Updated: 01/2021
DMMA Approved: 01/2021

Request for Prior Authorization for Remicade (infliximab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Remicade (infliximab) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Remicade (infliximab) Prior Authorization Criteria:

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

- Must be prescribed by or in consultation with a Rheumatologist, Gastroenterologist, or Dermatologist.
- Must have a therapeutic failure, contraindication, or intolerance to the biosimilar agent(s) approved or medically accepted for the member's diagnosis
- 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 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 be 6 years of age or older.
- 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 be 6 years of age or older.
- 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 **Ulcerative Colitis** and the following criteria is met:

- Member must meet the following age requirements:
  - Member must be 6 years of age or older to utilize Remicade, Renflexis, Avsola, or Inflectra.
  - Member must be 18 years of age or older to utilize Ixifi.
- 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:
    - 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.
- **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 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 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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REMICADE (INFLIXIMAB)
PRIOR AUTHORIZATION FORM – PAGE 1 of 2

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:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
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, 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)

Diagnosis:	ICD Code:

Has a biosimilar agent been tried? ☐ Yes, please list all below as previous therapy ☐ No

For Rheumatoid Arthritis:

- Has methotrexate or another DMARD been tried for at least 3 months? ☐ Yes ☐ No

For Psoriatic Arthritis:

- Which of the following are present (check all that apply)?
  - 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
- Has there been a four-week trial of at least 2 different NSAIDS? ☐ Yes ☐ No

For Ankylosing spondylitis:

- Has there been a four-week trial of at least 2 different NSAIDS? ☐ Yes ☐ No

For Plaque Psoriasis:

- Does the member have 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
- Did the member have a therapeutic failure of a three-month trial or a contraindication to ANY of the following:
  - Psoralens with UVA light (PUVA) or UVB light ☐ Yes ☐ No
  - Systemic treatments including either immunomodulators or retinoids ☐ Yes ☐ No

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REMICADE (INFLIXIMAB)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

For Crohn's Disease:

- Does the member have actively draining fistulas? ☐ Yes ☐ No
- Which of the following have been tried for at least 3 months?
  - Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®) ☐ Yes ☐ No
  - Antibiotics (*i.e.*, Metronidazole, Ciprofloxacin) ☐ Yes ☐ No
  - Steroids (*i.e.*, prednisone, Entocort®) ☐ Yes ☐ No
  - Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate) ☐ Yes ☐ No

For Ulcerative Colitis:

- Which of the following have been tried for at least 3 months?
  - Aminosalicylates, 5-ASAs (i.e., Sulfasalazine, Pentasa, Asacol, Colazal) ☐ Yes ☐ No
  - Steroids (i.e., prednisone, Entocort) ☐ Yes ☐ No
  - Immunomodulators (i.e., Azathioprine, 6-Mercaptopurine, Methotrexate) ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced improvement with treatment? ☐ Yes ☐ No

For Rheumatoid Arthritis and Psoriatic Arthritis:
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

For Ankylosing Spondylitis:
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

For Plaque Psoriasis:
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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date