Actemra

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*

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

 CareFirst MR SOC Actemra SGM – 06/2021.

Exception 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
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis

❑ Yes ❑ No *If No, skip to Site of Service Questions*

B. These are the preferred products for which coverage is provided for treatment of the following indications:
- Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis: **Remicade and Simponi Aria**
- Plaque psoriasis: **Ilumya and Remicade**
- Crohn's disease, ulcerative colitis: **Entyvio and Remicade**
- **Stelara IV** is indicated for a one time induction dose for Crohn's disease and ulcerative colitis.

Can the patient's treatment be switched to a preferred product?
❑ Yes, *Please obtain Form for preferred product and submit for corresponding PA*.
❑ No

If diagnosis is Plaque psoriasis, skip to Question K

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

E. What is the diagnosis?
❑ Ankylosing spondylitis
❑ Crohn's disease, *skip to Question H*
❑ Psoriatic arthritis
❑ Rheumatoid arthritis
❑ Ulcerative colitis, *skip to Question H*
❑ Other, *skip to Site of Service Questions*

F. Does the patient have a documented inadequate response or intolerable adverse event to both of the preferred products (Remicade, Simponi Aria)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes, *skip to Site of Service Questions* ❑ No

G. Does the patient have one of the following documented clinical reasons to avoid the preferred products that are TNF inhibitors (Remicade, Simponi Aria)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Not applicable – Requested medical is a TNF inhibitor *skip to Site of Service Questions*
❑ Yes – History of demyelinating disorder, *skip to Site of Service Questions*
❑ Yes – History of congestive heart failure *skip to Site of Service Questions*
❑ Yes – History of hepatitis B virus infection *skip to Site of Service Questions*
❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor) *skip to Site of Service Questions*
❑ Yes – Risk of lymphoma *skip to Site of Service Questions*
❑ No – None of the above *skip to Site of Service Questions*

H. Does the patient have a documented inadequate response or intolerable adverse event to both of the preferred products (Entyvio, Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** *If Yes, skip to Site of Service Questions* ❑ Yes ❑ No

I. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
- ❑ Not applicable – requested medication is a TNF inhibitor
- ❑ Yes – History of demyelinating disorder
- ❑ Yes – History of congestive heart failure
- ❑ Yes – History of hepatitis B virus infection
- ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
- ❑ Yes – Risk of lymphoma
- ❑ No- None of the above

J. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product that is not a TNF inhibitor (Entyvio)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
❑ Yes ❑ No *For yes or no, skip to Site of Service Questions*

K. Does the patient have a documented inadequate response or intolerable adverse event to the preferred products indicated for plaque psoriasis (Ilumya, Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
**If Yes, skip to Site of Service Questions* ❑ Yes ❑ No

L. Does the patient have one of the following documented clinical reasons to avoid the preferred product that is a TNF inhibitor (Remicade)? **Action Required:** ***If 'Yes', attach supporting chart note(s).***
- ❑ Not applicable – requested medication is a TNF inhibitor
- ❑ Yes – History of demyelinating disorder
- ❑ Yes – History of congestive heart failure
- ❑ Yes – History of hepatitis B virus infection
- ❑ Yes – Autoantibody formation/lupus-like syndrome (attributed to TNF inhibitor)
- ❑ Yes – Risk of lymphoma
- ❑ No- None of the above

M. Does the patient have a documented inadequate response or intolerable adverse event to the preferred product that is not a TNF inhibitor (Ilumya)? **Action Required:** ***If 'Yes', attach supporting chart note(s).*** ❑ Yes ❑ No

Site of Service Questions:

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Questions*
- ❑ Off-campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ On-campus Outpatient Hospital
- ❑ Pharmacy, *skip to Clinical Questions*

B. Is the patient less than 21 years old or 65 years of age or older?
- ❑ Yes – less than 21 years old, *skip to Clinical Criteria Questions*
- ❑ Yes – age 65 years or older, *skip to Clinical Criteria Questions*
- ❑ No

C. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes, this is a continuation of an existing treatment
- ❑ 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 have not responded to conventional interventions (e.g. 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: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

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: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Does the patient have severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

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: Attach supporting clinical documentation.*** *Indicate and continue to Clinical Criteria Questions* ❑ Yes ❑ No

Clinical Criteria Questions:

1. Has the patient been diagnosed with any of the following?
   ❑ Moderately to severely active rheumatoid arthritis (RA)
   ❑ Active polyarticular juvenile idiopathic arthritis (pJIA)
   ❑ Active oligoarticular juvenile idiopathic arthritis
   ❑ Active systemic juvenile idiopathic arthritis (sJIA)
   ❑ Giant cell arteritis
   ❑ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
   ❑ Unicentric Castleman's disease
   ❑ Multicentric Castleman's disease
   ❑ Immunotherapy-related inflammatory arthritis
   ❑ Cytokine release syndrome
   ❑ Acute graft versus host disease
   ❑ Other _____
2. What is the ICD-10 code? _____
3. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic disease-modifying antirheumatic drug (DMARD) (e.g., Olumiant, Otezla, Xeljanz)? ❑ Yes ❑ No
4. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis (TB)? *If Yes, skip to #6* ❑ Yes ❑ No
5. Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [PPD], interferon-release assay [IGRA], chest x-ray) within 6 months of initiating therapy? ❑ Yes ❑ No *Skip to #8*
6. Does the patient have risk factors for tuberculosis (TB) (e.g., persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB [e.g., Africa, Asia, Eastern Europe, Latin America, Russia]; children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission [e.g., homeless persons, injection drug users, persons with HIV infection], or persons who work or reside with people who are at an increased risk for active TB [e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters])? ❑ Yes ❑ No *If No, skip to Section A.*
7. Has the patient been tested for tuberculosis (TB) within the previous 12 months? ❑ Yes ❑ No
8. What were the results of the tuberculosis (TB) test?
   ❑ Positive for TB ❑ Negative for TB, *skip to Section A* ❑ Unknown
9. Does the patient have latent or active tuberculosis (TB)? ❑ Latent ❑ Active ❑ Unknown
10. Has treatment for latent tuberculosis (TB) infection been initiated or completed?
    ❑ Yes - treatment initiated
    ❑ Yes - treatment completed
    ❑ No

Section A: Requests for Unicentric or Multicentric Castleman's Disease

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

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

13. Is there evidence of unacceptable toxicity or disease progression on the current regimen? ❑ Yes ❑ No

14. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

15. What is the route of administration? ❑ Intravenous ❑ Subcutaneous

16. Does the prescribed dose exceed 8 mg per kg? ❑ Yes ❑ No

17. Is the prescribed frequency more frequent than one dose every 2 weeks? ❑ Yes ❑ No

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

Section B: Rheumatoid Arthritis

18. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #40*

19. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #40.* ❑ Yes ❑ No ❑ Unknown

20. What is the route of administration? ❑ Intravenous ❑ Subcutaneous, *skip to #31*

21. Does the prescribed dose exceed 4 mg per kg? *If Yes, skip to #25* ❑ Yes ❑ No

22. Is the prescribed frequency more frequent than one dose every 4 weeks? ❑ Yes ❑ No

23. Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug? ❑ Yes ❑ No

24. What is the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*** _____% *No further questions*

25. Is the prescribed frequency more frequent than one dose every 4 weeks? ❑ Yes ❑ No

26. Does the prescribed dose exceed 8 mg per kg? ❑ Yes ❑ No

27. Please select the situation that applies to the patient.
    ❑ Patient is continuing therapy on current dose
    ❑ Prescriber is increasing dose *Skip to #30*
    ❑ Prescriber is decreasing dose

28. Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug? ❑ Yes ❑ No

29. What is the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*** _____% *No further questions*

30. Does the patient require an increased dose due to lack of clinical response at the current dose? ❑ Yes ❑ No *No further questions*

31. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

32. What is the patient's weight? _____ kg *If greater than or equal to 100 kg, skip to #37*

33. Is the prescribed frequency more frequent than one dose EVERY OTHER WEEK? ❑ Yes ❑ No *If No, skip to #38*

34. Please select the situation that applies to the patient.
    ❑ Patient is continuing therapy at current frequency *Skip to #37*
    ❑ Prescriber is increasing dosing frequency

35. Does the patient require an increased dosing frequency due to lack of clinical response? ❑ Yes ❑ No

36. Is the prescribed frequency more frequent than one dose EVERY WEEK? ❑ Yes ❑ No *No further questions*

37. Is the prescribed frequency more frequent than one dose EVERY WEEK? ❑ Yes ❑ No

38. Has the patient achieved or maintained positive clinical response since starting treatment with the requested drug? ❑ Yes ❑ No

39. What is the percent of disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*** _____% *No further questions*

40. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic DMARD (e.g., Xeljanz) that is indicated for moderately to severely active rheumatoid arthritis? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried and skip to #51.*** ❑ Yes ❑ No

41. Does the patient meet BOTH of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker AND b) the RF biomarker test was positive? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #48*** ❑ Yes ❑ No

42. Does the patient meet BOTH of the following: a) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker AND b) the anti-CCP biomarker test was positive? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing and skip to #48*** ❑ Yes ❑ No

43. Has the patient been tested for the rheumatoid factor (RF) biomarker? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

44. Has the patient been tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

45. Has the patient been tested for the C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) biomarker(s)? ***ACTION REQUIRED: If 'Yes', please attach laboratory results, chart notes, or medical record documentation of biomarker testing.*** ❑ Yes ❑ No

46. Please indicate if the patient tested positive or negative for the C-reactive protein (CRP) biomarker, or if the test was not completed. ❑ Positive for CRP ❑ Negative for CRP ❑ Test for CRP was not completed

47. Please indicate if the patient tested positive or negative for the erythrocyte sedimentation rate (ESR) biomarker, or if the test was not completed. ❑ Positive for ESR ❑ Negative for ESR ❑ Test for ESR was not completed

48. Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 20 mg per week? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #51*** ❑ Yes ❑ No

49. Has the patient experienced an intolerance to methotrexate? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #51*** ❑ Yes ❑ No

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

51. What is the route of administration?
❑ Intravenous ❑ Subcutaneous, *skip to #54*

52. Does the prescribed dose exceed 4 mg per kg? ❑ Yes ❑ No

53. Is the prescribed frequency more frequent than one dose every 4 weeks? ❑ Yes ❑ No *No further questions*

54. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

55. What is the patient's weight? _____ kg *If greater than or equal to 100 kg, skip to #57*

56. Is the prescribed frequency more frequent than one dose every other week? ❑ Yes ❑ No *No further questions*

57. Is the prescribed frequency more frequent than one dose every week? ❑ Yes ❑ No

Section C: Polyarticular and Oligoarticular Juvenile Idiopathic Arthritis

58. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #62*

59. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #62.* ❑ Yes ❑ No ❑ Unknown

60. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug?
❑ Yes ❑ No

61. 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), *skip to #66*
❑ Number of joints with limitation of movement, *skip to #66*
❑ Functional ability, *skip to #66*
❑ None of the above

62. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease-modifying antirheumatic drug (DMARD) indicated for active articular juvenile idiopathic arthritis? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried and skip to #66.*** ❑ Yes ❑ No

63. Has the patient had an inadequate response to methotrexate or another non-biologic DMARD administered at an adequate dose and duration? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and skip to #66.*** ❑ Yes ❑ No

64. Does the patient have any of the following risk factors?
❑ Positive rheumatoid factor ❑ Positive anti-cyclic citrullinated peptide antibodies
❑ Pre-existing joint damage ❑ None of the above

65. Does the patient meet any of the following?
❑ High-risk joints are involved (e.g., cervical spine, wrist, or hip) ❑ High disease activity
❑ High risk for disabling joint disease ❑ None of the above

66. What is the route of administration? ❑ Intravenous ❑ Subcutaneous, *skip to #71*

67. Is the prescribed frequency more frequent than one dose every 4 weeks? ❑ Yes ❑ No

68. What is the patient's weight? _____ kg, *If greater than or equal to 30 kg, skip to #70*

69. Does the prescribed dose exceed 10 mg per kg? ❑ Yes ❑ No *No further questions*

70. Does the prescribed dose exceed 8 mg per kg? ❑ Yes ❑ No *No further questions*

71. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

72. What is the patient's weight? _____ kg *If greater than or equal to 30 kg, skip to #74*

73. Is the prescribed frequency more frequent than one dose every 3 weeks? ❑ Yes ❑ No *No further questions*

74. Is the prescribed frequency more frequent than one dose every 2 weeks? ❑ Yes ❑ No

Section D: Systemic Juvenile Idiopathic Arthritis (sJIA)

75. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #79*

76. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #79* ❑ Yes ❑ No ❑ Unknown

77. Has the patient achieved or maintained positive clinical response evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? ❑ Yes ❑ No

78. 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), *skip to #81*
    - ❑ Number of joints with limitation of movement, *skip to #81*
    - ❑ Functional ability, *skip to #81*
    - ❑ Systemic symptoms (e.g., fevers, evanescent skin rashes), *skip to #81*
    - ❑ None of the above

79. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for active systemic juvenile idiopathic arthritis? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried and skip to #81*** ❑ Yes ❑ No

80. Has the patient experienced an inadequate response to ANY of the following? *If Yes, please indicate.* ***ACTION REQUIRED: If 'Yes', please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.***
    - ❑ Yes - At least 1 month trial of NSAIDs
    - ❑ Yes - At least 2 weeks of treatment with corticosteroids
    - ❑ Yes - At least 3 months of treatment with methotrexate
    - ❑ Yes - At least 3 months of treatment with leflunomide
    - ❑ No - No history of an inadequate response to any of the above

81. What is the route of administration? ❑ Intravenous ❑ Subcutaneous, *skip to #86*

82. Is the prescribed frequency more frequent than one dose every 2 weeks? ❑ Yes ❑ No

83. What is the patient's weight? _____ kg, *If greater than or equal to 30 kg, skip to #85*

84. Does the prescribed dose exceed 12 mg per kg? ❑ Yes ❑ No *No further questions*

85. Does the prescribed dose exceed 8 mg per kg? ❑ Yes ❑ No *No further questions*

86. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

87. What is the patient's weight? _____ kg *If greater than or equal to 30 kg, skip to #89*

88. Is the prescribed frequency more frequent than one dose every 2 weeks?
    ❑ Yes ❑ No *No further questions*

89. Is the prescribed frequency more frequent than one dose every week? ❑ Yes ❑ No

Section E: Unicentric Castleman's Disease

90. Has the patient been tested for human immunodeficiency virus (HIV) ❑ Yes ❑ No

91. What were the results of the HIV test? ❑ Positive ❑ Negative ❑ Unknown

92. Has the patient been tested for herpesvirus-8? ❑ Yes ❑ No

93. What were the results of the herpesvirus-8 test? ❑ Positive ❑ Negative ❑ Unknown

94. Is the disease relapsed or refractory? ❑ Yes ❑ No

95. Will the requested drug be used as second-line therapy? ❑ Yes ❑ No

96. Will the requested drug be used as monotherapy? *If Yes, go back to #14* ❑ Yes ❑ No

Section F: Multicentric Castleman's Disease

97. Is the disease relapsed/refractory or progressive? ❑ Yes ❑ No

98. Will the requested drug be used as second-line therapy? ❑ Yes ❑ No

99. Will the requested drug be used as monotherapy? *If Yes, go back to #14* ❑ Yes ❑ No

Section G: Immunotherapy-Related Inflammatory Arthritis

100. Is the disease severe or refractory? ❑ Yes ❑ No

101. Has the patient tried and not responded to corticosteroids and anti-inflammatory agents? ***ACTION REQUIRED: If 'Yes', please also attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.*** ❑ Yes ❑ No

102. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

103. What is the route of administration? ❑ Intravenous ❑ Subcutaneous

104. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

105. Is the prescribed frequency more frequent than one dose every week? ❑ Yes ❑ No

Section H: Giant Cell Arteritis

106. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #110*

107. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #110* ❑ Yes ❑ No ❑ Unknown

108. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? ❑ Yes ❑ No

109. 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.*** *For any answer except None of the above, check the corresponding box and skip to #112*

❑ Headaches ❑ Scalp tenderness
❑ Jaw and/or tongue claudication ❑ Limb claudication
❑ Tenderness and/or thickening of superficial temporal arteries
❑ Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
❑ Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
❑ Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
❑ None of the above

110. Has the diagnosis been confirmed by temporal artery biopsy or cross-sectional imaging? *If Yes, skip to #112* ❑ Yes ❑ No

111. 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 ❑ No

112. What is the route of administration? ❑ Intravenous ❑ Subcutaneous

113. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

114. Is the prescribed frequency more frequent than one dose every week? ❑ Yes ❑ No

Section I: Cytokine Release Syndrome

115. Has the patient been diagnosed with chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS)? *If Yes, no further questions* ❑ Yes ❑ No

116. 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 ❑ No

Section J: Acute Graft versus Host Disease

117. 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 and skip to #119*** ❑ Yes ❑ No

118. 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, including response to therapy. If therapy is if not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

119. Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? ❑ Yes ❑ No

120. What is the route of administration? ❑ Intravenous ❑ Subcutaneous

121. Does the prescribed dose exceed 8 mg per kg? ❑ Yes ❑ No

122. Is the prescribed frequency more frequent than one dose every 2 weeks? ❑ Yes ❑ No

Section K:Systemic Sclerosis-Associated Interstitial Lung Disease

123. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to #125*

124. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No *If No, skip to #126* ❑ Unknown

125. 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 ❑ No

126. What is the route of administration? ❑ Intravenous ❑ Subcutaneous

127. Does the prescribed dose exceed 162 mg? ❑ Yes ❑ No

128. Is the prescribed frequency more frequent than one dose every week? ❑ Yes ❑ No

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