



MEDICARE FORM

Inflectra® (infliximab-dyyb) Injectable Medication Precertification Request

Page 1 of 5

(All fields must be completed and legible for Precertification Review.)

For Medicare Advantage Part B: PHONE: 1-866-503-0857 FAX: 1-844-268-7263

For other lines of business: Please use other form.

Note: Inflectra is non-preferred. Preferred products vary based on indication. See section G below.

Please indicate: Start of treatment: Start date / / Continuation of therapy: Date of last treatment / /

Precertification Requested By: Phone: Fax:

Form sections: A. PATIENT INFORMATION, B. INSURANCE INFORMATION, C. PRESCRIBER INFORMATION, D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION, E. PRODUCT INFORMATION, F. DIAGNOSIS INFORMATION, G. CLINICAL INFORMATION. Includes fields for patient details, insurance, prescriber info, and clinical notes.

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G. CLINICAL INFORMATION (continued) - Required clinical information must be completed in its entirety for all precertification requests.

Ankylosing Spondylitis and Other Spondyloarthropathies

Please select which of the following applies to the patient: Ankylosing spondylitis Other spondyloarthropathy

- Is there evidence that the disease is active?
Is there evidence of inflammatory disease?
Has the patient had an ineffective response to two or more non-steroidal anti-inflammatory drugs (NSAIDs)?
Please provide the names and length of treatment:
NSAID #1:
NSAID #2:

Behcet's Disease

- Is the disease refractory to corticosteroids or immunosuppressive drugs?
Please indicate: corticosteroids immunosuppressive drugs
Please provide the name of drug tried:

Behcet's Uveitis

- Is the disease refractory?

Chronic Cutaneous/Pulmonary sarcoidosis

- Has the patient remained symptomatic despite treatment with steroids?
Please provide the daily dose of steroids: Dose: mg
Has the patient remained symptomatic despite treatment with immunosuppressants?
Please select: azathioprine cyclophosphamide methotrexate Other, please explain:

Crohn's Disease

- Does the patient have a diagnosis of fistulizing Crohn's disease?
Please indicate how long the patient has been diagnosed with fistulizing Crohn's disease:
Does the patient have a diagnosis of Crohn's disease?
Please indicate the severity of the patient's disease: mild moderate severe
Does the patient have a documented diagnosis of active Crohn's disease?
Please select all signs/symptoms that apply:
abdominal pain arthritis bleeding diarrhea internal fistulae intestinal obstruction
megacolon perianal disease spondylitis weight loss None of the above
Have the Crohn's disease symptoms remained active despite treatment with 6-mercaptopurine, azathioprine, or corticosteroids?
Please check all medications that apply: 6-mercaptopurine azathioprine
corticosteroids- please identify: prednisone hydrocortisone methylprednisolone Other:

Hidradenitis Suppurativa

- Please indicate the stage of hidradenitis suppurativa: Hurley stage I (mild disease) Hurley stage II (moderate disease)
Hurley stage III (severe disease) Unknown
Has the patient completed a trial of antibiotics?
Does the patient have a contraindication to oral antibiotics?
Was the treatment with antibiotics ineffective?

Immune Checkpoint Inhibitor- Induced Toxicities

- Please indicate therapy used:
CTLA-4
Please select drug: ipilimumab Other:
PD-1
Please select drug: nivolumab pembrolizumab Other:
PD-L1
Please select drug: atezolizumab avelumab durvalumab Other:
Other
Please explain:
Do the immune checkpoint inhibitor-induced toxicities persist despite discontinuation of immune checkpoint inhibitors that target CTLA-4 or PD-1/PD-L1 (e.g., atezolizumab, ipilimumab, nivolumab, pembrolizumab)?

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

**Please indicate the toxicity (check all that apply):**

- Cardiac** Which life-threatening immune checkpoint inhibitor-induced cardiac toxicities does the patient have?  
Please select:  arrhythmias  impaired ventricular function  myocarditis  pericarditis
- Colitis** Please indicate the severity of the immune checkpoint inhibitor-induced colitis:  mild  moderate  severe  
Please indicate which of the following symptoms the patient exhibits:  7 or more stools per day over baseline  ileus  fever  None  
 Yes  No Has the patient been treated with corticosteroids?  
     Yes  No Did the patient show improvement after 48 hours of corticosteroids?  
    Please indicate the corticosteroid name: \_\_\_\_\_
- Elevated serum creatinine/acute renal failure**  
Please indicate the severity of the disease:  
 Severe (creatinine greater than 3 times baseline or greater than 4 mg/dL)  
 Life-threatening (creatinine greater than 6 times baseline; dialysis indicated)  
 None of the above  
 Yes  No Has the patient been treated with corticosteroids?  
    Please indicate the name and length of therapy: Name: \_\_\_\_\_ Length:  Less than 1 week  1 week or greater  
 Yes  No Did the creatinine level remain greater than 2 to 3 times above baseline after 1 week of treatment with corticosteroids?
- Inflammatory arthritis**  
 Yes  No Does the patient have refractory or severe disease?  refractory disease  severe disease  
 Yes  No Is the patient responding to corticosteroids or anti-inflammatory agents?  anti-inflammatory agents  corticosteroids
- Pneumonitis**  
Please indicate the severity of the disease:  mild  moderate  severe  
 Yes  No Has the patient been treated with corticosteroids for pneumonitis?  
    Please indicate the corticosteroid name: \_\_\_\_\_  
 Yes  No Did the patient show improvement after 48 hours of corticosteroids?

**Juvenile Idiopathic Arthritis (Juvenile Rheumatoid Arthritis)**

- Please indicate the severity of the patient's disease:  mild  moderate  severe
- Yes  No Is there evidence that the disease is active?
- Yes  No Does the patient have clinical documentation of polyarticular juvenile idiopathic arthritis (JRA)?
- Yes  No Was treatment with Enbrel (etanercept) ineffective?
- Yes  No Does the patient have a documented intolerance to Enbrel (etanercept)?
- Yes  No Does the patient have a documented contraindication to Enbrel (etanercept)?

**Noninfectious Uveitis**

- Yes  No Was the treatment with corticosteroids ineffective?  
    Please indicate the corticosteroid name: \_\_\_\_\_
- Yes  No Was the treatment with immunosuppressive drugs (e.g., azathioprine, cyclosporine, or methotrexate) ineffective?  
    Please provide the name: \_\_\_\_\_
- Yes  No Does the patient have a documented intolerance to corticosteroids or immunosuppressive drugs?  
    Please indicate the drug(s) the patient has intolerance to:  corticosteroids  immunosuppressive drugs
- Yes  No Does the patient have a documented contraindication to corticosteroids or immunosuppressive drugs?  
    Please indicate the drug(s) the patient has contraindication to:  corticosteroids  immunosuppressive drugs

**Plaque Psoriasis**

- Please indicate the severity of the patient's disease:  mild  moderate  severe
- Yes  No Is there evidence that the disease is active?
- Yes  No Is there clinical documentation of chronic disease?
- Yes  No Is the patient a candidate for systemic therapy or phototherapy?  
    Please select:  phototherapy  systemic therapy  phototherapy and systemic therapy
- Please provide the patient's Psoriasis Area and Severity Index (PASI) score: \_\_\_\_\_
- Please indicate the percentage of body surface area affected by plaque psoriasis: \_\_\_\_\_%
- Yes  No Does the plaque psoriasis involve sensitive areas? **If yes**, please select:  hands  feet  face  genitals
- Yes  No Was the trial with systemic conventional DMARD(s) (e.g., methotrexate, acetretin, or cyclosporine) ineffective?  
     Yes  No Was the trial with systemic conventional DMARD(s) not tolerated?  
     Yes  No Are systemic conventional DMARDs contraindicated?  
    Please select:  acetretin  cyclosporine  methotrexate  mycophenolate  None of the above
- Yes  No Was the trial with phototherapy ineffective?  
     Yes  No Was the trial with phototherapy not tolerated?  
     Yes  No Is phototherapy contraindicated?
- Yes  No Please check all that apply:  Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA)  UVB with coal tar or dithranol  
     UVB (standard or narrow band)  Home UVB  None of the above
- Please indicate the length of trial:  Less than 1 month  1 month  2 months  3 months or greater

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Psoriatic Arthritis

Is there evidence that the disease is active? Does the patient have axial psoriatic arthritis? Was the treatment with 2 or more non-steroidal anti-inflammatory drugs (NSAIDs) ineffective? Please provide the names and length of treatment: NSAID #1: NSAID #2: Does the patient have non-axial psoriatic arthritis? Does the patient have severe disease at presentation, defined as severe disability at onset with erosive disease involving multiple joints? Was the treatment with methotrexate ineffective? Was treatment with methotrexate not tolerated or contraindicated? Please select: not tolerated contraindicated Was treatment with another conventional DMARD ineffective? Please select: cyclophosphamide cyclosporine hydroxychloroquine leflunomide sulfasalazine Other, please explain:

Pyoderma Gangrenosum

Does the patient have a documented diagnosis of refractory pyoderma gangrenosum?

Reactive Arthritis (Reiter's syndrome) or Inflammatory Bowel Disease Arthritis (Enteropathic Arthritis)

Please select which applies to the patient: reactive arthritis (Reiter's syndrome) inflammatory bowel disease arthritis (enteropathic arthritis)

Was the treatment with methotrexate ineffective? Was the treatment with methotrexate not tolerated? Does the patient have a contraindication to methotrexate? Was the treatment with sulfasalazine ineffective? Was the treatment with sulfasalazine not tolerated? Does the patient have a contraindication to sulfasalazine? Was the treatment with non-steroidal anti-inflammatory drugs (NSAIDs) ineffective? Was the treatment with non-steroidal anti-inflammatory drugs (NSAIDs) not tolerated? Does the patient have a contraindication to non-steroidal anti-inflammatory drugs (NSAIDs)? Please provide the name:

Retinal Vasculitis

Was treatment with a conventional DMARD ineffective? Was treatment with a conventional DMARD not tolerated or contraindicated? not tolerated contraindicated

Rheumatoid Arthritis

Please indicate the severity of the patient's rheumatoid arthritis: mild moderate severe Is there evidence that the disease is active? Will the patient be using Inflectra (infliximab-dyyb) in combination with methotrexate? Was treatment with methotrexate ineffective? Was treatment with methotrexate not tolerated or contraindicated? not tolerated contraindicated Was treatment with another conventional DMARD (other than methotrexate) ineffective? Please select: azathioprine hydroxychloroquine leflunomide sulfasalazine

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**G. CLINICAL INFORMATION (continued) – Required clinical information must be completed in its entirety for all precertification requests.**

**Sarcoidosis**

Yes  No Is the disease refractory to corticosteroids?

**Ulcerative Colitis**

Yes  No Is the patient hospitalized with active fulminant ulcerative colitis?

Please indicate the severity of the patient's ulcerative colitis:  mild  moderate  severe

Yes  No Is there evidence that the disease is active?

Yes  No Is the patient refractory to immunosuppression with corticosteroids (e.g., hydrocortisone, methylprednisolone, prednisone)?

Yes  No Does the patient require continuous immunosuppression with corticosteroids (e.g., hydrocortisone, methylprednisolone, prednisone)?

Name and dose: Name: \_\_\_\_\_ Dose: \_\_\_\_\_

Please indicate the route:  Oral  IV

→ Name and dose: Name: \_\_\_\_\_ Dose: \_\_\_\_\_

Please indicate the route:  Oral  IV

Yes  No Was treatment with immunosuppressant agent (e.g., azathioprine, 6-mercaptopurine) ineffective?

Yes  No Was treatment with immunosuppressant agent (e.g., azathioprine, 6-mercaptopurine) not tolerated or contraindicated?

Please select:  not tolerated  contraindicated

→ Please select:  6-mercaptopurine  azathioprine  cyclosporine

Yes  No Was treatment with 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) ineffective?

Yes  No Was treatment with 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) not tolerated or contraindicated?

Please select:  not tolerated  contraindicated

→ Please select:  Colazal (balsalazide)  Ariso, Asacal, Delzicol, Lialda, Pentasa, Rowasa, Canasa (mesalamine)

Azulfidine (sulfasalazine)  Other, please explain: \_\_\_\_\_

→ Please select the symptoms the patient exhibit:  more than 10 stools per day  continuous bleeding  abdominal pain  
 distension  acute, severe toxic symptoms, including fever and anorexia

**For Continuation of Therapy (clinical documentation required for all requests):**

Please indicate the length of time on Inflectra (infliximab-dyyb): \_\_\_\_\_

Yes  No Is this continuation request a result of the patient receiving samples of Inflectra (infliximab-dyyb)?

Yes  No Will Inflectra (infliximab-dyyb) be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs (e.g., adalimumab, certolizumab)?

Yes  No Is there clinical documentation supporting disease stability?

Yes  No Is there clinical documentation supporting disease improvement?

Yes  No Does the patient have any risk factors for TB?

→  Yes  No Has the patient had a TB test within the past year?

(check all that apply):  PPD test  interferon-gamma assay (IGRA)  chest x-ray

Please enter the results of the TB test:  positive  negative  unknown

Yes  No Has the patient received Inflectra (infliximab-dyyb) within the past 6 months?

→  Yes  No Does the patient have a documented severe and/or potentially life-threatening adverse event that occurred during or following the previous infusion?

Yes  No Could the adverse reaction be managed through pre-medication in the home or office setting?

**For Crohn's disease, Juvenile idiopathic arthritis, Plaque psoriasis, Rheumatoid arthritis, Ulcerative colitis only:**

Please indicate the severity of the disease at baseline (pretreatment with Inflectra (infliximab-dyyb)):  mild  moderate  severe

**H. ACKNOWLEDGEMENT**

**Request Completed By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.