



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 1-855-330-1720.** 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.

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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

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Criteria Questions:

1. What is the prescribed dose and frequency?
 Stelara SQ 45mg Frequency: _____
 Stelara SQ 90mg Frequency: _____
 Stelara IV x 1 dose of 260mg, 390mg or 520mg then Stelara SQ 90mg Frequency: _____
 Other _____
2. What is the diagnosis?
 Plaque psoriasis (PsO)
 Psoriatic arthritis with co-existent plaque psoriasis
 Psoriatic arthritis WITHOUT co-existent plaque psoriasis
 Crohn's disease (CD)
 Ulcerative colitis (UC)
 Other _____
3. What is the ICD-10 code? _____ Patient's weight: _____ kg / lbs (*circle one*)
4. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic disease modifying antirheumatic drug (DMARD) (e.g., Olumiant, Otezla, Xeljanz)? Yes No
5. 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 #7* Yes No
6. 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? *If Yes, skip to #9* Yes No
7. 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 [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 Diagnosis section.*
8. Has the patient been tested for tuberculosis (TB) within the previous 12 months? Yes No
9. What were the results of the TB test? Positive for TB Negative for TB, *skip to diagnosis section*
 Unknown
10. Does the patient have latent or active tuberculosis (TB)? Latent Active Unknown
11. Has treatment for latent tuberculosis (TB) infection been initiated or completed?
 Yes - treatment initiated Yes - treatment completed No

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

Section A: Plaque Psoriasis

12. Has the patient been diagnosed with moderate to severe plaque psoriasis? Yes No
13. Is this request for continuation of therapy with the requested drug? Yes No *If No, skip to #18*
14. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
 Yes, *skip to #18*
 No
 Unknown, *skip to #18*
15. 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?
 Yes No

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16. Has the patient experienced a reduction in body surface areas (BSA) affected from baseline? **ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of decreased body surface area affected and skip to #46.** Yes No
17. 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 and skip to #46.** Yes No
18. Has the patient ever received (including current utilizers) Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis? **ACTION REQUIRED: If 'Yes', attach chart notes, medical record documentation, or claims history supporting previous medications tried and skip to #46.** Yes No
19. 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 affected areas and body surface area affected and skip to #46.** Yes No
20. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? **ACTION REQUIRED: Please attach chart notes or medical record documentation of affected area and body surface area affected.** _____ % *If greater than or equal to 10% of BSA, skip to #46.*
21. 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 submit chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #46.** Yes No
22. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin? **ACTION REQUIRED: If 'Yes', please submit documentation of clinical reason to avoid therapy.** Yes No *If Yes, indicate clinical reason:* _____

Section B: Psoriatic Arthritis with or WITHOUT co-existent plaque psoriasis

23. Has the patient been diagnosed with active psoriatic arthritis (PsA)? Yes No
24. Is this request for continuation of therapy with the requested drug? Yes No *If No, skip to #54*
25. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
 Yes, skip to #54
 No
 Unknown, skip to #54
26. 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?
 Yes No
27. Has the patient experienced improvement in any of the following from baseline? **ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. [Please select all that apply] and skip to #54.**
 Number of swollen joints Dactylitis Enthesitis Skin and/or nail involvement
 Number of tender joints
 None of the above

Section C: Crohn's Disease

28. Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? Yes No
29. Is this request for continuation of therapy with the requested drug? Yes No *If No, skip to #34*

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30. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
 Yes, skip to #34
 No
 Unknown, skip to #34
31. Has the patient achieved or maintained remission? **ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and skip to #60.** Yes No
32. 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?
 Yes No
33. Which of the following has the patient experienced improvement in from baseline? **ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. [Please select all that apply] and skip to #60.**
 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
34. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for Crohn's disease? **ACTION REQUIRED: If 'Yes', attach chart notes, medical record documentation, or claims history supporting previous medications tried and skip to #60.** Yes No
35. Has the patient tried and had an inadequate response to at least one conventional therapy option? **ACTION REQUIRED: If 'Yes', please attach patient's chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy. If Yes, indicate below and skip to #60.**
 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
36. 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)? **ACTION REQUIRED: If 'Yes', attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is if not advisable, please attach documentation of clinical reason to avoid therapy.** Yes No Skip to #60

Section D: Ulcerative Colitis

37. Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)? Yes No
38. Is this request for continuation of therapy with the requested drug? Yes No *If No, skip to #43*

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39. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
- Yes, skip to #43
- No
- Unknown, skip to #43
40. Has the patient achieved or maintained remission? **ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and skip to #60.** Yes No
41. 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?
- Yes No
42. 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 to therapy. [Please select all that apply] and skip to #60.**
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Endoscopic appearance of the mucosa
- Improvement on a disease activity scoring tool (e.g., Ulcerative colitis Endoscopic Index of Severity [UCEIS], Mayo Score)
- None of the above
43. 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? **ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried and skip to #60.** Yes No
44. Has the patient tried and had an inadequate response to at least one conventional therapy option? **ACTION REQUIRED: If 'Yes', please attach patient's chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy. If Yes, indicate below and skip to #60**
- Yes - Azathioprine (Azasan, Imuran)
- Yes - Corticosteroid (e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone)
- Yes - Cyclosporine (Sandimmune)
- Yes - Mesalamine (e.g., Asacol, Lialda, Pentasa, Canasa, Rowasa), balsalazide, olsalazine
- Yes - Mercaptopurine (Purinethol)
- Yes - Sulfasalazine
- Yes - Tacrolimus (Prograf)
- Yes - Metronidazole (Flagyl) or Ciprofloxacin (Cipro) (for pouchitis only)
- No
45. 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, methylprednisolone, prednisone, cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], balsalazide, olsalazine, mercaptopurine [Purinethol], sulfasalazine, tacrolimus [Prograf], metronidazole/ciprofloxacin [for pouchitis only]) **ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including clinical reason to avoid therap and skip to #60.** Yes No

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

Section E: Dosing for Plaque Psoriasis AND/OR Psoriatic Arthritis with Co-Existent Plaque Psoriasis

46. What is the requested formulation? Stelara for subcutaneous injection Stelara for intravenous infusion

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47. Is the patient currently receiving Stelara? Yes No *If no, skip to #51*
48. ***If patient's weight is less than or equal to 100kg:*** Does the prescribed dose exceed 45 mg? Yes No
If yes or no, skip to #50
49. ***If patient's weight is greater than 100kg:*** Does the prescribed dose exceed 90 mg? Yes No
50. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?
 Yes No *No further questions*
51. ***If patient's weight is less than or equal to 100kg:*** Does the prescribed dose exceed a loading dose of 45 mg at weeks 0 and 4, and a maintenance dose of 45 mg thereafter? Yes No *If yes or no, skip to #53*
52. ***If patient's weight is greater than 100kg:*** Does the prescribed dose exceed a loading dose of 90 mg at weeks 0 and 4, and a maintenance dose of 90 mg thereafter? Yes No
53. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? Yes No

Section F: Dosing for Psoriatic Arthritis WITHOUT co-existent plaque psoriasis

54. What is the requested formulation? Stelara for subcutaneous injection Stelara for intravenous infusion
55. Is the patient currently receiving Stelara? Yes No *If no, skip to #58*
56. Does the prescribed dose exceed 45 mg? Yes No
57. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?
 Yes No *No further questions*
58. Does the prescribed dose exceed a loading dose of 45 mg at weeks 0 and 4, and a maintenance dose of 45 mg thereafter? Yes No
59. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? Yes No

Section G: Dosing for Crohn's Disease and Ulcerative colitis

60. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? Yes No
61. Is the patient currently receiving Stelara? Yes No *If no skip to #63, 64 or 65*
62. Does the prescribed dose exceed 90 mg? Yes No *No further Questions*
63. ***If patient's weight is less than or equal to 55kg*** Does the prescribed dose exceed a one-time loading dose of 260 mg and a maintenance dose of 90 mg thereafter? Yes No *No further Questions*
64. ***If patient's weight is greater than 55kg to less than or equal to 85kg*** Does the prescribed dose exceed a one-time loading dose of 390 mg and a maintenance dose of 90 mg thereafter? Yes No *No further Questions*
65. ***If patient's weight is greater than 85kg*** Does the prescribed dose exceed a one-time loading dose of 520 mg and a maintenance dose of 90 mg thereafter? Yes 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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