Commercial PA Criteria

Effective: January 1, 2019

Prior Authorization: Cimzia

Products Affected: Cimzia (Certolizumab pegol) subcutaneous solution

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. **Ankylosing spondylitis**, for the treatment of adults with active disease.
2. **Crohn's disease**, for reducing signs and symptoms and maintaining clinical responses in adults with moderate to severe active disease who have had an inadequate response to conventional therapy.
3. **Non-radiographic axial spondyloarthritis**, in patients with objective signs of inflammation.
4. **Plaque psoriasis**, for the treatment of adults with moderately to severely active disease who are candidates for systemic therapy or phototherapy.
5. **Psoriatic arthritis**, for the treatment of adult patients with active disease.
6. **Rheumatoid arthritis**, for the treatment of adults with moderately to severely active disease.

Exclusion Criteria:

1. 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, Non-radiographic 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, 6 months (indication dependent)

Continuation: 1 year

Other Criteria:

1. **Ankylosing Spondylitis**
   Initial therapy: Approve for 6 months 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
   Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product.

Ankylosing Spondylitis
Enbrel
Adalimumab product
Taltz
Xeljanz/Xeljanz XR
Rinvoq

2. **Crohn's Disease**
   Initial therapy: Approve for 6 months if the patient meets the following criteria
   A. Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; **OR**
   B. Patient has tried one other conventional systemic therapy for Crohn's disease; **OR**
   Note: Examples of systemic therapies for Crohn's disease include azathioprine, 6-mercaptopurine, and methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.
   C. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; **OR**
   D. Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence **AND**
   E. Patient must have a trial and Documented failure of or intolerance to ONE **Adalimumab Product**
   Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, adalimumab-adbm, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry.

3. **Non-Radiographic Axial Spondyloarthritis**
   Initial therapy: Approve for 6 months if the patient meets the following criteria
   A. Patient has objective signs of inflammation, defined as at least ONE of the following (i **OR** ii):

i. C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; **OR**
ii. Sacroiliitis reported on magnetic resonance imaging (MRI)

4. Plaque Psoriasis

Initial therapy: Approve for 3 months if the patient meets the following criteria

A. Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; **OR**

Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to 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 psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

B. Patient has a contraindication to methotrexate, as determined by the prescriber; **AND**

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

Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, adalimumab-adbm, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product.

Plaque Psoriasis
Enbrel
Adalimumab Product
Otezla
Skyrizi SC
Sotyktu
Stelara SC
Taltz
Tremfya

5. <u>Psoriatic Arthritis</u>

Initial Therapy: Approve for 6 months 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

Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, adalimumab-adbm, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as ONE product.

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

6. Rheumatoid Arthritis

Initial Therapy: Approve for 6 months if the patient meets the following criteria (A, **AND** B)

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 of 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:

Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product.

Rheumatoid Arthritis
Enbrel
Adalimumab product

Actemra SC
Xeljanz/XR
Rinvoq

Continuation

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

B. Patient achieves or maintains a positive clinical response after at least initial duration therapy time frame with Cimzia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; December 2022.

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	Policy Update	Updated criteria for Crohn's Disease to step through Humira only, removed option for Stelara Added new indication nonradiographic axial spondyloarthritis	Other Criteria, Covered Uses	7/2/2019
4	Policy 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	Updated required trials for plaque psoriasis from two to three trials	Other Criteria	12/20/2019
7	Policy Update	Updated required trials for plaque psoriasis from three to two trials	Other Criteria	1/2020
8	Policy Update	Added Dosing limitations to match the FDA Label	Other Criteria	5/5/2020
9	Policy Update	Added Otezla as a preferred option for PsA diagnosis	Other Criteria	8/1/2020

10	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
11	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
12	Policy Update	Added Rinvoq as a preferred option for Ankylosing Spondylitis	Other Criteria	5/20/2022
13	Policy Update	Removed “Humira” and replaced with “Adalimumab” to account for biosimilar products (such as Amjevita)	Other Criteria	05/11/2023
14	Policy Update	Removed dosage limitations Removed Ankylosing Spondylitis/ Crohn’s Disease/ Non-radiographic spondylitis/ plaque psoriasis/ Psoriatic arthritis criteria and revised select criteria to implement to label coverage. Removal of *EmblemHealth does not consider alcohol use to be a clinical reason to use Cimzia over methotrexate.	Other Criteria	12/22/2023

15	Annual Review	Outlined specific coverage duration timeframes for individual indications.	Coverage duration	5/20/2024
16	Policy Update	For Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Plaque Psoriasis, and Crohn's Disease, Simlandi and adalimumab-ryvk were added to the list of Preferred adalimumab products that may have been tried prior to Cimzia. For Crohn's Disease, Zymfentra was added as a Preferred Product. A trial of two Step 1 or Step 2 Products is required (previously was two Step 1 Products). Sotyktu was added as a Step 1 Product that may have been tried prior to Cimzia. For Psoriatic Arthritis, Rinvoq LQ was added as a Step 2 Product that may have been tried prior to Cimzia.	Other Criteria	6/11/2024