CVS caremark™ {{PANUMCODE}}

Stelara

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 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** 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.

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Patient's Name: {{MEMFIRST}} {{MEMLAST}} **Date**: {{TODAY}}
Patient's ID: {{MEMBERID}} **Patient's Date of Birth:** {{MEMBERDOB}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}}
Specialty: _____, NPI#: _____
Physician Office Telephone: {{PHYSICIANPHONE}} **Physician Office Fax:** {{PHYSICIANFAX}}
Request Initiated For: {{DRUGNAME}}

1. What is the prescribed dose and frequency?
   a) **Loading dose:**
   - ❑ Stelara SQ 45 mg Quantity and Frequency: _____
   - ❑ Stelara SQ 90 mg Quantity and Frequency: _____
   - ❑ Stelara IV Quantity and Frequency: _____
   - ❑ Other _____

   b) **Maintenance dose:**
   - ❑ Stelara SQ 45 mg Quantity and Frequency: _____
   - ❑ Stelara SQ 90 mg Quantity and Frequency: _____
   - ❑ Stelara IV Quantity and Frequency: _____
   - ❑ Other _____

2. What is the diagnosis?
   - ❑ Moderate to severe plaque psoriasis (PsO)
   - ❑ Immune Checkpoint Inhibitor-Related Toxicity
   - ❑ Active psoriatic arthritis WITH co-existent plaque psoriasis (PsA)
     - What is the primary diagnosis being treated? ❑ Plaque psoriasis ❑ Psoriatic arthritis
   - ❑ Active psoriatic arthritis WITHOUT co-existent plaque psoriasis (PsA)
   - ❑ Moderately to severely active Crohn's disease (CD)
   - ❑ Moderately to severely active ulcerative colitis (UC)
   - ❑ Other _____

3. What is the ICD-10 code? _____ Patient's weight: _____ kg / lbs ***(circle one)***

4. Is the requested drug being prescribed by or in consultation with one of the following?
   - ❑ Dermatologist ❑ Rheumatologist
   - ❑ Gastroenterologist ❑ Hematologist
   - ❑ Oncologist ❑ Other _____

5. 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

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155

6. 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?
   If Yes, skip to #10 ❑ Yes ❑ No
7. 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
8. What were the results of the TB test?
   ❑ Positive for TB ❑ Negative for TB *If Negative, skip to #10* ❑ Unknown
9. Which of the following applies to the patient?
   ❑ Patient has latent TB and treatment for latent TB has been initiated
   ❑ Patient has latent TB and treatment for latent TB has been completed
   ❑ Patient has latent TB and treatment for latent TB has not been initiated
   ❑ Patient has active TB
10. Is the patient currently receiving Stelara? ❑ Yes ❑ No
11. Which of the following applies to this request for the requested drug?
    ❑ Initiation of the intravenous (IV) loading dose, *skip to diagnosis section.*
    ❑ Initiation of the subcutaneous (SQ) maintenance dose, *skip to diagnosis section.*
    ❑ Continuation of the subcutaneous (SQ) maintenance dose
12. *If the diagnosis is plaque psoriasis,* is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to diagnosis section.*
    ❑ Yes ❑ Unknown ❑ No ❑ N/A, diagnosis is not plaque psoriasis
13. 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

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

Section A: Plaque Psoriasis

Continuation

14. Has the patient experienced a reduction in body surface area (BSA) affected from baseline?
    ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. ❑ Yes ❑ No
15. Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms*** ❑ Yes ❑ No

Initiation

16. 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)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No
17. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected?
    ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of body surface area affected and no further questions. ❑ Yes ❑ No
18. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)?
    Indicate percentage _____ % ***ACTION REQUIRED: Please attach chart notes or medical record documentation of affected areas and body surface area affected.*** *If greater than or equal to 10% of BSA, no further questions.*

19. 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? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** ❑ Yes ❑ No

20. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid each therapy.*** ❑ Yes ❑ No

21. Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin.
    ❑ Drug Interaction ❑ Hypersensitivity
    ❑ Risk of treatment-related toxicity ❑ History of intolerance or adverse event
    ❑ Pregnancy or planning pregnancy ❑ Breastfeeding
    ❑ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
    ❑ Other _____

Section B: Psoriatic Arthritis

Continuation

22. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***
    ❑ Number of swollen joints
    ❑ Number of tender joints
    ❑ Axial disease
    ❑ Dactylitis
    ❑ Enthesitis
    ❑ Skin and/or nail involvement
    ❑ None of the above

Initiation

23. 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)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried and no further questions.*** ❑ Yes ❑ No

24. What is the patient's diease severity? ❑ Mild to moderate ❑ Severe *If Severe, no further questions.*

25. Does the patient have enthesitis or predominantly axial disease? *If Yes, no further questions.* ❑ Yes ❑ No

26. 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? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** ❑ Yes ❑ No

27. Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** ❑ Yes ❑ No

28. Does the patient have a contraindication to methotrexate or leflunomide? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No *If No, skip to #30*

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

30. Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.***
    ❑ Yes ❑ No

Section C: Crohn's Disease

Continuation

31. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission and no further questions.*** ❑ Yes ❑ No

32. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response and no further questions.***
    - ❑ 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)
    - ❑ None of the above

Section D: Ulcerative Colitis

Continuation

33. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission and no further questions.*** ❑ Yes ❑ No

34. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response and no further questions.***
    - ❑ Stool frequency
    - ❑ Rectal bleeding
    - ❑ Urgency of defecation
    - ❑ C-reactive protein (CRP)
    - ❑ Fecal calprotectin (FC)
    - ❑ 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., Ulcerative colitis Endoscopic Index of Severity [UCEIS], Mayo Score)
    - ❑ None of the above

Section E: Immune Checkpoint Inhibitor-Related Toxicity

35. Has the patient experienced an inadequate response to infliximab or vedolizumab? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #38.*** ❑ Yes ❑ No

36. Has the patient experienced an intolerance to infliximab or vedolizumab? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #38.*** ❑ Yes ❑ No

37. Does the patient have a contraindication to infliximab and vedolizumab? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

38. 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

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 Prior Authorization Fax: 1-866-249-6155