



Stelara and biosimilars

HMSAMCD - 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 1-866-237-5512.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414**. 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: _____ **Date:** _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

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

Additional Demographic Information:

Patient Weight: _____ *kg*
Patient Height: _____ *ft* _____ *inches*

Indicate where the drug is being dispensed:

- Office Outpatient Hospital Ambulatory Surgical Inpatient Hospital
- Off Campus Outpatient Hospital Urgent Care Emergency Room Birthing Center
- Military Facility Skilled Nursing Facility Nursing Facility Hospice
- Inpatient Psychiatric Psychiatric Residential Treatment End Stage Renal Facility
- Psychiatric Facility Pharmacy Other

Indicate where the drug is being administered:

- Ambulatory surgical Home Inpatient Hospital
- Office Outpatient Hospital Pharmacy

What is the ICD-10 code? _____

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- What product is being requested? Stelara IV Stelara SC Imuldosa IV Imuldosa SC
 Otulfi IV Otulfi SC Pyzchiva IV Pyzchiva SC Selarsdi IV Selarsdi SC
 Steqeyma IV Steqeyma SC Ustekinumab (unbranded Stelara) IV
 Ustekinumab (unbranded Stelara) SC Ustekinumab-aaaz (unbranded Otulfi) IV
 Ustekinumab-aaaz (unbranded Otulfi) SC Ustekinumab-aekn (unbranded Selarsdi) IV
 Ustekinumab-aekn (unbranded Selarsdi) SC Ustekinumab-stba (unbranded Steqeyma) IV
 Ustekinumab-stba (unbranded Steqeyma) SC Ustekinumab-ttwe (unbranded Pyzchiva) IV
 Ustekinumab ttwe (unbranded Pyzchiva) SC Wezlana IV Wezlana SC Yesintek IV Yesintek SC

Criteria Questions:

1. What is the requested product?

- Stelara, *Continue to #2*
 Imuldosa, *Continue to #2*
 Otulfi, *Continue to #2*
 Pyzchiva, *Continue to #10*
 Selarsdi, *Continue to #2*
 Steqeyma, *Continue to #2*
 Wezlana, *Continue to #2*
 Yesintek, *Continue to #10*
 ustekinumab-aekn, *Continue to #2*
 ustekinumab-ttwe, *Continue to #2*
 Other, *Continue to #2*

2. Does the member have an indication that is not FDA approved for any of the preferred products, Pyzchiva (Cordavis and Sandoz brand) and Yesintek?

- Yes, *Continue to #10*
 No, *Continue to #3*

3. Has the member had a documented intolerable adverse event to ALL of the preferred products (Pyzchiva and Yesintek), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference products and biosimilar products)? ***ACTION REQUIRED: If yes, please submit supporting documentation***

- Yes, *Continue to #10*
 No, *Continue to #10*

General Biologic/Targeted Synthetic Drug and TB

10. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Otezla, Xeljanz)?

- Yes, *Continue to #11*
 No, *Continue to #11*

11. 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?

- Yes, *Continue to #20*
 No, *Continue to #12*

12. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA])

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within 6 months of initiating therapy?

- Yes, *Continue to #13*
- No, *Continue to #20*

13. What were the results of the TB test?

- Positive for TB, *Continue to #14*
- Negative for TB, *Continue to #20*
- Unknown, *Continue to #20*

14. Which of the following applies to the patient?

- Patient has latent TB and treatment for latent TB has been initiated, *Continue to #20*
- Patient has latent TB and treatment for latent TB has been completed, *Continue to #20*
- Patient has latent TB and treatment for latent TB has not been initiated, *Continue to #20*
- Patient has active TB, *Continue to #20*

Indication

20. What is the diagnosis?

- Plaque psoriasis, *Continue to #100*
- Psoriatic arthritis WITH co-existent plaque psoriasis, *Continue to #21*
- Psoriatic arthritis, *Continue to #200*
- Crohn's disease, *Continue to #300*
- Ulcerative colitis, *Continue to #400*
- Immune Checkpoint inhibitor-related diarrhea or colitis, *Continue to #500*
- Other, *No Further Questions*

21. Is the patient 6 years of age or older?

- Yes, *Continue to #22*
- No, *Continue to #22*

22. Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?

- Yes, *Continue to #23*
- No, *Continue to #23*

23. What is the primary diagnosis being treated?

- Psoriatic arthritis, *Continue to #202*
- Plaque psoriasis, *Continue to #102*

Plaque Psoriasis

100. Is the patient 6 years of age or older?

- Yes, *Continue to #101*
- No, *Continue to #101*

101. Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a dermatologist?

- Yes, *Continue to #102*
- No, *Continue to #102*

102. Has the patient been diagnosed with moderate to severe plaque psoriasis?

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- Yes, *Continue to #103*
- No, *Continue to #103*

Continuation of Therapy

103. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?

- Yes, *Continue to #104*
- No, *Continue to #108*

104. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

- Yes, *Continue to #108*
- No, *Continue to #105*
- Unknown, *Continue to #108*

105. 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 or a biosimilar of the requested drug?

- Yes, *Continue to #106*
- No, *Continue to #106*

106. Has the patient experienced a reduction in body surface area (BSA) affected from baseline?

- Yes, *No Further Questions*
- No, *Continue to #107*

107. Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)?

- Yes, *No Further Questions*
- No, *No Further Questions*

Initial Therapy

Prior treatment with another biologic or targeted synthetic drug

108. 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 Further Questions*
- No, *Continue to #109*

Requirements regarding prior therapy

109. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected?

- Yes, *No Further Questions*
- No, *Continue to #110*

110. Is the percentage of body surface area (BSA) affected (prior to starting the requested medication) less than 3%?

- Yes, *Continue to #111*
- No, *Continue to #111*

111. What is the percentage of body surface area (BSA) affected (prior to starting the requested drug or a biosimilar of

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the requested drug)?

- Greater than or equal to 3% to less than 10% of BSA, *Continue to #112*
- Greater than or equal to 10% of BSA, *No Further Questions*

112. 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 Further Questions*
- No, *Continue to #113*

113. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin?

- Yes, *Continue to #114*
- No, *Continue to #114*

114. Please indicate clinical reason to avoid pharmacologic treatment

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*
- Risk of treatment-related toxicity, *No Further Questions*
- Pregnancy or currently planning pregnancy, *No Further Questions*
- Breastfeeding, *No Further Questions*
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *No Further Questions*
- Hypersensitivity, *No Further Questions*
- History of intolerance or adverse event, *No Further Questions*
- Other, *No Further Questions*

Psoriatic Arthritis

200. Is the patient 6 years of age or older?

- Yes, *Continue to #201*
- No, *Continue to #201*

201. Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?

- Yes, *Continue to #202*
- No, *Continue to #202*

Continuation of Therapy

202. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?

- Yes, *Continue to #203*
- No, *Continue to #206*

203. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

- Yes, *Continue to #206*
- No, *Continue to #204*
- Unknown, *Continue to #206*

204. 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, *Continue to #205*

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No, *Continue to #205*

205. Which of the following has the patient experienced an improvement in from baseline?

- Number of swollen joints, *No Further Questions*
- Number of tender joints, *No Further Questions*
- Dactylitis, *No Further Questions*
- Enthesitis, *No Further Questions*
- Skin and/or nail involvement, *No Further Questions*
- Functional status, *No Further Questions*
- C-reactive protein (CRP), *No Further Questions*
- None of the above, *No Further Questions*

Initial Therapy

206. Has the patient been diagnosed with active psoriatic arthritis (PsA)?

- Yes, *Continue to #207*
- No, *Continue to #207*

Prior treatment with another biologic or targeted synthetic drug

207. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)?

- Yes, *No Further Questions*
- No, *Continue to #208*

New starts

208. What is the patient's disease severity?

- Mild to moderate, *Continue to #209*
- Severe, *No Further Questions*

209. Does the patient have enthesitis?

- Yes, *No Further Questions*
- No, *Continue to #210*

210. 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 Further Questions*
- No, *Continue to #211*

211. Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)?

- Yes, *No Further Questions*
- No, *Continue to #212*

212. Does the patient have a contraindication to methotrexate or leflunomide?

- Yes, *Continue to #213*
- No, *Continue to #214*

213. Please indicate the contraindication

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- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*
- Drug interaction, *No Further Questions*
- Risk of treatment-related toxicity, *No Further Questions*
- Pregnancy or currently planning pregnancy, *No Further Questions*
- Breastfeeding, *No Further Questions*
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *No Further Questions*
- Hypersensitivity, *No Further Questions*
- History of intolerance or adverse event, *No Further Questions*
- Other, *No Further Questions*

214. Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)?

- Yes, *No Further Questions*
- No, *No Further Questions*

Crohn's Disease

300. Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)?

- Yes, *Continue to #301*
- No, *Continue to #301*

301. Is the patient an adult?

- Yes, *Continue to #302*
- No, *Continue to #302*

302. Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a gastroenterologist?

- Yes, *Continue to #303*
- No, *Continue to #303*

303. Which of the following applies to this request for the requested drug or a biosimilar of the requested drug?

- Initiation of the intravenous (IV) loading dose, *No Further Questions*
- Initiation of the subcutaneous (SQ) maintenance dose, *No Further Questions*
- Continuation of the subcutaneous (SQ) maintenance dose, *Continue to #304*

Continuation of Therapy

304. Has the patient achieved or maintained remission OR 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 or a biosimilar of the requested drug?

- Yes, achieved or maintained remission, *No Further Questions*
- Yes, achieved or maintained a positive clinical response, *Continue to #305*
- No or none of the above, *No Further Questions*

305. Which of the following has the patient experienced an improvement in from baseline?

- Abdominal pain or tenderness, *No Further Questions*
- Diarrhea, *No Further Questions*
- Body weight, *No Further Questions*
- Abdominal mass, *No Further Questions*
- Hematocrit, *No Further Questions*
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance

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enterography (MRE), or intestinal ultrasound, *No Further Questions*

Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index (CDAI) score, *No Further Questions*

None of the above, *No Further Questions*

Ulcerative Colitis

400. Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)?

Yes, *Continue to #401*

No, *Continue to #401*

401. Is the patient an adult?

Yes, *Continue to #402*

No, *Continue to #402*

402. Is the requested drug being prescribed by or in consultation with a gastroenterologist?

Yes, *Continue to #403*

No, *Continue to #403*

Continuation of Therapy

403. Is this request for initiation or continuation of treatment with requested drug or a biosimilar of the requested drug?

Initiation of the intravenous (IV) loading dose, *No Further Questions*

Initiation of the subcutaneous (SQ) maintenance dose, *No Further Questions*

Continuation of the subcutaneous (SQ) maintenance dose, *Continue to #404*

404. Has the patient achieved or maintained remission OR has the patient achieved or maintained a positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug?

Yes, achieved or maintained remission, *No Further Questions*

Yes, achieved or maintained a positive clinical response, *Continue to #405*

No, *No Further Questions*

405. Which of the following has the patient experienced an improvement in from baseline?

Stool frequency, *No Further Questions*

Rectal bleeding, *No Further Questions*

Urgency of defecation, *No Further Questions*

C-reactive protein (CRP), *No Further Questions*

Fecal calprotectin (FC), *No Further Questions*

Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound, *No Further Questions*

Improvement on a disease activity scoring tool (e.g., Ulcerative colitis Endoscopic Index of Severity [UCEIS], Mayo Score), *No Further Questions*

None of the above, *No Further Questions*

Immune Checkpoint Inhibitor-Related Toxicity

500. Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a gastroenterologist, hematologist or oncologist?

Yes, *Continue to #501*

No, *Continue to #501*

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501. Has the patient experienced an inadequate response to infliximab or vedolizumab?

Yes, *No Further Questions*

No, *Continue to #502*

502. Has the patient experienced an intolerance to infliximab or vedolizumab?

Yes, *No Further Questions*

No, *Continue to #503*

503. Does the patient have a contraindication to infliximab and vedolizumab?

Yes, *No Further Questions*

No, *No Further Questions*

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)

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