



## MEDICATION POLICY

**Generic Name:** Certolizumab Pegol

**Therapeutic Class or Brand Name:** Cimzia®

**Applicable Drugs (if Therapeutic Class):** N/A

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 9/20/16

**GPI Code:** 5250502010

### **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 D 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.
- 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. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products).

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### Exclusion Criteria:

- Coadministration of Cimzia® with another biologic DMARD, Otezla® (apremilast), or Xeljanz®/ XR (tofacitinib). Examples of biologic DMARDs include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Kineret® (anakinra)
  - Orencia® (abatacept)
  - Rituxan® (rituximab)
  - Stelara® (ustekinumab)
  - Taltz® (Ixekizumab)
  - TNF inhibitors [Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi®/Simponi® Aria® (golimumab)]
  - Tysabri® (natalizumab)

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- 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:

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1. <http://blue.regence.com/trgmedpol/drugs/dru160.pdf>.
2. <http://blue.regence.com/trgmedpol/drugs/dru160b.pdf>.
3. [Medispan](#).
4. [http://www.cimzia.com/assets/pdf/Prescribing\\_Information.pdf](http://www.cimzia.com/assets/pdf/Prescribing_Information.pdf).

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<b>Historical Tracking Of Changes Made To Policy</b>	
9/20/2016	1. <b>Reinserted</b> “Refer to Plan for individual adoption of specific Medication Policies” in <b>disclaimer</b> .
8/27/2016	<p>1. <b>Changed</b> “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)” <b>under Prior Authorization Criteria</b>.</p> <p>2. <b>Changed</b> “Coadministration of Cimzia® with...Xeljanz®(tofacitinib)...” to “Coadministration of Cimzia® with...Xeljanz®/ XR (tofacitinib)...” <b>under Exclusion Criteria</b>.</p> <p>3. <b>Changed</b> “Cosentyx™” to “Cosentyx®” <b>under Exclusion Criteria</b>.</p> <p>4. <b>Added</b> “Taltz® (Ixekizumab)” to list <b>under Exclusion Criteria</b>.</p> <p>5. <b>Removed</b>  <a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20RA%20&amp;%20PA%202014-12-26.pdf">“https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20RA%20&amp;%20PA%202014-12-26.pdf”</a> and <a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20Crohns%202014-12-26.pdf">“https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20Crohns%202014-12-26.pdf”</a> <b>under References</b> (links no longer valid).</p>
3/2/2015	1. <b>Added</b> “Cosentyx™ (secukinumab)” to list <b>under Exclusion Criteria</b> .
2/26/2015	<p>1. <b>Changed</b> “Certolizumab” to “Certolizumab Pegol” <b>under Generic Name</b>.</p> <p>2. <b>Changed</b> “Documented diagnosis of one of the following conditions A or B...: A. Moderate to Severe Rheumatoid Arthritis or Psoriatic Arthritis and criteria 1 through 3 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. The number of swollen joints and tender joints must be 3 or more; 3. Diagnosis must be established by a rheumatologist; B. 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, MTX, 6-mercaptopurine, azathioprine, corticosteroids, or budesonide)...” to “Documented diagnosis of one of the following conditions A through D... 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)...” <b>under Prior Authorization Criteria</b>.</p> <p>3. <b>Changed</b> “Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition” to “Absence of active serious infection or sepsis” <b>under Prior Authorization Criteria</b>.</p> <p>4. <b>Changed</b> “Refer to plan document for the list of preferred products. If Cimzia® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product” to “Documented failure, intolerance, or contraindication to ALL preferred products (refer to plan document for the list of preferred products)” <b>under Prior Authorization Criteria</b>.</p> <p>5. <b>Changed</b> “Cimzia® may not be given with other biologic agents such as Interferon, experimental medications, or combinations” to “Coadministration of Cimzia® with another biologic DMARD, Otezla® (apremilast), or Xeljanz® (tofacitinib). Examples of biologic DMARDs include the following: Actemra® (tocilizumab); Entyvio® (vedolizumab); Kineret® (anakinra); Orencia® (abatacept); Rituxan® (rituximab); Stelara® (ustekinumab); TNF inhibitors [Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi®/Simponi® Aria® (golimumab)]; Tysabri® (natalizumab)” <b>under Exclusion Criteria</b>.</p> <p>6. <b>Added</b> “<a href="http://blue.regence.com/trgmedpol/drugs/dru160b.pdf">http://blue.regence.com/trgmedpol/drugs/dru160b.pdf</a>” <b>under References</b>.</p>

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<b>Historical Tracking Of Changes Made To Policy</b>	
	<p>7. <b>Updated</b> “<a href="http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/allentries.php">http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/allentries.php</a>” to “<a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20RA%20&amp;%20PA%202014-12-26.pdf">https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20RA%20&amp;%20PA%202014-12-26.pdf</a>” and “<a href="https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20Crohns%202014-12-26.pdf">https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Cimzia%20Crohns%202014-12-26.pdf</a>” <b>under References.</b></p> <p>8. <b>Updated</b> “<a href="http://www.cimzia.com/pdf/Prescribing_Information.pdf">http://www.cimzia.com/pdf/Prescribing_Information.pdf</a>” to “<a href="http://www.cimzia.com/assets/pdf/Prescribing_Information.pdf">http://www.cimzia.com/assets/pdf/Prescribing_Information.pdf</a>” <b>under References.</b></p>
10/15/2013	<p>1. <b>Adapted policy to new format.</b></p> <p>2. <b>Added</b> “Refer to plan document for the list of preferred products. If Cimzia® is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product” <b>requirement.</b></p> <p>3. <b>Changed criteria for Moderate to Severe Rheumatoid Arthritis from:</b>  “History of treatment, incomplete response, or intolerance to Methotrexate, or one other DMARD or second line drug (azathioprine, sulphadiazine, leflunomide, penicillamine, hydroxychloroquine, etc.); The number of swollen joints must be 6 or more and the number of tender joints must be 9 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER”; Rheumatology consult within the last 60 days”  <b>to</b>  “History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.); The number of swollen joints and tender joints must be 3 or more; Diagnosis must be established by a rheumatologist”.</p> <p>4. <b>Added</b> “Psoriatic Arthritis” as a <b>covered diagnosis</b>, and <b>assigned</b> the same <b>criteria</b> to this diagnosis as the criteria listed for the Moderate to Severe Rheumatoid Arthritis diagnosis.</p> <p>5. <b>Changed criteria for Moderately to Severely Active Crohn's Disease from:</b>  “Documented inadequate response to conventional therapy (i.e. 5-aminosalicylates, antibiotics, MTX, 6-mercaptopurine, azathioprine, corticosteroids, or budesonide)”  <b>to</b>  “History of treatment failure, intolerance, or contraindication to conventional therapy (i.e. 5-aminosalicylates, antibiotics, MTX, 6-mercaptopurine, azathioprine, corticosteroids, or budesonide); Treatment must be prescribed by a gastroenterologist”.</p> <p>6. <b>Changed wording for “Quantity/Days Supply Restrictions” from:</b>  “6 syringe starter pack x 1 month, then 2 syringe maintenance pack per 28 days”  <b>to</b>  “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”.</p> <p>7. <b>Updated references</b> to include Cimzia Prescribing Information.</p>

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