MEDICARE FORM

Renflexis® (infliximab-abda) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

For Medicare Advantage Part B:
Phone: 1-866-503-0857 (TTY: 711)
FAX: 1-844-268-7263

For other lines of business:
Please use other form.

Note: Renflexis is non-preferred. Preferred products vary based on indication and plan type. 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 #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name: *(Check One)*: ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.				
Address:		City:	State:	ZIP:	
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider Email:	Office Contact Name:		Phone:		

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____
City: _____ State: _____ ZIP: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____
NPI: _____

Dispensing Provider/Pharmacy:
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other _____
Name: _____
Address: _____
City: _____ State: _____ ZIP: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____
NPI: _____

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: Renflexis is non-preferred. The preferred products for MA plans are Entyvio, Inflectra, Remicade, Simponi Aria and unbranded infliximab. For MAPD plans, Inflectra, Entyvio, Remicade and unbranded infliximab are preferred for ulcerative colitis and Enbrel, Humira, Kevzara, Otezla, Rinvoq, Skyrizi, Stelara and Xeljanz/Xeljanz XR 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 and failure, intolerance, or contraindication to any of the following? (select all that apply)
☐ Entyvio (vedolizumab) ☐ Inflectra (infliximab-dyyb) ☐ Remicade (infliximab) ☐ Simponi Aria (golimumab) ☐ Unbranded infliximab

☐ Yes ☐ No Has the patient had a trial and failure, intolerance, or contraindication to any of the following? (select all that apply)
☐ Enbrel (etanercept) ☐ Humira (adalimumab) ☐ Kevzara (sarilumab) ☐ Otezla (apremilast) ☐ Rinvoq (upadacitinib)
☐ Skyrizi (risankizumab-rzaa) ☐ Stelara (ustekinumab) ☐ Xeljanz/Xeljanz XR (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 the apply)
☐ Entyvio (vedolizumab) ☐ Inflectra (infliximab-dyyb) ☐ Remicade (infliximab) ☐ Simponi Aria (golimumab) ☐ Unbranded infliximab

_____

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) ☐ Kevzara (sarilumab) ☐ Otezla (apremilast) ☐ Rinvoq (upadacitinib)
☐ Skyrizi (risankizumab-rzaa) ☐ Stelara (ustekinumab) ☐ Xeljanz/Xeljanz XR (tofacitinib)

_____

_____

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB

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

☐ 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)?

Ankylosing Spondylitis and Other Spondyloarthropathies

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

☐ Yes ☐ No Is there evidence that the disease is active?

☐ Yes ☐ No Is there evidence of inflammatory disease?

☐ Yes ☐ No 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: _____
NSAID1 #2: _____

Behcet's Disease

☐ Yes ☐ No Is the disease refractory to corticosteroids or immunosuppressive drugs?
→ Please indicate: ☐ corticosteroids ☐ immunosuppressive drugs
Please provide the name of drug tried: _____

Behcet's Uveitis

☐ Yes ☐ No Is the disease refractory?

Chronic Cutaneous/Pulmonary Sarcoidosis

☐ Yes ☐ No Has the patient remained symptomatic despite treatment with steroids?
→ Please provide the daily dose of steroids: Dose: _____mg

☐ Yes ☐ No Has the patient remained symptomatic despite treatment with immunosuppressants?
→ Please select: ☐ azathioprine ☐ cyclophosphamide ☐ methotrexate ☐ Other, please explain: _____

Crohn's Disease

☐ Yes ☐ No 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:

☐ Yes ☐ No Does the patient have a diagnosis of Crohn's disease?
→ Please indicate the severity of the patient's disease: ☐ mild ☐ moderate ☐ severe

☐ Yes ☐ No 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

☐ Yes ☐ No 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

☐ Yes ☐ No Has the patient completed a trial of antibiotics?
→ ☐ Yes ☐ No Does the patient have a contraindication to oral antibiotics?
→ ☐ Yes ☐ No 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: _____

☐ Yes ☐ No 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)?

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: ☐ acitretin ☐ 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.

☐ Yes ☐ No Was the trial with phototherapy ineffective?
- ☐ Yes ☐ No Was the trial with phototherapy not tolerated?
- ☐ Yes ☐ No 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

☐ Yes ☐ No Is there evidence that the disease is active?

☐ Yes ☐ No Does the patient have **axial** psoriatic arthritis?
- ☐ Yes ☐ No 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: _____

☐ Yes ☐ No Does the patient have **non-axial** psoriatic arthritis?
- ☐ Yes ☐ No Does the patient have severe disease at presentation, defined as severe disability at onset with erosive disease involving multiple joints?
  - ☐ Yes ☐ No Was the treatment with methotrexate ineffective?
    - ☐ Yes ☐ No Was treatment with methotrexate not tolerated or contraindicated?
      - Please select: ☐ not tolerated ☐ contraindicated
      - ☐ Yes ☐ No Was treatment with another conventional DMARD ineffective?
        - Please select: ☐ cyclophosphamide ☐ cyclosporine ☐ hydroxychloroquine ☐ leflunomide ☐ sulfasalazine ☐ Other, please explain: _____

Pyoderma Gangrenosum

☐ Yes ☐ No 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)

☐ Yes ☐ No Was the treatment with methotrexate ineffective?
- ☐ Yes ☐ No Was the treatment with methotrexate not tolerated?
- ☐ Yes ☐ No Does the patient have a contraindication to methotrexate?

☐ Yes ☐ No Was the treatment with sulfasalazine ineffective?
- ☐ Yes ☐ No Was the treatment with sulfasalazine not tolerated?
- ☐ Yes ☐ No Does the patient have a contraindication to sulfasalazine?

☐ Yes ☐ No Was the treatment with non-steroidal anti-inflammatory drugs (NSAIDs) ineffective?
- ☐ Yes ☐ No Was the treatment with non-steroidal anti-inflammatory drugs (NSAIDs) not tolerated?
- ☐ Yes ☐ No Does the patient have a contraindication to non-steroidal anti-inflammatory drugs (NSAIDs)?

Please provide the name: _____

Retinal Vasculitis

☐ Yes ☐ No Was treatment with a conventional DMARD ineffective?
- ☐ Yes ☐ No 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

☐ Yes ☐ No Is there evidence that the disease is active?

☐ Yes ☐ No Will the patient be using Renflexis (infliximab-abda) in combination with methotrexate?
- ☐ Yes ☐ No Was treatment with methotrexate ineffective?
  - ☐ Yes ☐ No Was treatment with methotrexate not tolerated or contraindicated? ☐ not tolerated ☐ contraindicated
    - ☐ Yes ☐ No 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 Renflexis (infliximab-abda): _____

☐ Yes ☐ No Is this continuation request a result of the patient receiving samples of Renflexis (infliximab-abda)?

☐ Yes ☐ No Will Renflexis (infliximab-abda) 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 Renflexis (infliximab-abda) 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, and Rheumatoid arthritis, Ulcerative colitis only:

Please indicate the severity of the disease at baseline (pretreatment with Renflexis (infliximab-abda)): ☐ 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.