



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.

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

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

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Exception Criteria Questions:

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

- ☐ Yes, Entyvio, *Please obtain Form for preferred product and submit for corresponding PA*
- ☐ Yes, Simponi Aria, *Please obtain Form for preferred product and submit for corresponding PA*
- ☐ Yes, Skyrizi, *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*
- ☐ Plaque Psoriasis, *Continue to Question F*
- ☐ Rheumatoid arthritis, Ankylosing spondylitis, Polyarticular juvenile idiopathic arthritis, *Skip to Question G*
- ☐ Crohn's disease, Ulcerative colitis, *Skip to Question H*
- ☐ Other, *Skip to Site of Service Questions*

E. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Simponi aria, Skyrizi 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 Skyrizi 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*

G. 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*

H. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to Entyvio, Skyrizi and Stelara? **Action Required: If 'Yes', attach supporting chart note(s)**

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

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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 (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: 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*

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Criteria Questions:

What product is being requested? ☐ Actemra ☐ Avtozma ☐ 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 12 months of initiating therapy?

- ☐ Yes, *Continue to 4*
☐ No, *Continue to 4*

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

- ☐ Positive for TB, *Continue to 5*
☐ Negative for TB, *Continue to 6*
☐ Unknown, *Continue to 6*

5. Which of the following applies to the patient?

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

6. What is the diagnosis?

- ☐ 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 68*
☐ Systemic sclerosis-associated interstitial lung disease (SSc-ILD), *Continue to 82*
☐ Unicentric Castleman disease, *Continue to 40*
☐ Multicentric Castleman disease, *Continue to 50*
☐ Immune checkpoint inhibitor-related toxicity, *Continue to 57*
☐ Immune checkpoint inhibitor-related inflammatory arthritis, *Continue to 60*
☐ Cytokine release syndrome, *Continue to 76*
☐ Acute graft versus host disease, *Continue to 79*
☐ Polymyalgia rheumatica, *Continue to 87*
☐ 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*

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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 98*
☐ 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 98*
☐ No, *Continue to 98*

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 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 98*
☐ 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 98*
☐ 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)?

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ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing.

☐ Yes, *Continue to 98*

☐ No, *Continue to 98*

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 98*

☐ Number of joints with limitation of movement **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ Functional ability **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ None of the above, *Continue to 98*

25. Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz) indicated for 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 98*

☐ 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?

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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 98*

☐ 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 98*

☐ 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 98*

☐ No, *Continue to 98*

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?

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- ☐ 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 98*
☐ Number of joints with limitation of movement **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*
☐ Functional ability **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*
☐ Systemic features (e.g., fevers, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*
☐ None of the above, *Continue to 98*

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 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 98*
☐ No, *Continue to 39*

39. Does the patient have active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)?

- ☐ Yes, *Continue to 98*
☐ No, *Continue to 98*

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 98*
☐ No, *Continue to 98*

44. Has the patient been tested for human immunodeficiency virus (HIV)?

- ☐ Yes, *Continue to 45*
☐ No, *Continue to 45*

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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 or is the disease surgically unresectable?

- ☐ Yes, *Continue to 49*
- ☐ No, *Continue to 49*

49. Will the requested drug be used as a single agent?

- ☐ Yes, *Continue to 98*
- ☐ No, *Continue to 98*

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 98*
- ☐ No, *Continue to 98*

54. Is the requested drug being used as a substitute for siltuximab when there is a shortage of siltuximab or it is not available?

- ☐ Yes, *Continue to 98*
- ☐ No, *Continue to 55*

55. Has the disease progressed following treatment of relapsed/refractory or progressive disease?

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

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56. Will the requested drug be used as a single agent?

- ☐ Yes, *Continue to 98*
☐ No, *Continue to 98*

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

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

58. Has the patient had an inadequate response or intolerance 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 98*
☐ No, *Continue to 59*

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

- ☐ Yes, *Continue to 98*
☐ No, *Continue to 98*

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

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

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

- ☐ Yes, *Continue to 62*
☐ No, *Continue to 64*

62. 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 64*
☐ No, *Continue to 63*
☐ Unknown, *Continue to 64*

63. 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 98*
☐ No, *Continue to 98*

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

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

65. 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 98*
☐ No, *Continue to 66*

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66. 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 67*

☐ No, *Continue to 67*

67. 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 98*

☐ No, *Continue to 98*

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

☐ Yes, *Continue to 69*

☐ No, *Continue to 69*

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

☐ Yes, *Continue to 70*

☐ No, *Continue to 70*

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

☐ Yes, *Continue to 71*

☐ No, *Continue to 74*

71. 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 74*

☐ No, *Continue to 72*

☐ Unknown, *Continue to 74*

72. 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 73*

☐ No, *Continue to 73*

73. 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 98*

☐ Scalp tenderness **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ Tenderness and/or thickening of superficial temporal arteries **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ Jaw and/or tongue claudication **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

☐ Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 98*

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- ☐ Limb claudication **ACTION REQUIRED:** Submit supporting documentation, Continue to 98
☐ None of the above, Continue to 98

74. Has the diagnosis been confirmed by temporal artery biopsy or cross-sectional imaging?

- ☐ Yes, Continue to 98
☐ No, Continue to 75

75. 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 98
☐ No, Continue to 98

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

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

77. Is the requested drug being prescribed for prophylaxis or treatment of cytokine release syndrome (CRS)?

- ☐ Yes, Continue to 78
☐ No, Continue to 78

78. What is the route of administration?

- ☐ Intravenous, No further questions
☐ Subcutaneous, No further questions

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

- ☐ Yes, Continue to 80
☐ No, Continue to 80

80. 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 98
☐ No, Continue to 81

81. 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 98
☐ No, Continue to 98

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

- ☐ Yes, Continue to 83
☐ No, Continue to 83

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

- ☐ Yes, Continue to 84
☐ No, Continue to 84

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

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- ☐ Yes, *Continue to 85*
☐ No, *Continue to 86*

85. 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 86*
☐ No, *Continue to 98*
☐ Unknown, *Continue to 86*

86. 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 98*
☐ No, *Continue to 98*

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

- ☐ Yes, *Continue to 88*
☐ No, *Continue to 88*

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

- ☐ Yes, *Continue to 89*
☐ No, *Continue to 92*

89. 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 92*
☐ No, *Continue to 90*
☐ Unknown, *Continue to 92*

90. 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 91*
☐ No, *Continue to 91*

91. 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 98*
☐ Hip or shoulder pain **ACTION REQUIRED:** Submit supporting documentation, *Continue to 98*
☐ Hip or shoulder range of motion **ACTION REQUIRED:** Submit supporting documentation, *Continue to 98*
☐ C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 98*
☐ None of the above, *Continue to 98*

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

- ☐ Yes, *Continue to 98*
☐ No, *Continue to 93*

93. Has the patient had 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,

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including response to therapy.

- ☐ Yes, *Continue to 98*
- ☐ No, *Continue to 94*

94. Has the patient had 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 98*
- ☐ No, *Continue to 95*

95. 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 96*
- ☐ No, *Continue to 96*

96. 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 97*
- ☐ No, *Continue to 97*

97. Please indicate the contraindication to methotrexate.

- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, *Continue to 98*
- ☐ Drug interaction, *Continue to 98*
- ☐ Risk of treatment-related toxicity, *Continue to 98*
- ☐ Pregnancy or currently planning pregnancy, *Continue to 98*
- ☐ Breastfeeding, *Continue to 98*
- ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension), *Continue to 98*
- ☐ Hypersensitivity, *Continue to 98*
- ☐ History of intolerance or adverse event, *Continue to 98*
- ☐ Other, please specify. _____, *Continue to 98*

98. What is the diagnosis?

- ☐ Rheumatoid arthritis, *Continue to 99*
- ☐ Polyarticular juvenile idiopathic arthritis (pJIA), *Continue to 107*
- ☐ Oligoarticular juvenile idiopathic arthritis, *Continue to 107*
- ☐ Systemic juvenile idiopathic arthritis (sJIA), *Continue to 115*
- ☐ Giant cell arteritis, *Continue to 146*
- ☐ Systemic sclerosis-associated interstitial lung disease (SSc-ILD), *Continue to 154*
- ☐ Unicentric Castleman disease, *Continue to 123*
- ☐ Multicentric Castleman disease, *Continue to 123*
- ☐ Acute graft versus host disease, *Continue to 123*
- ☐ Immune checkpoint inhibitor-related toxicity, *Continue to 128*
- ☐ Immune checkpoint inhibitor-related inflammatory arthritis, *Continue to 137*
- ☐ Polymyalgia rheumatica, *Continue to 137*

99. What is the requested product?

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- ☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tyenne, *Continue to 100*
☐ Tofidence (IV only), *Continue to 101*

100. What is the route of administration?

- ☐ Intravenous, *Continue to 101*
☐ Subcutaneous, *Continue to 104*

101. Does the prescribed dose exceed 8 mg per kg?

- ☐ Yes, *Continue to 102*
☐ No, *Continue to 102*

102. Is the prescribed frequency more frequent than one dose every 4 weeks?

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

103. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tofidence, *No further questions*
☐ Tyenne, *No further questions*

104. Does the prescribed dose exceed 162 mg?

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

105. Is the prescribed frequency more frequent than one dose every week?

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

106. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tyenne, *No further questions*

107. What is the requested product?

- ☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tyenne, *Continue to 108*
☐ Tofidence (IV only), *Continue to 109*

108. What is the route of administration?

- ☐ Intravenous, *Continue to 109*
☐ Subcutaneous, *Continue to 112*

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

- ☐ Yes, *Continue to 110*
☐ No, *Continue to 110*

110. Is the prescribed frequency more frequent than one dose every 4 weeks?

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

111. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tofidence, *No further questions*
☐ Tyenne, *No further questions*

112. Does the prescribed dose exceed 162 mg?

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

113. Is the prescribed frequency more frequent than one dose every 2 weeks?

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

114. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tyenne, *No further questions*

115. What is the requested product?

- ☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tyenne, *Continue to 116*
☐ Tofidence (IV only), *Continue to 117*

116. What is the route of administration?

- ☐ Intravenous, *Continue to 117*
☐ Subcutaneous, *Continue to 120*

117. Does the prescribed dose exceed 12 mg per kg?

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

118. Is the prescribed frequency more frequent than one dose every 2 weeks?

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

119. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tofidence, *No further questions*
☐ Tyenne, *No further questions*

120. Does the prescribed dose exceed 162 mg?

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- ☐ Yes, *Continue to 121*
☐ No, *Continue to 121*

121. Is the prescribed frequency more frequent than one dose every week?

- ☐ Yes, *Continue to 122*
☐ No, *Continue to 122*

122. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tyenne, *No further questions*

123. 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 124*
☐ No, *Continue to 124*

124. What is the route of administration?

- ☐ Intravenous, *Continue to 125*
☐ Subcutaneous, *Continue to 125*

125. Does the prescribed dose exceed 8 mg per kg?

- ☐ Yes, *Continue to 126*
☐ No, *Continue to 126*

126. Is the prescribed frequency more frequent than one dose every 2 weeks?

- ☐ Yes, *Continue to 127*
☐ No, *Continue to 127*

127. What is the requested product?

- ☐ Actemra, *No further questions*
☐ Avtozma, *No further questions*
☐ tocilizumab-aazg, *No further questions*
☐ tocilizumab-anoh, *No further questions*
☐ Tofidence, *No further questions*
☐ Tyenne, *No further questions*

128. 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 129*
☐ No, *Continue to 129*

129. What is the requested product?

- ☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tyenne, *Continue to 130*
☐ Tofidence (IV only), *Continue to 134*

130. What is the route of administration?

- ☐ Intravenous, *Continue to 134*
☐ Subcutaneous, *Continue to 131*

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131. Does the prescribed dose exceed 162 mg?

- ☐ Yes, *Continue to 132*
- ☐ No, *Continue to 132*

132. Is the prescribed frequency more frequent than one dose every week?

- ☐ Yes, *Continue to 133*
- ☐ No, *Continue to 133*

133. What is the requested product?

- ☐ Actemra, *No further questions*
- ☐ Avtozma, *No further questions*
- ☐ tocilizumab-aazg, *No further questions*
- ☐ tocilizumab-anoh, *No further questions*
- ☐ Tynne, *No further questions*

134. Does the prescribed dose exceed 8 mg per kg?

- ☐ Yes, *Continue to 135*
- ☐ No, *Continue to 135*

135. Is the prescribed frequency more frequent than one dose every 4 weeks?

- ☐ Yes, *Continue to 136*
- ☐ No, *Continue to 136*

136. What is the requested product?

- ☐ Actemra, *No further questions*
- ☐ Avtozma, *No further questions*
- ☐ tocilizumab-aazg, *No further questions*
- ☐ tocilizumab-anoh, *No further questions*
- ☐ Tofidence, *No further questions*
- ☐ Tynne, *No further questions*

137. 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 138*
- ☐ No, *Continue to 138*

138. What is the requested product?

- ☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tynne, *Continue to 139*
- ☐ Tofidence (IV only), *Continue to 143*

139. What is the route of administration?

- ☐ Intravenous, *Continue to 143*
- ☐ Subcutaneous, *Continue to 140*

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*

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142. What is the requested product?

- ☐ Actemra, *No further questions*
- ☐ Avtozma, *No further questions*
- ☐ tocilizumab-aazg, *No further questions*
- ☐ tocilizumab-anoh, *No further questions*
- ☐ Tyenne, *No further questions*

143. Does the prescribed dose exceed 8 mg per kg?

- ☐ Yes, *Continue to 144*
- ☐ No, *Continue to 144*

144. Is the prescribed frequency more frequent than one dose every 4 weeks?

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

145. What is the requested product?

- ☐ Actemra, *No further questions*
- ☐ Avtozma, *No further questions*
- ☐ tocilizumab-aazg, *No further questions*
- ☐ tocilizumab-anoh, *No further questions*
- ☐ Tofidence, *No further questions*
- ☐ Tyenne, *No further questions*

146. What is the requested product?

- ☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tyenne, *Continue to 147*
- ☐ Tofidence (IV only), *Continue to 148*

147. What is the route of administration?

- ☐ Intravenous, *Continue to 148*
- ☐ Subcutaneous, *Continue to 151*

148. Does the prescribed dose exceed 6 mg per kg?

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

149. Is the prescribed frequency more frequent than one dose every 4 weeks?

- ☐ Yes, *Continue to 150*
- ☐ No, *Continue to 150*

150. What is the requested product?

- ☐ Actemra, *No further questions*
- ☐ Avtozma, *No further questions*
- ☐ tocilizumab-aazg, *No further questions*
- ☐ tocilizumab-anoh, *No further questions*
- ☐ Tofidence, *No further questions*
- ☐ Tyenne, *No further questions*

151. Does the prescribed dose exceed 162 mg?

- ☐ Yes, *Continue to 152*
- ☐ No, *Continue to 152*

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152. Is the prescribed frequency more frequent than one dose every week?

☐ Yes, *Continue to 153*

☐ No, *Continue to 153*

153. What is the requested product?

☐ Actemra, *No further questions*

☐ Avtozma, *No further questions*

☐ tocilizumab-aazg, *No further questions*

☐ tocilizumab-anoh, *No further questions*

☐ Tyenne, *No further questions*

154. What is the requested product?

☐ Actemra, Avtozma, tocilizumab-aazg, tocilizumab-anoh, or Tyenne, *Continue to 155*

☐ Tofidence, *Continue to 155*

155. What is the route of administration?

☐ Intravenous, *Continue to 156*

☐ Subcutaneous, *Continue to 156*

156. Does the prescribed dose exceed 162 mg?

☐ Yes, *Continue to 157*

☐ No, *Continue to 157*

157. Is the prescribed frequency more frequent than one dose every week?

☐ Yes, *Continue to 158*

☐ No, *Continue to 158*

158. What is the requested product?

☐ Actemra, *No further questions*

☐ Avtozma, *No further questions*

☐ tocilizumab-aazg, *No further questions*

☐ tocilizumab-anoh, *No further questions*

☐ Tyenne, *No further questions*

Step Therapy Override 2197-D: Complete if Applicable for the state of Maryland.		Please Circle	
1.	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
2.	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
3.	Is the alternate drug FDA-approved for the medical condition being treated? <i>If No, No Further Questions</i>	Yes	No
4.	Has the prescriber documented in the patient's chart that the requested drug was ordered for the patient in the past 180 days? <i>If No, Skip to 6</i>	Yes	No
5.	Has the prescriber documented in the patient's chart that in their opinion the requested drug is effective for the patient's condition? <i>If Yes or No, No Further Questions</i>	Yes	No
6.	Is the alternate drug contraindicated or will likely cause an adverse reaction to the patient? <i>If Yes, No Further Questions</i>	Yes	No

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

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7. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
8. Is the patient stable on the requested drug for the medical condition under consideration? <i>If Yes, No Further Questions</i>	Yes	No
9. Has the patient tried a prescription drug while covered under their current policy or a previous source of coverage, that is in the same pharmacologic class or has the same mechanism of action as the alternate drug and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? <i>No Further Questions</i>	Yes	No

Step Therapy Override 3145-D: Complete if Applicable for the state of Virginia.	Please Circle	
1. 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
2. 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
3. Is the alternate drug contraindicated? <i>If Yes, No Further Questions</i>	Yes	No
4. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
5. Has the patient tried the alternate 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? NOTE: Pharmaceutical drug samples are not considered trial and failure of a preferred drug. <i>If Yes, No Further Questions</i>	Yes	No
6. Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition? <i>No Further Questions</i>	Yes	No

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

X

Prescriber or Authorized Signature

Date (mm/dd/yy)

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