Humira and biosimilars

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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____Date: _____
Patient's ID: _____Patient's Date of Birth: _____
Physician's Name: _____
Specialty: _____ NPI#: _____
Physician Office Telephone: _____Physician Office Fax: _____
Request Initiated For: _____

1. What is the prescribed product? ❑ Humira ❑ Amjevita ❑ Other _____

2. What is the prescribed dose and frequency?
   a) **Loading dose:**
   ❑ Humira pediatric Crohn's starter pack_____mg Quantity and Frequency:_____
   ❑ Humira adult Crohn's/UC/HS starter pack _____mg Quantity and Frequency:_____
   ❑ Humira psoriasis, uveitis, adolescent HS starter pack_____mg Quantity and Frequency:_____
   ❑ Other _____

   b) **Maintenance dose:**
   ❑ Humira 10 mg PFS/Pen Quantity and Frequency: _____
   ❑ Humira 20 mg PFS/Pen Quantity and Frequency: _____
   ❑ Humira 40 mg PFS/Pen Quantity and Frequency: _____
   ❑ Humira 80 mg PFS/Pen Quantity and Frequency: _____
   ❑ Other _____

3. 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

4. Has the patient been diagnosed with any of the following? *List continues on following page.*
   ❑ Moderately to severely active rheumatoid arthritis (RA)
   ❑ Moderately to severely active Crohn's disease (CD)
   ❑ Moderate to severe Plaque Psoriasis
   ❑ Moderately to severely active ulcerative colitis (UC)
   ❑ Active psoriatic arthritis (PsA)
   ❑ Active psoriatic arthritis (PsA) WITH co-existent plaque psoriasis
   Please indicate primary diagnosis being treated: ❑ Psoriatic arthritis ❑ Plaque psoriasis
   ❑ Active ankylosing spondylitis (AS)
   ❑ Active non-radiographic axial spondyloarthritis
   ❑ Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
   ❑ Moderately to severely active oligoarticular juvenile idiopathic arthritis
   ❑ Active systemic juvenile idiopathic arthritis

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❑ Moderate to severe hidradenitis suppurativa
❑ Behcet's disease
❑ Pyoderma gangrenosum
❑ Non-infectious intermediate, posterior or panuveitis uveitis
❑ Severe/refractory immunotherapy-related inflammatory arthritis
❑ Other _____

5. What is the ICD-10 code? _____

6. What is the patient's weight? _____ kg or lbs ***(circle one)***

Section A: Preferred Product - *Complete the following section if Abrilada, Cyltezo, Hadlima, Hulio, Idacio, Yuflyma or Yusimry is prescribed*

7. Coverage for the requested drug is provided when the patient has tried and had a treatment failure with three of the formulary medications for their indication, or all of the formulary medications if there are fewer than three. The formulary alternatives for the requested drug are:
   a. For plaque psoriasis: Humira, Otezla, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya
   b. For ankylosing spondylitis: Cosentyx, Enbrel, Humira, Rinvoq
   c. For psoriatic arthritis: Cosentyx, Enbrel, Humira, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya
   d. For rheumatoid arthritis: Enbrel, Humira, Kevzara, Orencia, Rinvoq, Xeljanz/Xeljanz XR
   e. For non-radiographic axial spondyloarthritis: Cimzia, Cosentyx, Rinvoq
   f. For Crohn's disease: Humira, Rinvoq, Skyrizi, Stelara
   g. For ulcerative colitis: Humira, Rinvoq, Stelara, Xeljanz/Xeljanz XR, Zeposia
   h. For all other indications: Enbrel, Humira
   Can the patient's treatment be switched to a formulary alternative?
   If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.
   ❑ Yes - *Please specify:* _____ ❑ No - Continue request for non-preferred product.

8. Has the patient tried and had a documented inadequate response or intolerable adverse reaction to at least three of the formulary alternatives, or all of the formulary alternatives if there are fewer than three? Note: Formulary medications should be prescribed first unless the patient is unable to use or receive treatment with the alternative. ❑ Yes ❑ No

   If Yes, indicate the formulary alternative(s) and the reason for treatment failure and skip to #10.

   Drug name: _____ Reason for treatment failure: _____

   Drug name: _____ Reason for treatment failure: _____

   Drug name: _____ Reason for treatment failure: _____

9. Does the patient have a documented contraindication to at least three of the formulary alternatives, or all of the formulary alternatives if there are fewer than three? ❑ Yes ❑ No

   If Yes, indicate the formulary alternative(s) and describe the contraindication(s):

   Drug name: _____ Specify contraindication: _____

   Drug name: _____ Specify contraindication: _____

   Drug name: _____ Specify contraindication: _____

10. Has chart note(s) or other documentation supporting the inadequate response, intolerable adverse reaction, or contraindication to the necessary number of formulary alternatives been submitted? ***ACTION REQUIRED: Submit chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.*** ❑ Yes ❑ No

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

Section B: Preferred Product- *Complete the following section if Humira is prescribed*

11. The preferred products for which coverage is provided for the treatment of non-radiographic axial spondyloarthritis: **Cimzia syringe, Cosentyx, Rinvoq.** Can the patient's treatment be switched to a preferred product? ❑ Yes - Please specify: _____ ***If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.***
    ❑ No ❑ Not applicable - Requested for condition not listed above, *skip to Section C: All Requests*

12. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No *If No, skip to Section C.*

13. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. ❑ Yes ❑ No *If No, skip to Section C.*

14. Does the patient have a documented inadequate response or intolerable adverse event to any of the preferred products indicated? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** *Indicate ALL that apply.*
    ❑ Cosentyx: ❑ Inadequate response ❑ Intolerable adverse event
    ❑ Cimzia syringe: ❑ Inadequate response ❑ Intolerable adverse event
    ❑ Rinvoq: ❑ Inadequate response ❑ Intolerable adverse event
    ❑ No - none of the above

15. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a JAK inhibitor (Rinvoq)? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).***
    ❑ Yes - History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy
    ❑ Yes - History or risk of major adverse cardiovascular events (MI, stroke, etc.)
    ❑ Yes - History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.)
    ❑ Yes - History of hepatitis B or hepatitis C virus infection
    ❑ Yes - History of being a primary non-responder to a JAK inhibitor (i.e., no clinical response with initial treatment)
    ❑ No - None of the above

Section C: All Requests

16. Is the requested drug being prescribed by or in consultation with any of the following?
    ❑ Dermatologist ❑ Rheumatologist ❑ Gastroenterologist ❑ Ophthalmologist ❑ Oncologist
    ❑ Hematologist ❑ None of the above

17. 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

18. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Olumiant, Xeljanz) associated with an increased risk of tuberculosis?
    If Yes, skip to #22 ❑ Yes ❑ No

19. 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

20. What were the results of the tuberculosis (TB) test?
    ❑ Positive for TB ❑ Negative for TB, *skip to #22* ❑ Unknown

21. 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

22. Is this request for continuation of therapy with the requested drug or a biosimilar?
    ❑ Yes ❑ No *If No, skip to diagnosis section.*

23. Is the patient currently receiving the requested drug or a biosimilar drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to diagnosis section.* ❑ Yes ❑ No ❑ Unknown

24. *If patient's diagnosis is Crohn's Disease or Ulcerative Colitis,* has the patient achieved or maintained remission? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission.*** ❑ Yes ❑ No

25. 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? ❑ Yes ❑ No

Complete the following section based on the patient's <u>primary</u> diagnosis, if applicable.

<u>Section D: Rheumatoid Arthritis</u>

Continuation

26. Has the patient experienced substantial disease activity improvement (e.g., at least 20% from baseline) in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting positive clinical response and substantial disease activity improvement.*** ❑ Yes ❑ No

Initiation

27. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid 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

28. Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and the anti-CCP biomarker test was positive. ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #30.*** ❑ Yes ❑ No

29. Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ***ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

30. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 mg per week? ***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

31. Has the patient experienced an intolerance to methotrexate? ***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

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

33. Please indicate the contraindication to methotrexate.
    - ❑ Drug interaction
    - ❑ Risk of treatment-related toxicity
    - ❑ Pregnancy or currently planning pregnancy
    - ❑ Breastfeeding
    - ❑ Hypersensitivity
    - ❑ History of intolerance or adverse event
    - ❑ 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: _____

Section E: Polyarticular Juvenile Idiopathic Arthritis, Oligoarticular Juvenile Idiopathic Arthritis

Continuation of Therapy

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.
❑ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion) ❑ Functional ability
❑ Number of joints with limitation of movement ❑ None of the above

Initial Therapy

35. Has the patient ever received or is currently receiving a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic 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

36. Has the patient had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) 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

37. Has the patient had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No *If No, skip to #39*

38. Does the patient have any of the following risk factors for poor outcome: a) involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ), b) presence of erosive disease or enthesitis, c) delay in diagnosis, d) elevated levels of inflammation markers, or e) symmetric disease?
If Yes, no further questions. ❑ Yes ❑ No

39. Does the patient have any of the following risk factors for disease severity and potentially a more refractory disease course: a) positive rheumatoid factor, b) positive anti-cyclic citrullinated peptide antibodies, or c) pre-existing joint damage? ❑ Yes ❑ No

40. Does the patient meet any of the following: a) high-risk joints are involved (e.g., cervical spine, wrist, or hip), b) high disease activity, or c) high risk for disabling joint disease? ❑ Yes ❑ No

Section F: Psoriatic Arthritis

Continuation of Therapy

41. 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 ❑ Dactylitis
❑ Enthesitis ❑ Axial disease ❑ Skin and/or nail involvement ❑ None of the above

Initial Therapy

42. Has the patient ever received or is currently receiving a biologic 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

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

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

45. 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

46. 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

47. Does the patient have a contraindication to methotrexate or leflunomide? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy and no further questions.*** ❑ Yes ❑ No

48. Please indicate the contraindication to methotrexate or leflunomide.
    - ❑ Drug interaction
    - ❑ Risk of treatment-related toxicity
    - ❑ Pregnancy or currently planning pregnancy
    - ❑ Breastfeeding
    - ❑ Hypersensitivity
    - ❑ History of intolerance or adverse event
    - ❑ 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: _____

49. 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 G: Ankylosing Spondylitis or Axial Spondyloarthritis

Continuation of Therapy

50. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical records supporting positive clinical response.***
    - ❑ Functional status
    - ❑ Total spinal pain
    - ❑ Inflammation (e.g., morning stiffness)
    - ❑ None of the above

Initial Therapy

51. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) that is indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis (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

52. Has the patient experienced an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least two NSAIDs? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section H: Crohn's Disease

Continuation of Therapy

53. 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
    - ❑ Diarrhea
    - ❑ Body weight
    - ❑ Abdominal mass
    - ❑ 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)
    - ❑ Hematocrit
    - ❑ None of the above

Section I: Ulcerative Colitis

Continuation of Therapy

54. *If patient is 18 years old or older,* is this a continuation of a regimen with the requested drug or a biosimilar that was started before the patient turned 18 years old?
❑ Yes ❑ No ❑ Not applicable, *no further questions*

55. Is the patient well-controlled on the requested regimen? ❑ Yes ❑ No

56. 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 ❑ Rectal bleeding
❑ Urgency of defecation ❑ C-reactive protein (CRP)
❑ Fecal calprotectin (FC) ❑ None of the above
❑ 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])
❑ Fecal calprotectin (FC) ❑ None of the above

Section J: Plaque Psoriasis

Continuation of Therapy

57. What is the patient's current psoriasis involvement in body surface area (BSA) percent? _____% involvement
ACTION REQUIRED: Attach supporting chart note(s) or medical record documentation for current psoriasis involvement of BSA percent. *If less than or equal to 3% of BSA, no further questions.*

58. What is the patient's percent improvement in body surface area (BSA) from baseline? _____ % improvement
If greater than or equal to 75% of BSA, no further questions.

59. What is the patient's percent reduction in the Psoriasis Area Severity Index (PASI) score from baseline?
ACTION REQUIRED: Attach supporting chart note(s) or medical record documentation for percent reduction of PASI score from baseline. _____ % reduction *If greater than or equal to 75% of BSA, no further questions.*

60. What is the patient's Dermatology Life Quality Index (DLQI) score? ***ACTION REQUIRED: Attach supporting chart note(s) or medical record documentation for Dermatology Life Quality Index (DLQI) score.***
_____

Initial Therapy

61. Has the patient received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) in the past 120 days 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 supporting chart note(s), medical record documentation, or claims history supporting previous medications tried and no further questions. ❑ Yes ❑ No

62. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)?
ACTION REQUIRED: Attach supporting chart notes or medical record documentation of body surface area (BSA). _____ % *If less than 3% skip to #64. If greater than or equal to 10%, go to #72*

63. What is the patient's Psoriasis Area Severity Index (PASI) score? _____
ACTION REQUIRED: Attach supporting chart note(s) or medical record documentation of Psoriasis Area Severity Index (PASI) score. *If greater than or equal to 10, skip to #65*

64. Is the affected area severe at localized sites and associated with significant functional impairment and/or high levels of distress (e.g., nail disease or involvement of high-impact and difficult-to-treat sites such as face, scalp, palms, soles, flexures and genitals)? ***ACTION REQUIRED: If Yes, please attach supporting chart notes or medical record documentation of affected area(s) with significant functional impairment and/or high levels of distress and skip to #72.*** ❑ Yes ❑ No

65. Has the patient had an inadequate response at the maximum tolerated dose to a medium to super-high potency topical corticosteroid therapy for a duration of at least 4 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart notes, medical record documentation, and claims history of all prior and current use of treatment regimens for topical corticosteroid therapy, including dosage, duration, and response to therapy and skip to #72.*** ❑ Yes ❑ No

66. Has the patient had an inadequate response at the maximum tolerated dose to a topical calcineurin inhibitor therapy for a duration of at least 8 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for topical calcineurin inhibitor therapy, including dosage, duration, and response to therapy and skip to #72.*** ❑ Yes ❑ No

67. Has the patient had an inadequate response at the maximum tolerated dose to a topical vitamin D analog therapy for a duration of at least 12 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for topical vitamin D analog therapy, including dosage, duration, and response to therapy and skip to #72.*** ❑ Yes ❑ No

68. Has the patient had an inadequate response at the maximum tolerated dose to a topical retinoid therapy for a duration of at least 12 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for topical retinoid therapy, including dosage, duration, and response to therapy and skip to #72.***
❑ Yes ❑ No

69. Has the patient had an inadequate response at the maximum tolerated dose to a topical aryl hydrocarbon receptor agonist therapy for a duration of at least 12 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for topical aryl hydrocarbon receptor agonist therapy, including dosage, duration, and response to therapy and skip to #72.*** ❑ Yes ❑ No

70. Has the patient had an inadequate response at the maximum tolerated dose to a topical phosphodiesterase 4 inhibitor therapy for a duration of at least 8 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for topical phosphodiesterase 4 inhibitor therapy, including dosage, duration, and response to therapy and skip to #72.*** ❑ Yes ❑ No

71. 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.***
❑ Yes ❑ No

72. Has the patient had a trial of phototherapy (e.g., UVB, PUVA) for a duration of at least 3 months? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or medical record documentation for phototherapy, including dosage, duration, and response to therapy and skip to #74.*** ❑ Yes ❑ No

73. Does the patient meet any of the following criteria? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous treatments tried (if applicable), including dosage, duration, and response to therapy. If therapy is not advisable, please attached documentation of clinical reason to avoid therapy.***
❑ Yes - Intolerable adverse event with phototherapy
❑ Yes - Does not have access to phototherapy
❑ Yes - Clinical reason to avoid phototherapy
❑ No - None of the above

74. Has the patient had a trial of methotrexate at a dose of at least 25 mg/week or at the maximum tolerated dose for a duration of at least 3 months? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for methotrexate, including dosage, duration, and response to therapy.*** ❑ Yes ❑ No

75. Has the patient had a trial of cyclosporine at a dose of at least 5 mg/kg/day or at the maximum tolerated dose for a duration of at least 6 weeks? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for cyclosporine, including dosage, duration, and response to therapy and no further questions.***
❑ Yes ❑ No

76. Has the patient had a trial of acitretin at a dose of at least 50 mg/day or at the maximum tolerated dose for a duration of at least 3 months? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s), medical record documentation, and claims history of all prior and current use of treatment regimens for acitretin, including dosage, duration, and response to therapy and no further questions***.
❑ Yes ❑ No

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

78. Please indicate clinical reason to avoid pharmacologic treatment. to methotrexate, cyclosporine, and acitretin.
❑ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
❑ Drug interaction
❑ Risk of treatment-related toxicity (If checked, no further questions)
❑ Pregnancy or currently planning pregnancy (If checked, no further questions)
❑ Breastfeeding (If checked, no further questions)
❑ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, no further questions)
❑ Hypersensitivity (If checked, no further questions)
❑ History of intolerance or adverse event (If checked, no further questions)
❑ Other: _____

Section K: Hidradenitis Suppurativa

Continuation of Therapy

79. Which of the following has the patient experienced an improvement in since starting treatment with the requested drug or a biosimilar of the requested drug? ***ACTION REQUIRED: Please attach chart notes or medical records supporting positive clinical response.***
❑ Reduction in pain from baseline
❑ Reduction in suppuration from baseline
❑ Improvement in frequency of relapses from baseline
❑ Improvement in quality of life from baseline
❑ Reduction in abscess and inflammatory nodule count from baseline
❑ Reduced formation of new sinus tracts and scarring
❑ Decrease in frequency of inflammatory lesions from baseline
❑ Improvement on a disease severity assessment tool from baseline
❑ None of the above

Initial Request

80. Has the patient ever received or is currently receiving a biologic indicated for the treatment of moderate to severe hidradenitis suppurativa (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 medication tried and no further questions.***
❑ Yes ❑ No

81. Has the patient experienced an inadequate response after at least 90 days of treatment with an oral antibiotic? ***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

82. Has the patient experienced intolerance to oral antibiotics? ***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

83. Does the patient have a contraindication to oral antibiotics? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section L: Behcet's Disease

Initial Request

84. Has the patient ever received or is currently receiving Otezla or a biologic indicated for the treatment of Behcet's disease (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

85. Has the patient had an inadequate response to at least one non-biologic medication for Behçet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine)? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

Section M: Uveitis

Continuation of Therapy

86. Which of the following has the patient experienced an improvement in from baseline?
ACTION REQUIRED: Please attach chart notes or medical records supporting positive clinical response.
❑ Reduced frequency of disease flares compared to baseline
❑ Stability or improvement in anterior chamber (AC) cell grade compared to baseline
❑ Stability or improvement in vitreous haze (VH) grade compared to baseline
❑ Stability or improvement in visual acuity compared to baseline
❑ Reduction in glucocorticoid requirements from baseline
❑ No new active inflammatory chorioretinal and/or inflammatory retinal vascular lesions relative to baseline
❑ None of the above

Initial Request

87. Has the patient ever received or is currently receiving a biologic indicated for the treatment of non-infectious intermediate, posterior, and panuveitis (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

88. Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate)? ***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

89. Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate)? ***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

90. Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate)? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section N: Pyoderma Gangrenosum

Initial Request

91. Has the patient ever received or is currently receiving a biologic indicated for the treatment of pyoderma gangrenosum (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

92. Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)? ***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

93. Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)? ***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

94. Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section O: Immunotherapy-Related Inflammatory Arthritis

95. Has the patient tried and not responded to corticosteroids and anti-inflammatory agents? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ 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