



# Avsola™ (infliximab-axxq) Injectable Medication Precertification Request

Page 1 of 6

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

Aetna Precertification Notification

Phone: 1-866-752-7021

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

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:
Provider E-mail:		Office Contact Name:			Phone:
Specialty (Check one): <input type="checkbox"/> Dermatologist <input type="checkbox"/> Gastroenterologist <input type="checkbox"/> Rheumatologist <input type="checkbox"/> Other: _____					

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION	
<b>Place of Administration:</b> <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: _____	<b>Dispensing Provider/Pharmacy: Patient Selected choice</b> <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: _____ PIN: _____

E. PRODUCT INFORMATION
Request is for: <b>Avsola (infliximab-axxq) Dose:</b> _____ <b>Frequency:</b> _____

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.
<b>For All Requests (clinical documentation required for all requests):</b> <input type="checkbox"/> Yes <input type="checkbox"/> No Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic disease-modifying anti-rheumatic drug (DMARD) (e.g., Olumiant, Otezla, Xeljanz)? <input type="checkbox"/> Yes <input type="checkbox"/> No Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis (TB)? <input type="checkbox"/> Yes <input type="checkbox"/> 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): <input type="checkbox"/> PPD test <input type="checkbox"/> interferon-gamma assay (IGRA) <input type="checkbox"/> chest x-ray Please enter the results of the tuberculosis (TB) test: <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> unknown <b>If positive</b> , Does the patient have latent or active tuberculosis TB? <input type="checkbox"/> latent <input type="checkbox"/> active <input type="checkbox"/> unknown <b>If latent tuberculosis</b> <input type="checkbox"/> Yes <input type="checkbox"/> No Has treatment for latent tuberculosis (TB) infection been initiated or completed? Please select: <input type="checkbox"/> treatment initiated <input type="checkbox"/> treatment completed <input type="checkbox"/> Yes <input type="checkbox"/> No Does the patient have risk factors for tuberculosis (TB)? (e.g., persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB [e.g., Africa, Asia, Eastern Europe, Latin America, Russia]; children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission [e.g., homeless persons, injection drug users, persons with HIV infection], or persons who work or reside with people who are at an increased risk for active TB [e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters])? <input type="checkbox"/> Yes <input type="checkbox"/> No Has the patient been tested for tuberculosis (TB) within the previous 12 months? (Check all that apply): <input type="checkbox"/> PPD test <input type="checkbox"/> interferon-gamma assay (IGRA) <input type="checkbox"/> chest x-ray Please enter the results of the tuberculosis (TB) test: <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> unknown <b>If positive</b> , Does the patient have latent or active tuberculosis (TB)? <input type="checkbox"/> latent <input type="checkbox"/> active <input type="checkbox"/> unknown <b>If latent tuberculosis</b> <input type="checkbox"/> Yes <input type="checkbox"/> No Has treatment for latent tuberculosis (TB) infection been initiated or completed? Please select: <input type="checkbox"/> treatment initiated <input type="checkbox"/> treatment completed

Continued on next page



# Avsola™ (infliximab-axxq) Injectable Medication Precertification Request

Page 2 of 6

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For Medicare Advantage Part B:

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB
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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 member's ability to tolerate a large volume or load or predispose the member 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):

#### 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 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 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 axial spondyloarthritis

Yes  No Has the patient ever received (including current utilizers) a biologic (e.g., Cimzia) indicated for active ankylosing spondylitis or active 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?

Please indicate the preferred alternatives for ankylosing spondylitis (AS) or axial spondyloarthritis that have been ineffective, not tolerated, or are contraindicated:  
 Cosentyx  Enbrel  Humira  Remicade  Simponi Aria

#### 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 Has the patient ever received (including current utilizers) Otezla or a biologic (e.g., Humira) indicated for the treatment of Behçet's disease?

→  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)?

#### Crohn's disease

Please indicate loading dose at weeks 0, 2 and 6: \_\_\_\_\_ Please indicate maintenance dose: \_\_\_\_\_ frequency: \_\_\_\_\_ weeks

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)?

→ 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?

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

Yes  No Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for moderately to severely active Crohn's disease?

→  Yes  No Does the patient have fistulizing Crohn's disease?

→  Yes  No Has the patient tried and had an inadequate response to at least one conventional therapy option?

→  Yes  No Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], budesonide [Entocort EC], ciprofloxacin [Cipro], mercaptopurine [Purinethol], methylprednisolone [Solu-Medrol], methotrexate IM or SC, metronidazole [Flagyl], prednisone, sulfasalazine [Azulfidine, Sulfazine], rifaximin [Xifaxan], tacrolimus)?

→ Please select:  Sulfasalazine (Azulfidine, Sulfazine)  Metronidazole (Flagyl)  Ciprofloxacin (Cipro)  
 Prednisone  Budesonide (Entocort EC)  Azathioprine (Azasan, Imuran)  Mercaptopurine (Purinethol)  Methotrexate IM or SQ  Methylprednisolone (Solu-Medrol)  Rifaximin (Xifaxan)  Tacrolimus

Please indicate the preferred alternatives for Crohn's disease that have been ineffective, not tolerated, or are contraindicated:  
 Humira  Entyvio  Remicade  Stelara (intravenous formulation)

Continued on next page



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Page 3 of 6

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

**Granulomatosis with polyangiitis (Wegener's granulomatosis)**

- 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 experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)?
  - Yes  No Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)?
    - Yes  No Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)?

**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 Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of severe, refractory hidradenitis suppurativa?
  - Yes  No Has the patient experienced an inadequate response after at least 90 days of treatment with oral antibiotics?
    - Yes  No Has the patient experienced an intolerable adverse effect to oral antibiotics?
      - Yes  No Does the patient have a contraindication to oral antibiotics?
- Yes  No Has the patient had an ineffective response, contraindication or intolerance to Humira?

**Juvenile idiopathic 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 Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease-modifying antirheumatic drug (DMARD) indicated for juvenile idiopathic arthritis?
  - Yes  No Has the patient experienced an inadequate response to ANY of the following?
    - Please select:  At least 1-month trial of NSAIDs  At least 2 weeks of treatment with corticosteroids (e.g., prednisone, methylprednisolone)  At least 3 months of treatment with methotrexate  At least 3 months of treatment with leflunomide
- Yes  No Has the patient had an ineffective response, contraindication or intolerance to Humira?
- Yes  No Has the patient had an ineffective response, contraindication or intolerance to Enbrel?

**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 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?

**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 Has the patient ever received (including current utilizers) Otezla or a biologic (e.g., Humira) indicated for the treatment of moderate to severe plaque psoriasis?
    - 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  Cannot be used due to risk of treatment-related toxicity  Drug interaction  Pregnancy or currently planning pregnancy  Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)  Other, please explain: \_\_\_\_\_

Please indicate the preferred alternatives for plaque psoriasis that have been ineffective, not tolerated, or are contraindicated:

- Humira  Ilumya  Otezla  Remicade  Skyrizi  Stelara  Taltz  Tremfya

**Psoriatic 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 active psoriatic arthritis (PsA)?
  - Please indicate which of the following applies to the patient:  WITH co-existent plaque psoriasis  WITHOUT co-existent plaque psoriasis
  - Please indicate the preferred alternatives for psoriatic arthritis that have been ineffective, not tolerated, or are contraindicated:
    - Cosentyx  Enbrel  Humira  Otezla  Remicade  Simponi Aria

**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)?

Continued on next page



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Page 4 of 6

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

- Yes  No Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of pyoderma gangrenosum?  
 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 Has the patient ever received (including current utilizers) a biologic (e.g., Enbrel) indicated for the treatment of reactive arthritis?  
 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 20 mg per week?  
 Yes  No Has the patient experienced intolerance to methotrexate?  
 Yes  No Does the patient have a contraindication to methotrexate?  
 Please indicate the contraindication:  History of intolerance or adverse event  
 Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease  
 Elevated liver transaminases  Interstitial pneumonitis or clinically significant pulmonary fibrosis  
 Renal impairment  Pregnancy or currently planning pregnancy  
 Breastfeeding  Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)  
 Myelodysplasia  Hypersensitivity  Significant drug interaction  
 Other, please explain: \_\_\_\_\_

#### Rheumatoid arthritis

- Please indicate loading dose at weeks 0, 2 and 6: \_\_\_\_\_ Please indicate maintenance dose: \_\_\_\_\_ frequency: \_\_\_\_\_ weeks  
 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)?  
 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?  
 Yes  No Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)?  
 Yes  No Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease modifying drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis?  
 Yes  No Has the patient been tested for the rheumatoid factor (RF) biomarker?  
 Please indicate the test result:  positive  negative  not completed  
 Yes  No Has the patient been tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker?  
 Please indicate the test result:  positive  negative  not completed  
 Yes  No Has the patient been tested for the C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) biomarker(s)?  
 Please indicate the test result:  positive  negative  not completed  
 Yes  No Has the patient been tested for the erythrocyte sedimentation rate (ESR) biomarker?  
 Please indicate the test result:  positive  negative  not completed  
 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:  History of intolerance or adverse event  
 Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease  
 Elevated liver transaminases  
 Interstitial pneumonitis or clinically significant pulmonary fibrosis  
 Renal impairment  
 Pregnancy or currently planning pregnancy  
 Breastfeeding  
 Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)  
 Myelodysplasia  
 Hypersensitivity  
 Significant drug interaction  
 Other, please explain: \_\_\_\_\_  
 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 20 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:  History of intolerance or adverse event  
 Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease  
 Elevated liver transaminases  
 Interstitial pneumonitis or clinically significant pulmonary fibrosis  
 Renal impairment  
 Pregnancy or currently planning pregnancy  
 Breastfeeding  
 Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)  
 Myelodysplasia  
 Hypersensitivity  
 Significant drug interaction  
 Other, please explain: \_\_\_\_\_  
 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:  History of intolerance or adverse event  
 Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease  
 Elevated liver transaminases  
 Interstitial pneumonitis or clinically significant pulmonary fibrosis  
 Renal impairment  
 Pregnancy or currently planning pregnancy  
 Breastfeeding  
 Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)  
 Myelodysplasia  
 Hypersensitivity  
 Significant drug interaction  
 Other, please explain: \_\_\_\_\_  
 No clinical reason not to use methotrexate or leflunomide

Continued on next page



# Avsola™ (infliximab-axxq) Injectable Medication Precertification Request

Page 5 of 6

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

Please indicate the preferred alternatives for rheumatoid arthritis have been ineffective, not tolerated, or are contraindicated:

- Enbrel  Humira  Kevzara  Orencia  Remicade  Rinvoq  Simponi Aria  Xeljanz/Xeljanz XR

#### 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 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 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
- Yes  No Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)?
- Yes  No Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease modifying drug (e.g., Xeljanz) indicated for moderately to severely active ulcerative colitis?
- Yes  No Has the patient been hospitalized for acute severe ulcerative colitis (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia)?
- Yes  No Has the patient tried and had an inadequate response to at least one conventional therapy option?
- Yes  No Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], corticosteroid [e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone, cyclosporine [Sandimmune], mesalamine [e.g., Apriso, Asacol, Lialda, Pentasa, Canasa, Rowasa] balsalazide, or olsalazine], mercaptopurine [Purinethol], sulfasalazine, tacrolimus [Prograf], metronidazole [Flagyl] or ciprofloxacin [Cipro] [for pouchitis only])?
- Please select:  Azathioprine (Azasan, Imuran)  Corticosteroid (e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone)  Cyclosporine (Sandimmune)  Mesalamine (e.g., Apriso, Asacol, Lialda, Pentas, Canasa, Rowasa) balsalazide, or olsalazine  Mercaptopurine (Purinethol)  Sulfasalazine  Tacrolimus (Prograf)  Metronidazole (Flagyl) or Ciprofloxacin (Cipro) (for pouchitis only)

Please indicate the preferred alternatives for ulcerative colitis that have been ineffective, not tolerated, or are contraindicated:

- Humira  Entyvio  Remicade  Xeljanz  Stelara (intravenous formulation)

#### 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 Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of uveitis?
- 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 had an ineffective response, contraindication or intolerance to Humira?

#### For Continuation Requests (clinical documentation required for all requests):

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 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 All Conditions (Exception Crohns and Rheumatoid arthritis)

- Yes  No Has the patient achieved or maintained 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?

#### Acute graft versus host disease

- Yes  No Has the patient experienced an inadequate response to systemic corticosteroids?
- Yes  No Does the patient have an intolerance or contraindication to corticosteroids?

Continued on next page



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Page 6 of 6

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

#### Ankylosing spondylitis and axial spondyloarthritis

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

#### Crohn's disease

Yes  No Is this a request for a change in dosing regimen?

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

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 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:

- abdominal pain or tenderness
- diarrhea
- body weight
- abdominal mass
- hematocrit
- endoscopic appearance of the mucosa
- improvement on a disease activity scoring tool (e.g., Crohn's disease Activity Index [CDAI] score)
- none of the above

#### Hidradenitis suppurativa

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

#### Immune checkpoint inhibitor toxicity

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?

#### Juvenile idiopathic arthritis

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

- number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- number of joints with limitation of movement
- functional ability
- none of the above

#### Plaque psoriasis

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

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
- skin and/or nail involvement
- none of the above

#### Reactive arthritis

Yes  No Has the patient achieved or maintained 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)?

#### Rheumatoid arthritis

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 prescribed dose exceed 10 mg per kg?

Yes  No Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug?

→ Please indicate the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability: \_\_\_\_\_ %

Yes  No Does the patient require dosing more frequent than every 8 weeks due to an incomplete response at the current dosing frequency?

#### Ulcerative colitis:

Yes  No Has the patient achieved or maintained remission?

→ Please indicate which of the following the patient experienced from baseline:  stool frequency  rectal bleeding

C-reactive protein (CRP)  fecal calprotectin (FC)  endoscopic appearance of the mucosa  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

#### Uveitis

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.