



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: FAX: 1-844-268-7263 PHONE: 1-866-503-0857

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:

A. PATIENT INFORMATION

Form fields for Patient Information: First Name, Last Name, Address, City, State, ZIP, Home Phone, Work Phone, Cell Phone, DOB, Allergies, Email, Current Weight, Height

B. INSURANCE INFORMATION

Form fields for Insurance Information: Aetna Member ID #, Group #, Insured, Does patient have other coverage?, Carrier Name

C. PRESCRIBER INFORMATION

Form fields for Prescriber Information: First Name, Last Name, Address, City, State, ZIP, Phone, Fax, St Lic #, NPI #, DEA #, UPIN, Office Contact Name

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Form fields for Dispensing Provider/Pharmacy: Place of Administration, Dispensing Provider/Pharmacy, Address, City, State, ZIP, Phone, Fax, TIN, PIN, NPI

E. PRODUCT INFORMATION - Please select the medication being requested

Request is for: Inflectra (infliximab-dyyb) Dose: Frequency: HCPCS Code:

F. DIAGNOSIS INFORMATION - Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: Secondary ICD Code: Other ICD Code:

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

For Initiation Requests (clinical documentation required for all requests): Note: Inflectra is non-preferred. Preferred products vary based on indication. Has the patient had prior therapy with Inflectra... Please explain if there are any other medical reason(s) that the patient cannot use any of the following preferred products...

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

Will Inflectra (infliximab-dyyb) be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs... Has the patient been tested for TB with a PPD test, interferon-release assay (IGRAs) or chest x-ray within 6 months of initiation a biologic therapy?

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)?

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?
Colitis Please indicate the severity of the immune checkpoint inhibitor-induced colitis: mild moderate severe
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
Inflammatory arthritis Does the patient have refractory or severe disease? refractory disease severe disease
Pneumonitis Please indicate the severity of the disease: mild moderate severe

Juvenile Idiopathic Arthritis (Juvenile Rheumatoid Arthritis)

- Please indicate the severity of the patient's disease: mild moderate severe
Is there evidence that the disease is active?
Does the patient have clinical documentation of polyarticular juvenile idiopathic arthritis (JRA)?
Was treatment with Enbrel (etanercept) ineffective?
Does the patient have a documented intolerance to Enbrel (etanercept)?
Does the patient have a documented contraindication to Enbrel (etanercept)?

Noninfectious Uveitis

- Was the treatment with corticosteroids ineffective?
Was the treatment with immunosuppressive drugs (e.g., azathioprine, cyclosporine, or methotrexate) ineffective?
Does the patient have a documented intolerance to corticosteroids or immunosuppressive drugs?
Does the patient have a documented contraindication to corticosteroids or immunosuppressive drugs?

Plaque Psoriasis

- Please indicate the severity of the patient's disease: mild moderate severe
Is there evidence that the disease is active?
Is there clinical documentation of chronic disease?
Is the patient a candidate for systemic therapy or phototherapy?
Please provide the patient's Psoriasis Area and Severity Index (PASI) score:
Please indicate the percentage of body surface area affected by plaque psoriasis: %
Does the plaque psoriasis involve sensitive areas? If yes, please select: hands feet face genitals
Was the trial with systemic conventional DMARD(s) (e.g., methotrexate, acetretin, or cyclosporine) ineffective?
Was the trial with phototherapy ineffective?
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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Sarcoidosis

Is the disease refractory to corticosteroids?

Ulcerative Colitis

Is the patient hospitalized with active fulminant ulcerative colitis?

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

Is there evidence that the disease is active?

Is the patient refractory to immunosuppression with corticosteroids (e.g., hydrocortisone, methylprednisolone, prednisone)?

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

Was treatment with immunosuppressant agent (e.g., azathioprine, 6-mercaptopurine) ineffective?

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

Was treatment with 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) ineffective?

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):

Is this continuation request a result of the patient receiving samples of Inflectra (infliximab-dyyb)?

Will Inflectra (infliximab-dyyb) be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs (e.g., adalimumab, certolizumab)?

Is there clinical documentation supporting disease stability?

Is there clinical documentation supporting disease improvement?

Does the patient have any risk factors for TB?

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

Has the patient received Inflectra (infliximab-dyyb) within the past 6 months?

Does the patient have a documented severe and/or potentially life-threatening adverse event that occurred during or following the previous infusion?

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.