

Infliximab

HMSA - Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** 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: |
| Patient's Phone Number: | |
| Physician's Name: | |
| Specialty: | NPI#: |
| Physician Office Telephone: | Physician Office Fax: |

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

 Patient Weight:
 _____kg

 Patient Height:
 ft

Indicate where the drug is being dispensed:

- □ Office □ Outpatient Hospital □ Ambulatory Surgical □ Inpatient Hospital
- □ Off Campus Outpatient Hospital □ Urgent Care □ Emergency Room □ Birthing Center
- □ Military Facility □ Skilled Nursing Facility □ Nursing Facility □ Hospice
- □ Inpatient Psychiatric □ Psychiatric Residential Treatment □ End Stage Renal Facility
- □ Psychiatric Facility □ Pharmacy □ Other

Indicate where the drug is being administered:

□ Ambulatory surgical □ Home □ Inpatient Hospital □ Office □ Outpatient Hospital □ Pharmacy

What is the ICD-10 code? _____

Exception Criteria Questions:

If the requested product is unbranded infliximab or Inflectra, skip to Criteria Questions

- A. Is the product being requested for the treatment of an ADULT patient (18 years of age or older) with one of the following indications?
 - Ankylosing spondylitis
 - Crohn's disease
 - Plaque psoriasis

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- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis
- □ Yes □ No If No, skip to Criteria Questions
- B. These are the preferred products for which coverage is provided for treatment of the following indications:
 - Ankylosing spondylitis: Cosentyx, Enbrel, Humira, Inflectra, Rinvoq, Simponi Aria, Taltz, and unbranded infliximab
 - Crohn's disease: Entyvio, Humira, Inflectra, Rinvoq, Skyrizi, Stelara, and unbranded infliximab
 - Plaque psoriasis: Cosentyx, Enbrel, Humira, Inflectra, Otezla, Skyrizi, Stelara, Taltz, Tremfya, and unbranded infliximab
 - Psoriatic arthritis: Cosentyx, Enbrel, Humira, Inflectra, Otezla, Rinvoq, Simponi Aria, Skyrizi, Stelara, Taltz Tremfya, unbranded infliximab, and Xeljanz/Xeljanz XR
 - Rheumatoid arthritis: Enbrel, Humira, Inflectra, Rinvoq, Simponi Aria, unbranded infliximab, and Xeljanz/Xeljanz XR
 - Ulcerative Colitis: Entyvio, Humira, Inflectra, Rinvoq, Stelara, unbranded infliximab, and Xeljanz/Xeljanz XR

Can the patient's treatment be switched to a preferred product?

Yes, Please obtain Form for preferred product and submit for corresponding PA.
 No

- C. Is this request for continuation of therapy with the requested product? \Box Yes \Box No If No, skip to Question E
- D. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. \Box Yes \Box No *If No, skip to Criteria Questions*
- E. What is the diagnosis?

 \Box Crohn's disease, *Skip to Question G*

 \Box Plaque psoriasis, *Skip to Question H* \Box

Psoriatic arthritis, Skip to Question I
 Ulaemting colities Skip to Question K

- $\square Rheumatoid arthritis, Skip to Question J \qquad \square Ulcerative colitis, Skip to Question K$
- F. Does the patient have a documented inadequate response, intolerable adverse event or contraindication to both of the following preferred products indicated for ankylosing spondylitis: Inflectra or unbranded infliximab and Simponi Aria? Yes No If Yes or No, skip to Criteria Questions
- G. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to all of the following preferred products indicated for Crohn's disease: Entyvio, Inflectra or unbranded infliximab, Skyrizi IV and Stelara IV? Yes No If Yes or No, skip to Criteria Questions
- H. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to the following preferred products indicated for plaque psoriasis: Inflectra or unbranded infliximab?
 □ Yes □ No If Yes or No, skip to Criteria Questions
- I. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to all of the following preferred products indicated for psoriatic arthritis: Inflectra or unbranded infliximab and Simponi Aria?
 □ Yes □ No If Yes or No, skip to Criteria Questions
- J. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to both of the following preferred products indicated for rheumatoid arthritis: Inflectra or unbranded infliximab and Simponi Aria? Aria? Yes No *If Yes or No, skip to Criteria Questions*
- K. Does the patient have a documented inadequate response, intolerable adverse event, or contraindication to all of the following preferred products indicated for ulcerative colitis: Entyvio, Inflectra or unbranded infliximab, and Stelara IV? \Box Yes \Box No

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Criteria Questions:

What is the prescribed drug? 🗆 Remicade 🗅 unbranded infliximab 📮 Inflectra 📮 Renflexis 📮 Avsola

General Biologic/Targeted Synthetic Drug and TB

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)?

 $\square Yes, Continue to #2$

 \square No, *Continue to #2*

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

□ Yes, Continue to #9

 \square No, *Continue to #3*

3. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [PPD], interferon-release assay [IGRA], chest x-ray) within 6 months of initiating therapy?

□ Yes, Continue to #4

□ No, *Continue to #9*

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

D Positive for TB, *Continue to #5*

□ Negative for TB, *Continue to #9*

□ Unknown, *Continue to #9*

5. Which of the following applies to the patient?

D Patient has latent TB and treatment for latent TB has been initiated, *Continue to #9*

D Patient has latent TB and treatment for latent TB has been completed, *Continue to #9*

D Patient has latent TB and treatment for latent TB has not been initiated, Continue to #9

D Patient has active TB, Continue to #9

Indication

9. What is the diagnosis?

- Crohn's disease, *Continue to #100*
- □ Ulcerative colitis, *Continue to #200*
- □ Rheumatoid arthritis, *Continue to #300*

□ Ankylosing spondylitis, *Continue to #400*

Axial spondyloarthritis, *Continue to #400*

Desoriatic arthritis WITHOUT co-existent plaque psoriasis, *Continue to #500*

Description Psoriatic arthritis with co-existent plaque psoriasis, Continue to #10

□ Plaque psoriasis, *Continue to #600*

□ Behcet's disease, Continue to #750

□ Hidradenitis suppurativa, Continue to #800

D Pyoderma gangrenosum, Continue to #825

□ Sarcoidosis, Continue to #850

□ Takayasu's arteritis, *Continue to #870*

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Uveitis, *Continue to #900*

Reactive arthritis, *Continue to #925*

Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity, *Continue to #950*

□ Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity – Immunotherapy arthritis, *Continue to* #960

□ Acute graft versus host disease, *Continue to #975*

Other, No Further Questions

10. What is the primary diagnosis being treated?

□ Psoriatic arthritis, *Continue to #500*

□ Plaque psoriasis, *Continue to #600*

Crohn's Disease

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

□ Yes, Continue to #101

□ No, *Continue to #101*

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

□ Yes, Continue to #102

 \square No, Continue to #102

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

Yes, *Continue to #103* No, *Continue to #103*

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

□ Yes, Continue to #104

□ No, No Further Questions

Continuation of Therapy

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

□ Yes, No Further Questions

□ No, Continue to #105

Unknown, No Further Questions

105. Has the patient achieved or maintained remission?

□ Yes, No Further Questions

□ No, *Continue to #106*

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

□ Yes, *Continue to #107*

□ No, Continue to #107

107. Which of the following has the patient experienced an improvement in from baseline?

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Abdominal pain or tenderness, No Further Questions

Diarrhea, No Further Questions

Body weight, No Further Questions

□ Abdominal mass, No Further Questions

Hematocrit, *No Further Questions*

□ Endoscopic appearance of the mucosa, *No Further Questions*

□ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score), No Further Questions

□ None of the above, *No Further Questions*

Ulcerative Colitis

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

□ Yes, Continue to #201

 \square No, Continue to #201

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

 \Box Yes, *Continue to #202*

□ No, *Continue to #202*

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

□ Yes, Continue to #203

□ No, Continue to #203

Continuation of Therapy

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

□ Yes, *Continue to #204*

□ No, No Further Questions

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

□ Yes, No Further Questions

 \square No, *Continue to #205*

Unknown, No Further Questions

205. Has the patient achieved or maintained remission?

□ Yes, *No Further Questions*

□ No, *Continue to #206*

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

□ Yes, *Continue to #207*

 \square No, *Continue to #207*

207. Which of the following has the patient experienced an improvement in from baseline?

□ Stool frequency, No Further Questions

C Rectal bleeding, No Further Questions

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Urgency of defecation, No Further Questions

C-reactive protein (CRP), *No Further Questions*

□ Fecal calprotectin (FC), No Further Questions

□ Endoscopic appearance of the mucosa, No Further Questions

□ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score]), No Further Questions

□ None of the above, *No Further Ouestions*

<u>Rheumatoid Arthritis</u>

300. Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)? \Box Yes. Continue to #301 \square No, Continue to #301

301. Is the patient an adult? \square Yes, Continue to #302 \square No, Continue to #302

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

 \Box Yes, Continue to #303

 \square No, Continue to #303

Continuation of Therapy

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

 \Box Yes, Continue to #304

 \square No, *Continue to #350*

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

 \Box Yes, Continue to #350

 \square No, Continue to #305

□ Unknown, *Continue to #350*

305. Has the patient a chieved or maintained positive clinical response since starting treatment with the requested drug or biosimilar?

 \Box Yes, Continue to #306

 \square No, Continue to #306

306. 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?

□ Yes, No Further Questions

□ No, No Further Questions

Initial Therapy

Prior treatment with another biologic or targeted synthetic drug

350. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis?

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Yes, Continue to #351
 No, Continue to #353

Combination with methotrexate or leflunomide

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

TYes, No Further Questions

 \square No, *Continue to #352*

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

History of intolerance or adverse event, No Further Questions

Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*

D Elevated liver transaminases, No Further Questions

Interstitial pneumonitis or clinically significant pulmonary fibrosis, *No Further Questions*

□ Renal impairment, *No Further Questions*

D Pregnancy or currently planning pregnancy, No Further Questions

□ Breastfeeding, *No Further Questions*

Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), No Further Questions

□ Myelodysplasia, No Further Questions

□ Hypersensitivity, *No Further Questions*

Significant drug interaction, No Further Questions

Other, *No Further Questions*

□ No clinical reason not to use methotrexate or leflunomide, *No Further Questions*

Biomarker testing and combination with methotrexate or leflunomide

353. 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?

□ Yes, *Continue to #355*

 \square No, *Continue to #354*

354. 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)?

□ Yes, *Continue to #355*

□ No, *Continue to #355*

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

□ Yes, *Continue to #357*

□ No, *Continue to #356*

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

□ History of intolerance or adverse event, *Continue to #357*

Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *Continue to* #357

Elevated liver transaminases, *Continue to #357*

□ Interstitial pneumonitis or clinically significant pulmonary fibrosis, Continue to #357

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□ Renal impairment, Continue to #357

□ Pregnancy or currently planning pregnancy, *Continue to #357*

□ Breastfeeding, *Continue to #357*

Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), Continue to #357

□ Myelodysplasia, *Continue to #357*

□ Hypersensitivity, *Continue to #357*

□ Significant drug interaction, *Continue to #357*

□ Other, *Continue to #357*

□ No clinical reason not to use methotrexate or leflunomide, Continue to #357

Requirements regarding prior therapy

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

D Yes, No Further Questions

□ No, *Continue to #358*

358. Has the patient experienced an intolerance to methotrexate?

□ Yes, No Further Questions

 \square No, Continue to #359

359. Does the patient have a contraindication to methotrex ate?

□ Yes, *Continue to #360*

□ No, No Further Questions

360. Please indicate the contraindication

History of intolerance or adverse event, No Further Questions

Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*

D Elevated liver transaminases, No Further Questions

Interstitial pneumonitis or clinically significant pulmonary fibrosis, No Further Questions

□ Renal impairment, *No Further Questions*

D Pregnancy or currently planning pregnancy, No Further Questions

□ Breastfeeding, No Further Questions

Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), No Further Questions

- □ Myelodysplasia, No Further Questions
- Hypersensitivity, No Further Questions
- Significant drug interaction, No Further Questions

Other, *No Further Questions*

Ankylosing spondylitis and axial spondyloarthritis

400. Has the patient been diagnosed with active ankylosing spondylitis (AS) or active axial spondyloarthritis?

□ Yes – Active ankylosing spondylitis, *Continue to #401*

□ Yes – Active axial spondyloarthritis, *Continue to #401*

□ No, *Continue to #401*

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401. Is the patient an adult?
□ Yes, *Continue to #402*□ No, *Continue to #402*

402. Is the requested drug being prescribed by or in consultation with a rheumatologist?
□ Yes, *Continue to #403*□ No, *Continue to #403*

Continuation of Therapy

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

□ Yes, Continue to #404

 \square No, Continue to #407

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

□ Yes, Continue to #407

 \square No, *Continue to #405*

□ Unknown, *Continue to #407*

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

□ Yes, Continue to #406

□ No, Continue to #406

406. Which of the following has the patient experienced an improvement in from baseline?

G Functional status, No Further Questions

Total spinal pain, No Further Questions

□ Inflammation (e.g., morning stiffness), No Further Questions

□ None of the above, *No Further Questions*

<u>Initial Therapy</u>

Prior treatment with another biologic or targeted synthetic drug

407. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) that is indicated for active ankylosing spondylitis or active axial spondyloarthritis?

□ Yes, No Further Questions

□ No, *Continue to #408*

Requirements regarding prior therapy

408. Has the patient experienced an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least two NSAIDs?

□ Yes, No Further Questions

D No, *No Further Questions*

Psoriatic Arthritis

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500. Is the patient an adult?
□ Yes, *Continue to #501*□ No, *Continue to #501*

501. Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist?
□ Yes, *Continue to #502*□ No, *Continue to #502*

Continuation of Therapy

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

□ Yes, Continue to #503

 \square No, Continue to #506

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

□ Yes, Continue to #506

 \square No, *Continue to #504*

□ Unknown, *Continue to #506*

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

□ Yes, *Continue to #505*

□ No, Continue to #505

505. Which of the following has the patient experienced an improvement in from baseline?

D Number of swollen joints, No Further Questions

D Number of tender joints, No Further Questions

Dactylitis, No Further Questions

□ Enthesitis, *No Further Questions*

Axial disease, No Further Questions

Skin and/or nail involvement, No Further Questions

□ None of the above, *No Further Questions*

<u>Initial Therapy</u>

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

□ Yes, Continue to #507

□ No, Continue to #507

Prior treatment with another biologic or targeted synthetic drug

507. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) that is indicated for active psoriatic arthritis?

□ Yes, No Further Questions

 \square No, Continue to #508

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New starts

508. Does the patient have mild to moderate disease?

□ Yes, Continue to #509

 \square No, *Continue to #515*

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

□ Yes, *No Further Questions*

 \square No, *Continue to #510*

510. 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?

□ Yes, *No Further Questions* □ No, *Continue to #511*

511. Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)?

□ Yes, No Further Questions

 \square No, *Continue to #512*

512. Does the patient have a contraindication to methotrexate or leflunomide?

□ Yes, *Continue to #513*

 \square No, Continue to #514

513. Please indicate the contraindication

History of intolerance or adverse event, No Further Questions

Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*

D Elevated liver transaminases, No Further Questions

Interstitial pneumonitis or clinically significant pulmonary fibrosis, No Further Questions

C Renal impairment, No Further Questions

D Pregnancy or currently planning pregnancy, No Further Questions

□ Breastfeeding, No Further Questions

Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), No Further Questions

D Myelodysplasia, No Further Questions

Hypersensitivity, No Further Questions

Significant drug interaction, No Further Questions

O Other, *No Further Questions*

514. Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)?

□ Yes, No Further Questions

D No, No Further Questions

515. Does the patient have severe disease?

T Yes, *No Further Questions*

D No, *No Further Questions*

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Moderate to Severe Plaque Psoriasis

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

□ Yes, *Continue to #601*

 \square No, *Continue to #601*

601. Is the patient an adult? □ Yes, *Continue to #602* □ No, *Continue to #602*

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

□ Yes, Continue to #603

 \square No, Continue to #603

Continuation of Therapy

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

□ Yes, *Continue to #604*

 \square No, *Continue to #608*

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

□ Yes, Continue to #608

□ No, *Continue to #605*

□ Unknown, *Continue to #608*

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

□ Yes, *Continue to #606*

□ No, Continue to #606

606. Has the patient experienced a reduction in body surface area (BSA) affected from baseline?

□ Yes, No Further Questions

D No, *Continue to #607*

607. Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)?

□ Yes, No Further Questions

D No, *No Further Questions*

Initial Therapy

Prior treatment with another biologic or targeted synthetic drug

608. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis?

T Yes, *No Further Questions*

□ No, *Continue to #609*

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Requirements regarding prior therapy

609. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected?

□ Yes, No Further Questions

 \square No, *Continue to #610*

610. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? $\Box = 100\%$ (BSA) C = 100% (BSA) affected (prior to starting the requested medication)?

Greater than or equal to 3% to less than 10% of BSA, *Continue to #611*

Greater than or equal to 10% of BSA, No Further Questions

Less than 3% of BSA, *Continue to #611*

611. 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?

□ Yes, No Further Questions

□ No, *Continue to #612*

612. Does the patient have a clinical reason to a void pharmacologic treatment with methotrexate, cyclosporine and acitretin?

□ Yes, *Continue to #613*

□ No, No Further Questions

613. Please indicate clinical reason to avoid pharmacologic treatment

Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*

□ Breastfeeding, No Further Questions

Cannot be used due to risk of treatment-related toxicity, *No Further Questions*

Drug interaction, No Further Questions

D Pregnancy or currently planning pregnancy, *No Further Questions*

□ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *No Further Questions*

Other, No Further Questions

Behcet's disease

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

□ Yes, Continue to #751

□ No, *Continue to #751*

Continuation of Therapy

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

□ Yes, Continue to #752

 \square No, *Continue to #754*

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

□ Yes, Continue to #754

□ No, *Continue to #753*

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□ Unknown, Continue to #754

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

Yes, No Further Questions
No, No Further Questions

Prior treatment with another biologic drug or Otezla

754. Has the patient ever received (including current utilizers) Otezla or a biologic (e.g., Humira) indicated for the treatment of Behcet's disease?

□ Yes, No Further Questions

□ No, Continue to #755

<u>New Starts</u>

755. Has the patient had an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine)?

Yes, No Further Questions
No, No Further Questions

Hidradenitis suppurativa

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

☐ Yes, Continue to #801

□ No, *Continue to #801*

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

□ Yes, *Continue to #802*

□ No, *Continue to #802*

Continuation of Therapy

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

□ Yes, Continue to #803

□ No, Continue to #806

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

□ Yes, *Continue to #806*

□ No, *Continue to #804*

Unknown, *Continue to #806*

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

□ Yes, Continue to #805

 \square No, *Continue to #805*

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- 805. Which of the following has the patient experienced since starting treatment with the requested drug?
- C Reduction in abscess and inflammatory nodule count from baseline, No Further Questions
- C Reduced formation of new sinus tracts and scarring, No Further Questions
- Decrease in frequency of inflammatory lesions from baseline, No Further Questions
- C Reduction in pain from baseline, No Further Questions
- **D** Reduction in suppuration from baseline, *No Further Questions*
- Improvement in frequency of relapses from baseline, *No Further Questions*
- Improvement in quality of life from baseline, No Further Questions
- Improvement on a disease severity assessment tool from baseline, No Further Questions
- □ None of the above, *No Further Questions*

Initial Therapy

Prior treatment with another biologic drug

806. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of severe, refractory hidradenitis suppurativa?

Yes, No Further Questions
No, Continue to #807

Requirements regarding prior therapy

807. Has the patient experienced an inadequate response after at least 90 days of treatment with an oral antibiotic?
Yes, *No Further Questions*No, *Continue to #808*

808. Has the patient experienced an intolerable adverse effect to oral antibiotics?

□ Yes, No Further Questions

□ No, *Continue to #809*

809. Does the patient have a contraindication to oral antibiotics?

□ Yes, No Further Questions

□ No, No Further Questions

<u>Pyoderma Gangrenosum</u>

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

□ Yes, *Continue to #826*

 \square No, *Continue to #826*

Continuation of Therapy

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

□ Yes, Continue to #827

 \square No, *Continue to #829*

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

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□ Yes, Continue to #829

 \square No, *Continue to #828*

□ Unknown, *Continue to #829*

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

Yes, No Further Questions
No, No Further Questions

Initial Therapy

Prior treatment with another biologic drug

829. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of pyoderma gangrenosum?

Yes, No Further Questions
No, Continue to #830

Requirements regarding prior therapy

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

Yes, No Further Questions
No. Continue to #831

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

Yes, No Further Questions
No, Continue to #832

832. Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)?

□ Yes, No Further Questions

□ No, *No Further Questions*

<u>Sarcoidosis</u>

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

□ Yes, Continue to #851

□ No, *Continue to #851*

Continuation of Therapy

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

□ Yes, Continue to #852

 \square No, *Continue to #854*

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

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□ Yes, Continue to #854

□ No, *Continue to #853*

Unknown, *Continue to #854*

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

Yes, No Further Questions
No, No Further Questions

Initial Therapy

Requirements regarding prior therapy

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

Yes, No Further Questions
No, Continue to #855

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

□ Yes, No Further Questions

 \square No, Continue to #856

856. Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, methotrexate)?

Yes, No Further QuestionsNo, No Further Questions

Takayasu's arteritis

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

□ Yes, *Continue to #875* □ No. *Continue to #875*

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

□ Yes, Continue to #876

□ No, *Continue to #876*

Continuation of Therapy

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

□ Yes, Continue to #877

D No, *Continue to #879*

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

□ Yes, Continue to #879

□ No, *Continue to #878*

□ Unknown, *Continue to #879*

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

Yes, No Further Questions
No, No Further Questions

<u>Initial Therapy</u>

Requirements regarding prior therapy

879. Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

Yes, No Further Questions
No. Continue to #880

880. Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

Yes, No Further Questions
No, Continue to #881

881. Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

Yes, No Further Questions
No, No Further Questions

<u>Uveitis</u>

900. Is the requested drug being prescribed by or in consultation with an ophthalmologist or rheumatologist? □ Yes, *Continue to #901*

□ No, *Continue to #901*

Continuation of Therapy

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

□ Yes, Continue to #902

□ No, *Continue to #905*

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

□ Yes, *Continue to #905*

□ No, *Continue to #903*

Unknown, *Continue to #905*

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

□ Yes, Continue to #904

 \square No, *Continue to #904*

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904. Which of the following has the patient experienced since starting treatment with the requested drug or a biosimilar?

□ Reduced frequency of recurrence compared to baseline, *No Further Questions*

□ Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline, *No Further Questions*

Decreased reliance on topical corticosteroids, No Further Questions

□ None of the above, *No Further Questions*

Initial Therapy

Prior treatment with another biologic drug

905. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of uveitis?

T Yes, *No Further Questions*

□ No, *Continue to #906*

Requirements regarding prior therapy

906. Has the patient experienced an inadequate response with corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

Yes, No Further Questions
No, Continue to #907

907. Has the patient experienced an intolerance to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

Yes, No Further Questions
No, Continue to #908

908. Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil)?

TYes, No Further Questions

□ No, No Further Questions

Reactive arthritis

Continuation of Therapy

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

□ Yes, *Continue to #926*

□ No, *Continue to #926*

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

□ Yes, Continue to #927

No, *Continue to #929*

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

□ Yes, *Continue to #929*

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□ No, Continue to #928

Unknown, *Continue to #929*

928. Has the patient achieved or maintained 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, or pain) since starting treatment with the requested drug or a biosimilar?

Yes, No Further Questions
No, No Further Questions

Initial Therapy

Prior treatment with another biologic drug

929. Has the patient ever received (including current utilizers) a biologic (e.g., Enbrel) indicated for the treatment of reactive arthritis?

Yes, No Further Questions
No, Continue to #930

Requirements regarding prior therapy

930. Has the patient experienced an inadequate response after at least 3 months of treatment with either of the following: a) sulfasalazine at a dose of 1000 mg twice daily or maximally tolerated dose, or b) methotrexate at a dose greater than or equal to 15 mg per week or maximally tolerated dose?

□ Yes, No Further Questions

□ No, *Continue to #931*

931. Has the patient experienced intolerance to sulfasalazine and methotrexate?

□ Yes, *No Further Questions*

□ No, *Continue to #932*

932. Does the patient have a contraindication to sulfasalazine (e.g., porphyria, intestinal or urinary obstruction)?

□ Yes, *Continue to #933*

 \square No, Continue to #933

933. Does the patient have a contraindication to methotrexate?

□ Yes, Continue to #934

□ No, No Further Questions

934. Please indicate the contraindication

History of intolerance or adverse event, No Further Questions

Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, *No Further Questions*

D Elevated liver transaminases, No Further Questions

Interstitial pneumonitis or clinically significant pulmonary fibrosis, *No Further Questions*

□ Renal impairment, *No Further Questions*

D Pregnancy or currently planning pregnancy, No Further Questions

D Breastfeeding, *No Further Questions*

Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), No Further Questions

D Myelodysplasia, No Further Questions

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Hypersensitivity, No Further Questions
 Significant drug interaction, No Further Questions
 Other, No Further Questions

Immune checkpoint inhibitor toxicity

950. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
Yes, *Continue to #951*No, *Continue to #951*

951. Has the patient experienced an inadequate response to corticosteroids?
□ Yes, No Further Questions
□ No, Continue to #952

952. Has the patient experienced an intolerance to corticosteroids?
□ Yes, No Further Questions
□ No, Continue to #953

953. Does the patient have a contraindication to corticosteroids?
□ Yes, No Further Questions
□ No, Continue to #954

954. Does the patient have moderate or severe diarrhea or colitis?
Yes, No Further Questions
No, No Further Questions

Immune checkpoint inhibitor toxicity – Inflammatory arthritis

960. Does the patient have severe disease?
□ Yes, *Continue to #961*□ No, *Continue to #961*

961. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
Yes, *Continue to #962*No, *Continue to #962*

962. Has the patient experienced an inadequate response to corticosteroids?
□ Yes, No Further Questions
□ No, Continue to #963

963. Has the patient experienced an intolerance or contraindication to corticosteroids?
Yes, No Further Questions
No, No Further Questions

Acute graft versus host disease

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

□ Yes, *Continue to #976*

□ No, Continue to #976

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976. Has the patient experienced an inadequate response to systemic corticosteroids?

□ Yes, No Further Questions

D No, *Continue to #977*

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

Tes, No Further Questions

□ No, No Further Questions

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

Х

Prescriber or Authorized Signature

Date (mm/dd/yy)

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