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:**
  o 6 months
• **Reauthorization Criteria**
  o 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).
  o **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:**
  o Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
  o **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:**
  o Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
  o **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.
# 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

<table>
<thead>
<tr>
<th>Requesting Provider:</th>
<th>NPI:</th>
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<tbody>
<tr>
<td>Provider Specialty:</td>
<td>Office Contact:</td>
</tr>
<tr>
<td>Office Address:</td>
<td>Office Phone:</td>
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<td></td>
<td>Office Fax:</td>
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## MEMBER INFORMATION

<table>
<thead>
<tr>
<th>Member Name:</th>
<th>DOB:</th>
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<tr>
<td>Gateway ID:</td>
<td>Member weight: _____________ pounds or ____________ kg</td>
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## REQUESTED DRUG INFORMATION

<table>
<thead>
<tr>
<th>Medication:</th>
<th>Strength:</th>
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<tr>
<td>Frequency:</td>
<td>Duration:</td>
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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**

<table>
<thead>
<tr>
<th>Name:</th>
<th>NPI:</th>
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<td>Address:</td>
<td>Phone:</td>
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## 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:
    - [ ] 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:
    - [ ] 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

  o 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. Poralens with UVA light (PUVA) or UVB light  
      ☐ Yes  ☐ No
   ii. Systemic treatments including either immunomodulators or retinoids  
      ☐ Yes  ☐ No

☐ Other Diagnosis: ______________________________

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<tr>
<th>CURRENT or PREVIOUS THERAPY</th>
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<tbody>
<tr>
<td>Medication Name</td>
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<th>REAUTHORIZATION</th>
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| 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: ________________________________

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<th>SUPPORTING INFORMATION or CLINICAL RATIONALE</th>
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<tr>
<th>Prescribing Provider Signature</th>
<th>Date</th>
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