Cimzia

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical*	❑ *Home*	❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital*	❑ *Office*	❑ *Pharmacy*

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Exception Criteria Questions:

A. Is the product being requested for the treatment of an ADULT patient (18 years of age or older) with one of the following indications?
- Ankylosing spondylitis
- Crohn's disease
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis

❑ Yes ❑ No *If No, skip to Clinical Criteria Questions*

B. These are the preferred products for which coverage is provided for treatment of the following indications:
- Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis: **Remicade and Simponi Aria**
- Plaque psoriasis: **Ilumya and Remicade**
- Crohn's disease, ulcerative colitis: **Entyvio and Remicade**
- **Stelara IV** is indicated for a one time induction dose for Crohn's disease and ulcerative colitis.

Can the patient's treatment be switched to a preferred product?
❑ Yes, *Please obtain Form for preferred product and submit for corresponding PA.*
❑ No

If diagnosis is Plaque psoriasis, skip to Question M

C. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No, *If No, skip to Question E*

D. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. ❑ Yes ❑ No, *skip to Clinical Criteria Questions*

E. What is the diagnosis?
❑ Ankylosing spondylitis
❑ Crohn's disease, *skip to Question I*
❑ Psoriatic arthritis
❑ Rheumatoid arthritis
❑ Ulcerative colitis, *skip to Question J*
❑ Other, *skip to Clinical Criteria Questions*

F. Is the patient currently pregnant or breastfeeding? ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Does the patient have a documented inadequate response or intolerable adverse event to both of the preferred products (Remicade, Simponi Aria)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Does the patient have one of the following documented clinical reasons to avoid the preferred products that are TNF inhibitors (Remicade, Simponi Aria)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Not applicable – Requested medical is a TNF inhibitor *skip to Clinical Criteria Questions*
❑ Yes – History of demyelinating disorder, *skip to Clinical Criteria Questions*
❑ Yes – History of congestive heart failure *skip to Clinical Criteria Questions*
❑ Yes – History of hepatitis B virus infection *skip to Clinical Criteria Questions*
❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor) *skip to Clinical Criteria Questions*
❑ Yes – Risk of lymphoma *skip to Clinical Criteria Questions*
❑ No – None of the above *skip to Clinical Criteria Questions*

I. Is the patient currently pregnant or breastfeeding? ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

J. Does the patient have a documented inadequate response or intolerable adverse event to both of the preferred products (Entyvio, Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** *If Yes, skip to Clinical Criteria Questions* ❑ Yes ❑ No

K. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
- ❑ Not applicable – requested medication is a TNF inhibitor
- ❑ Yes – History of demyelinating disorder
- ❑ Yes – History of congestive heart failure
- ❑ Yes – History of hepatitis B virus infection
- ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
- ❑ Yes – Risk of lymphoma
- ❑ No- None of the above

L. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product that is not a TNF inhibitor (Entyvio)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes ❑ No *For yes or no, skip to Clinical Criteria Questions*

M. Is the patient currently pregnant or breastfeeding? ❑ Yes ❑ No

N. Does the patient have a documented inadequate response or intolerable adverse event to the preferred products indicated for plaque psoriasis (Ilumya, Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
If Yes, skip to Clinical Criteria Questions ❑ Yes ❑ No

O. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
- ❑ Not applicable – requested medication is a TNF inhibitor
- ❑ Yes – History of demyelinating disorder
- ❑ Yes – History of congestive heart failure
- ❑ Yes – History of hepatitis B virus infection
- ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
- ❑ Yes – Risk of lymphoma
- ❑ No- None of the above

P. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product that is not a TNF inhibitor (Ilumya)? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

Clinical Criteria Questions:

1. Has the patient been diagnosed with any of the following?
   - ❑ Moderately to severely active rheumatoid arthritis (RA)
   - ❑ Active psoriatic arthritis (PsA)
   - ❑ Active ankylosing spondylitis (AS)
   - ❑ Active axial spondyloarthritis
   - ❑ Moderately to severely active Crohn's disease (CD)
   - ❑ Moderate to severe plaque psoriasis
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. 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
4. 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? *If Yes, skip to #6* ❑ Yes ❑ No
5. 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? ❑ Yes ❑ No *If yes, skip to #8*

6. 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])? ❑ Yes ❑ No *If No, skip to #11*

7. Has the patient been tested for tuberculosis (TB) within the previous 12 months? ❑ Yes ❑ No

8. What were the results of the tuberculosis (TB) test?
❑ Positive for TB ❑ Negative for TB, *skip to #11* ❑ Unknown

9. Does the patient have latent or active tuberculosis (TB)? ❑ Latent ❑ Active ❑ Unknown

10. Has treatment for latent tuberculosis (TB) infection been initiated or completed?
❑ Yes – treatment initiated ❑ Yes – treatment completed ❑ No

11. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to diagnosis section and dosing section.*

12. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to diagnosis section and dosing section.*

13. 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?
❑ Yes ❑ No *Skip to Dosing section*

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Rheumatoid Arthritis

14. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis?
If Yes, skip to 29 ❑ Yes ❑ No

15. 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? *If Yes, skip to #29* ❑ Yes ❑ No

16. Has the patient experienced intolerance to methotrexate? *If Yes, skip to #29* ❑ Yes ❑ No

17. Does the patient have a contraindication to methotrexate? ❑ Yes ❑ No
If Yes, indicate the contraindication and Skip to #29: _____
_____

Section B: Ankylosing Spondylitis or Axial Spondyloarthritis

18. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for active ankylosing spondylitis or active axial spondyloarthritis? *If Yes, skip to #29* ❑ Yes ❑ No

19. 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 *Skip to #29*

Section C: Crohn's Disease

20. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for moderately to severely active Crohn's disease? *If Yes, skip to #38* ❑ Yes ❑ No

21. Does the patient have fistulizing Crohn's disease? *If Yes, skip to #38* ❑ Yes ❑ No

22. Has the patient tried and had an inadequate response to at least one conventional therapy option?
If Yes, indicate below and skip to #38
❑ Yes - Sulfasalazine (Azulfidine, Sulfazine)
❑ Yes - Metronidazole (Flagyl)
❑ Yes - Ciprofloxacin (Cipro)
❑ Yes - Prednisone
❑ Yes - Budesonide (Entocort EC)
❑ Yes - Azathioprine (Azasan, Imuran)
❑ Yes - Mercaptopurine (Purinethol)
❑ Yes – Methotrexate intramuscular (IM) or subcutaneous (SC)
❑ Yes - Methylprednisolone (Solu-Medrol)
❑ Yes - Rifaximin (Xifaxan)
❑ Yes - Tacrolimus
❑ No

23. 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, metronidazole [Flagyl], prednisone, sulfasalazine [Azulfidine, Sulfazine], rifaximin [Xifaxan], tacrolimus)? ❑ Yes ❑ No *Skip to #38*

Section D: Plaque Psoriasis

24. Has the patient ever received (including current utilizers) Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis? *If Yes, skip to #43.* ❑ Yes ❑ No

25. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected?
If Yes, skip to #43 ❑ Yes ❑ No

26. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)?
_____% *If greater than 10% of BSA, skip to #43*

27. Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine and acitretin?
If Yes, skip to #43 ❑ Yes ❑ No

28. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin? ❑ Yes ❑ No
If Yes, indicate clinical reason and skip to #43 : _____
_____

Complete the following dosing section based on the patient's diagnosis, if applicable.

Section E: Dosing for Rheumatoid Arthritis, Psoriatic Arthritis,and Ankylosing Spondylitis or Axial Spondyloarthritis

29. Is the patient currently receiving the requested drug? ❑ Yes ❑ No *If No, skip to #34*

30. Does the prescribed dose exceed 200 mg? *If Yes, skip to #32* ❑ Yes ❑ No

31. Is the prescribed frequency for the maintenance dose more frequent than one dose every other week?
❑ Yes ❑ No *No further questions*

32. Does the prescribed dose exceed 400 mg? ❑ Yes ❑ No

33. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?
❑ Yes ❑ No *No further questions*

34. Does the prescribed dose exceed a loading dose of 400 mg at weeks 0, 2, and 4, and a maintenance dose of 200 mg thereafter? *If Yes, skip to #36* ❑ Yes ❑ No

35. Is the prescribed frequency for the maintenance dose more frequent than one dose every other week?
❑ Yes ❑ No *No further questions*

36. Does the prescribed dose exceed a loading dose of 400 mg at weeks 0, 2, and 4, and a maintenance dose of 400 mg thereafter? ❑ Yes ❑ No

37. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?
❑ Yes ❑ No *No further questions*

Section F: Dosing for Chron's Disease

38. Is the patient currently receiving the requested drug? ❑ Yes ❑ No *If No, skip to #41*

39. Does the prescribed dose exceed 400 mg? ❑ Yes ❑ No

40. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?
❑ Yes ❑ No *No further questions*

41. Does the prescribed dose exceed a loading dose of 400 mg at weeks 0, 2, and 4, and a maintenance dose of 400 mg thereafter? ❑ Yes ❑ No

42. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?
❑ Yes ❑ No *No further questions*

Section G: Dosing for Plaque Psoriasis

43. Is the patient currently receiving the requested drug? ❑ Yes ❑ No *If No, skip to #49*

44. What is the patient's weight? _____kg *If greater than 90kg, skip to #47*

45. Does the prescribed dose exceed 200 mg? *If Yes, skip to #47* ❑ Yes ❑ No

46. Is the prescribed frequency for the maintenance dose more frequent than one dose every other week?
❑ Yes ❑ No *No further questions*

47. Does the prescribed dose exceed 400 mg? ❑ Yes ❑ No

48. Is the prescribed frequency for the maintenance dose more frequent than one dose every other week?
❑ Yes ❑ No *No further questions*

49. What is the patient's weight? _____kg *If greater than 90kg, skip to #53*

50. Does the patient require a loading dose followed by a maintenance dose*?* ❑ Yes ❑ No *If No, skip to #53*

51. Does the prescribed dose exceed a loading dose of 400 mg at weeks 0, 2, and 4, and a maintenance dose of 200 mg thereafter? ❑ Yes ❑ No

52. Is the prescribed frequency for the maintenance dose more frequent than one dose every other week?
❑ Yes ❑ No *No further questions*

53. Does the prescribed dose exceed 400 mg? ❑ Yes ❑ No

54. Is the prescribed frequency for the maintenance dose more frequent than one dose every other week?
❑ Yes ❑ No

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720