



Remicade and Biosimilars CareFirst 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

What is the ICD-10 code? _____

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

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Exception Criteria Questions:

A. What product is being requested?

- ☐ Avsola, *Continue to Skip to Site of Service Questions*
- ☐ Inflectra, *Continue to Skip to Site of Service Questions*
- ☐ Renflexis, *Continue to Question B*
- ☐ Infliximab, *Continue to Question B*
- ☐ Remicade, *Continue to Question B*

B. The preferred products for your patient's health plan are Avsola, and Inflectra. Can the patient's treatment be switched to the preferred product?

- ☐ Yes, Avsola, *Skip to Site of Service Questions*
- ☐ Yes, Inflectra, *Skip to Site of Service Questions*
- ☐ No, *Continue to Question C*

C. Did the patient have a documented intolerable adverse event to BOTH of the preferred products (Avsola and Inflectra)? **ACTION REQUIRED:** *If 'yes', attach supporting chart note(s)*

- ☐ Yes, *Continue to Question D*
- ☐ No, *Continue to Question E*

D. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)? **ACTION REQUIRED:** *If 'no', attach supporting chart note(s)*

- ☐ Yes, *Continue to Question E*
- ☐ No, *Skip to Site of Service Questions*

E. Did the patient have a documented inadequate response to BOTH of the preferred products (Avsola and Inflectra)? **ACTION REQUIRED:** *If yes, attach supporting chart note(s)*

- ☐ Yes, *Skip to Site of Service Questions*
- ☐ No, *Continue to Question F*

F. Does the patient have a contraindication to BOTH of the preferred products (Avsola and Inflectra)? **ACTION REQUIRED:** *If yes, attach supporting chart note(s)*

- ☐ Yes, *Continue to Site of Service Questions*
- ☐ No, *Continue to Site of Service Questions*

Site of Service Questions:

A. Where will this drug be administered?

- ☐ Ambulatory surgical, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
- ☐ Home infusion, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
- ☐ Off-campus Outpatient Hospital, *Continue to B*
- ☐ On-campus Outpatient Hospital, *Continue to B*
- ☐ Physician office, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
- ☐ Pharmacy, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*

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- B. Is the patient less than 14 years of age?
☐ Yes, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to C*
- C. Is this request to continue previously established treatment with the requested medication?
☐ Yes – This is a continuation of an existing treatment, *Continue to D*
☐ Yes – This is a continuation request, however a gap in therapy of greater than 2 doses has occurred, **ACTION REQUIRED: Please attach supporting clinical documentation.** *Skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No – This is a new therapy request (patient has not received requested medication in the last 6 months), **ACTION REQUIRED: Please attach supporting clinical documentation.** *Skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No – This is a request for a different brand infliximab product that the patient has not received previously, **ACTION REQUIRED: Please attach supporting clinical documentation.** *Skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
- D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
☐ Yes, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to E*
- E. Does the patient have laboratory confirmed antibodies to infliximab? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
☐ Yes, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to F*
- F. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
☐ Yes, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to G*
- G. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
☐ Yes, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to H*
- H. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? **ACTION REQUIRED: If Yes, please attach supporting clinical documentation.**
☐ Yes, *skip to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to I*
- I. Are *all* alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? **ACTION REQUIRED: If Yes, please attach supporting documentation.**
☐ Yes, *Continue to Psoriasis Enhanced SGM 4179-A Criteria Questions*
☐ No, *Continue to Psoriasis Enhanced SGM 4179-A Criteria Questions*

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Psoriasis Enhanced SGM 4179-A Criteria Questions:

Is the diagnosis moderate or severe plaque psoriasis?

☐ Yes, *Continue to Question 1*

☐ No, *Skip to Remicade and biosimilars SGM 2182-A Criteria Questions*

1. What is the patient's age? Indicate in years.

☐ 18 years of age or older _____, *Continue to 2*

☐ Less than 18 years of age _____, *Skip to Remicade and biosimilars SGM 2182-A Criteria Questions*

2. What is the diagnosis?

☐ Plaque psoriasis, *Continue to 3*

☐ Plaque psoriasis with co-existing psoriatic arthritis, *Skip to Remicade and biosimilars SGM 2182-A Criteria Questions*

☐ Other, please specify: _____, *Skip to Remicade and biosimilars SGM 2182-A Criteria Questions*

3. Is the request for Sotyktu?

☐ Yes, *Continue to 4*

☐ No, *Continue to 5*

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

☐ Yes, *Continue to 7*

☐ No, *Continue to 7*

5. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Otezla, Sotyktu) for the same indication?

☐ Yes, *Continue to 6*

☐ No, *Continue to 6*

6. What is the requested medication?

☐ Otezla, *Continue to 11*

☐ Other, please specify: _____, *Continue to 7*

7. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis?

☐ Yes, *Continue to 12*

☐ No, *Continue to 8*

8. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 12 months of initiating therapy?

☐ Yes, *Continue to 9*

☐ No, *Continue to 11*

9. What were the results of the TB test?

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- ☐ Positive for TB, *Continue to 10*
- ☐ Negative for TB, *Continue to 12*
- ☐ Unknown, *No further questions*

10. Which of the following applies to the patient?

- ☐ Patient has latent TB and treatment for latent TB has been initiated, *Continue to 12*
- ☐ Patient has latent TB and treatment for latent TB has been completed, *Continue to 12*
- ☐ Patient has latent TB and treatment for latent TB has not been initiated, *Continue to 12*
- ☐ Patient has active TB, *Continue to 12*

11. What is the severity of the disease?

- ☐ Mild plaque psoriasis, *Skip to Remicade and biosimilars SGM 2182-A Criteria Questions*
- ☐ Moderate plaque psoriasis, *Continue to 13*
- ☐ Severe plaque psoriasis, *Continue to 13*

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

- ☐ Yes, *Continue to 13*
- ☐ No, *Continue to 13*

13. Is the requested drug prescribed by or in consultation with a dermatologist?

- ☐ Yes, *Continue to 14*
- ☐ No, *Continue to 14*

14. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug (if applicable)?

- ☐ Yes, *Continue to 15*
- ☐ No, *Continue to 21*

15. Is the patient currently receiving the requested drug or a biosimilar of the requested drug (if applicable) through samples or a manufacturer's patient assistance program?

- ☐ Yes, *Continue to 21*
- ☐ No, *Continue to 16*
- ☐ Unknown, *Continue to 21*

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

- ☐ Yes, *Continue to 17*
- ☐ No, *Continue to 17*

17. What is the patient's current psoriasis involvement in body surface area (BSA) percent? Indicate in percentage. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation for current psoriasis involvement of BSA percent.

- ☐ Less than or equal to 3% _____% **ACTION REQUIRED:** Submit supporting documentation, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*

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☐ Greater than 3% _____% **ACTION REQUIRED:** Submit supporting documentation.
Continue to 18

18. What is the patient's percent improvement in body surface area (BSA) from baseline? Indicate in percentage. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation for percent improvement of BSA from baseline.

☐ Less than 75% BSA improvement _____% **ACTION REQUIRED:** Submit supporting documentation, *Continue to 19*

☐ Greater than or equal to 75% BSA improvement _____% **ACTION REQUIRED:** Submit supporting documentation, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*

19. What is the patient's percent reduction in the Psoriasis Area Severity Index (PASI) score from baseline? Indicate score reduction in percentage. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation for percent reduction of PASI score from baseline.

☐ Greater than or equal to 75% reduction _____% **ACTION REQUIRED:** Submit supporting documentation, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*

☐ Greater than or equal to 50% and less than 75% reduction _____% **ACTION REQUIRED:** Submit supporting documentation, *Continue to 20*

☐ Less than 50% reduction _____%, *Continue to 20*

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

☐ Less than or equal to 5 _____ **ACTION REQUIRED:** Submit supporting documentation, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*

☐ Greater than 5 _____, *No further questions*

21. Has the patient received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) within 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 chart notes, medical record documentation, or claims history supporting previous medications tried.

☐ Yes, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*

☐ No, *Continue to 22*

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

☐ Yes, *Continue to 23*

☐ No, *Continue to 23*

23. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? Indicate in percentage. **ACTION REQUIRED:** Attach supporting chart notes or medical record documentation of body surface area (BSA) affected.

☐ Greater than or equal to 3% but less than 10% _____% **ACTION REQUIRED:** Submit supporting documentation, *Continue to 24*

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☐ Greater than or equal to 10% _____% **ACTION REQUIRED:** Submit supporting documentation, *Continue to 33*

24. What is the patient's Psoriasis Area Severity Index (PASI) score? Indicate patient's PASI score. **ACTION REQUIRED:** Attach supporting chart note(s) or medical record documentation of Psoriasis Area Severity Index (PASI) score.

☐ Greater than or equal to 10 _____ **ACTION REQUIRED:** Submit supporting documentation, *Continue to 26*

☐ Less than 10 _____ **ACTION REQUIRED:** Submit supporting documentation, *Continue to 25*

25. 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.

☐ Yes, *Continue to 33*

☐ No, *Continue to 33*

26. 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, or claims history of all prior and current use of treatment regimens for topical corticosteroid therapy, including dosage, duration, and response to therapy.

☐ Yes, *Continue to 33*

☐ No, *Continue to 27*

27. 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, or claims history of all prior and current use of treatment regimens for topical calcineurin inhibitor therapy, including dosage, duration, and response to therapy.

☐ Yes, *Continue to 33*

☐ No, *Continue to 28*

28. 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, or claims history of all prior and current use of treatment regimens for topical vitamin D analog therapy, including dosage, duration, and response to therapy.

☐ Yes, *Continue to 33*

☐ No, *Continue to 29*

29. 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, or claims history of all prior and current use of treatment regimens for topical retinoid therapy, including dosage, duration, and response to therapy.

☐ Yes, *Continue to 33*

☐ No, *Continue to 30*

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30. 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, or 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.

☐ Yes, *Continue to 33*

☐ No, *Continue to 31*

31. 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, or claims history of all prior and current use of treatment regimens for topical phosphodiesterase 4 inhibitor therapy, including dosage, duration, and response to therapy.

☐ Yes, *Continue to 33*

☐ No, *Continue to 32*

32. 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, *Continue to 33*

☐ No, *Continue to 33*

33. 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.

☐ Yes, *Continue to 35*

☐ No, *Continue to 34*

34. Does the patient meet any of the following criteria: a) the patient has experienced an intolerable adverse event with phototherapy, b) the patient has a clinical reason to avoid phototherapy, or c) the patient does not have access to phototherapy? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous treatments tried (if applicable), including duration and response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.

☐ Yes, intolerable adverse event to phototherapy **ACTION REQUIRED:** Submit supporting documentation, *Continue to 35*

☐ Yes, clinical reason to avoid phototherapy **ACTION REQUIRED:** Submit supporting documentation, *Continue to 35*

☐ Yes, does not have access to phototherapy **ACTION REQUIRED:** Submit supporting documentation, *Continue to 35*

☐ None of the above, *Continue to 35*

35. 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, or claims history of all prior and current use of treatment regimens for methotrexate, including dosage, duration, and response to therapy.

☐ Yes, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*

☐ No, *Continue to 36*

36. 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, or claims history of all prior and current use of treatment regimens for cyclosporine, including dosage, duration, and response to therapy.

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- ☐ Yes, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ No, *Continue to 37*

37. 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, or claims history of all prior and current use of treatment regimens for acitretin, including dosage, duration, and response to therapy.

- ☐ Yes, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ No, *Continue to 38*

38. 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, *Continue to 39*
☐ No, *Continue to 39*

39. 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, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Drug interaction, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Risk of treatment-related toxicity, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Pregnancy or currently planning pregnancy, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Breastfeeding, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Hypersensitivity, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ History of intolerance or adverse event, *Skip to Remicade and biosimilars SGM 2182-A Criteria Question 257*
☐ Other, please specify. _____, *No Further Questions*

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What product is being requested?

☐ Remicade ☐ unbranded infliximab ☐ Avsola ☐ Inflectra ☐ Renflexis ☐ Zymfentra

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) for the same indication?

☐ Yes, *Continue to 2*

☐ 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 (TB)?

☐ Yes, *Continue to 6*

☐ No, *Continue to 3*

3. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 12 months of initiating therapy?

☐ Yes, *Continue to 4*

☐ No, *Continue to 4*

4. What were the results of the tuberculosis (TB) test?

☐ Positive for TB, *Continue to 5*

☐ Negative for TB, *Continue to 6*

☐ Unknown, *Continue to 6*

5. Which of the following applies to the patient?

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

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

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

☐ Patient has active TB, *Continue to 6*

6. What is the diagnosis?

☐ Crohn's disease, *Continue to 9*

☐ Ulcerative colitis, *Continue to 16*

☐ Rheumatoid arthritis, *Continue to 23*

☐ Ankylosing spondylitis, *Continue to 42*

☐ Non-radiographic axial spondyloarthritis, *Continue to 42*

☐ Psoriatic arthritis, *Continue to 52*

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

☐ Plaque psoriasis, *Continue to 68*

☐ Behcet's disease, *Continue to 84*

☐ Hidradenitis suppurativa, *Continue to 91*

☐ Pyoderma gangrenosum, *Continue to 102*

☐ Sarcoidosis, *Continue to 110*

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- ☐ Takayasu's arteritis, *Continue to 117*
- ☐ Uveitis, *Continue to 125*
- ☐ Reactive arthritis, *Continue to 134*
- ☐ Immune checkpoint inhibitor-related toxicity, *Continue to 146*
- ☐ Immune checkpoint inhibitor-related inflammatory arthritis, *Continue to 150*
- ☐ Acute graft versus host disease, *Continue to 160*
- ☐ Other, please specify. _____, *No further questions*

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

- ☐ Yes, *Continue to 8*
- ☐ No, *Continue to 8*

8. What is the primary diagnosis being treated?

- ☐ Psoriatic arthritis, *Continue to 53*
- ☐ Plaque psoriasis, *Continue to 69*

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

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

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

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

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

- ☐ Yes, *Continue to 12*
- ☐ No, *Continue to 164*

12. Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

- ☐ Yes, achieved or maintained remission **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*
- ☐ Yes, achieved or maintained a positive clinical response, *Continue to 13*
- ☐ No or none of the above, *Continue to 14*

13. 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 164*
- ☐ Diarrhea **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*
- ☐ Body weight **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*
- ☐ Abdominal mass **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*
- ☐ Hematocrit **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

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☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ None of the above, *Continue to 14*

14. Is the request for Zymfentra?

☐ Yes, *Continue to 15*

☐ No, *Continue to 15*

15. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

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

☐ Yes, *Continue to 17*

☐ No, *Continue to 17*

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

☐ Yes, *Continue to 18*

☐ No, *Continue to 18*

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

☐ Yes, *Continue to 19*

☐ No, *Continue to 164*

19. Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ Yes, achieved or maintained a positive clinical response, *Continue to 20*

☐ No or none of the above, *Continue to 21*

20. 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 164*

☐ Rectal bleeding **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ Urgency of defecation **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ C-reactive protein (CRP) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ Fecal calprotectin (FC) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

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- ☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*
- ☐ 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 164*
- ☐ None of the above, *Continue to 21*

21. Is the request for Zymfentra?

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

22. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 164*

23. Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)?

- ☐ Yes, *Continue to 24*
- ☐ No, *Continue to 24*

24. Is the patient an adult (18 years of age or older)?

- ☐ Yes, *Continue to 25*
- ☐ No, *Continue to 25*

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

- ☐ Yes, *Continue to 26*
- ☐ No, *Continue to 26*

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

- ☐ Yes, *Continue to 27*
- ☐ No, *Continue to 31*

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

- ☐ Yes, *Continue to 31*
- ☐ No, *Continue to 28*
- ☐ Unknown, *Continue to 31*

28. Has the patient achieved or maintained a positive clinical response since starting treatment with the requested drug or a biosimilar of the requested drug?

- ☐ Yes, *Continue to 29*
- ☐ No, *Continue to 30*

29. 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.

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- ☐ Yes, *Continue to 164*
☐ No, *Continue to 30*

30. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 164*

31. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of 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.

- ☐ Yes, *Continue to 32*
☐ No, *Continue to 34*

32. Is the requested medication being prescribed in combination with methotrexate or leflunomide?

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 33*

33. Please indicate a clinical reason for the patient to not use methotrexate or leflunomide.

- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 164*
☐ Drug interaction, *Continue to 164*
☐ Risk of treatment-related toxicity, *Continue to 164*
☐ Pregnancy or currently planning pregnancy, *Continue to 164*
☐ Breastfeeding, *Continue to 164*
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 164*
☐ Hypersensitivity, *Continue to 164*
☐ History of intolerance or adverse event, *Continue to 164*
☐ Other, please specify. _____, *Continue to 164*
☐ No clinical reason not to use methotrexate or leflunomide, *Continue to 164*

34. 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.

- ☐ Yes, *Continue to 36*
☐ No, *Continue to 35*

35. 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.

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- ☐ Yes, *Continue to 36*
☐ No, *Continue to 36*

36. Is the requested medication being prescribed in combination with methotrexate or leflunomide?

- ☐ Yes, *Continue to 38*
☐ No, *Continue to 37*

37. Please indicate a clinical reason for the patient to not use methotrexate or leflunomide.

- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 38*
☐ Drug interaction, *Continue to 38*
☐ Risk of treatment-related toxicity, *Continue to 38*
☐ Pregnancy or currently planning pregnancy, *Continue to 38*
☐ Breastfeeding, *Continue to 38*
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 38*
☐ Hypersensitivity, *Continue to 38*
☐ History of intolerance or adverse event, *Continue to 38*
☐ Other, please specify. _____, *Continue to 38*
☐ No clinical reason not to use methotrexate or leflunomide, *Continue to 38*

38. Has the patient had 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.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 39*

39. Has the patient had 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.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 40*

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

- ☐ Yes, *Continue to 41*
☐ No, *Continue to 41*

41. Please indicate the contraindication to methotrexate.

- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 164*
☐ Drug interaction, *Continue to 164*
☐ Risk of treatment-related toxicity, *Continue to 164*
☐ Pregnancy or currently planning pregnancy, *Continue to 164*
☐ Breastfeeding, *Continue to 164*

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☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 164*

☐ Hypersensitivity, *Continue to 164*

☐ History of intolerance or adverse event, *Continue to 164*

☐ Other, please specify _____, *Continue to 164*

42. Is the patient an adult (18 years of age or older)?

☐ Yes, *Continue to 43*

☐ No, *Continue to 43*

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

☐ Yes, *Continue to 44*

☐ No, *Continue to 44*

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

☐ Yes, *Continue to 45*

☐ No, *Continue to 49*

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

☐ Yes, *Continue to 49*

☐ No, *Continue to 46*

☐ Unknown, *Continue to 49*

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

☐ Yes, *Continue to 47*

☐ No, *Continue to 48*

47. 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.

☐ Functional status **ACTION REQUIRED:** Submit supporting documentation, *Continue to 164*

☐ Total spinal pain **ACTION REQUIRED:** Submit supporting documentation, *Continue to 164*

☐ Inflammation (e.g., morning stiffness) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 164*

☐ Swollen joints **ACTION REQUIRED:** Submit supporting documentation, *Continue to 164*

☐ Tender joints **ACTION REQUIRED:** Submit supporting documentation, *Continue to 164*

☐ C-reactive protein (CRP) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 164*

☐ None of the above, *Continue to 48*

48. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

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49. Has the patient been diagnosed with active ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA)?

- ☐ Yes - Active ankylosing spondylitis, *Continue to 50*
- ☐ Yes - Active non-radiographic axial spondyloarthritis, *Continue to 50*
- ☐ No, *Continue to 50*

50. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of 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.

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 51*

51. Has the patient experienced an inadequate response with at least TWO non-steroidal 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, *Continue to 164*
- ☐ No, *Continue to 164*

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

- ☐ Yes, *Continue to 53*
- ☐ No, *Continue to 53*

53. Is the patient an adult (18 years of age or older)?

- ☐ Yes, *Continue to 54*
- ☐ No, *Continue to 54*

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

- ☐ Yes, *Continue to 55*
- ☐ No, *Continue to 59*

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

- ☐ Yes, *Continue to 59*
- ☐ No, *Continue to 56*
- ☐ Unknown, *Continue to 59*

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

- ☐ Yes, *Continue to 57*
- ☐ No, *Continue to 58*

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57. 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 **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Number of tender joints **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Dactylitis **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Enthesitis **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Axial disease **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Skin and/or nail involvement **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Functional status **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ C-reactive protein (CRP) **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ None of the above, Continue to 58

58. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

- ☐ Yes, Continue to 164
- ☐ No, Continue to 164

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

- ☐ Yes, Continue to 60
- ☐ No, Continue to 60

60. Has the patient ever received or is currently receiving a biologic (e.g., Humira) 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.

- ☐ Yes, Continue to 164
- ☐ No, Continue to 61

61. What is the patient's disease severity?

- ☐ Mild to moderate, Continue to 62
- ☐ Severe, Continue to 164

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

- ☐ Yes, Continue to 164
- ☐ No, Continue to 63

63. 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.

- ☐ Yes, Continue to 164
- ☐ No, Continue to 64

64. 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.

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- ☐ Yes, *Continue to 164*
☐ No, *Continue to 65*

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

- ☐ Yes, *Continue to 66*
☐ No, *Continue to 67*

66. Please indicate the contraindication to methotrexate or leflunomide.

- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 164*
☐ Drug interaction, *Continue to 164*
☐ Risk of treatment-related toxicity, *Continue to 164*
☐ Pregnancy or currently planning pregnancy, *Continue to 164*
☐ Breastfeeding, *Continue to 164*
☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 164*
☐ Hypersensitivity, *Continue to 164*
☐ History of intolerance or adverse event, *Continue to 164*
☐ Other, please specify _____, *Continue to 164*

67. 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, *Continue to 164*
☐ No, *Continue to 164*

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

- ☐ Yes, *Continue to 69*
☐ No, *Continue to 69*

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

- ☐ Yes, *Continue to 70*
☐ No, *Continue to 70*

70. Is the patient an adult (18 years of age or older)?

- ☐ Yes, *Continue to 71*
☐ No, *Continue to 71*

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

- ☐ Yes, *Continue to 72*
☐ No, *Continue to 77*

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

- ☐ Yes, *Continue to 77*

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☐ No, *Continue to 73*

☐ Unknown, *Continue to 77*

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

☐ Yes, *Continue to 74*

☐ No, *Continue to 76*

74. 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.

☐ Yes, *Continue to 164*

☐ No, *Continue to 75*

75. 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.

☐ Yes, *Continue to 164*

☐ No, *Continue to 76*

76. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

77. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.

☐ Yes, *Continue to 164*

☐ No, *Continue to 78*

78. 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, *Continue to 164*

☐ No, *Continue to 79*

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

☐ Yes, *No Further Questions*

☐ No, *Continue to 80*

80. 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 affected areas and body surface area affected.

☐ Greater than or equal to 3% to less than 10% of BSA _____ **ACTION REQUIRED:** *Submit supporting documentation, Continue to 81*

☐ Greater than or equal to 10% of BSA _____ **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

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81. 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.

☐ Yes, *Continue to 164*

☐ No, *Continue to 82*

82. 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 therapy.

☐ Yes, *Continue to 83*

☐ No, *Continue to 83*

83. 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 164*

☐ Drug interaction, *Continue to 164*

☐ Risk of treatment-related toxicity, *Continue to 164*

☐ Pregnancy or currently planning pregnancy, *Continue to 164*

☐ Breastfeeding, *Continue to 164*

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 164*

☐ Hypersensitivity, *Continue to 164*

☐ History of intolerance or adverse event, *Continue to 164*

☐ Other, please specify. _____, *Continue to 164*

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

☐ Yes, *Continue to 85*

☐ No, *Continue to 85*

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

☐ Yes, *Continue to 86*

☐ No, *Continue to 89*

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

☐ Yes, *Continue to 89*

☐ No, *Continue to 87*

☐ Unknown, *Continue to 89*

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

☐ Yes, *Continue to 164*

☐ No, *Continue to 88*

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88. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

89. Has the patient ever received or is currently receiving Otezla or a biologic (e.g., Humira) 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.

☐ Yes, *Continue to 164*

☐ No, *Continue to 90*

90. Has the patient had an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

91. Has the patient been diagnosed with severe, refractory hidradenitis suppurativa?

☐ Yes, *Continue to 92*

☐ No, *Continue to 92*

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

☐ Yes, *Continue to 93*

☐ No, *Continue to 93*

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

☐ Yes, *Continue to 94*

☐ No, *Continue to 98*

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

☐ Yes, *Continue to 98*

☐ No, *Continue to 95*

☐ Unknown, *Continue to 98*

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

☐ Yes, *Continue to 96*

☐ No, *Continue to 97*

96. Which of the following signs and symptoms has the patient experienced an improvement in from baseline?

ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.

☐ Reduction in abscess and inflammatory nodule count from baseline **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

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- ☐ Reduced formation of new sinus tracts and scarring **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Decrease in frequency of inflammatory lesions from baseline **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Reduction in pain from baseline **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Reduction in suppuration from baseline **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Improvement in frequency of relapses from baseline **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Improvement in quality of life from baseline **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ Improvement on a disease severity assessment tool from baseline **ACTION REQUIRED:** Submit supporting documentation, Continue to 164
- ☐ None of the above, Continue to 97

97. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

- ☐ Yes, Continue to 164
- ☐ No, Continue to 164

98. Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for the treatment of severe, refractory 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 medications tried.

- ☐ Yes, Continue to 164
- ☐ No, Continue to 99

99. Has the patient had an inadequate response after at least 90 days of treatment with an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, Continue to 164
- ☐ No, Continue to 100

100. Has the patient had an intolerance to oral antibiotics used for the treatment of hidradenitis suppurativa? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, Continue to 164
- ☐ No, Continue to 101

101. Does the patient have a contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa? **ACTION REQUIRED:** If Yes, please attach documentation of clinical reason to avoid therapy.

- ☐ Yes, Continue to 164
- ☐ No, Continue to 164

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

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

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

- ☐ Yes, *Continue to 104*
☐ No, *Continue to 107*

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

- ☐ Yes, *Continue to 107*
☐ No, *Continue to 105*
☐ Unknown, *Continue to 107*

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

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 106*

106. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 164*

107. Has the patient ever received or is currently receiving a biologic (e.g., Humira) 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.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 108*

108. Has the patient had an inadequate response to 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.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 109*

109. Does the patient have an intolerance or contraindication 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 (if applicable), including response to therapy. If therapy is not advisable, please provide clinical reason to avoid therapy.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 164*

110. Is the requested drug being prescribed by or in consultation with a dermatologist, pulmonologist, rheumatologist, cardiologist, neurologist, or ophthalmologist?

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

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

- ☐ Yes, *Continue to 112*
☐ No, *Continue to 115*

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

- ☐ Yes, *Continue to 115*
☐ No, *Continue to 113*
☐ Unknown, *Continue to 115*

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

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 114*

114. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 164*

115. Has the patient had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, methotrexate)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 116*

116. Does the patient have an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, methotrexate)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 164*

117. Has the patient been diagnosed with refractory Takayasu's arteritis?

- ☐ Yes, *Continue to 118*
☐ No, *Continue to 118*

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

- ☐ Yes, *Continue to 119*
☐ No, *Continue to 119*

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

- ☐ Yes, *Continue to 120*
☐ No, *Continue to 123*

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

☐ Yes, *Continue to 123*

☐ No, *Continue to 121*

☐ Unknown, *Continue to 123*

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

☐ Yes, *Continue to 164*

☐ No, *Continue to 122*

122. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

123. Has the patient had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 124*

124. Does the patient have an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please provide clinical reason to avoid therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

125. Is the requested drug being prescribed by or in consultation with an ophthalmologist or rheumatologist?

☐ Yes, *Continue to 126*

☐ No, *Continue to 126*

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

☐ Yes, *Continue to 127*

☐ No, *Continue to 131*

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

☐ Yes, *Continue to 131*

☐ No, *Continue to 128*

☐ Unknown, *Continue to 131*

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

☐ Yes, *Continue to 129*

☐ No, *Continue to 130*

129. Which of the following signs and symptoms has the patient experienced an improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response.

☐ Reduced frequency of flare recurrence compared to baseline **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ Decreased reliance on topical corticosteroids **ACTION REQUIRED:** *Submit supporting documentation, Continue to 164*

☐ None of the above, *Continue to 130*

130. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

131. Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for the treatment of uveitis (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.

☐ Yes, *Continue to 164*

☐ No, *Continue to 132*

132. Has the patient had an inadequate response with corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medication tried, including response to therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 133*

133. Does the patient have an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please provide clinical reason to avoid therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

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

☐ Yes, *Continue to 135*

☐ No, *Continue to 135*

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

☐ Yes, *Continue to 136*

☐ No, *Continue to 139*

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

☐ Yes, *Continue to 139*

☐ No, *Continue to 137*

☐ Unknown, *Continue to 139*

137. 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 (e.g., tender joint count, swollen joint count, pain) since starting treatment with the requested drug or a biosimilar of the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation supporting positive clinical response.

☐ Yes, *Continue to 164*

☐ No, *Continue to 138*

138. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

139. Has the patient ever received or is currently receiving a biologic (e.g., Enbrel) indicated for the treatment of reactive 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.

☐ Yes, *Continue to 164*

☐ No, *Continue to 140*

140. Has the patient had an inadequate response to methotrexate or sulfasalazine? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 141*

141. Does the patient have 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.

☐ Yes, *Continue to 144*

☐ No, *Continue to 142*

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

☐ Yes, *Continue to 143*

☐ No, *Continue to 143*

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143. Please indicate the contraindication to methotrexate.

- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 144*
- ☐ Drug interaction, *Continue to 144*
- ☐ Risk of treatment-related toxicity, *Continue to 144*
- ☐ Pregnancy or currently planning pregnancy, *Continue to 144*
- ☐ Breastfeeding, *Continue to 144*
- ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 144*
- ☐ Hypersensitivity, *Continue to 144*
- ☐ History of intolerance or adverse event, *Continue to 144*
- ☐ Other, please specify. _____, *Continue to 144*

144. Does the patient have an intolerance to sulfasalazine? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 145*

145. Does the patient have a contraindication to sulfasalazine (e.g., porphyria, intestinal or urinary obstruction)? **ACTION REQUIRED:** If Yes, please attach documentation of clinical reason to avoid therapy.

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 164*

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

- ☐ Yes, *Continue to 147*
- ☐ No, *Continue to 147*

147. Has the patient had an inadequate response to systemic corticosteroids? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 148*

148. Does the patient have an intolerance to corticosteroids? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 149*

149. Does the patient have a contraindication to corticosteroids? **ACTION REQUIRED:** If Yes, please attach documentation of clinical reason to avoid therapy.

- ☐ Yes, *Continue to 164*
- ☐ No, *Continue to 164*

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150. Is the requested drug being prescribed by or in consultation with an oncologist, hematologist, or rheumatologist?

☐ Yes, *Continue to 151*

☐ No, *Continue to 151*

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

☐ Yes, *Continue to 152*

☐ No, *Continue to 155*

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

☐ Yes, *Continue to 155*

☐ No, *Continue to 153*

☐ Unknown, *Continue to 155*

153. 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? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation supporting positive clinical response.

☐ Yes, *Continue to 164*

☐ No, *Continue to 154*

154. Is this request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 164*

☐ No, *Continue to 164*

155. Does the patient have moderate or severe immunotherapy-related inflammatory arthritis?

☐ Yes, *Continue to 156*

☐ No, *Continue to 156*

156. Has the patient had an inadequate response to corticosteroids? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 157*

157. Has the patient had an inadequate response to a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

☐ Yes, *Continue to 164*

☐ No, *Continue to 158*

158. Does the patient have an intolerance or contraindication to corticosteroids? **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.

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- ☐ Yes, *Continue to 159*
☐ No, *Continue to 159*

159. Does the patient have an intolerance or contraindication to a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)? **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, *Continue to 164*
☐ No, *Continue to 164*

160. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?

- ☐ Yes, *Continue to 161*
☐ No, *Continue to 161*

161. Has the patient had an inadequate response to systemic corticosteroids? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 162*

162. Does the patient have an intolerance to corticosteroids? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 163*

163. Does the patient have a contraindication to corticosteroids? **ACTION REQUIRED:** If Yes, please attach documentation of clinical reason to avoid therapy.

- ☐ Yes, *Continue to 164*
☐ No, *Continue to 164*

164. What is the diagnosis?

- ☐ Crohn's disease, *Continue to 165*
☐ Ulcerative colitis, *Continue to 196*
☐ Rheumatoid arthritis, *Continue to 233*
☐ Ankylosing spondylitis, *Continue to 245*
☐ Non-radiographic axial spondyloarthritis, *Continue to 245*
☐ Psoriatic arthritis, *Continue to 257*
☐ Psoriatic arthritis WITH co-existent plaque psoriasis, *Continue to 257*
☐ Plaque psoriasis, *Continue to 257*
☐ Behcet's disease, *Continue to 269*
☐ Hidradenitis suppurativa, *Continue to 269*
☐ Pyoderma gangrenosum, *Continue to 269*
☐ Sarcoidosis, *Continue to 269*

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- ☐ Takayasu's arteritis, *Continue to 269*
- ☐ Uveitis, *Continue to 274*
- ☐ Reactive arthritis, *Continue to 269*
- ☐ Immune checkpoint inhibitor-related toxicity, *Continue to 279*
- ☐ Immune checkpoint inhibitor-related inflammatory arthritis, *Continue to 269*
- ☐ Acute graft versus host disease, *Continue to 269*

165. What is the prescribed product?

- ☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 168*
- ☐ Zymfentra (subcutaneous), *Continue to 166*

166. Does the prescribed maintenance dose exceed 120 mg?

- ☐ Yes, *Continue to 167*
- ☐ No, *Continue to 167*

167. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

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

168. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

- ☐ Yes, *Continue to 169*
- ☐ No, *Continue to 189*

169. What is the patient's age?

- ☐ Less than 18 years old, *Continue to 170*
- ☐ 18 years old or older, *Continue to 182*

170. Does the prescribed dose exceed 5 mg per kg?

- ☐ Yes, *Continue to 173*
- ☐ No, *Continue to 171*

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

- ☐ Yes, *Continue to 177*
- ☐ No, *Continue to 172*

172. What is the patient's weight? (kg).

_____ kg, *No further questions*

173. Does the prescribed dose exceed 10 mg per kg?

- ☐ Yes, *Continue to 174*
- ☐ No, *Continue to 174*

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

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- ☐ Yes, *Continue to 177*
☐ No, *Continue to 175*

175. Does the prescriber recognize that a dose above 5 mg per kg every 8 weeks is a higher dose and the prescriber confirms that appropriate monitoring will be done?

- ☐ Yes, *Continue to 176*
☐ No, *Continue to 176*

176. What is the patient's weight? (kg)

_____ kg, *No further questions*

177. Please select the situation that applies to the patient.

- ☐ Patient is continuing therapy at current dose and/or frequency, *Continue to 179*
☐ Prescriber is increasing dose and/or frequency, *Continue to 178*
☐ Prescriber is decreasing dose and/or frequency, *Continue to 179*

178. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose and/or frequency?

- ☐ Yes, *Continue to 179*
☐ No, *Continue to 179*

179. Does the prescribed dose and frequency exceed 10 mg per kg every 4 weeks?

- ☐ Yes, *Continue to 180*
☐ No, *Continue to 180*

180. Does the prescriber recognize that a dose above 5 mg per kg every 8 weeks is a higher dose and the prescriber confirms that appropriate monitoring will be done?

- ☐ Yes, *Continue to 181*
☐ No, *Continue to 181*

181. What is the patient's weight? (kg)

_____ kg, *No further questions*

182. Does the prescribed dose exceed 5 mg per kg?

- ☐ Yes, *Continue to 185*
☐ No, *Continue to 183*

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

- ☐ Yes, *Continue to 185*
☐ No, *Continue to 184*

184. What is the patient's weight? (kg).

_____ kg, *No further questions*

185. Please select the situation that applies to the patient.

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- ☐ Patient is continuing therapy at current dose and/or frequency, *Continue to 187*
- ☐ Prescriber is increasing dose and/or frequency, *Continue to 186*
- ☐ Prescriber is decreasing dose and/or frequency, *Continue to 187*

186. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

- ☐ Yes, *Continue to 187*
- ☐ No, *Continue to 187*

187. Does the prescribed dose and frequency exceed 10 mg per kg every 4 weeks?

- ☐ Yes, *Continue to 188*
- ☐ No, *Continue to 188*

188. What is the patient's weight? (kg)

_____ kg, *No further questions*

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

- ☐ Yes, *Continue to 190*
- ☐ No, *Continue to 190*

190. Does the prescribed dose exceed an induction dose of 5 mg per kg at week 0, week 2, and week 6, and a maintenance dose of 5 mg per kg thereafter?

- ☐ Yes, *Continue to 192*
- ☐ No, *Continue to 191*

191. What is the patient's weight? (kg)

_____ kg, *No further questions*

192. What is the patient's age?

- ☐ Less than 18 years old, *Continue to 193*
- ☐ 18 years of age or older, *Continue to 193*

193. Does the prescriber recognize that a dose above 5 mg per kg every 8 weeks is a higher dose and the prescriber confirms that appropriate monitoring will be done?

- ☐ Yes, *Continue to 194*
- ☐ No, *Continue to 194*

194. Does the prescribed dose exceed an induction dose of 10 mg per kg at week 0, week 2, and week 6, and a maintenance dose of 10 mg per kg thereafter?

- ☐ Yes, *Continue to 195*
- ☐ No, *Continue to 195*

195. What is the patient's weight? (kg)

_____ kg, *No further questions*

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196. What is the prescribed product?

- ☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 199*
☐ Zymfentra (subcutaneous), *Continue to 197*

197. Does the prescribed maintenance dose exceed 120 mg?

- ☐ Yes, *Continue to 198*
☐ No, *Continue to 198*

198. Is the prescribed frequency for the maintenance dose more frequent than one dose every 2 weeks?

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

199. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

- ☐ Yes, *Continue to 200*
☐ No, *Continue to 226*

200. What is the patient's age?

- ☐ Less than 18 years old, *Continue to 201*
☐ 18 years old or older, *Continue to 213*

201. Does the prescribed dose exceed 5 mg per kg?

- ☐ Yes, *Continue to 204*
☐ No, *Continue to 202*

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

- ☐ Yes, *Continue to 208*
☐ No, *Continue to 203*

203. What is the patient's weight? (kg)

_____ kg, *No further questions*

204. Does the prescribed dose exceed 10 mg per kg?

- ☐ Yes, *Continue to 205*
☐ No, *Continue to 205*

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

- ☐ Yes, *Continue to 208*
☐ No, *Continue to 206*

206. Does the prescriber recognize that a dose above 5 mg per kg every 8 weeks is a higher dose and the prescriber confirms that appropriate monitoring will be done?

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

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207. What is the patient's weight? (kg).

_____ kg, *No further questions*

208. Please select the situation that applies to the patient.

- ☐ Patient is continuing therapy at current dose and/or frequency, *Continue to 210*
- ☐ Prescriber is increasing dose and/or frequency, *Continue to 209*
- ☐ Prescriber is decreasing dose and/or frequency, *Continue to 210*

209. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

- ☐ Yes, *Continue to 210*
- ☐ No, *Continue to 210*

210. Does the prescribed dose and frequency exceed 10 mg per kg every 4 weeks?

- ☐ Yes, *Continue to 211*
- ☐ No, *Continue to 211*

211. Does the prescriber recognize that a dose above 5 mg per kg every 8 weeks is a higher dose and the prescriber confirms that appropriate monitoring will be done?

- ☐ Yes, *Continue to 212*
- ☐ No, *Continue to 212*

212. What is the patient's weight? (kg)

_____ kg, *No further questions*

213. Does the prescribed dose exceed 5 mg per kg?

- ☐ Yes, *Continue to 216*
- ☐ No, *Continue to 214*

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

- ☐ Yes, *Continue to 222*
- ☐ No, *Continue to 215*

215. What is the patient's weight? (kg)

_____ kg, *No further questions*

216. Was the patient on a dose exceeding 5 mg per kg as a pediatric patient and is continuing that dose into adulthood?

- ☐ Yes, *Continue to 219*
- ☐ No, *Continue to 217*

217. Please select the situation that applies to the patient.

- ☐ Patient is continuing therapy at current dose, *Continue to 219*
- ☐ Prescriber is increasing dose, *Continue to 218*
- ☐ Prescriber is decreasing dose, *Continue to 219*

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218. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose?

☐ Yes, *Continue to 219*

☐ No, *Continue to 219*

219. Does the prescribed dose exceed 10 mg per kg?

☐ Yes, *Continue to 220*

☐ No, *Continue to 220*

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

☐ Yes, *Continue to 222*

☐ No, *Continue to 221*

221. What is the patient's weight? (kg)

_____ kg, *No further questions*

222. Please select the situation that applies to the patient.

☐ Patient is continuing therapy at current frequency, *Continue to 224*

☐ Prescriber is increasing frequency, *Continue to 223*

☐ Prescriber is decreasing frequency, *Continue to 224*

223. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

☐ Yes, *Continue to 224*

☐ No, *Continue to 224*

224. Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?

☐ Yes, *Continue to 225*

☐ No, *Continue to 225*

225. What is the patient's weight? (kg)

_____ kg, *No further questions*

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

☐ Yes, *Continue to 227*

☐ No, *Continue to 227*

227. Does the prescribed dose exceed an induction dose of 5 mg per kg at week 0, week 2, and week 6, and 5 mg per kg thereafter?

☐ Yes, *Continue to 229*

☐ No, *Continue to 228*

228. What is the patient's weight? (kg)

_____ kg, *No further questions*

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229. What is the patient's age?

- ☐ Less than 18 years old, *Continue to 230*
☐ 18 years of age or older, *Continue to 230*

230. Does the prescriber recognize that a dose above 5 mg per kg every 8 weeks is a higher dose and the prescriber confirms that appropriate monitoring will be done?

- ☐ Yes, *Continue to 231*
☐ No, *Continue to 231*

231. Does the prescribed dose exceed an induction dose of 10 mg per kg at week 0, week 2, and week 6, and a maintenance dose of 10 mg per kg thereafter?

- ☐ Yes, *Continue to 232*
☐ No, *Continue to 232*

232. What is the patient's weight? (kg)

_____ kg, *No further questions*

233. What is the prescribed product?

- ☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 234*
☐ Zymfentra (subcutaneous), *Continue to 234*

234. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

- ☐ Yes, *Continue to 235*
☐ No, *Continue to 242*

235. Does the prescribed dose exceed 3 mg per kg?

- ☐ Yes, *Continue to 238*
☐ No, *Continue to 236*

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

- ☐ Yes, *Continue to 238*
☐ No, *Continue to 237*

237. What is the patient's weight? (kg)

_____ kg, *No further questions*

238. Please select the situation that applies to the patient.

- ☐ Patient is continuing therapy at current dose and/or frequency, *Continue to 240*
☐ Prescriber is increasing dose and/or frequency, *Continue to 239*
☐ Prescriber is decreasing dose and/or frequency, *Continue to 240*

239. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

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- ☐ Yes, *Continue to 240*
☐ No, *Continue to 240*

240. Does the prescribed dose and frequency exceed 10 mg per kg every 4 weeks?

- ☐ Yes, *Continue to 241*
☐ No, *Continue to 241*

241. What is the patient's weight? (kg)

_____ kg, *No further questions*

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

- ☐ Yes, *Continue to 243*
☐ No, *Continue to 243*

243. Does the prescribed dose exceed an induction dose of 3 mg per kg at week 0, week 2, and week 6, and a maintenance dose of 3 mg per kg thereafter?

- ☐ Yes, *Continue to 244*
☐ No, *Continue to 244*

244. What is the patient's weight? (kg)

_____ kg, *No further questions*

245. What is the prescribed product?

- ☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 246*
☐ Zymfentra (subcutaneous), *Continue to 246*

246. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

- ☐ Yes, *Continue to 247*
☐ No, *Continue to 254*

247. Does the prescribed dose exceed 5 mg per kg?

- ☐ Yes, *Continue to 250*
☐ No, *Continue to 248*

248. Is the prescribed frequency for the maintenance dose more frequent than one dose every 6 weeks?

- ☐ Yes, *Continue to 250*
☐ No, *Continue to 249*

249. What is the patient's weight? (kg)

_____ kg, *No further questions*

250. Please select the situation that applies to the patient.

- ☐ Patient is continuing therapy at current dose and/or frequency, *Continue to 252*
☐ Prescriber is increasing dose and/or frequency, *Continue to 251*
☐ Prescriber is decreasing dose and/or frequency, *Continue to 252*

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251. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

☐ Yes, *Continue to 252*

☐ No, *Continue to 252*

252. Does the prescribed dose and frequency exceed 7.5 mg per kg every 4 weeks?

☐ Yes, *Continue to 253*

☐ No, *Continue to 253*

253. What is the patient's weight? (kg)

_____ kg, *No further questions*

254. Is the prescribed frequency for the maintenance dose more frequent than one dose every 6 weeks?

☐ Yes, *Continue to 255*

☐ No, *Continue to 255*

255. Does the prescribed dose exceed an induction dose of 5 mg per kg at week 0, week 2, and week 6, and 5 mg per kg thereafter?

☐ Yes, *Continue to 256*

☐ No, *Continue to 256*

256. What is the patient's weight? (kg)

_____ kg, *No further questions*

257. What is the prescribed product?

☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 258*

☐ Zymfentra (subcutaneous), *Continue to 258*

258. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

☐ Yes, *Continue to 259*

☐ No, *Continue to 266*

259. Does the prescribed dose exceed 5 mg per kg?

☐ Yes, *Continue to 262*

☐ No, *Continue to 260*

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

☐ Yes, *Continue to 262*

☐ No, *Continue to 261*

261. What is the patient's weight? (kg)

_____ kg, *No further questions*

262. Please select the situation that applies to the patient.

☐ Patient is continuing therapy at current dose and/or frequency, *Continue to 264*

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- ☐ Prescriber is increasing dose and/or frequency, *Continue to 263*
☐ Prescriber is decreasing dose and/or frequency, *Continue to 264*

263. Is this a request for an increase in dosing regimen due to the patient not achieving an adequate clinical response at the current dose or frequency?

- ☐ Yes, *Continue to 264*
☐ No, *Continue to 264*

264. Does the prescribed dose and frequency exceed 10 mg per kg every 4 weeks?

- ☐ Yes, *Continue to 265*
☐ No, *Continue to 265*

265. What is the patient's weight? (kg)

_____ kg, *No further questions*

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

- ☐ Yes, *Continue to 267*
☐ No, *Continue to 267*

267. Does the prescribed dose exceed an induction dose of 5 mg per kg at week 0, week 2, and week 6, and 5 mg per kg thereafter?

- ☐ Yes, *Continue to 268*
☐ No, *Continue to 268*

268. What is the patient's weight? (kg)

_____ kg, *No further questions*

269. What is the prescribed product?

- ☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 270*
☐ Zymfentra (subcutaneous), *Continue to 270*

270. 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, *Continue to 271*
☐ No, *Continue to 271*

271. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

- ☐ Yes, *Continue to 272*
☐ No, *Continue to 272*

272. What is the patient's weight? (kg)

_____ kg, *No further questions*

274. What is the prescribed product?

- ☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 275*
☐ Zymfentra (subcutaneous), *Continue to 275*

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275. 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, *Continue to 276*

☐ No, *Continue to 276*

276. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

☐ Yes, *Continue to 277*

☐ No, *Continue to 277*

277. What is the patient's weight? (kg)

_____ kg, *No further questions*

279. What is the prescribed product?

☐ Avsola, Inflectra, infliximab, Remicade, or Renflexis (intravenous), *Continue to 280*

☐ Zymfentra (subcutaneous), *Continue to 280*

280. 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, *Continue to 281*

☐ No, *Continue to 281*

281. Is the patient currently receiving the requested drug or a biosimilar of the requested drug?

☐ Yes, *Continue to 282*

☐ No, *Continue to 282*

282. What is the patient's weight? (kg)

_____ kg, *No further questions*

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle
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Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	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)

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