



MEDICARE FORM

Renflexis® (infliximab-abda) Injectable Medication Precertification Request

Page 1 of 6

(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: Renflexis is preferred for MA plans. Preferred status for MAPD plans varies 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

First Name:		Last Name:	
Address:		City:	State: ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	E-mail:	
Current Weight: _____ lbs or _____ kgs		Height: _____ inches or _____ cms	

B. INSURANCE INFORMATION

Aetna Member ID #:	Does patient have other coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No
Group #:	If yes, provide ID#: _____ Carrier Name: _____
Insured:	Insured: _____

C. PRESCRIBER INFORMATION

First Name:		Last Name:		(Check One): <input type="checkbox"/> M.D. <input type="checkbox"/> D.O. <input type="checkbox"/> N.P. <input type="checkbox"/> P.A.	
Address:		City:	State:	ZIP:	
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Office Contact Name:				Phone:	

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration: <input type="checkbox"/> Self-administered <input type="checkbox"/> Physician's Office <input type="checkbox"/> Outpatient Infusion Center Phone: _____ Center Name: _____ <input type="checkbox"/> Home Infusion Center Phone: _____ Agency Name: _____ <input type="checkbox"/> Administration code(s) (CPT): _____ Address: _____	Dispensing Provider/Pharmacy: <input type="checkbox"/> Physician's Office <input type="checkbox"/> Retail Pharmacy <input type="checkbox"/> Specialty Pharmacy <input type="checkbox"/> Other _____ Name: _____ Address: _____ Phone: _____ Fax: _____ TIN: _____ NPI: _____
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E. PRODUCT INFORMATION

Request is for: Renflexis (infliximab-abda): 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: Entyvio, Remicade, Renflexis, and Simponi Aria are the preferred products for MA Plans. For MAPD plans, Entyvio, Remicade, and Renflexis are preferred for ulcerative colitis and Enbrel, Humira, Rinvoq, Skyrizi, and Xeljanz are preferred for other indications. Preferred products vary based on indication.

Yes No Has the patient had prior therapy with Renflexis (infliximab-abda) within the last 365 days?
 Yes No Has the patient had a trial, intolerance, or contraindication to any of the following? (select all that apply)
 Enbrel (etanercept) Humira (adalimumab) Rinvoq (upadacitinib) Skyrizi (risankizumab-rzaa) Xeljanz (tofacitinib)
Please explain if there are any other medical reason(s) that the patient cannot use any of the following preferred products when indicated for the patient's diagnosis (select all that apply).
 Enbrel (etanercept) Humira (adalimumab) Rinvoq (upadacitinib) Skyrizi (risankizumab-rzaa) Xeljanz (tofacitinib)

Yes No Will Renflexis (infliximab-abda) be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs (e.g., adalimumab, certolizumab)?
 Yes No 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?
→ (check all that apply): PPD test interferon-gamma assay (IGRA) chest x-ray
Please enter results of the TB test: positive negative unknown
If positive, Does the patient have latent or active TB? latent active
If latent TB, Yes No Will TB treatment be started before initiation of therapy with Renflexis (infliximab-abda)?

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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? **If yes**, please indicate the corticosteroid name: _____
 Yes No Did the patient show improvement after 48 hours of corticosteroids?
- 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, acetrein, or cyclosporine) ineffective?
 _____ Yes No Was the trial with systemic conventional DMARD(s) not tolerated?
 _____ Yes No Are systemic conventional DMARDs contraindicated?
 _____ Please select: acitrein cyclosporine methotrexate mycophenolate None of the above

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

Was the trial with phototherapy ineffective? Was the trial with phototherapy not tolerated? Is phototherapy contraindicated? 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

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 Renflexis (infliximab-abda) 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

Is the disease refractory to corticosteroids?

Yes No

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 Renflexis (infliximab-abda):

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

Will Renflexis (infliximab-abda) 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 Renflexis (infliximab-abda) 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, and Rheumatoid arthritis, Ulcerative colitis only:

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

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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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.