Actemra 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.

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

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

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 product is being requested?

❑ Actemra IV ❑ Actemra SC ❑ Tofidence
❑ Tyenne IV ❑ Tyenne SC
❑ Other _____

What is the ICD-10 code? _____

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

 CareFirst MR C26742-A Actemra and Biosimilars 1959-A SGM CFT SOC 5938-A – 01/2025.

Exception Criteria Questions:

A. The preferred products for your patient's health plan are Simponi Aria and Stelara. Can the patient's treatment be switched to one of the preferred products?

❒ Yes, Simponi Aria, *Please obtain Form for preferred product and submit for corresponding PA.*

❒ Yes, Stelara, *Please obtain Form for preferred product and submit for corresponding PA.*

❒ No, *Continue to Question B*

B. Is this request for continuation of therapy with the requested product?

❒ Yes, *Continue to Question C*

❒ No, *Continue to Question D*

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

❒ Yes, *Continue to Question D*

❒ No, *Skip to Site of Service Questions*

❒ Unknown, *Continue to Question D*

D. What is the diagnosis?
❒ Psoriatic Arthritis, *Continue to Question E*
❒ Rheumatoid arthritis, Ankylosing spondylitis, Polyarticular juvenile idiopathic arthritis, *Skip to Question F*
❒ Crohn's disease, Ulcerative colitis, Plaque psoriasis, *Skip to Question G*
❒ Other, *Skip to Site of Service Questions*

E. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to BOTH preferred products (Simponi aria and Stelara)? ***Action Required: If 'Yes', attach supporting chart note(s)***

❒ Yes, *Skip to Site of Service Questions*
❒ No, *Skip to Site of Service Questions*

F. Did the patient have a documented inadequate response, intolerable adverse event or contraindication to Simponi Aria*?* ***Action Required***: ***If 'Yes', attach supporting chart note(s)***
❒ Yes, *Skip to Site of Service Questions*
❒ No, *Skip to Site of Service Questions*

G. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Stelara? ***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 Clinical Criteria Questions*
- ❑ Home infusion, *skip to Clinical Criteria Questions*
- ❑ Off-campus Outpatient Hospital, *Continue to B*
- ❑ On-campus Outpatient Hospital, *Continue to B*
- ❑ Physician office, *skip to Clinical Criteria Questions*
- ❑ Pharmacy, *skip to Clinical Criteria Questions*

B. Is the patient less than 14 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to C*

C. Is this request to continue previously established treatment with the requested medication? ***ACTION REQUIRED: If No, please attach supporting clinical documentation.***
- ❑ Yes - This is a continuation of an existing treatment., *Continue to D*
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months)., *skip to Clinical 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, or other pre-medications) 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 Clinical Criteria Questions*
- ❑ No, *Continue to E*

E. 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 Clinical Criteria Questions*
- ❑ No, *Continue to F*

F. 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 Clinical Criteria Questions*
- ❑ No, *Continue to G*

G. 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 Clinical Criteria Questions*
- ❑ No, *Continue to H*

H. 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 Clinical Criteria Questions*
- ❑ No, *Continue to Clinical Criteria Questions*

Clinical Criteria Questions:

What product is being requested? ❑ Actemra ❑ Tofidence ❑ Tyenne

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)?
❒ 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 6 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 5*

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?
❒ Rheumatoid arthritis, *Continue to 7*
❒ Polyarticular juvenile idiopathic arthritis (pJIA), *Continue to 18*
❒ Oligoarticular juvenile idiopathic arthritis, *Continue to 18*
❒ Systemic juvenile idiopathic arthritis (sJIA), *Continue to 31*
❒ Giant cell arteritis, *Continue to 64*
❒ Systemic sclerosis-associated interstitial lung disease (SSc-ILD), *Continue to 80*
❒ Unicentric Castleman disease, *Continue to 40*
❒ Multicentric Castleman disease, *Continue to 50*
❒ Immune checkpoint inhibitor-related inflammatory arthritis, *Continue to 56*
❒ Cytokine release syndrome, *Continue to 72*
❒ Acute graft versus host disease, *Continue to 77*
❒ Polymyalgia rheumatica, *Continue to 85*
❒ Other, please specify. _____, *No Further Questions*

7. Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)?
❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Is the patient an adult (18 years of age or older)?
❒ Yes, *Continue to 9*
❒ No, *Continue to 9*

9. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to 10*
❒ No, *Continue to 10*

10. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 11*
❒ No, *Continue to 15*

11. 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 15*

❒ No, *Continue to 12*

❒ Unknown, *Continue to 15*

12. 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 13*
❒ No, *Continue to 14*

13. Has the patient experienced substantial disease activity improvement (e.g., at least 20% from baseline) in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive clinical response and substantial disease activity improvement.
❒ Yes, *Continue to 96*
❒ No, *Continue to 14*

14. 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 96*
❒ No, *Continue to 96*

15. 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 96*
❒ No, *Continue to 16*

16. 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 96*
❒ No, *Continue to 17*

17. Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ***ACTION REQUIRED***: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing.
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

18. Has the patient been diagnosed with active articular juvenile idiopathic arthritis?
❒ Yes, *Continue to 19*
❒ No, *Continue to 19*

19. Is the patient 2 years of age or older?
❒ Yes, *Continue to 20*
❒ No, *Continue to 20*

20. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

21. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 22*
❒ No, *Continue to 25*

22. 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 25*

❒ No, *Continue to 23*

❒ Unknown, *Continue to 25*

23. 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 24*
❒ No, *Continue to 24*

24. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED***: Please attach chart notes or medical record documentation supporting positive clinical response.
❒ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Number of joints with limitation of movement ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ Functional ability ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ None of the above, *Continue to 96*

25. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz) indicated for the treatment of active articular juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.
❒ Yes, *Continue to 96*
❒ No, *Continue to 26*

26. Has the patient had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
❒ Yes, *Continue to 96*
❒ No, *Continue to 27*

27. Has the patient had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
❒ Yes, *Continue to 28*
❒ No, *Continue to 29*

28. Does the patient have one of the following risk factors for poor outcome: a) involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ), b) presence of erosive disease or enthesitis, c) delay in diagnosis, d) elevated levels of inflammation markers, or e) symmetric disease?
❒ Yes, *Continue to 96*
❒ No, *Continue to 29*

29. Does the patient have any of the following risk factors for disease severity and potentially a more refractory disease course: a) positive rheumatoid factor, b) positive anti-cyclic citrullinated peptide antibodies, or c) pre-existing joint damage?
❒ Yes, *Continue to 30*
❒ No, *Continue to 30*

30. Does the patient meet any of the following: a) high-risk joints are involved (e.g., cervical spine, wrist, or hip), b) high disease activity, or c) high risk for disabling joint disease?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

31. Is the patient 2 years of age or older?
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

32. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to 33*
❒ No, *Continue to 33*

33. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 34*
❒ No, *Continue to 37*

34. 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 37*

❒ No, *Continue to 35*

❒ Unknown, *Continue to 37*

35. 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 36*
❒ No, *Continue to 36*

36. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED***: Please attach chart notes or medical record documentation supporting positive clinical response.
❒ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Number of joints with limitation of movement ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ Functional ability ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Systemic features (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ None of the above, *Continue to 96*

37. Has the patient been diagnosed with active systemic juvenile idiopathic arthritis (sJIA)?
❒ Yes, *Continue to 38*
❒ No, *Continue to 38*

38. Has the patient ever received or is currently receiving a biologic (e.g., Humira) indicated for the treatment of active systemic juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.
❒ Yes, *Continue to 96*
❒ No, *Continue to 39*

39. Does the patient have active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

40. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
❒ Yes, *Continue to 41*
❒ No, *Continue to 41*

41. Is this a request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 42*
❒ No, *Continue to 44*

42. 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 44*

❒ No, *Continue to 43*

❒ Unknown, *Continue to 44*

43. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

44. Has the patient been tested for human immunodeficiency virus (HIV)?
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

45. What were the results of the HIV test?

❒ Positive, *Continue to 46*

❒ Negative, *Continue to 46*

❒ Unknown, *Continue to 46*

46. Has the patient been tested for herpesvirus-8?
❒ Yes, *Continue to 47*
❒ No, *Continue to 47*

47. What were the results of the herpesvirus-8 test?

❒ Positive, *Continue to 48*

❒ Negative, *Continue to 48*

❒ Unknown, *Continue to 48*

48. Has the disease progressed following treatment of relapsed or refractory disease?
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

49. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

50. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
❒ Yes, *Continue to 51*
❒ No, *Continue to 51*

51. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 52*
❒ No, *Continue to 54*

52. 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 54*

❒ No, *Continue to 53*

❒ Unknown, *Continue to 54*

53. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

54. Has the disease progressed following treatment of relapsed/refractory or progressive disease?
❒ Yes, *Continue to 55*
❒ No, *Continue to 55*

55. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

56. Is the requested drug being prescribed by or in consultation with an oncologist, hematologist, or rheumatologist?
❒ Yes, *Continue to 57*
❒ No, *Continue to 57*

57. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 58*
❒ No, *Continue to 60*

58. 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 60*

❒ No, *Continue to 59*

❒ Unknown, *Continue to 60*

59. 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? ***ACTION REQUIRED***: Please attach chart notes or medical record documentation supporting positive clinical response.
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

60. Does the patient have severe immunotherapy-related inflammatory arthritis?
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

61. Has the patient had an inadequate response to corticosteroids or 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, including response to therapy.
❒ Yes, *Continue to 96*
❒ No, *Continue to 62*

62. 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 if not advisable, please attach documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 63*
❒ No, *Continue to 63*

63. 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 if not advisable, please attach documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

64. Is the patient an adult (18 years of age or older)?
❒ Yes, *Continue to 65*
❒ No, *Continue to 65*

65. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to 66*
❒ No, *Continue to 66*

66. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 67*
❒ No, *Continue to 70*

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

❒ Yesc *Continue to 70*

❒ No, *Continue to 68*

❒ Unknown, *Continue to 70*

68. 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 69*
❒ No, *Continue to 69*

69. 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.

❒ Headaches ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ Scalp tenderness ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Tenderness and/or thickening of superficial temporal arteries ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Jaw and/or tongue claudication ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ Limb claudication ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*
❒ None of the above, *Continue to 96*

70. Has the diagnosis been confirmed by temporal artery biopsy or cross-sectional imaging?
❒ Yes, *Continue to 96*
❒ No, *Continue to 71*

71. Has the diagnosis been confirmed by acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])?
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

72. Is the requested drug being prescribed by or in consultation with an oncologist or hematologist?
❒ Yes, *Continue to 73*
❒ No, *Continue to 73*

73. Has the patient been diagnosed with chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS)?
❒ Yes, *Continue to 74*
❒ No, *Continue to 75*

74. Is the patient 2 years of age or older?
❒ Yes, *Continue to 76*
❒ No, *Continue to 76*

75. Does the patient have refractory cytokine release syndrome (CRS) related to blinatumomab therapy?
ACTION REQUIRED: If Yes, please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
❒ Yes, *Continue to 76*
❒ No, *Continue to 76*

76. What is the route of administration?
❒ Intravenous, *No Further Questions*
❒ Subcutaneous, *No Further Questions*

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

❒ Yes, *Continue to 78*
❒ No, *Continue to 78*

78. Has the patient experienced an inadequate response to systemic corticosteroids? ***ACTION REQUIRED***: If Yes, please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
❒ Yes, *Continue to 96*
❒ No, *Continue to 79*

79. 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 if not advisable, please attach documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

80. Is the patient an adult (18 years of age or older)?
❒ Yes, *Continue to 81*
❒ No, *Continue to 81*

81. Is the requested drug being prescribed by or in consultation with a rheumatologist or pulmonologist?
❒ Yes, *Continue to 82*
❒ No, *Continue to 82*

82. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 83*
❒ No, *Continue to 84*

83. 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 84*

❒ No, *Continue to 96*

❒ Unknown, *Continue to 84*

84. Has the diagnosis been confirmed by a high-resolution computed tomography (HRCT) study of the chest? ***ACTION REQUIRED***: If Yes, please attach the radiology report.
❒ Yes, *Continue to 96*
❒ No, *Continue to 96*

85. Is the requested drug being prescribed by or in consultation with a rheumatologist?
❒ Yes, *Continue to 86*
❒ No, *Continue to 86*

86. Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug?
❒ Yes, *Continue to 87*
❒ No, *Continue to 90*

87. 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 90*

❒ No, *Continue to 88*

❒ Unknown, *Continue to 90*

88. 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 89*

❒ No, *Continue to 89*

89. 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.

❒ Morning stiffness ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ Hip or shoulder pain ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ Hip or shoulder range of motion ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 96*

❒ None of the above, *Continue to 96*

90. Has the patient experienced 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 96*

❒ No, *Continue to 91*

91. Has the patient experienced a disease flare during a taper with 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 96*

❒ No, *Continue to 92*

92. Has the patient experienced an inadequate response 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 96*

❒ No, *Continue to 93*

93. Does the patient have an intolerance or contraindication 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. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.

❒ Yes, *Continue to 94*

❒ No, *Continue to 94*

94. Does the patient have an intolerance or contraindication to methotrexate? ***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 attach documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 95*
❒ No, *Continue to 95*

95. Please indicate the contraindication to methotrexate.
❒ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 96*
❒ Drug interaction, *Continue to 96*
❒ Risk of treatment-related toxicity, *Continue to 96*
❒ Pregnancy or currently planning pregnancy, *Continue to 96*
❒ Breastfeeding, *Continue to 96*
❒ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 96*
❒ Hypersensitivity, *Continue to 96*
❒ History of intolerance or adverse event, *Continue to 96*
❒ Other, please specify. _____, *Continue to 96*

96. What is the diagnosis?
❒ Rheumatoid arthritis, *Continue to 97*
❒ Polyarticular juvenile idiopathic arthritis (pJIA), *Continue to 105*
❒ Oligoarticular juvenile idiopathic arthritis, *Continue to 105*
❒ Systemic juvenile idiopathic arthritis (sJIA), *Continue to 113*
❒ Giant cell arteritis, *Continue to 135*
❒ Systemic sclerosis-associated interstitial lung disease (SSc-ILD), *Continue to 143*
❒ Unicentric Castleman disease, *Continue to 121*
❒ Multicentric Castleman disease, *Continue to 121*
❒ Acute graft versus host disease, *Continue to 121*
❒ Immune checkpoint inhibitor-related inflammatory arthritis, *Continue to 126*
❒ Polymyalgia rheumatica, *Continue to 126*

97. What is the requested product?
❒ Actemra or Tyenne, *Continue to 98*
❒ Tofidence (IV only), *Continue to 99*

98. What is the route of administration?
❒ Intravenous, *Continue to 99*
❒ Subcutaneous, *Continue to 102*

99. Does the prescribed dose exceed 8 mg per kg?
❒ Yes, *Continue to 100*
❒ No, *Continue to 100*

100. Is the prescribed frequency more frequent than one dose every 4 weeks?
❒ Yes, *Continue to 101*
❒ No, *Continue to 101*

101. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tofidence, *No Further Questions*

❒ Tyenne, *No Further Questions*

102. Does the prescribed dose exceed 162 mg?
❒ Yes, *Continue to 103*
❒ No, *Continue to 103*

103. Is the prescribed frequency more frequent than one dose every week?
❒ Yes, *Continue to 104*
❒ No, *Continue to 104*

104. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tyenne, *No Further Questions*

105. What is the requested product?

❒ Actemra or Tyenne, *Continue to 106*

❒ Tofidence (IV only), *Continue to 107*

106. What is the route of administration?

❒ Intravenous, *Continue to 107*

❒ Subcutaneous, *Continue to 110*

107. Does the prescribed dose exceed 10 mg per kg?
❒ Yes, *Continue to 108*
❒ No, *Continue to 108*

108. Is the prescribed frequency more frequent than one dose every 4 weeks?
❒ Yes, *Continue to 109*
❒ No, *Continue to 109*

109. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tofidence, *No Further Questions*

❒ Tyenne, *No Further Questions*

110. Does the prescribed dose exceed 162 mg?
❒ Yes, *Continue to 111*
❒ No, *Continue to 111*

111. Is the prescribed frequency more frequent than one dose every 2 weeks?
❒ Yes, *Continue to 112*
❒ No, *Continue to 112*

112. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tyenne, *No Further Questions*

113. What is the requested product?

❒ Actemra or Tyenne, *Continue to 114*

❒ Tofidence (IV only), *Continue to 115*

114. What is the route of administration?

❒ Intravenous, *Continue to 115*

❒ Subcutaneous, *Continue to 118*

115. Does the prescribed dose exceed 12 mg per kg?
❒ Yes, *Continue to 116*
❒ No, *Continue to 116*

116. Is the prescribed frequency more frequent than one dose every 2 weeks?
❒ Yes, *Continue to 117*
❒ No, *Continue to 117*

117. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tofidence, *No Further Questions*

❒ Tyenne, *No Further Questions*

118. Does the prescribed dose exceed 162 mg?
❒ Yes, *Continue to 119*
❒ No, *Continue to 119*

119. Is the prescribed frequency more frequent than one dose every week?
❒ Yes, *Continue to 120*
❒ No, *Continue to 120*

120. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tyenne, *No Further Questions*

121. 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 122*
❒ No, *Continue to 122*

122. What is the route of administration?

❒ Intravenous, *Continue to 123*

❒ Subcutaneous, *Continue to 123*

123. Does the prescribed dose exceed 8 mg per kg?
❒ Yes, *Continue to 124*
❒ No, *Continue to 124*

124. Is the prescribed frequency more frequent than one dose every 2 weeks?
❒ Yes, *Continue to 125*
❒ No, *Continue to 125*

125. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tofidence, *No Further Questions*

❒ Tyenne, *No Further Questions*
126. 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 127*
❒ No, *Continue to 127*

127. What is the requested product?

❒ Actemra or Tyenne, *Continue to 128*

❒ Tofidence (IV only), *Continue to 132*

128. What is the route of administration?

❒ Intravenous, *Continue to 132*

❒ Subcutaneous, *Continue to 129*

129. Does the prescribed dose exceed 162 mg?
❒ Yes, *Continue to 130*
❒ No, *Continue to 130*

130. Is the prescribed frequency more frequent than one dose every week?
❒ Yes, *Continue to 131*
❒ No, *Continue to 131*

131. What is the requested product?

❒ Actemra, *No Further Questions*

❒ Tyenne, *No Further Questions*

132. Does the prescribed dose exceed 8 mg per kg?
❒ Yes, *Continue to 133*
❒ No, *Continue to 133*

133. Is the prescribed frequency more frequent than one dose every 4 weeks?
❒ Yes, *Continue to 134*
❒ No, *Continue to 134*

134. What is the requested product?
❒ Actemra, *No Further Questions*
❒ Tofidence, *No Further Questions*
❒ Tyenne, *No Further Questions*
135. What is the requested product?
❒ Actemra or Tyenne, *Continue to 136*
❒ Tofidence (IV only), *Continue to 137*
136. What is the route of administration?
❒ Intravenous, *Continue to 137*
❒ Subcutaneous, *Continue to 140*
137. Does the prescribed dose exceed 6 mg per kg?
❒ Yes, *Continue to 138*
❒ No, *Continue to 138*

138. Is the prescribed frequency more frequent than one dose every 4 weeks?
❒ Yes, *Continue to 139*
❒ No, *Continue to 139*

139. What is the requested product?
❒ Actemra, *No Further Questions*
❒ Tofidence, *No Further Questions*
❒ Tyenne, *No Further Questions*
140. Does the prescribed dose exceed 162 mg?
❒ Yes, *Continue to 141*
❒ No, *Continue to 141*

141. Is the prescribed frequency more frequent than one dose every week?
❒ Yes, *Continue to 142*
❒ No, *Continue to 142*

142. What is the requested product?
❒ Actemra, *No Further Questions*
❒ Tyenne, *No Further Questions*
143. What is the requested product?
❒ Actemra or Tyenne, *Continue to 144*
❒ Tofidence, *Continue to 144*

144. What is the route of administration?

❒ Intravenous, *Continue to 145*

❒ Subcutaneous, *Continue to 145*

145. Does the prescribed dose exceed 162 mg?
❒ Yes, *Continue to 146*
❒ No, *Continue to 146*

146. Is the prescribed frequency more frequent than one dose every week?
❒ Yes, *Continue to 147*
❒ No, *Continue to 147*

147. What is the requested product?

❒ Actemra, *No Further Questions*
❒ Tyenne, *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	
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)**

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