Commercial/Healthcare Exchange PA Criteria

Effective: June 2009

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: N/A

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: 3 months
Continuation: 3 years

Other Criteria:

Dosing Limitations: ***Only allow additional quantity for loading dose purposes.***

Psoriatic Arthritis, Ankylosing Spondylitis, Rheumatoid Arthritis

1. ***The recommended dose is 50 mg administered by subcutaneous injection once a month.***

Ulcerative Colitis

1. ***The recommended induction dosage is a 200mg subcutaneous injection at Week 0, followed by 100 mg at Week 2, and then maintenance therapy with 100 mg every 4 weeks.***

Initiation

Rheumatoid Arthritis or Psoriatic Arthritis:

A. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
B. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); A**ND**

C. Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications [documentation required]:

Rheumatoid Arthritis	Psoriatic Arthritis
Actemra SC	Cosentyx
Enbrel	Enbrel
Humira	Humira
Xeljanz/XR	Stelara SC
Rinvoq	Xeljanz/XR
	Otezla

Ankylosing Spondylitis:

A. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy.

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

Ankylosing Spondylitis
Cosentyx
Enbrel
Humira

Ulcerative Colitis:

A. Prescribed by or in consultation with a gastroenterologist
B. Patient has clinically diagnosed ulcerative colitis
C. Patient has had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine; AND
D. Documented failure of or intolerance to **Humira or Xeljanz/XR** [documentation required]

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.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Simponi over methotrexate.

References:

1. Simponi full prescribing information. Horsham, PA. Centocor Ortho Biotech Inc.

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	CCI Adopted EH template CCI P&T Review History: 6/09, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 2/16, 11/16, 11/17, 11/18 CCI Revision Record: 11/12, 5/13, 10/13, 12/13, 9/14, 11/15, 1/16, 5/16, 11/16, 11/17, 11/18, 12/18	All	7/19/2019
4	Update	Removed DMARD requirement for AS diagnosis	Other Criteria	7/22/2019
5	Policy Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019

6	Policy Update	Added Dosing Limitations according to FDA label	Other Criteria	5/6/2020
7	Policy Update	Added Otezla as a preferred option for PsA diagnosis	Other Criteria	8/1/2020