BlueCross BlueShield Federal Employee Program.

CIMZIA
(certolizumab pegol)

Pre - PA Allowance

None

Prior-Approval Requirements

Cimzia Lyophilized Powder submitted under the medical benefit is not subject to biologic step edits.

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe Crohn's disease (CD)
    - **a.** 18 years of age or older
    - b. Inadequate treatment response, intolerance or contraindication to at least **ONE** conventional therapy option (see Appendix 1)
    - c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    - d. Patient **MUST** have tried Humira if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Moderate to severely active rheumatoid arthritis (RA)
    - a. 18 years of age or older
    - b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 3)
    - c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    - d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Active polyarticular juvenile idiopathic arthritis (pJIA)
    - a. 2 years of age or older
    - b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
    - c. Prescriber will not exceed the FDA labeled maintenance dose of the following:

i. Age 2-17, weight 10kg to < 20kg: 50 mg every other week
ii. Age 2-17, weight 20kg to < 40kg: 100 mg every other week
iii. Age 2-17, weight ≥40kg: 200 mg every other week
iv. Age 18 and older: 200 mg every other week

d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Active psoriatic arthritis (PsA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 3)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Active ankylosing spondylitis (AS)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

6. Active non-radiographic axial spondyloarthritis (nr-axSpA)
    a. 18 years of age or older
    b. Patient has objective signs of inflammation
    c. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
    d. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks

7. Moderate to severe plaque psoriasis (PsO)

a. 18 years of age or older
b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 3) or phototherapy
    i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate response, intolerance, or contraindication to the other treatment option
c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every other week
d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated.
3. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 3)
5. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Diagnosis	Starter Pack	Strength	Quantity
Ankylosing Spondylitis	**Yes**	200 mg	1 starter pack and 6 units per 84 days
Crohn's Disease			
Psoriatic Arthritis			
Rheumatoid Arthritis			
Non-radiographic Axial Spondyloarthritis			
Plaque Psoriasis	**Yes**	200 mg	1 starter pack and 12 units per 84 days
Polyarticular Juvenile Idiopathic Arthritis	**Yes**	200 mg	1 starter pack and 6 units per 84 days

Duration 12 months

Prior – Approval *Renewal* Requirements

***Cimzia Lyophilized Powder submitted under the medical benefit is not subject to biologic step edits*.**

Diagnoses

Patient must have **ONE** of the following:

1. Crohn's disease (CD)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    c. Patient **MUST** have tried Humira if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Polyarticular juvenile idiopathic arthritis (pJIA)
    a. 2 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Age 2-17, weight 10kg to < 20kg: 50 mg every other week
        ii. Age 2-17, weight 20kg to < 40kg: 100 mg every other week
        iii. Age 2-17, weight ≥40kg: 200 mg every other week
        iv. Age 18 and older: 200 mg every other week
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Psoriatic arthritis (PsA)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Ankylosing spondylitis (AS)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

6. Non-radiographic axial spondyloarthritis (nr-axSpA)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks

7. Plaque psoriasis (PsO)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every other week
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:

1. Condition has improved or stabilized with Cimzia
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 3)
4. **NOT** given concurrently with live vaccines

CIMZIA
(certolizumab pegol)

Prior - Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Ankylosing Spondylitis	200 mg	6 units per 84 days
Crohn's Disease		
Psoriatic Arthritis		
Rheumatoid Arthritis		
Non-radiographic Axial Spondyloarthritis		
Plaque Psoriasis	200 mg	12 units per 84 days
Polyarticular Juvenile Idiopathic Arthritis	200 mg	6 units per 84 days

Duration 18 months

Appendix 1 - List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Appendix 2 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix 3 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil

leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 4 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Ankylosing spondylitis (AS)	*must try **TWO** preferred products: Enbrel Humira** Rinvoq Taltz	*must try **ONE** preferred product: Enbrel Humira**

CIMZIA
(certolizumab pegol)

Crohn's disease (CD)	*must try **Humira** first: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira**
Plaque psoriasis (PsO)	*must try **TWO** preferred products: Enbrel Humira** Otezla Skyrizi Stelara (SC) Taltz Tremfya	*must try **ONE** preferred product: Enbrel Humira**
Polyarticular juvenile idiopathic arthritis (pJIA)	*must try **TWO** preferred products: Actemra (SC) Enbrel Humira** Rinvoq Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**
Psoriatic arthritis (PsA)	*must try **TWO** preferred products: Enbrel Humira** Otezla Rinvoq Skyrizi Stelara (SC) Taltz Tremfya Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**
Rheumatoid arthritis (RA)	*must try **TWO** preferred products Actemra (SC) Enbrel Humira** Rinvoq Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)