Updated: 03/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Remicade (infliximab) and Infliximab Biosimilars

All requests for Remicade (infliximab) and Infliximab Biosimilars require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Infliximab Biosimilars include Renflexis™, Inflectra™, and Ixifi™. New products with this classification will require the same documentation.

The following agents are on formulary:

- Remicade™
- All other biosimilars are considered non-formulary and require documentation of failure with Remicade™ in addition to meeting the criteria outlined below.
- Members who are currently established on a Remicade biosimilar will not be required to change to a preferred/formulary product.

For all requests for Remicade (infliximab) and Infliximab Biosimilars all of the following criteria must be met:

- The prescribing physician must be a Rheumatologist, Gastroenterologist, or Dermatologist.
- 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 is 18 years of age or older.
- 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 is 18 years of age or older

- Member has active psoriatic arthritis or clinical features that suggest psoriatic arthritis.
- **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 be 6 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to a steroid (*i.e.*, prednisone) 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 be 6 years of age or older.
- Member must have clinical documentation of Crohn's disease with actively draining fistulas.
- **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 **Ulcerative Colitis** and the following criteria is met:

- Member must be 6 years of age or older (Remicade only, for all biosimilars patient must be 18 years of age or older).
- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including ONE of the following for at least 3 months:
  - Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)
  - 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.
    - **authorization 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 be 18 years of age or older
- 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 be 18 years of age or older
- 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

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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Remicade and Infliximab Biosimilars
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

- 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 active psoriatic arthritis or clinical features that suggest psoriatic arthritis
      ☐ 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 the following for at least 3 months of each medication:
    i. Steroids (*i.e.*, prednisone, Entocort®)
    ☐ 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

☐ Ulcerative Colitis, if selected please answer the following questions:

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

b. Does the have a history of trial and failure, contraindication, or intolerance to ANY the following treatments for at least 3 months:
i. Aminosalicylates, 5-ASAs (i.e., Sulfasalazine, Pentasa, Asacol, Colazal)
☐ Yes ☐ No

ii. Steroids (i.e., prednisone, Entocort)
☐ Yes ☐ No

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

b. 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

c. Did the member have a therapeutic failure of a three-month trial or a contraindication to 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. Ulcerative Colitis ☐ Yes ☐ No
      i. Is there documented, significant improvement with prior courses of treatment?
      ☐ Yes ☐ No

   f. 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

g. 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

h. Other Diagnosis: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	Date