Medical Coverage Criteria
Remicade® (infliximab)

This document contains the most current medical coverage criteria using guidance from experts and approved by the Physicians Plus Pharmacy and Therapeutics Committee. This document remains dynamic and will be updated from time to time as new evidence becomes available reflecting substantive changes in care. The most recent version of the medical coverage criteria can be found at www.pplusic.com.

Boxed Warning (see full prescribing information for details)

1. Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.
2. Discontinue infliximab if a patient develops a serious infection.
3. Perform test for latent TB; if positive, start treatment for TB prior to starting infliximab. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.
4. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab.
5. Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers including infliximab. All infliximab cases were reported in patients with Crohn's disease or ulcerative colitis, the majority of whom were adolescent or young adult males. All had received azathioprine or 6-mercaptopurine concomitantly with infliximab at or prior to diagnosis.

FDA Indications (see full prescribing information for disease specific dosage and administration)

Crohn’s Disease
• Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
• Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

Pediatric Crohn’s Disease
• Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis
• Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis
• Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis in combination with methotrexate
• Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.

Ankylosing Spondylitis
• Reducing signs and symptoms in patients with active disease.

Psoriatic Arthritis
• Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

Plaque Psoriasis
• Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

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START HERE

Member & Prescriber Information

Member Name: __________________________
Prescriber Name: _______________________

Member Date of Birth: ___________________
Prescriber Specialty: ____________________

Member ID #: __________________________
Prescriber Phone #: _____________________

Member PCP Name & Address: _____________
Name & Location of Infusion Center: ______

Criteria
Complete and submit all pages of request
Use in non-FDA approved indications require specialist referral and written documentation outlining treatment and follow-up plans.
Submit copies of all immunoglobulin lab reports showing thresholds for low levels.
Note: needle phobic patients may prefer clinic administered Cimzia for appropriate indications.

Current status of patient therapy (check a box):
- New to Infliximab therapy
- Continuing Infliximab therapy
- Primary use in condition that is non-FDA approved

Primary indication being treated:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab (Humira)</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Budesonide EC</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Cyclosporine</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Prednisone</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>Sulfasalazine/Mesalamine / Balsalazide</td>
<td>active, inactive, not used</td>
</tr>
<tr>
<td>6-Mercaptopurine</td>
<td>active, inactive, not used</td>
</tr>
</tbody>
</table>

Regimen (dependant on product availability)

Anticipated Start Date: ________________ Stop Date: ________________
Total Dose: __________________________
Mg/Kg: __________________________
Dosing Frequency: ____________________
Weight: __________________________

Prescriber Signature: __________________________ Date: ________________
Prescriber NPI (required): __________________________

Mailing Address
Physicians Plus Insurance Corporation
Attn: Pharmacy Services
P.O. Box 2078
Madison WI 53701-2078

Physicians Plus Pharmacy Services Fax: (608) 327-0324
Prior Authorization Questions?
(608) 260-7803 or (800) 545-5015
www.pplusic.com/providers
Condition Specific Criteria
(complete and submit this page, too)

Step 1:
Choose primary condition being treated

Step 2:
Select condition criteria that apply

Step 3:
Check all treatment criteria that apply

- **Crohn Colitis**
  - Severe disease activity
  - Received infliximab in hospital
  - Fistulizing Crohn’s for at least 3 months
  - Must be prescribed by a gastroenterologist
  - Failed Humira

- **Ulcerative Colitis**
  - Moderate to Severe disease activity
  - Must be prescribed by a gastroenterologist
  - Failed Humira

- **Crohn’s Disease**
  - Moderate disease activity
  - Must be prescribed by a gastroenterologist
  - Failed Humira

- **Rheumatoid Arthritis in combination with methotrexate**
  - Moderate to severe disease activity
  - Must be prescribed by a rheumatologist
  - Failed Humira and Enbrel

- **Ankylosing Spondylitis**
  - Moderate to severe disease activity
  - Must be prescribed by a rheumatologist
  - Failed two or more NSAIDS
  - Failed at least one DMARD (sulfasalazine, Hydroxychloroquine or methotrexate)
  - Failed Humira and Enbrel

- **Plaque Psoriasis**
  - Moderate to severe disease activity
  - Affects ≥ 10% body surface area
  - PASI score of 10 or more
  - Must be prescribed by a dermatologist
  - Failed at least 2 months of phototherapy or reason not appropriate:
  - Failed Humira and Enbrel

- **Psoriatic Arthritis**
  - Moderate to severe disease activity
  - Must be prescribed by a dermatologist or rheumatologist
  - Failed Humira and Enbrel

Describe in detail the nature of not using listed formulary therapies (supply clinic notes for off-label use)