# 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**

**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 diagnosis section* ❑ 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? ❑ Yes ❑ No

7. What were the results of the TB test?
   ❑ Positive for TB ❑ Negative for TB, *skip to diagnosis section* ❑ Unknown

8. 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

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

Section A: Plaque Psoriasis

9. Has the patient been diagnosed with moderate to severe plaque psoriasis? ❑ Yes ❑ No

10. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #15*

11. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
    - ❑ Yes, *skip to #15*
    - ❑ No
    - ❑ Unknown, *skip to #15*

12. 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

13. 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 #44.*** ❑ Yes ❑ No

14. 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 #44.*** ❑ Yes ❑ No

15. 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 #44.*** ❑ Yes ❑ No

16. 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 #44.*** ❑ Yes ❑ No

17. 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 #44.*

18. 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 #44.*** ❑ Yes ❑ No

19. 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:*** _____ *Skip to #44*

<u>Section B: Psoriatic Arthritis with or WITHOUT co-existent plaque psoriasis</u>

20. Has the patient been diagnosed with active psoriatic arthritis (PsA)? ❑ Yes ❑ No

21. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #52*

22. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
    ❑ Yes, *skip to #52*
    ❑ No
    ❑ Unknown, *skip to #52*

23. 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

24. 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. and skip to #52.***
    ❑ Number of swollen joints
    ❑ Dactylitis
    ❑ Enthesitis
    ❑ Skin and/or nail involvement
    ❑ Number of tender joints
    ❑ None of the above

<u>Section C: Crohn's Disease</u>

25. Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? ❑ Yes ❑ No

26. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #31*

27. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
    ❑ Yes, *skip to #31*
    ❑ No
    ❑ Unknown, *skip to #31*

28. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and skip to #58.*** ❑ Yes ❑ No

29. 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

30. 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 and skip to #58.***
❑ 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

31. 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 #58.*** ❑ Yes ❑ No

32. Does the patient have fistulizing Crohn's Disease? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation supporting diagnosis and skip to #58.*** ❑ Yes ❑ No

33. 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 #58.***
❑ 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

34. 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 #58*

Section D: Ulcerative Colitis

35. Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)? ❑ Yes ❑ No

36. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #41*

37. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
❑ Yes, *skip to #41*
❑ No
❑ Unknown, *skip to #41*

38. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and skip to #58.*** ❑ Yes ❑ No

39. 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

40. 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 and skip to #58.***
❑ 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

41. 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 #58.*** ❑ Yes ❑ No

42. 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 #58***
❑ 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

43. 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 #58.*** ❑ 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

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

45. Is the patient currently receiving Stelara? ❑ Yes ❑ No *If no, skip to #49*

46. ***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 #48*

47. ***If patient's weight is greater than 100kg:*** Does the prescribed dose exceed 90 mg? ❑ Yes ❑ No

48. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?
❑ Yes ❑ No *No further questions*

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49. ***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 #51*

50. ***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

51. 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

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

53. Is the patient currently receiving Stelara? ❑ Yes ❑ No *If no, skip to #56*

54. Does the prescribed dose exceed 45 mg? ❑ Yes ❑ No

55. Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? ❑ Yes ❑ No *No further questions*

56. 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

57. 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

58. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? ❑ Yes ❑ No

59. Is the patient currently receiving Stelara? ❑ Yes ❑ No *If no skip to #61, 62 or 63*

60. Does the prescribed dose exceed 90 mg? ❑ Yes ❑ No *No further Questions*

61. ***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*

62. ***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*

63. ***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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