Updated: 03/2020
DMMA Approved: 03/2020

Request for Prior Authorization for Cimzia™ (certolizumab pegol)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Cimzia™ (certolizumab pegol) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Cimzia™ (certolizumab pegol) Prior Authorization Criteria:

For all requests for Cimzia™ (certolizumab pegol) all of the following criteria must be met:

- Member is 18 years of age or older
- The prescribing physician must be a Rheumatologist, Gastroenterologist, or Dermatologist.
- Cimzia™ is a non-preferred product, and requires that formulary alternative(s) were adequately tried and failed in addition to meeting criteria as outlined.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of **Rheumatoid Arthritis** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD.
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Psoriatic Arthritis** and the following criteria is met:

- Member has moderately to severely active psoriatic arthritis indicated by the presence of at least ONE of the following:
  - Erosive Disease
  - Elevated Markers of inflammation attributable to psoriatic arthritis
  - Long-term damage that interferes with function (i.e., joint deformities)
  - Highly active disease that causes a major impairment in quality of life
  - Active PsA at many sites including dactylitis, enthesitis
  - Function-limiting PsA at a few sites
  - Rapidly progressive disease.
- Member must have a history of trial and failure, contraindication, or intolerance to a four- week trial each of at least 2 NSAIDs
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Number of

swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Crohn's Disease** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including two or more of the following for at least 3 months of each medication:
  - Aminosalicylates, 5-ASAs (*i.e.,* Sulfasalazine, Pentasa®, Asacol®, Colazal®)
  - Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin)
  - Steroids (*i.e.,* prednisone, Entocort®)
  - Immunomodulators (*i.e.,* Azathioprine, 6-Mercaptopurine, Methotrexate)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Fistulizing Crohn's Disease** and the following criteria is met:

- Member must have clinical documentation of Crohn's disease with actively draining fistulas.
- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including all of the following for at least 3 months of each medication:
  - Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin)
  - Immunomodulators (*i.e.,* Azathioprine, 6-Mercaptopurine, Methotrexate)
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
  - **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Ankylosing Spondylitis and axial spondyloarthritis** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance to a four- week trial each of at least 2 NSAIDs.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
  - Reauthorization benefit will be approved if there is evidence of positive clinical response and/or stabilization involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, occiput-to-wall measurement.
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Plaque Psoriasis** and the following criteria is met:

- Member must have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 10% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals.
- Members must have therapeutic failure of a three-month trial or a contraindication to at least BOTH of the following:
    - Psoralens with UVA light (PUVA) or UVB light
    - Systemic treatments including ONE of the following:
        - Immunomodulators (i.e. Methotrexate, Cyclosporine)
        - Retinoids (i.e. Soriatane)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
    - Clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline must be submitted
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

HIGHMARK. Delaware HEALTH OPTIONS

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Cimzia™ (certolizumab pegol)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

- Is the prescribing physician a Rheumatologist, Gastroenterologist, or Dermatologist?
  ☐ Yes ☐ No

- Which of the following diagnoses is the medication being used for:
  ☐ Rheumatoid Arthritis, if selected please answer the following questions:

    - Is member 18 years of age or older?
      ☐ Yes ☐ No

    - Does the member have a history of trial, and failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD?
      ☐ Yes ☐ No

  ☐ Psoriatic Arthritis, if selected please answer the following questions:

    - Is member 18 years of age or older?

☐ Yes ☐ No

- Does the member have moderately to severely active psoriatic arthritis indicated by the presence of at least ONE of the following:
  - Erosive Disease
    ☐ Yes ☐ No
  - Elevated Markers of inflammation attributable to psoriatic arthritis
    ☐ Yes ☐ No
  - Long-term damage that interferes with function (i.e., joint deformities)
    ☐ Yes ☐ No
  - Highly active disease that causes a major impairment in quality of life
    ☐ Yes ☐ No
  - Active PsA at many sites including dactylitis, enthesitis
    ☐ Yes ☐ No
  - Function-limiting PsA at a few sites
    ☐ Yes ☐ No
  - Rapidly progressive disease
    ☐ Yes ☐ No

- Does member have a history of trial and failure, contraindication, or intolerance to a four-week trial of at least 2 NSAIDS?
  ☐ Yes ☐ No

☐ Crohn's Disease, if selected please answer the following questions:

- Is the member 6 years of age or older?
  ☐ Yes ☐ No

- Does the member have a history of trial and failure, contraindication, or intolerance to conventional treatments including two or more of the following for at least 3 months of each medication:
  i. Aminosalicylates, 5-ASAs (*i.e.,* Sulfasalazine, Pentasa®, Asacol®, Colazal®)
     ☐ Yes ☐ No

  ii. Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin)
     ☐ Yes ☐ No

  iii. Steroids (*i.e.,* prednisone, Entocort®)
     ☐ Yes ☐ No

  iv. Immunomodulators (*i.e.,* Azathioprine, 6-Mercaptopurine, Methotrexate)
     ☐ Yes ☐ No

☐ Fistulizing Crohn's Disease, if selected please answer the following questions:

a. Is the member 6 years of age or older?
   ☐ Yes ☐ No

b. Does the member have clinical documentation of Crohn's disease with actively draining fistulas?

☐ Yes ☐ No

c. Does the member have a history of trial and failure, contraindication, or intolerance to conventional treatments including two or more of the following for at least 3 months of each medication:

i. Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin)
☐ Yes ☐ No

ii. Immunomodulators (*i.e.,* Azathioprine, 6-Mercaptopurine, Methotrexate)
☐ Yes ☐ No

☐ Ankylosing spondylitis, or axial spondyloarthritis, if selected please answer the following questions:

a. Is the member 18 years of age or older?
☐ Yes ☐ No

b. Does the member have a history of trial and failure, contraindication, or intolerance to a four- week trial each of at least 2 NSAIDs?
☐ Yes ☐ No

☐ Plaque Psoriasis, if selected please answer the following questions:

a. Is there clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 10% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals?
☐ Yes ☐ No

b. Did the member have a therapeutic failure of a three-month trial or a contraindication to at ANY of the following:
i. Psoralens with UVA light (PUVA) or UVB light
☐ Yes ☐ No

ii. Systemic treatments including either immunomodulators or retinoids
☐ Yes ☐ No

☐ Other Diagnosis: _____

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION
1. Which of the following diagnoses will the medication be used for:

Please check the one that applies

a. Rheumatoid Arthritis ☐ Yes ☐ No
   i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
   ☐ Yes ☐ No

b. Psoriatic Arthritis ☐ Yes ☐ No
   i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
   ☐ Yes ☐ No

c. Crohn's Disease ☐ Yes ☐ No
   i. Is there documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

d. Fistulizing Crohn's Disease ☐ Yes ☐ No
   i. Is there documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

e. Ankylosing Spondylitis ☐ Yes ☐ No
   i. Is yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, occiput-to-wall measurement?
   ☐ Yes ☐ No

f. Plaque Psoriasis ☐ Yes ☐ No
   i. Is there clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline must be submitted? Clinical documentation must be submitted.
   ☐ Yes ☐ No

g. Other Diagnosis: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date