MEDICARE FORM

Cimzia® (certolizumab pegol) Injectable Medication Precertification Request

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

For Michigan MMP:
FAX: 1-844-241-2495
PHONE: 1-855-676-5772

For other lines of business:
Please use other form.

Note: Cimzia is non-preferred. Preferred products vary based on indication. See section G below.

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:	DOB:	
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	Email:
Patient Current Weight: ____ lbs or ____ kgs Patient Height: ____ inches or ____ cms		Allergies:	

B. INSURANCE INFORMATION

Aetna Member ID #: _____	Does patient have other coverage? ☐ Yes ☐ No
Group #: _____	If yes, provide ID#: _____ Carrier Name: _____
Insured:	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 Email:		Office Contact Name:		Phone:	

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

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office ☐ Home
☐ 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: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Mail Order
☐ Other: _____
Name: _____
Address: _____
City: _____ State: _____ ZIP: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____
NPI: _____

E. PRODUCT INFORMATION

Request is for Cimzia (certolizumab pegol) Dose: _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other any other where applicable (*).

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

G. CLINICAL INFORMATION - Required clinical information must be completed for ALL precertification requests.

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

Note: Cimzia is non-preferred. Entyvio, Inflectra, Remicade, and Simponi Aria are preferred for MA plans. For MAPD plans, Enbrel, Humira, Kevzara, Otezla, Rinvoq, Skyrizi, and Xeljanz/Xeljanz XR are preferred. Preferred products vary based on indication.

☐ Yes ☐ No Has the patient had prior therapy with Cimzia (certolizumab pegol) 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)

☐ 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) ☐ 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 that apply)
☐ Entyvio (vedolizumab) ☐ Inflectra (infliximab-dyyb) ☐ Remicade (infliximab) ☐ Simponi Aria (golimumab)

_____

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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.

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) ☐ Xeljanz/Xeljanz XR (tofacitinib)

_____

_____

☐ Yes ☐ 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)?

☐ Yes ☐ 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?

→ ☐ 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-gamma assay (IGRA) ☐ chest x-ray
Please enter the results of the tuberculosis (TB) test: ☐ positive ☐ negative ☐ unknown
If positive, Does the patient have latent or active tuberculosis TB? ☐ latent ☐ active ☐ unknown
If latent tuberculosis ☐ Yes ☐ No Has treatment for latent tuberculosis (TB) infection been initiated or completed?
→ Please select: ☐ treatment initiated ☐ treatment completed

For Initiation Requests (clinical documentation required):

Ankylosing spondylitis and axial spondyloarthritis

Please indicate loading dose at weeks 0, 2 and 4: _____ 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., Humira) 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 does the patient have an intolerance or contraindication to at least two NSAIDs?

Crohn's disease

Please indicate loading dose at weeks 0, 2, and 4: _____ Please indicate maintenance dose: _____ frequency: _____weeks

☐ 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 SC ☐ Methylprednisolone (Solu-Medrol)
☐ Rifaximin (Xifaxan) ☐ Tacrolimus

Plaque psoriasis

Please indicate loading dose at weeks 0, 2 and 4: _____ 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): _____%

<u>If less than 10% of BSA:</u>

☐ 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: _____

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

Psoriatic arthritis

Please indicate loading dose at weeks 0, 2 and 4: _____ Please indicate maintenance dose: _____ frequency: _____weeks

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

☐ Yes ☐ No Does the patient have psoriatic arthritis with co-existent plaque psoriasis?

Rheumatoid arthritis

Please indicate loading dose at weeks 0, 2 and 4: _____ Please indicate maintenance dose: _____ frequency: _____weeks

☐ 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 (DMARD) (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 test result: ☐ positive ☐ negative ☐ not completed

☐ Yes ☐ No Has the patient been tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker?
Please indicate test result: ☐ positive ☐ negative ☐ not completed

☐ Yes ☐ No Has the patient been tested for the C-reactive protein (CRP) biomarker?
Please indicate test result: ☐ positive ☐ negative ☐ not completed

☐ Yes ☐ No Has the patient been tested for the erythrocyte sedimentation rate (ESR) biomarker?
Please indicate test result: ☐ positive ☐ negative ☐ not completed

☐ 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 20mg 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 ☐ Renal impairment ☐ Hypersensitivity
☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
☐ Elevated liver transaminases ☐ Significant drug interaction ☐ Myelodysplasia ☐ Breastfeeding
☐ Interstitial pneumonitis or clinically significant pulmonary fibrosis
☐ Pregnancy or currently planning pregnancy
☐ Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
☐ Other, please explain: _____

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 Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms since starting treatment with the requested drug?

Ankylosing spondylitis and axial spondyloarthritis

Please indicate which of the following has the patient experienced:
☐ Functional status ☐ Total spinal pain ☐ Inflammation (e.g., morning stiffness) ☐ None of the above

Crohn's disease

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

Please indicate which of the following has the patient experienced:
☐ Abdominal pain or tenderness ☐ Abdominal mass ☐ Body weight ☐ Diarrhea ☐ Endoscopic appearance of the mucosa ☐ Hematocrit
☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) ☐ 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 only

Please indicate which of the following has the patient experienced:
☐ Number of swollen joints ☐ Number of tender joints ☐ Dactylitis ☐ Enthesitis ☐ Skin and/or nail involvement ☐ None of the above

Rheumatoid arthritis

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

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.