Renflexis® (infliximab-abda) Injectable Medication Precertification Request

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

Aetna Precertification Notification
Phone: 1-866-752-7021 **(TTY:** 711**)**
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

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:	E-mail:
Current Weight: _____ lbs or _____ kgs Height: _____ inches or _____ cms			Allergies:	

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

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

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

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 E-mail:		Office Contact Name:		Phone:	

Specialty *(Check one):* ☐ **Dermatologist** ☐ **Gastroenterologist** ☐ **Rheumatologist** ☐ **Other**: _____

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: _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for: Renflexis (infliximab-abda) Dose: _____ **Frequency:** _____

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 All Requests (clinical documentation required):

☐ Yes ☐ No Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Otezla, Xeljanz)?
☐ Yes ☐ No Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis (TB)?
→ ☐ Yes ☐ No Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [PPD], interferon-release assay [IGRA], chest x-ray) within 6 months of initiating therapy?
→ (Check all that apply): ☐ PPD test ☐ interferon-release assay (IGRA) ☐ chest x-ray
Please enter the results of the tuberculosis (TB) test: ☐ positive ☐ negative ☐ unknown
If positive, please indicate which applies to the patient:
☐ latent TB and treatment for latent TB has been initiated
☐ latent TB and treatment for latent TB has been completed
☐ latent TB and treatment for latent TB has not been initiated
☐ active TB

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

☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?
→ ☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?
☐ Yes ☐ No Has the patient developed antibodies to infliximab which increases the risk for infusion related reactions?
☐ Yes ☐ No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?
☐ Yes ☐ No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?
→ Please provide a description of the behavioral issue or impairment: _____
☐ Yes ☐ No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the patient's ability to tolerate a large volume or load or predispose the patient to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
→ Please provide a description of the condition: ☐ Cardiopulmonary: _____
☐ Respiratory: _____
☐ Renal: _____
☐ Other: _____

For Initiation Requests (clinical documentation required for all requests):

☐ Yes ☐ No Is the medication requested for initiation of treatment at a higher dose or frequency of administration (e.g., loading dose)?
☐ Yes ☐ No Is the requested quantity supported by the manufacturer's prescribing information or dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?
→ Please select: ☐ Supported by the manufacturer's prescribing information
→ ☐ Yes ☐ No Is the requested dose and frequency supported by the manufacturer's prescribing information for the patient's diagnosis?
☐ Supported by dosing guidelines found in the compendia or current literature
→ ☐ Yes ☐ No Is the supporting information attached?

Acute graft versus host disease

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
☐ Yes ☐ No Has the patient experienced an inadequate response to systemic corticosteroids?
→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids?
→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids?

Ankylosing spondylitis and Non-radiographic axial spondyloarthritis

Please indicate loading dose at weeks 0, 2 and 6: _____ Please indicate maintenance dose: _____ frequency: _____weeks
Please select which of the following applies to the patient: ☐ Active ankylosing spondylitis (AS) ☐ Active non-radiographic axial spondyloarthritis (nr-axSpA)
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?
☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) that is indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis?
→ ☐ Yes ☐ No Has the patient experienced an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least TWO NSAIDs?
☐ Yes ☐ No Has the patient had an ineffective response, contraindication, or intolerance to Simponi Aria?
☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra
→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Behçet's disease

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?
☐ Yes ☐ No Has the patient ever received or is currently receiving Otezla or a biologic (e.g., Humira) indicated for the treatment of Behçet's disease (excluding receiving the drug via samples or a manufacturer's patient assistance program)?
→ ☐ Yes ☐ No Has the patient had an inadequate response to at least one nonbiologic medication for Behçet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine)?

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

Crohn's disease

Please indicate loading dose at weeks 0, 2 and 6: _____ Please indicate maintenance dose: _____ frequency: _____weeks

For under 18 years of age only:

☐ Yes ☐ No Does the prescriber recognize that a dose above 5 mg per kg is a higher dose and the prescriber confirms that appropriate monitoring will be done?
→ ☐ Yes ☐ No Does the prescribed dose exceed an induction dose of 10 mg per kg at week 0, week 2, and week 6, and a maintenance dose of 10 mg per kg thereafter?

All requests:

☐ Yes ☐ No Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a gastroenterologist?
☐ Yes ☐ No Is the patient 18 years of age or older?
→ ☐ Yes ☐ No Has the patient had an ineffective response, contraindication, or intolerance to Entyvio?
☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra
→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Hidradenitis suppurativa

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?
☐ Yes ☐ No Has the patient been diagnosed with severe, refractory hidradenitis suppurativa?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?
☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for the treatment of severe, refractory hidradenitis suppurativa (excluding receiving the drug via samples or a manufacturer's patient assistance program)?
→ ☐ Yes ☐ No Has the patient experienced an inadequate response after at least 90 days of treatment with an oral antibiotic?
→ ☐ Yes ☐ No Has the patient experienced an intolerance to oral antibiotics?
→ ☐ Yes ☐ No Does the patient have a contraindication to oral antibiotics?
☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra
→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
☐ Yes ☐ No Has the patient experienced an inadequate response to corticosteroids?
→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids?
→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids?
→ ☐ Yes ☐ No Does the patient have moderate or severe diarrhea or colitis?

Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity – (Immunotherapy arthritis)

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?
☐ Yes ☐ No Does the patient have severe disease?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
☐ Yes ☐ No Has the patient experienced an inadequate response to corticosteroids?
→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids?
→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids?

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Plaque psoriasis

Please indicate loading dose at weeks 0, 2 and 6: _____ Please indicate maintenance dose: _____ frequency: _____weeks

☐ Yes ☐ No Has the patient been diagnosed with moderate to severe plaque psoriasis?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a dermatologist?

☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

→ ☐ Yes ☐ No Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected?

→ Please indicate the percentage of body surface area (BSA) affected (prior to starting the requested medication): _____%

If less than 10% of BSA:

☐ Yes ☐ No Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin?

→ ☐ Yes ☐ No Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin?

→ Please indicate clinical reason to avoid pharmacologic treatment: ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease ☐ Breastfeeding ☐ Drug interaction ☐ Pregnancy or currently planning pregnancy ☐ History of intolerance or adverse event ☐ Hypersensitivity ☐ Risk of treatment-related toxicity ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) ☐ Other, please explain: _____

☐ Yes ☐ No Has the patient had an ineffective response, contraindication, or intolerance to Ilumya?

☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra

→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Psoriatic arthritis with or without co-existent plaque psoriasis

Please indicate loading dose at weeks 0, 2 and 6: _____ Please indicate maintenance dose: _____ frequency: _____weeks

Please indicate which of the following applies to the patient:

☐ WITH co-existent plaque psoriasis

→ ☐ Yes ☐ No Is the plaque psoriasis being treated as the primary diagnosis?

→ Please go to **plaque psoriasis** section

☐ Yes ☐ No Has the patient been diagnosed with active psoriatic arthritis (PsA)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?

☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

→ ☐ Yes ☐ No Does the patient have mild to moderate disease?

→ ☐ Yes ☐ No Does the patient have severe disease?

☐ Yes ☐ No Does the patient have enthesitis or predominantly axial disease?

→ ☐ Yes ☐ No Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration?

→ ☐ Yes ☐ No Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)?

→ ☐ Yes ☐ No Does the patient have a contraindication to methotrexate or leflunomide?

→ ☐ Yes ☐ No Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)?

Please indicate the contraindication:

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease ☐ Drug interaction ☐ Risk of treatment-related toxicity ☐ Pregnancy or currently planning pregnancy ☐ Breastfeeding ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) ☐ Hypersensitivity ☐ History of intolerance or adverse event ☐ Other: _____

☐ Yes ☐ No Has the patient had an ineffective response, contraindication, or intolerance to Simponi Aria?

☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra

→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

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

Pyoderma gangrenosum

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a dermatologist?

☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for the treatment of pyoderma gangrenosum (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

→ ☐ Yes ☐ No Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)?

→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)?

→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)?

Reactive arthritis

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?

☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Enbrel) indicated for the treatment of reactive arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

→ ☐ Yes ☐ No Has the patient experienced an inadequate response after at least 3 months of treatment with either of the following: a) sulfasalazine at a dose of 1000 mg twice daily or maximally tolerated dose, or b) methotrexate at a dose greater than or equal to 15 mg per week or maximally tolerated dose?

→ ☐ Yes ☐ No Has the patient experienced an intolerance to sulfasalazine and methotrexate?

→ ☐ Yes ☐ No Does the patient have a contraindication to sulfasalazine (e.g., porphyria, intestinal or urinary obstruction)?

→ ☐ Yes ☐ No Does the patient have a contraindication to methotrexate?

Please indicate the contraindication:

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease ☐ Drug interaction ☐ Risk of treatment-related toxicity
☐ Pregnancy or currently planning pregnancy ☐ Breastfeeding
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) ☐ Hypersensitivity
☐ History of intolerance or adverse event
☐ Other: _____

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

Rheumatoid arthritis

Please indicate loading dose at weeks 0, 2 and 6: _____ Please indicate maintenance dose: _____ frequency: _____weeks

☐ Yes ☐ No Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?

☐ Yes ☐ No Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

→ ☐ Yes ☐ No Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and the anti-CCP biomarker test was positive?

→ ☐ Yes ☐ No Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)?

☐ Yes ☐ No Is the requested medication being prescribed in combination with methotrexate or leflunomide?

→ Please indicate a clinical reason for the patient to not use methotrexate or leflunomide:

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease ☐ Drug interaction
☐ Risk of treatment-related toxicity ☐ Pregnancy or currently planning pregnancy ☐ Breastfeeding
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) ☐ Hypersensitivity ☐ History of intolerance or adverse event
☐ Other: _____

☐ Yes ☐ No Does the patient have other reason or no clinical reason not to use methotrexate or leflunomide?

→ ☐ Yes ☐ No Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 mg per week?

→ ☐ Yes ☐ No Has the patient experienced an intolerance to methotrexate?

→ ☐ Yes ☐ No Does the patient have a contraindication to methotrexate?

→ Please indicate the contraindication:

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease ☐ Drug interaction ☐ Risk of treatment-related toxicity
☐ Pregnancy or currently planning pregnancy ☐ Breastfeeding
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) ☐ Hypersensitivity
☐ History of intolerance or adverse event
☐ Other: _____

→ ☐ Yes ☐ No Is the requested medication being prescribed in combination with methotrexate or leflunomide?

→ Please indicate a clinical reason for the patient to not use methotrexate or leflunomide:

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
☐ Drug interaction ☐ Risk of treatment-related toxicity ☐ Pregnancy or currently planning pregnancy
☐ Breastfeeding ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) ☐ Hypersensitivity ☐ History of intolerance or adverse event
☐ Other: _____
☐ No clinical reason not to use methotrexate or leflunomide

☐ Yes ☐ No Has the patient had an ineffective response, contraindication, or intolerance to Simponi Aria?

☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra

→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

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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.

Sarcoidosis

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a dermatologist or pulmonologist?

☐ Yes ☐ No Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., azathioprine, methotrexate)?

→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., azathioprine, methotrexate?

→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, methotrexate?

Takayasu's arteritis

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?

☐ Yes ☐ No Has the patient been diagnosed with refractory Takayasu's arteritis?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?

☐ Yes ☐ No Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

Ulcerative colitis

Please indicate loading dose at weeks 0, 2 and 6: _____ Please indicate maintenance dose: _____ frequency: _____weeks

For under 18 years of age only:

☐ Yes ☐ No Does the prescriber recognize that a dose above 5 mg per kg is a higher dose and the prescriber confirms that appropriate monitoring will be done?

☐ Yes ☐ No Does the prescribed dose exceed an induction dose of 10 mg per kg at week 0, week 2, and week 6, and a maintenance dose of 10 mg per kg thereafter?

All requests:

☐ Yes ☐ No Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a gastroenterologist?

☐ Yes ☐ No Is the pateint 18 years of age or older?

→ ☐ Yes ☐ No Has the patient had an ineffective response, contraindication, or intolerance to Entyvio?

☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra

→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Uveitis

☐ Yes ☐ No Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an ophthalmologist or rheumatologist?

☐ Yes ☐ No Has the patient ever received or currently receiving a biologic (e.g., Humira) indicated for the treatment of uveitis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

→ ☐ Yes ☐ No Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra

→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Continued on next page

Renflexis® (infliximab-abda) Injectable Medication Precertification Request

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

Aetna Precertification Notification
Phone: 1-866-752-7021 **(TTY:** 711**)**
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

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.

For Continuation Requests (clinical documentation required):

Please indicate maintenance dose: _____ frequency: _____weeks

☐ Yes ☐ No Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

☐ Yes ☐ No Is the requested quantity supported by the manufacturer's prescribing information or dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?

→ Please select: ☐ Supported by the manufacturer's prescribing information

→ ☐ Yes ☐ No Is the requested dose and frequency supported by the manufacturer's prescribing information for the patient's diagnosis?

☐ Supported by dosing guidelines found in the compendia or current literature

→ ☐ Yes ☐ No Is the supporting information attached?

For Crohn's disease, Ulcerative colitis, Rheumatoid arthritis, Ankylosing spondylitis, Non-radiographic axial spondylitis, Psoriatic arthritis, Plaque psoriasis, Hidradenitis suppurativa, or Uveitis only:

☐ Yes ☐ No Has the patient tried and failed treatment with Avsola (infliximab-axxq) or Inflectra (infliximab-dyyb) due to a documented intolerable adverse event (e.g., rash, nausea, vomiting)? Please indicate: ☐ Avsola ☐ Inflectra

→ ☐ Yes ☐ No Was the adverse event unexpected and not attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)?

Acute graft versus host disease

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?

☐ Yes ☐ No Has the patient experienced an inadequate response to systemic corticosteroids?

→ ☐ Yes ☐ No Does the patient have an intolerance or contraindication to corticosteroids?

Ankylosing spondylitis and Non-radiographic axial spondyloarthritis

Please select which of the following applies to the patient: ☐ Active ankylosing spondylitis (AS) ☐ Active non-radiographic axial spondyloarthritis (nr-axSpA)

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?

☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

→ Please indicate which of the following the patient has experienced an improvement in from baseline:

☐ functional status ☐ total spinal pain ☐ inflammation (e.g., morning stiffness) ☐ none of the above

Behcet's disease

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?

☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

Crohn's disease

☐ Yes ☐ No Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a gastroenterologist?

For under 18 years of age only:

☐ Yes ☐ No Does the prescriber recognize that a dose above 5 mg per kg is a higher dose and the prescriber confirms that appropriate monitoring will be done?

For 18 years of age or older only:

Please select which applies to this request: ☐ Dosage decrease ☐ Dosage increase ☐ Continued therapy on current dose

☐ Yes ☐ No Is the requested drug for an adult patient following loss of response?

☐ Yes ☐ No Does the patient require a dose above 5 mg per kg due to loss of response at the current dose?

All requests:

☐ Yes ☐ No Does the prescribed dose exceed 10 mg per kg?

☐ Yes ☐ No Has the patient achieved or maintained remission?

→ ☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

→ ☐ Yes ☐ No Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

→ Please indicate which of the following the patient has experienced an improvement in from baseline:

☐ abdominal pain or tenderness ☐ diarrhea ☐ body weight ☐ abdominal mass ☐ hematocrit ☐ appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound ☐ improvement on a disease activity scoring tool (e.g., Crohn's disease Activity Index [CDAI] score)

If none of the above applies: ☐ Yes ☐ No Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

Hidradenitis suppurativa

☐ Yes ☐ No Has the patient been diagnosed with severe, refractory hidradenitis suppurativa?

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?

☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

Please indicate which of the following the patient has experienced since starting treatment with the requested drug:

☐ reduction in abscess and inflammatory nodule count from baseline ☐ reduced formation of new sinus tracts and scarring

☐ decrease in frequency of inflammatory lesions from baseline ☐ reduction in pain from baseline ☐ reduction in suppuration from baseline

☐ improvement in frequency of relapses from baseline ☐ improvement in quality of life from baseline

☐ improvement on a disease severity assessment tool from baseline ☐ 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

Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
☐ Yes ☐ No Has the patient experienced an inadequate response to corticosteroids?
→ ☐ Yes ☐ No Has the patient experienced an intolerance to corticosteroids?
→ ☐ Yes ☐ No Does the patient have a contraindication to corticosteroids?
→ ☐ Yes ☐ No Does the patient have cardiac toxicity?

Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity- (Immunotherapy arthritis)

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

Plaque psoriasis or Psoriatic arthritis WITH co-existent plaque psoriasis

☐ Yes ☐ No Has the patient been diagnosed with moderate to severe plaque psoriasis?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a dermatologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?
☐ Yes ☐ No Has the patient experienced a reduction in body surface area (BSA) affected from baseline?
→ ☐ Yes ☐ No Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)?

Psoriatic arthritis WITHOUT co-existent plaque psoriasis

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?
→ Please indicate which of the following the patient has experienced an improvement in from baseline:
☐ number of swollen joints ☐ number of tender joints ☐ dactylitis ☐ enthesitis ☐ axial disease ☐ skin and/or nail involvement
☐ none of the above

Pyoderma gangrenosum

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a dermatologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

Reactive arthritis

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, or pain) since starting treatment with the requested drug?

Rheumatoid arthritis

☐ Yes ☐ No Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?
☐ Yes ☐ No Is this a request for a change in dosing regimen?
☐ Yes ☐ No Does the patient require a dose above 3 mg per kg due to an incomplete response at the current dose?
☐ Yes ☐ No Does the patient require dosing more frequent than every 8 weeks due to an incomplete response at the current dosing frequency?
☐ Yes ☐ No For 18 years of age or older only: Is the requested drug for an adult patient with incomplete response?
☐ Yes ☐ No Does the prescribed dose exceed 10 mg per kg?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response since starting treatment with the requested drug?
→ ☐ Yes ☐ No Has the patient experienced substantial disease activity improvement (e.g., at least 20% from baseline) in tender joint count, swollen joint count, pain, or disability?
→ ☐ Yes ☐ No Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

Sarcoidosis

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a dermatologist or pulmonologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

Takayasu's arteritis

☐ Yes ☐ No Has the patient been diagnosed with refractory Takayasu's arteritis?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a rheumatologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?

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

Ulcerative colitis:

☐ Yes ☐ No Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)?
☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with a gastroenterologist?
☐ Yes ☐ No Has the patient achieved or maintained remission?
→ ☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?
↓ Please indicate which of the following the patient experienced an improvement on from baseline: ☐ stool frequency ☐ rectal bleeding ☐ C-reactive protein (CRP) ☐ fecal calprotectin (FC) ☐ appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound ☐ urgency of defecation ☐ improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) ☐ none of the above

For under 18 years of age only:

☐ Yes ☐ No Does the prescriber recognize that a dose above 5 mg per kg is a higher dose and the prescriber confirms that appropriate monitoring will be done?

For 18 years of age or older only:

☐ Yes ☐ No Was the patient on a dose exceeding 5 mg per kg as a pediatric patient and is continuing that dose into adulthood?
→ ☐ Yes ☐ No Does the prescriber recognize that a dose above 5 mg per kg is a higher dose and the prescriber confirms that appropriate monitoring will be done?

Uveitis

☐ Yes ☐ No Is the requested drug being prescribed by or in consultation with an ophthalmologist or rheumatologist?
☐ Yes ☐ No Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?
→ Please indicate which of the following the patient has experienced since starting treatment with the requested drug:
☐ reduced frequency of recurrence compared to baseline ☐ decreased reliance on topical corticosteroids ☐ zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline ☐ none of the above

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.