## Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications

1. Moderately to severely active Crohn’s disease
2. Moderately to severely active Ulcerative colitis
3. Moderately to severely active Rheumatoid arthritis in combination with methotrexate
4. Active Ankylosing spondylitis
5. Active Psoriatic arthritis
6. Chronic severe Plaque psoriasis

### Compendial Uses

1. Axial spondyloarthritis
2. Behcet’s syndrome
3. Granulomatosis with polyangiitis (Wegener’s granulomatosis)
4. Hidradenitis suppurativa
5. Juvenile idiopathic arthritis
6. Pyoderma gangrenosum
7. Sarcoidosis
8. Takayasu’s arteritis
9. Uveitis

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**Inflectra® (infliximab-dyyb)**
**Remicade® (infliximab)**
**Renflexis® (infliximab-abda)**

Effective 02/20/19

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ MassHealth</td>
<td>☒ Prior Authorization</td>
</tr>
<tr>
<td>☐ Commercial/Exchange</td>
<td>☒ Quantity Limit</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Benefit</th>
<th>☒ Pharmacy Benefit</th>
<th>☐ Medical Benefit (NLX)</th>
<th>☐ Step Therapy</th>
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</table>

**Specialty Limitations**

This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

### Contact Information

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Plans Phone: 866-814-5506 Fax: 866-249-6155</td>
<td>MassHealth Phone: 877-433-7643 Fax: 866-255-7569</td>
</tr>
<tr>
<td>Commercial Phone: 800-294-5979 Fax: 888-836-0730</td>
<td>Exchange Phone: 855-582-2022 Fax: 855-245-2134</td>
</tr>
</tbody>
</table>

| Medical Specialty Medications (NLX) | All Plans Phone: 844-345-2803 Fax: 844-851-0882 |

**Exceptions**

N/A
All other indications are considered experimental/investigational and are not a covered benefit.

**Coverage Guidelines**

**Rheumatoid arthritis (RA), Ankylosing spondylitis (AS), or Psoriatic arthritis (PsA)**
Authorization may be granted for members with a diagnosis of RA, AS, or PsA when ALL the following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following*:
   a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
   b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
   c. Note: *DMARD trial is not required in members with active Ankylosing spondylitis or Psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs.

2. Dosing is appropriate (see appendix A).
3. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira (i.e., member has had an inadequate response, adverse reaction, or contraindication to Enbrel AND Humira).

**Moderate-severe plaque psoriasis**
Authorization may be granted for members with a diagnosis of moderate-severe plaque psoriasis when ALL the following criteria are met, and documentation is provided:

1. Member is ≥18 years of age.
2. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
      i. 1 topical agent + 1 systemic agent
      ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
      iii. 1 systemic agent + 1 phototherapy
      iv. 2 systemic agents
   b. Contraindication to ALL conventional therapies
      i. Topical agents
      ii. Phototherapy
      iii. Systemic agents
   c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis

3. Dosing is appropriate (see appendix A).
4. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira (i.e., member has had an inadequate response, adverse reaction, or contraindication to Enbrel AND Humira)

**Crohn’s disease**
Authorization may be granted for members with a diagnosis of Crohn’s disease when ALL the following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following:
a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
  i. Aminosalicylate
  ii. Antibiotic
  iii. Corticosteroid
  iv. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
     1. Note: * If a request documents severe disease, a trial of an oral
        immunomodulator may be bypassed.

b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved
   for the requested indication

2. Dosing is appropriate (see appendix A).
3. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira
   (i.e., has had an inadequate response, adverse reaction, or contraindication to Enbrel AND
   Humira).

**Fistulizing Crohn’s disease**
Authorization may be granted for members with a diagnosis of fistulizing Crohn’s disease when ALL the
following criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction or contraindication to ONE immunomodulator
      (e.g., azathioprine or 6-mercaptopurine)
   b. Clinical rationale for use over oral immunomodulator (e.g., medical necessity for a faster-
      acting agent such as severe/refractory perianal disease, recent or planned surgical
      resection)
   c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved
      for Crohn’s disease

2. Dosing is appropriate (see appendix A).

**Ulcerative colitis**
Authorization may be granted for members with a diagnosis of ulcerative colitis when ALL the following
criteria are met, and documentation is provided:

1. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to at least ALL the following:
      i. Aminosalicylate
      ii. Corticosteroid
      iii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
         1. Note: * If a request documents severe disease, a trial of an oral
            immunomodulator may be bypassed.
   b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved
      for the requested indication

2. Dosing is appropriate (see appendix A for dosing).
3. Prescriber provides clinical rationale for use of the requested agent instead of Enbrel and Humira
   (i.e., member has had an inadequate response, adverse reaction, or contraindication to Enbrel
   AND Humira).

**Continuation of Therapy**
Reauthorization requires physician documentation indicating a positive response to therapy.

**Limitations**
1. Initial approvals will be varied based on the treatment:
   a. For RA, AS/PsA, CD, UC, approvals will be for 6 months.
   b. For plaque psoriasis, approvals will be for 3 months.
2. Reauthorizations will be for 12 months

**Appendices**

**Appendix A: Dosing**

<table>
<thead>
<tr>
<th>Pediatric Dosing</th>
<th>Other Dosing</th>
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</thead>
<tbody>
<tr>
<td><strong>Remicade®</strong> (infliximab)</td>
<td><strong>Ankylosing spondylitis:</strong> 5 mg/kg IV at weeks 0, 2, and 6, then every 6 weeks</td>
</tr>
<tr>
<td>Crohn’s Disease (moderate-severe) in patients with inadequate response to conventional therapy (≥ 6 years old): 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks</td>
<td>Crohn’s disease-fistulizing or moderate-severe not responding to conventional treatment: 5 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks</td>
</tr>
<tr>
<td>Ulcerative colitis (≥ 6 years old): 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks</td>
<td>Loss of response: 10 mg/kg IV every 8 weeks</td>
</tr>
<tr>
<td><strong>Plaque psoriasis-chronic, severe:</strong> 5 mg/kg IV at weeks 0, 2, and 6; then every 8 weeks</td>
<td><strong>Psoriatic arthritis:</strong> 5 mg/kg IV at weeks 0, 2, and 6 then every 8 weeks; with or without methotrexate</td>
</tr>
<tr>
<td><strong>Renflexis®</strong> (infliximab-abda)</td>
<td>Rheumatoid arthritis (moderate-severe)-in combination with methotrexate: 3 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks</td>
</tr>
<tr>
<td>Crohn’s Disease (moderate-severe) in patients with inadequate response to conventional therapy (≥ 6 years old): 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks</td>
<td>Incomplete response: 10 mg/kg IV every 8 weeks or 3 mg/kg IV every 4 weeks</td>
</tr>
</tbody>
</table>
| **Ulcerative colitis-in patients with inadequate response to conventional therapy:** 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks | **Psoriatic arthritis:**
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<tr>
<td>Inflectra® (infliximab-dyyb)</td>
<td><strong>Crohn’s Disease (moderate-severe) in patients with inadequate response to conventional therapy (≥ 6 years old):</strong> 5 mg/kg IV over 2 hours at weeks 0, 2, and 6; then every 8 weeks</td>
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<td></td>
<td><strong>Ankylosing spondylitis:</strong> 5 mg/kg IV at weeks 0, 2, and 6, then every 6 weeks</td>
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<td><strong>Crohn’s disease-fistulizing or moderate-severe not responding to conventional treatment:</strong> 5 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks</td>
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<td><strong>Rheumatoid arthritis (moderate-severe)-in combination with methotrexate:</strong> 3 mg/kg IV at weeks 0, 2, and 6, then every 8 weeks</td>
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<td><strong>Incomplete response:</strong> 10 mg/kg IV every 8 weeks or 3 mg/kg IV every 4 weeks</td>
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<td><strong>Ulcerative colitis-in patients with inadequate response to conventional therapy:</strong> 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks</td>
</tr>
</tbody>
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**References**

1. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc; June 2018.


**Review History**

03/21/05 – Reviewed
05/15/05 – Effective
02/27/06 – Reviewed and revised
02/25/08 – Reviewed and revised
02/23/09 – Reviewed and revised
02/22/10 – Reviewed
02/28/11 – Reviewed and revised
02/27/12 – Reviewed and revised
02/25/13 – Reviewed and revised
02/24/14 – Reviewed and revised
02/23/15 – Reviewed
02/22/16 – Reviewed
02/27/17 – Reviewed and revised (added Inflectra; adopted SGM & ST) in P&T Meeting
03/01/18 – Reviewed and revised
02/20/19 – Reviewed in P&T Meeting

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