Commercial/Healthcare Exchange PA Criteria

Effective: June 2008

Prior Authorization: Cimzia

Products Affected: Cimzia (certolizumab pegol) injection

Medication Description: Certolizumab pegol is a tumor necrosis factor (TNF) inhibitor, which acts by binding and selectively neutralizing TNF-alfa. It does not neutralize TNF-beta. The inhibition of TNF-alfa, which is strongly expressed in the bowel wall and feces of patients with Crohn's disease results in an interference in the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor, and nitric oxide.

Covered Uses:

1. Treatment of moderate to severe Crohn's disease who have had an inadequate response to conventional therapy
2. Treatment of moderate to severe rheumatoid arthritis
3. Treatment of psoriatic arthritis
4. Treatment of ankylosing spondylitis
5. Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
6. Treatment of nonradiographic axial spondyloarthritis with objective signs of inflammation

Exclusion Criteria: Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD)

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions:

Ankylosing Spondylitis, rheumatoid arthritis, nonradiographic axial spondyloarthritis: Prescribed by, or in consultation, with a rheumatologist.
Crohn's Disease: Prescribed by, or in consultation, with a gastroenterologist.
Psoriatic Arthritis: Prescribed by, or in consultation, with a rheumatologist or a dermatologist.
Plaque psoriasis: Prescribed by, or in consultation, with a dermatologist.

Coverage Duration:

Initial: 3 months
Continuation: 3 years

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

Subcutaneous Adult Dosage Regimen (Crohn's disease)

1. ***The recommended dose is 400 mg (given as two subcutaneous injections of 200 mg) given at Week 0, Week 2 and 4, followed by every 4 weeks thereafter.***

Subcutaneous Adult Dosage Regimen (Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Non-Radiographic Axial Spondyloarthritis)

1. ***The recommended dose is 400 mg (given as two subcutaneous injections of 200 mg) at Week 0, Week 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.***

Subcutaneous Adult Dosage Regimen (Plaque Psoriasis)

1. ***The recommended dose is 400 mg (given as 2 subcutaneous injections of 200 mg each) every other week.***
2. ***For patients weighing less than 90kg, a dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) at Week 0, Weeks 2 and 4, followed by 200 mg every other week may be considered.***

Pharmacy Benefit:
Crohn's Disease

- Patient has had a previous trial with, contraindication to, or intolerance to at least **ONE** form of conventional therapy including: aminosalicylates (e.g. mesalamine and sulfasalazine), immunomodulators (i.e. azathioprine) or corticosteroids; **OR**
- Crohn's disease is steroid dependent and unable to be weaned or patient has Crohn's related fistulas; **AND**
- Documented failure of, intolerance to Adalimumab

Rheumatoid arthritis and Psoriatic Arthritis

- Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
- 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); **AND**
- 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	Taltz
Enbrel	Enbrel
Adalimumab	Adalimumab

Xeljanz/Xeljanz XR	Stelara SC
Rinvoq	Xeljanz/XR
	Skyrizi
	Otezla
	Tremfya
	Rinvoq

Ankylosing Spondylitis

- Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy **AND**
- Patient must have a trail and documented failure of, or intolerance to, **TWO** of the following medications [documentation required]:

Ankylosing Spondylitis
Taltz
Enbrel
Adalimumab
Xeljanz/Xeljanz XR
Rinvoq

Nonradiographic Axial Spondyloarthritis:

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

Plaque Psoriasis

- Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; **AND**
- Patient has a documented failure of, or intolerance to, or contraindication to at least **one** traditional systemic agent (e.g., MTX, cyclosporin) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed*; **AND**
- Documented failure of, or intolerance to, **TWO** of the following [documentation required]:

Psoriasis
Enbrel
Adalimumab
Otezla
Skyrizi
Stelara SC
Tremfya
Taltz

Continuation

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

NOTE: ConnectiCare does not consider alcohol use to be a clinical reason to use Cimzia over methotrexate.

References:

Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; April 2019

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/2008

2	Policy Update	CCI to adopt EH Policy Template, CCI P&T Review History: 6/08, 6/09, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 11/16, 11/17, 11/18 CCI Revision History: 5/09, 12/09, 11/12, 11/13, 9/14, 2/16, 11/16, 1/18, 8/18, 9/18, 12/18, 1/19	All	7/2/2019
2	Policy Update	Updated criteria for Crohn's Disease to step through Humira only, removed option for Stelara; Added new indication nonradiographic axial spondyloarthritis; removed DMARD from AS diagnosis; Updated Template from CCI to EH	Other Criteria, Covered Uses	7/2/2019
3	Update	Update, changed continuation approval length from 1 year to 3 years	Coverage Duration	7/1/2019
4	Policy Update	Added Rinvoq as a preferred product for RA	Other Criteria	10/18/2019
5	Policy Update	Updated required trials for plaque psoriasis from two to three trials	Other Criteria	12/20/2019
6	Policy Update	Added Dosing limitations to match the FDA Label	Other Criteria	5/5/2020
7	Policy Update	Added Otezla as a preferred option for PsA diagnosis	Other Criteria	8/1/2020
8	Policy Update	Removed Actemra SQ as a preferred product for RA. Added Taltz as preferred option for PsA, Psoriasis, and Ankylosing spondylitis. Removed Cosentyx as a preferred product for PsA, Psoriasis, and Ankylosing spondylitis Added Tremfya as a preferred option for PsA diagnosis Added Enbrel as a preferred option for Psoriasis diagnosis Removed Patient has chronic (greater than or equal to 1 year) plaque psoriasis	All	1/1/2021

9	Policy Update	Added Taltz, Skyrizi, Tremfya, and Rinvoq as preferred option for PsA diagnosis. Removed Cosentyx Added Enbrel and Taltz as preferred option for Plaque Psoriasis. Removed Cosentyx. Added Xeljanz/Xeljanz XR and Taltz as preferred option for Ankylosing spondylitis. Removed Cosentyx	Other Criteria	02/16/2022
10	Policy Update	Added Rinvoq as a preferred option for Ankylosing Spondylitis	Other Criteria	5/20/2022
11	Policy Update	Removed “Humira” and replaced with “Adalimumab” to account for biosimilar products (such as Amjevita)	Other Criteria	05/11/2023