

# Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to:  **Commercial (Traditional)**     **Commercial (Individual/Optimized)**

**Medicaid**

This request is:  **Urgent** (life threatening)     **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

## Renflexis™ (infliximab-abda)

### Member

Last Name: \_\_\_\_\_ First Name: \_\_\_\_\_  
 ID #: \_\_\_\_\_ DOB: \_\_\_\_\_ Gender: \_\_\_\_\_  
 Primary Care Physician: \_\_\_\_\_  
 Requesting Physician: \_\_\_\_\_ Phys. Phone: \_\_\_\_\_ Phys. Fax: \_\_\_\_\_  
 Physician Address: \_\_\_\_\_  
 Physician NPI: \_\_\_\_\_ Contact Name: \_\_\_\_\_  
 Provider Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Product and Billing Information

New Request     Continuation Request  
 Drug product:  Renflexis 100 mg vial    **Dose:** \_\_\_\_\_ **Dose Frequency:** \_\_\_\_\_  
**Start date** (or date of next dose): \_\_\_\_\_  
**Date of last dose** (if applicable): \_\_\_\_\_  
**Date of next dose:** \_\_\_\_\_

Place of administration:  Physician's office  
 Outpatient infusion    Facility: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_  
 Home infusion    Facility: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

Billing:  Physician to buy and bill  
 Facility to buy and bill  
 Specialty Pharmacy    Pharmacy: \_\_\_\_\_ NPI: \_\_\_\_\_ Fax: \_\_\_\_\_

ICD-10 Diagnosis code(s): \_\_\_\_\_

## INFLIXIMAB COVERAGE POLICY

### Precertification Requirements

On and after May 1, 2016, infusion of infliximab is not covered at hospital-affiliated infusion centers. Patients age 17 and younger may choose to have this drug administered at a hospital-affiliated infusion center.

Before infliximab is covered, the patient must meet all of the requirements for the treatment diagnosis listed in this policy and the prescribe dose is within covered dosing limits. Priority Health only covers the diagnoses listed below in this policy. Priority Health may consider a diagnosis not listed in this policy to be not medically necessary and/or experimental and investigational. If the criteria outlined in this coverage policy are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary.

For all diagnoses, the patient must:

- have evidence of a negative TB test result within 12 months of starting infliximab, and
- not have moderate to severe heart failure.

1. Ankylosing spondylitis

Infliximab is covered for ankylosing spondylitis if the patient has:

- a) active disease present for at least 4 weeks;
- b) a therapeutic trial with two nonsteroidal anti-inflammatory drugs (NSAID's) during a single 3-month period

2. Crohn's disease – mild

Infliximab is covered for mild Crohn's disease if the patient has a therapeutic trial with:

- a) corticosteroids;
- b) one of the following: sulfasalazine, olsalazine, mesalamine, azathioprine, 6-MP, or methotrexate

3. Crohn's disease – moderate to severe

Priority Health considers a patient to have moderate to severe Crohn's disease if the initial diagnosis of Crohn's disease was before age 30 years; the condition has extensive anatomic involvement, perianal and/or severe disease, deep ulcers, stricturing and/or penetrating behavior, or fistulas; or the patient had a prior surgical resection.

Infliximab is covered for moderate to severe Crohn's disease if the patient has a therapeutic trial with:

- a) Corticosteroids; and

Priority Health will cover infliximab more frequently than 10 mg/kg every eight weeks (a shortened dose interval) for Crohn's disease, after the patient has completed induction dosing, for no more than two months to allow the patient to achieve disease remission once again. Shortened dosing is covered when the patient:

- o previously responded to infliximab by achieving disease remission when dosed every eight weeks, and
- o is currently experiencing a flare of Crohn's disease likely to result in a hospitalization.

4. Hidradenitis Suppurativa

Infliximab is covered for hidradenitis suppurativa if the patient has:

- a) documented inadequate response to intralesional corticosteroids; and
- b) documented inadequate response to procedural interventions (punch debridement) in combination with pharmacologic therapies; and
- c) documented inadequate response of systemic and topical antibiotic therapy including:
  - o three months of topical antibiotic; and
  - o three months of oral doxycycline; and
  - o three months of clindamycin plus rifampin

5. Plaque psoriasis – severe (extensive and disabling)

Infliximab is covered for severe (extensive and disabling) plaque psoriasis if the patient has:

- a) disease involvement of more than 10% body surface area, unless the hands, feet, head, neck, or genitalia are involved; and
- b) a documented therapeutic trial with:
  1. one topical agent;
  2. phototherapy (UVA, UVA plus methoxsalen, or UVB);
  3. one of the following non-biologic drugs: acitretin, azathioprine, cyclosporine, or methotrexate

6. Psoriatic arthritis

Infliximab is covered for psoriatic arthritis after the patient first has a therapeutic trial with:

- a) one non-biologic DMARD

7. Rheumatoid arthritis

Infliximab is covered for rheumatoid arthritis if the patient:

- a) has a therapeutic treatment with one non-biologic disease-modifying antirheumatic drug (DMARD)
- b) is treated with methotrexate following infliximab infusions.

8. Ulcerative colitis – severe

Priority Health considers a patient to have severe ulcerative colitis when the patient has 6 or more loose bloody stools with severe cramps and systemic toxicity. If the patient has also previously tried corticosteroids, infliximab is covered.

Infliximab is covered for every 8 week dosing following induction therapy. When dosed more frequently than every 8 weeks for severe ulcerative colitis (post-induction), approval for shortened interval dosing is covered for 8 weeks for a maximum of two months if required to treat a flare of disease previously under control if all of the following criteria are met:

- a) Patient must have previously responded to infliximab dosed every 8 weeks
- b) Patient must be experiencing a flare of ulcerative colitis
- c) The ulcerative colitis flare must be likely to result in hospitalization

9. Ulcerative colitis - mild to moderate

Infliximab is covered for mild to moderate ulcerative colitis after the patient has a:

- a) moderate to severe attack; AND
- b) documented therapeutic trial with one of the following: aminosalicylates, corticosteroids, azathioprine, 6-mercaptopurine

10. Uveitis

Infliximab is covered for treatment refractory uveitis after the patient has:

- a) trial and failure of periocular, intraocular, or systemic corticosteroids, and
- b) trial and failure of immunosuppressive drugs (e.g., azathioprine, cyclosporine, mycophenolate or methotrexate) at maximally tolerated doses

**Additional information**

**Note:** Priority Health does not cover this medication in combination with any other biologic therapies.

**Dosing limitations**

**Table 1. Dose and duration of authorization covered by Priority Health**

Condition	Initial authorization	Continued authorization
<ul style="list-style-type: none"> <li>▪ Ankylosing spondylitis</li> </ul>	<ul style="list-style-type: none"> <li>• Approved for 2 years</li> <li>• 19 infusions given as 5 mg/kg at 0, 2, 6, and 12 weeks, then every 6 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 17 infusions approved for an additional 2 years given as 5 mg/kg every 6 weeks</li> </ul>
<ul style="list-style-type: none"> <li>▪ Crohn's disease</li> <li>▪ Pediatric Crohn's disease</li> </ul>	<ul style="list-style-type: none"> <li>• Approved for 2 years</li> <li>• 16 infusions given as 5 mg/kg at 0, 2, 6, and 14 weeks, then every 8 weeks, up to 10mg/kg</li> </ul>	<ul style="list-style-type: none"> <li>• 13 infusions approved for an additional 2 years given as 5 mg/kg, up to 10 mg/kg, every 8 weeks</li> <li>• For patients experiencing a Crohn's disease flare unresponsive to every 8 week dosing, shortened interval dosing is approved for a maximum of two months. After two months, a dose reduction to every 8 week dosing is required.</li> </ul>
<ul style="list-style-type: none"> <li>▪ Ulcerative colitis</li> <li>▪ Pediatric ulcerative colitis</li> </ul>	<ul style="list-style-type: none"> <li>• Approved for 2 years</li> <li>• 16 infusions given as 5 mg/kg at 0, 2, 6, and 14 weeks, then every 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 13 infusions approved for an additional 2 years given as 5 mg/kg every 8 weeks</li> <li>• For patients experiencing an ulcerative colitis flare unresponsive to every 8 week dosing, shortened interval dosing is approved for a maximum of two months. After two months, a dose reduction to every 8 week dosing is required.</li> </ul>
<ul style="list-style-type: none"> <li>▪ Plaque psoriasis</li> <li>▪ Psoriatic arthritis</li> </ul>	<ul style="list-style-type: none"> <li>• Approved for 2 years</li> <li>• 16 infusions given as 5 mg/kg at 0, 2, 6, and 14 weeks, then every 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 13 infusions approved for an additional 2 years given as 5 mg/kg every 8 weeks</li> </ul>
<ul style="list-style-type: none"> <li>▪ Rheumatoid arthritis</li> </ul>	<ul style="list-style-type: none"> <li>• Must be taken with methotrexate</li> <li>• Approved for 2 years</li> <li>• 16 infusions given as 3 mg/kg at 0, 2, 6, and 14 weeks, then every 8 weeks, up to 10mg/kg</li> </ul>	<ul style="list-style-type: none"> <li>• 13 infusions approved for an additional 2 years given as 3 mg/kg, up to 10 mg/kg, every 8 weeks</li> <li style="text-align: center;">—or—</li> <li>• 26 infusions approved for an additional 2 years given as 3 mg/kg every 4 weeks <i>(This option is for patients who do not adequately respond to treatment when infusions are given every 8 weeks.)</i></li> </ul>
<ul style="list-style-type: none"> <li>▪ Hidradenitis Suppurativa</li> <li>▪ Uveitis</li> </ul>	<ul style="list-style-type: none"> <li>• Approved for 2 years</li> <li>• 16 infusions given as 5mg/kg at 0, 2, 6, and 14 weeks, then every 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 13 infusions approved for an additional 2 years given as 5 mg/kg every 8 weeks</li> </ul>

**New request  
Priority Health Precertification Documentation**

**What is the date and result of the patient's most recent TB test?**

Date of test: \_\_\_\_\_  Negative  Positive

**Does the patient have moderate to severe heart failure?**

Yes  
 No

**Use this section for shortened interval dosing requests for Crohn's disease or ulcerative colitis.**

Limited evidence is available evaluating the infliximab dosed more frequently than every eight weeks. Clinical practice experience, however, suggests shortened dosing intervals may be effective in patients experiencing a flare of CD or UC disease while using the drug every eight weeks.

**A. Has the patient responded previously to every eight week dosing?**

Yes  No – *Rationale for use:* \_\_\_\_\_

**B. Is the patient experiencing a Crohn's disease or ulcerative colitis flare?**

Yes  No – *Rationale for use:* \_\_\_\_\_

**C. Is the patient's Crohn's Disease or ulcerative colitis flare likely to result in hospitalization?**

Yes  No – *Rationale for use:* \_\_\_\_\_

Covered condition (Place an "X" in the box for the condition this drug is being requested for.)	Requirements that must be met before the drug is covered (Place an "X" in the appropriate box to indicate the patient has met the required criteria.)
<input type="checkbox"/> Ankylosing spondylitis	1. Has the patient: had active disease present for 4 weeks or longer? <input type="checkbox"/> Yes <input type="checkbox"/> No  2. What nonsteroidal anti-inflammatory drugs (NSAID's) has the patient tried, and when? Drug: _____ Dates: _____ Drug: _____ Dates: _____
<input type="checkbox"/> Psoriatic arthritis <input type="checkbox"/> Rheumatoid arthritis	1. What non-biologic DMARD has the patient tried? <input type="checkbox"/> auranofin <input type="checkbox"/> aurothioglucose <input type="checkbox"/> azathioprine <input type="checkbox"/> cyclosporine <input type="checkbox"/> d-penicillamine <input type="checkbox"/> gold sodium thiomalate <input type="checkbox"/> hydroxychloroquine <input type="checkbox"/> leflunomide <input type="checkbox"/> methotrexate <input type="checkbox"/> sulfasalazine <input type="checkbox"/> None, the patient has tried: _____  2. Will the patient also take methotrexate following the Inflectra infusion? <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Plaque psoriasis	1. What disease involvement does the patient have? <input type="checkbox"/> _____% body surface area <input type="checkbox"/> neck <input type="checkbox"/> hands <input type="checkbox"/> feet <input type="checkbox"/> head <input type="checkbox"/> genitalia  2. What topical drug(s) has the patient tried? _____  3. What type of phototherapy has the patient tried? <input type="checkbox"/> UVA <input type="checkbox"/> UVB <input type="checkbox"/> UVA+methoxsalen <input type="checkbox"/> None  4. What non-biologic systemic drug has the patient tried? <input type="checkbox"/> azathioprine <input type="checkbox"/> cyclosporine <input type="checkbox"/> methotrexate <input type="checkbox"/> Soriatane One of the listed non-biologic drugs was not used because: _____ _____

<input type="checkbox"/> Crohn's disease	<p>1. Which, if any, of the following apply to this patient's condition?</p> <input type="checkbox"/> diagnosed before age 30 years <input type="checkbox"/> extensive anatomic involvement <input type="checkbox"/> perianal and/or severe disease <input type="checkbox"/> deep ulcers <input type="checkbox"/> stricturing and/or penetrating behavior <input type="checkbox"/> fistulas <input type="checkbox"/> prior surgical resection
<input type="checkbox"/> Ulcerative colitis	<p>2. Which of the following drugs has the patient tried?</p> <input type="checkbox"/> corticosteroids <input type="checkbox"/> sulfasalazine <input type="checkbox"/> olsalazine <input type="checkbox"/> mesalamine <input type="checkbox"/> azathioprine <input type="checkbox"/> 6-MP <input type="checkbox"/> methotrexate <input type="checkbox"/> Other drug(s): _____
<input type="checkbox"/> Hidradenitis Suppurativa	<p>1. Which, if any, of the following apply to this patient's condition?</p> <input type="checkbox"/> Currently experiencing 6 or more loose, bloody stools with severe cramps <input type="checkbox"/> Patient has systemic toxicity
<input type="checkbox"/> Uveitis	<p>2. Which of the following drugs has the patient tried?</p> <input type="checkbox"/> aminosalicylates <input type="checkbox"/> azathioprine <input type="checkbox"/> corticosteroids <input type="checkbox"/> 6-MP <input type="checkbox"/> Other drug(s): _____
<input type="checkbox"/> Hidradenitis Suppurativa	<p>1. Which of the following does the patient have a documented inadequate response to?</p> <input type="checkbox"/> intralesional corticosteroids Drug/dose: _____ Dates: _____ Drug/dose: _____ Dates: _____ <input type="checkbox"/> procedural interventions (punch debridement) in combination with pharmacologic therapies
<input type="checkbox"/> Uveitis	<p>2. Which of the following systemic and topical antibiotic therapies has the patient tried?</p> <input type="checkbox"/> 3 months of a topical antibiotic Drug/dose: _____ Dates: _____ <input type="checkbox"/> 3 months of oral doxycycline <input type="checkbox"/> 3 months of clindamycin plus rifampin
<input type="checkbox"/> Uveitis	<p>1. Which of the following drugs has the patient tried?</p> <input type="checkbox"/> periocular, intraocular corticosteroids <input type="checkbox"/> systemic corticosteroids <input type="checkbox"/> Other drug(s): _____
<input type="checkbox"/> Uveitis	<p>2. Which of the following drugs has the patient tried?</p> <input type="checkbox"/> azathioprine <input type="checkbox"/> cyclosporine <input type="checkbox"/> mycophenolate <input type="checkbox"/> methotrexate <input type="checkbox"/> Other drug(s): _____