Generic Name: Certolizumab Pegol

Therapeutic Class or Brand Name: Cimzia®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 5250502010

Preferred: N/A.

Non-preferred: N/A.

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/20/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through F AND must meet criteria listed under applicable diagnosis:

A. Active Ankylosing Spondylitis and criterion 1 is met:

1. Diagnosis must be established by a rheumatologist.

B. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 and 2 are met:

1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Diagnosis must be established by a rheumatologist.

C. Active Psoriatic Arthritis and criterion 1 is met:

1. Diagnosis must be established by a rheumatologist or dermatologist.

D. Moderately to Severely Active Crohn's Disease and criteria 1 and 2 are met:

1. History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, methotrexate, 6-mercaptopurine, azathioprine, corticosteroids, or budesonide).
2. Treatment must be prescribed by a gastroenterologist.

E. Moderate to Severe Plaque Psoriasis and criteria 1 through 3 are met:

1. History of treatment failure, intolerance, or contraindication with phototherapy or photochemotherapy.
2. History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (i.e. cyclosporine, methotrexate, acitretin, etc.).
3. Diagnosis must be established by a dermatologist or a rheumatologist.

F. Active non-radiographic axial spondyloarthritis with objective signs of inflammation and criteria 1 is met:
    1. Diagnosis must be established by a rheumatologist.

II. Absence of active serious infection or sepsis.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

IV. Minimum age requirement: 18 years old.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Coadministration of Cimzia® with another targeted immune modulator. Examples of targeted immune modulators include the following:
    - Actemra® (tocilizumab)
    - Cosentyx® (secukinumab)
    - Entyvio® (vedolizumab)
    - Kevzara® (sarilumab)
    - Kineret® (anakinra)
    - Olumiant® (baricitinib)
    - Orencia® (abatacept)
    - Otezla® (apremilast)
    - Rinvoq™ (upadacitinib)
    - Rituxan® (rituximab)
    - Siliq™ (brodalumab)
    - Stelara® (ustekinumab)
    - Taltz® (Ixekizumab)
    - TNF inhibitors [Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
    - Tremfya™ (guselkumab)
    - Tysabri® (natalizumab)

- Xeljanz®/XR (tofacitinib)

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Plaque psoriasis patients weighing > 90 kg:
  - Quantities of up to 4 of the 200mg syringes or vials every 28 days.
- All other approved diagnoses, including plaque psoriasis patients weighing ≤ 90 kg:
  - Quantities of up to one 6 syringe starter pack (contains 6 of the 200mg syringes) for the first month, then in quantities of up to 2 of the 200mg syringes or vials every 28 days.

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

APPENDIX

N/A.

REFERENCES

1. U.S. Food and Drug Administration (FDA). FDA approves treatment for patients with a type of inflammatory arthritis. March 2019. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-patients-type-inflammatory-arthritis
2. Medispan®
3. Cimzia® [Package Insert]. Smyrna, GA: UCB. September 2019. Available at: https://www.cimzia.com/themes/custom/cimzia/docs/CIMZIA_full_prescribing_information.pdf

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/21/2020	1. **Added** "I. F. Active non-radiographic axial spondyloarthritis with objective signs of inflammation and criteria 1 is met: 1. Diagnosis must be established by a rheumatologist." **Under Prior Authorization Criteria**.

	2. **Changed** "Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products)" **to** "Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s)" **under Prior Authorization Criteria**. 3. **Changed** "Coadministration of Cimzia® with another biologic DMARD, Otezla® (apremilast), or Xeljanz®/XR (tofacitinib). Examples of biologic DMARDs include" **to** "Coadministration of Cimzia® with another targeted immune modulator. Examples of targeted immune modulators" **under Exclusion Criteria.** 4. **Added** "Rinvoq™ (upadacitinib)"; "Olumiant® (baricitinib)"; "Otezla® (apremilast)"; "Xeljanz®/XR (tofacitinib)" **under Exclusion Criteria**. 5. **Removed** "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru444reg.pdf" **Added** "https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-patients-type-inflammatory-arthritis" **under References**.
8/17/2018	1. **Deleted** Reference #2 (http://blue.regence.com/trgmedpol/drugs/dru160b.pdf) which was a duplicate of reference #1 2. **Changed** Reference #1 http://blue.regence.com/trgmedpol/drugs/dru160b.pdf (obsolete URL) to https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru444reg.pdf 3. **Added** Section E under PA criteria I for new plaque psoriasis indication: E. Moderate to Severe Plaque Psoriasis and criteria 1 through 3 are met: 1. History of treatment failure, intolerance, or contraindication with phototherapy or photochemotherapy. 2. History of treatment failure, intolerance, or contraindication with at least one appropriate systemic agent (i.e. cyclosporine, methotrexate, acitretin, etc.). 3. Diagnosis must be established by a dermatologist or a rheumatologist. 4. **Added** in Quantities/Days Supply Restrictions section: • Plaque psoriasis patients weighing > 90 kg: o Quantities of up to 4 of the 200mg syringes or vials every 28 days. • All other approved diagnoses, including plaque psoriasis patients weighing < 90 kg: 5. **Changed** existing "Quantities of up to one 6 syringe starter pack (contains 6 of the 200mg syringes) for the first month, then in quantities of up to 2 of the 200mg syringes or vials every 28 days" **to** a sub-bullet of added heading "All other approved diagnoses, including plaque psoriasis patients weighing > 90 kg:"
11/21/2017	1. **Added** "Kevzara® (sarilumab)", "Siliq™ (brodalumab)", **and** "Tremfya™ (guselkumab)" **to**

	list under Exclusion Criteria. 2. **Added** "Inflectra® (infliximab-dyyb)" **and** "Renflexis™ (infliximab-abda)" **following TNF Inhibitors to list under Exclusion Criteria**.
9/20/2016	1. **Reinserted** "Refer to Plan for individual adoption of specific Medication Policies" **in disclaimer**.
8/27/2016	1. **Changed** "V. Documented failure, intolerance, or contraindication to ALL preferred products (refer to plan document for the list of preferred products)" **to** "V. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 2. **Changed** "Coadministration of Cimzia® with…Xeljanz®(tofacitinib)…" **to** "Coadministration of Cimzia® with…Xeljanz®/ XR (tofacitinib)…" **under Exclusion Criteria**. 3. **Changed** "Cosentyx™" **to** "Cosentyx®" **under Exclusion Criteria**. 4. **Added** "Taltz® (Ixekizumab)" **to list under Exclusion Criteria**. 5. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20RA%20&%20PA%202014-12-26.pdf"**and** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20Crohns%202014-12-26.pdf" **under References** (links no longer valid).