Updated: 10/2018
PARP Approved: 12/2018

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.

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

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 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)
- 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 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)
- 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 documented, significant improvement with prior courses of treatment.
- **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 which must include documentation of either active psoriatic lesions or documented history of psoriasis.
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following:
    - Member without axial disease:
        - Four- week trial each of at least 2 NSAIDs.
        - Eight week trial of methotrexate or other DMARD
    - Member with axial disease
        - 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.
- 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 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 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 documented, significant improvement with prior courses of treatment.
- **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**:
    - 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

*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

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PARP Approved: 12/2018

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:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6253 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 Arthrits, if selected please answer the following questions:

    - 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:

- Does the member have moderately to severely active psoriatic arthritis which includes documentation of either active psoriatic lesions or documented history of psoriasis?
  ☐ Yes ☐ No

- If the member is without axial disease, did the member have a four- week trial each of at least 2 NSAIDs AND eight week trial of methotrexate or other DMARD?
  ☐ Yes ☐ No

- If the member is with axial disease, did the member have a four- week trial each of at least 2 NSAIDs?
  ☐ Yes ☐ No

- If the member has psoriatic arthritis with enthesitis, did the member have a four- week trial each of at least 2 NSAIDs?
  ☐ Yes ☐ No

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

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

b. 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

☐ 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 5% 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) If the diagnosis is Rheumatoid Arthritis, Psoriatic Arthritis, Crohn's Disease, Fistulizing Crohn's Disease, ankylosing spondylitis and/or ankylosing spondylitis, has the member experienced a significant improvement with treatment? ☐ Yes ☐ No

2) If the diagnosis is Plaque Psoriasis, does the member have Clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline must be submitted**?**
☐ Yes ☐ No

Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date