

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:	
Physician's Name:	
Specialty:	
Physician Office Telephone:	
<u>Referring</u> Provider Info:	sting Provider
Name:	NPI#:
Fax:	Phone:
Rendering Provider Info:	ring 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: Patient Height:	kg cm			
Please indicate the place of service for the requested drug:				
Ambulatory Surgical	Home	D Off Campus Outpatient Hospital		
On Campus Outpatient Hospital	Office	^D Pharmacy		

Criteria Questions:

What is the ICD-10 code?

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

 \Box Yes, Continue to 2

 \square No, Continue to 2

2. 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?

 \Box Yes, Continue to 6

 \square No, Continue to 3

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

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3. 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, Continue to 4

 \square No, *Continue to 4*

4. What were the results of the TB test?

D Positive for TB, *Continue to 5*

□ Negative for TB, *Continue to 6*

Unknown, No further questions

5. Which of the following applies to the patient?

D Patient has latent TB and treatment for latent TB has been initiated, Continue to 6

D Patient has latent TB and treatment for latent TB has been completed, Continue to 6

D Patient has latent TB and treatment for latent TB has not been initiated, Continue to 6

D Patient has active TB, Continue to 6

6. What is the diagnosis?

□ Plaque psoriasis, *Continue to 8*

D Psoriatic arthritis WITH co-existent plaque psoriasis, Continue to 7

□ Psoriatic arthritis, *Continue to 22*

Crohn's disease, Continue to 37

□ Ulcerative colitis, *Continue to 44*

□ Immune checkpoint inhibitor-related diarrhea or colitis, *Continue to 51*

□ Other, please specify. ______, *No further questions*

7. What is the primary diagnosis being treated?

□ Psoriatic arthritis, *Continue to 22*

□ Plaque psoriasis, *Continue to* 8

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

□ Yes, Continue to 9

□ No, *Continue to* 9

9. Is the patient 6 years of age or older?
□ Yes, *Continue to 10*□ No, *Continue to 10*

10. Is the requested drug being prescribed by or in consultation with a dermatologist?
□ Yes, *Continue to 11*□ No. *Continue to 11*

11. Is this request for continuation of therapy with the requested drug?
□ Yes, *Continue to 12*□ No, *Continue to 16*

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

□ Yes, Continue to 16

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No, Continue to 13
Unknown, Continue to 16

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, *Continue to 14*□ No, *Continue to 14*

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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 56* □ No, *Continue to 15*

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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 56* □ No, *Continue to 56*

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 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. *ACTION REQUIRED*: Submit supporting documentation

 \Box Yes, Continue to 56 \Box No, Continue to 17

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 affected areas. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 56* □ No, *Continue to 18*

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 body surface area affected.

Greater than or equal to 3% to less than 10% of BSA	A ACTION REQUIRED:
Submit supporting documentation, Continue to 19	
Greater than or equal to 10% of BSA	ACTION REQUIRED: Submit
supporting documentation, Continue to 56	
□ Less than 3% of BSA	. Continue to 19

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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, Continue to 56

□ No, Continue to 20

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. *ACTION REQUIRED*: Submit supporting documentation

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□ Yes, *Continue to 21* □ No, *Continue to 21*

21. Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin.

Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 56*

Drug interaction, Continue to 56

□ Risk of treatment-related toxicity, *Continue to 56*

D Pregnancy or currently planning pregnancy, *Continue to 56*

Breastfeeding, *Continue to 56* Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 56*

□ Hypersensitivity, *Continue to 56*

History of intolerance or adverse event, *Continue to 56*

□ Other, please specify _____, Continue to 56

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

□ Yes, *Continue to 23*

□ No, Continue to 23

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

□ Yes, Continue to 24

□ No, *Continue to 24*

24. Is this request for continuation of therapy with the requested drug?

□ Yes, Continue to 25

□ No, Continue to 28

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

□ Yes, Continue to 28

□ No, *Continue to 26*

Unknown, *Continue to 28*

26. 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 27*

□ No, Continue to 27

27. 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.

D Number of swollen joints ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Number of tender joints ACTION REQUIRED: Submit supporting documentation, Continue to 56

Dactylitis ACTION REQUIRED: Submit supporting documentation, Continue to 56

D Enthesitis ACTION REQUIRED: Submit supporting documentation, Continue to 56

Axial disease ACTION REQUIRED: Submit supporting documentation, Continue to 56

Skin and/or nail involvement ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ None of the above, *Continue to 56*

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

□ Yes, Continue to 29

□ No, Continue to 29

29. 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)? *ACTION REQUIRED*: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 56*

 \square No, Continue to 30

30. What is the patient's disease severity?

☐ Mild to moderate, *Continue to 31*

□ Severe, Continue to 56

31. Does the patient have enthesitis or predominantly axial disease?

□ Yes, Continue to 56

 \square No, Continue to 32

32. 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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, Continue to 56

□ No, Continue to 33

33. 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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 56*

□ No, Continue to 34

34. Does the patient have a contraindication to methotrexate or leflunomide? *ACTION REQUIRED*: If Yes, please attach documentation of clinical reason to avoid therapy. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 35* □ No, *Continue to 36*

35. Please indicate the contraindication to methotrexate or leflunomide.

Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, Continue to 56

Drug interaction, Continue to 56

□ Risk of treatment-related toxicity, Continue to 56

D Pregnancy or currently planning pregnancy, *Continue to 56*

□ Breastfeeding, Continue to 56

□ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 56*

□ Hypersensitivity, Continue to 56

History of intolerance or adverse event, *Continue to 56*

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_____, Continue to 56 □ Other, please specify.

36. Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ACTION **REOUIRED:** If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REOUIRED: Submit supporting documentation □ Yes, Continue to 56 □ No, Continue to 56

37. Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? □ Yes, Continue to 38 □ No, Continue to 38

38. Is the patient an adult (18 years of age or older)? □ Yes, Continue to 39 □ No. Continue to 39

39. Is the requested drug being prescribed by or in consultation with a gastroenterologist? □ Yes, Continue to 40 □ No, Continue to 40

40. Which of the following applies to this request for the requested drug?

□ Initiation of the intravenous (IV) loading dose, Continue to 56

□ Initiation of the subcutaneous (SQ) maintenance dose, Continue to 56

Continuation of the subcutaneous (SQ) maintenance dose, Continue to 41

41. Has the patient achieved or maintained remission? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission. ACTION REQUIRED: Submit supporting documentation □ Yes. Continue to 56

 \square No, Continue to 42

42. 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 43

□ No, Continue to 43

43. 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.

□ Abdominal pain or tenderness ACTION REQUIRED: Submit supporting documentation, Continue to 56

Diarrhea ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Body weight ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Abdominal mass ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Hematocrit ACTION REQUIRED: Submit supporting documentation, Continue to 56

Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) ACTION **REQUIRED**: Submit supporting documentation, Continue to 56

□ None of the above, *Continue to 56*

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

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□ Yes, *Continue to 45* □ No, *Continue to 45*

45. Is the patient an adult (18 years of age or older)?
□ Yes, *Continue to 46*□ No, *Continue to 46*

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

□ Yes, *Continue to 47*

□ No, *Continue to 47*

47. Which of the following applies to this request for the requested drug?

□ Initiation of the intravenous (IV) loading dose, Continue to 56

□ Initiation of the subcutaneous (SQ) maintenance dose, Continue to 56

Continuation of the subcutaneous (SQ) maintenance dose, *Continue to 48*

48. Has the patient achieved or maintained remission? *ACTION REQUIRED*: If Yes, please attach chart notes or medical record documentation of remission. *ACTION REQUIRED*: Submit supporting documentation □ Yes, *Continue to 56*

□ No, Continue to 49

49. 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?

□ Yes, *Continue to 50*

□ No, Continue to 50

50. 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.

Stool frequency ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Rectal bleeding ACTION REQUIRED: Submit supporting documentation, Continue to 56

Urgency of defecation ACTION REQUIRED: Submit supporting documentation, Continue to 56

C-reactive protein (CRP) ACTION REQUIRED: Submit supporting documentation, Continue to 56

□ Fecal calprotectin (FC) *ACTION REQUIRED:* Submit supporting documentation, Continue to 56 □ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound *ACTION REQUIRED:* Submit supporting documentation, Continue to 56

□ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) *ACTION REQUIRED:* Submit supporting documentation, Continue to 56

□ None of the above, *Continue to 56*

51. Is the requested drug being prescribed by or in consultation with a hematologist or oncologist?

□ Yes, Continue to 52

□ No, Continue to 52

52. 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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, Continue to 55

□ No, Continue to 53

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53. 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. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 55*

□ No, *Continue to 54*

54. Does the patient have a contraindication to infliximab and vedolizumab? *ACTION REQUIRED*: If Yes, please attach documentation of clinical reason to avoid therapy. *ACTION REQUIRED*: Submit supporting documentation

□ Yes, *Continue to 55* □ No. *Continue to 55*

 \Box No, Continue to 55

55. 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 Further Questions*

□ No, No Further Questions

56. What is the diagnosis?

□ Plaque psoriasis, *Continue to 57*

D Psoriatic arthritis WITH co-existent plaque psoriasis, Continue to 57

D Psoriatic arthritis, Continue to 69

Crohn's disease, *Continue to 75*

Ulcerative colitis, Continue to 75

57. What is the requested formulation?

□ Stelara for subcutaneous injection, *Continue to 58*

□ Stelara for intravenous infusion, Continue to 58

58. Is the patient currently receiving Stelara?

□ Yes, *Continue to 59* □ No, *Continue to 64*

59. What is the patient's weight? Indicate in kilograms (kg).

□ Less than or equal to 100 kg _____, *Continue to 60*

Greater than 100 kg _____, Continue to 62

60. Does the prescribed maintenance dose exceed 45 mg?

□ Yes, Continue to 61

□ No, *Continue to 61*

61. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?

□ Yes, No Further Questions

□ No, No Further Questions

62. Does the prescribed maintenance dose exceed 90 mg?
□ Yes, *Continue to 63*□ No, *Continue to 63*

63. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?

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Yes, No Further Questions
No, No Further Questions

64. What is the patient's weight? Indicate in kilograms (kg).

Less than or equal to 100 kg _____, Continue to 65

Greater than 100 kg _____, Continue to 67

65. Does the prescribed dose exceed a loading dose of 45 mg at weeks 0 and 4, and a maintenance dose of 45 mg thereafter?

■ No, *Continue to 66*

66. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?
□ Yes, *No Further Questions*□ No, *No Further Questions*

67. 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, *Continue to 68*□ No, *Continue to 68*

68. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?

□ Yes, No Further Questions

□ No, No Further Questions

69. What is the requested formulation?

□ Stelara for subcutaneous injection, *Continue to 70*

□ Stelara for intravenous infusion, *Continue to* 70

70. Is the patient currently receiving Stelara?
Yes, *Continue to 71*No, *Continue to 73*

71. Does the prescribed maintenance dose exceed 45 mg?
Yes, *Continue to 72*No, *Continue to 72*

72. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?
□ Yes, *No Further Questions*□ No, *No Further Questions*

73. 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, *Continue to 74* □ No, *Continue to 74*

74. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? Yes, *No Further Questions*

□ No, No Further Questions

75. Which of the following applies to this request for the requested drug?

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□ Initiation of the intravenous (IV) loading dose, Continue to 76

□ Initiation of the subcutaneous (SQ) maintenance dose, *Continue to* 77

Continuation of the subcutaneous (SQ) maintenance dose, *Continue to* 77

76. What is the patient's weight? Indicate in kilograms (kg).

□ Less than or equal to 55 kg _____, *Continue to 79*

Greater than 55 kg to less than or equal to 85 kg _____, Continue to 81

Greater than 85 kg _____, *Continue to 83*

77. Does the prescribed maintenance dose exceed 90 mg?

□ Yes, *Continue to* 78

□ No, Continue to 78

78. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?
□ Yes, *No Further Questions*□ No, *No Further Questions*

79. Does the prescribed dose exceed a one-time loading dose of 260 mg and a maintenance dose of 90 mg thereafter?
Yes, *Continue to 80*No, *Continue to 80*

80. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?
Yes, *No Further Questions*No, *No Further Questions*

81. Does the prescribed dose exceed a one-time loading dose of 390 mg and a maintenance dose of 90 mg thereafter?

Yes, Continue to 82
No, Continue to 82

82. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?

□ Yes, No Further Questions

□ No, No Further Questions

83. Does the prescribed dose exceed a one-time loading dose of 520 mg and a maintenance dose of 90 mg thereafter?

□ Yes, *Continue to 84* □ No, *Continue to 84*

84. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?
□ 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.

Prescriber or Authorized Signature

Date (mm/dd/yy)

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