Updated: 03/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Cimzia (certolizumab pegol)

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

1) Member is an adult age of 18 years or older
2) The prescribing physician must be a Rheumatologist, Gastroenterologist, or Dermatologist.
3) 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 **Crohn's disease** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance to a steroid (*i.e.*, prednisone) for at least 3 months.
- Member must have a history of trial and failure, contraindication, or intolerance to Humira* for at least 3 months.
- **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 Humira* for at least 3 months.
- **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 **Rheumatoid Arthritis** and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD**.**
- Member must have a history of trial and failure, contraindication, or intolerance to Humira* or Enbrel* for at least 3 months.

- Member must have a history of trial and failure, contraindication, or intolerance to Xeljanz* for at least 3 months.
- **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 active psoriatic arthritis or clinical features that suggest psoriatic arthritis.
- Member must have a history of trial and failure, contraindication, or intolerance to Humira* or Enbrel* for at least 3 months.
- Member must have a history of trial and failure, contraindication, or intolerance to Xeljanz* for at least 3 months.
- **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 **Ankylosing Spondylitis and axial spondylarthritis** 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.
- Member must have a history of trial and failure, contraindication, or intolerance to Humira* or Enbrel* for at least 3 months.
- **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 5% 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**:
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval**: 12 months

*Enbrel, Humira and Xeljanz both require prior authorization. Member who is currently established on Cimzia will not be required to change to a preferred/formulary product.

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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

Updated: 03/2019
PARP Approved: 04/2019

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 Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 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:
Gateway 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:

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
- Is member 18 years of age or older?
  ☐ Yes ☐ No
- Which of the following diagnoses is the medication being used for:
  a. ☐ Crohn's Disease, if selected please answer the following questions:
     i. Does the member have a history of trial, and failure, contraindication, or intolerance to a three-month trial with a steroid (i.e. prednisone, etc)?
     ☐ Yes ☐ No
     ii. Does the member have history of trial and failure, contraindication, or intolerance to Humira* for at least 3 months?
     ☐ Yes ☐ No

b. ☐ Fistulizing Crohn's disease, if selected please answer the following questions:

i. Does the member have clinical documentation of Crohn's disease with actively draining fistulas?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to Humira* for at least 3 months?
☐ Yes ☐ No

c. ☐ Rheumatoid Arthritis, if selected please answer the following questions:

i. Does the member have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to Humira* or Enbrel* for at least 3 months?
☐ Yes ☐ No

iii. Does the member have a history of trial and failure, contraindication, or intolerance to Xeljanz* for at least 3 months?
☐ Yes ☐ No

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

i. Does the member have active psoriatic arthritis or clinical features that suggest psoriatic arthritis?
☐ Yes ☐ No

ii. Does the member have a history of trial and failure, contraindication, or intolerance to Humira* or Enbrel* for at least 3 months?
☐ Yes ☐ No

iii. Does the member have a history of trial and failure, contraindication, or intolerance to Xeljanz* for at least 3 months?
☐ Yes ☐ No

e. Ankylosing Spondylitis and , if selected please answer the following questions:

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

ii. Does the member have a history of trial and failure, contraindication, or intolerance to Humira* or Enbrel* for at least 3 months?
☐ Yes ☐ No

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

i. Does the member have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals?

☐ Yes ☐ No

ii. Does the members must have therapeutic failure of a three-month trial or a contraindication to any of the following?

1. Psoralens with UVA light (PUVA) or UVB light
   ☐ Yes ☐ No

2. Systemic treatments of the following:
   a. Immunomodulators (i.e. Methotrexate, Cyclosporine)
      ☐ Yes ☐ No

   b. Retinoids (i.e. Soriatane)
      ☐ 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. Crohn's Disease ☐ Yes ☐ No
      i. Is there documented, significant improvement with prior courses of treatment?
         ☐ Yes ☐ No

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

   c. 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

   d. 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

   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 documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

g. Other Diagnosis: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date