnosis	Other Criteria	8/1/2020
7	Policy Update	Removed Actemra SQ as a preferred product for RA Added Taltz as a preferred product for PsA, Ankylosing Spondylitis Removed Cosentyx as preferred product for PsA, Ankylosing Spondylitis Added Tremfya as a preferred option for PsA diagnosis Removed Xeljanz/XR as a preferred product for UC	Other Criteria	1/1/2021
8	Policy Update	Added Rinvoq and Skyrizi as preferred option for PsA Added Xeljanz/XR as preferred option for AS. Added Actemra SQ as a preferred product for RA	Other Criteria	02/16/2022
9	Policy Update	Added Rinvoq as a preferred product for AS	Other Criteria	05/20/2022
10	Policy Update	Other Criteria: Changed “Humira” to “Adalimumab”	Other Criteria	05/11/2023
11	Policy Update	Other Criteria: Ulcerative Colitis - Changed “Humira: to “Adalimumab”	Other Criteria	6/2/2023

12	Update	Addition to Exclusion criteria - Concurrent Use with a Biologic or with DMARD & Plaque psoriasis without psoriatic arthritis Removed Dosing Limits Removed RA/Ankylosing Spondylitis/Psoriatic Arthritis/Ulcerative Coltis criteria and revised select criteria to implement to label coverage. Removal of *Connetiicare does not consider alcohol use to be a clinical reason to use Simponi over methotrexate. Updated coverage duration: Initial from 3 months to 6 months, Continuation from 3 years to 1 year	Exclusion Criteria Other Criteria Coverage duration	12/21/2023