



Remicade and biosimilars

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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

Referring Provider Info: Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: Same as Referring Provider Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

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

Required Demographic Information:

Patient Weight: _____ *kg*

Patient Height: _____ *cm*

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

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Site of Service Questions:

- A. Where will this drug be administered?
 Ambulatory surgical, *skip to Clinical Questions* Home infusion, *skip to Clinical Questions*
 Off-campus Outpatient Hospital On-campus Outpatient Hospital
 Physician office, *skip to Clinical Questions* Pharmacy, *skip to Clinical Questions*
- B. Is this request to continue previously established treatment with the requested medication?
 Yes – This is a continuation of an existing treatment
 Yes – This is a continuation request, however a gap in therapy of greater than 2 doses has occurred. *Skip to Clinical Criteria Questions*
 No – This is a new therapy request (patient has not received requested medication in the last 6 months). *Skip to Clinical Criteria Questions*
 No – This is a request for a different brand infliximab product that the patient has not received previously. *Skip to Clinical Criteria Questions*
- C. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre- medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*** Yes, *skip to Clinical Criteria Questions* No
- D. Does the patient have laboratory confirmed antibodies to infliximab? ***ACTION REQUIRED: If Yes, please 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: If Yes, please 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: If Yes, please 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: If Yes, please attach supporting clinical documentation. Yes No

Criteria Questions:

1. What is the prescribed drug? Remicade Avsola Inflectra Renflexis
2. What is the prescribed dose and frequency?
a) **Loading dose:**
 Remicade 100 mg Quantity and Frequency: _____
 Avsola 100 mg Quantity and Frequency: _____
 Inflectra 100 mg Quantity and Frequency: _____
 Renflexis 100 mg Quantity and Frequency: _____
 Other _____
- b) **Maintenance dose:**
 Remicade 100 mg Quantity and Frequency: _____
 Avsola 100 mg Quantity and Frequency: _____
 Inflectra 100 mg Quantity and Frequency: _____
 Renflexis 100 mg Quantity and Frequency: _____
 Other _____

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- c) **Dosing (other):** *Indicate all that apply.*
- This is a request for a change in dosing regimen.
 - The requested quantity is supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines).
 - The patient requires a dose above 5 mg per kg due to loss of response at current dose.
 - The patient requires a dose above 3 mg per kg due to an incomplete response at current dose.
3. Has the patient been diagnosed with any of the following?
- Moderately to severely active Crohn's disease (CD)
 - Moderately to severely active ulcerative colitis (UC)
 - Moderately to severely active rheumatoid arthritis (RA)
 - Active ankylosing spondylitis (AS)
 - Active axial spondyloarthritis
 - Active psoriatic arthritis WITHOUT co-existent plaque psoriasis (PsA)
 - Active psoriatic arthritis with co-existent plaque psoriasis (PsA)
 - Moderate to severe plaque psoriasis
 - Juvenile idiopathic arthritis
 - Behcet's disease
 - Granulomatosis with polyangiitis (Wegener's granulomatosis)
 - Severe, refractory hidradenitis suppurativa
 - Pyoderma gangrenosum
 - Sarcoidosis
 - Refractory Takayasu's arteritis
 - Uveitis
 - Reactive arthritis
 - Immune checkpoint inhibitor (e.g., CTLA-4, PD-L1 inhibitor) toxicity
 - Acute graft versus host disease
 - Other _____
4. What is the ICD-10 code? _____
5. What is the patient's weight? _____ kg or lbs (*circle one*)
6. Is the patient currently receiving Remicade or a biosimilar? Yes No

Section A: All Requests

7. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic disease-modifying anti-rheumatic drug (DMARD) (e.g., Olumiant, Otezla, Xeljanz)? Yes No
8. 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 #10 Yes No
9. 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? *If Yes, skip to #12* Yes No
10. 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 #15*
11. Has the patient been tested for tuberculosis (TB) within the previous 12 months? Yes No
12. What were the results of the tuberculosis (TB) test?
 Positive for TB Negative for TB, *skip to #15* Unknown

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13. Does the patient have latent or active tuberculosis(TB)? Latent Active Unknown
14. Has treatment for latent tuberculosis (TB) infection been initiated or completed?
 Yes - treatment initiated Yes - treatment completed No
15. Is this request for continuation of therapy with the requested drug or a biosimilar?
 Yes No *If No, skip to #18*
16. Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #18* Yes No Unknown
17. 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
18. Has the patient ever received (including current utilizers) any of the following? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.***
 A biologic (e.g., Humira, Cimzia, Enbrel) indicated for the diagnosis, *indicate biologic:* _____
 Targeted synthetic disease modifying drug (e.g., Rinvoq, Xeljanz) indicated for the diagnosis
 Otezla
 No - None of the above

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

Section B: Crohn's Disease

19. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of remission and no further questions.*** Yes No
20. *If the patient is less than 18 years old*, does the prescriber recognize that a dose above 5 mg per kg is a higher dose and the prescriber confirms that appropriate monitoring will be done? Yes No

Continuation

21. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy and no further questions.***
 Abdominal pain or tenderness
 Diarrhea
 Body weight
 Abdominal mass
 Hematocrit
 Endoscopic appearance of the mucosa
 Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)
 None of the above

Initiation

22. Does the patient have fistulizing disease? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting diagnosis. and no further questions.*** Yes No
23. Has the patient tried and had an inadequate response to at least one conventional therapy option?
ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.
 Yes - Sulfasalazine (Azulfidine, Sulfazine) Yes - Budesonide (Entocort EC)
 Yes - Mercaptopurine (Purinethol) Yes - Azathioprine (Azasan, Imuran)
 Yes - Metronidazole (Flagyl) Yes - Methotrexate IM or SC
 Yes - Ciprofloxacin (Cipro) Yes - Methylprednisolone (Solu-Medrol)

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32. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], corticosteroid [e.g., budesonide, [Entocort, Uceris], hydrocortisone, methylprednisolone, prednisone], cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], balsalazide, olsalazine, mercaptopurine [Purinethol], sulfasalazine, tacrolimus [Prograf], metronidazole/ciprofloxacin [for pouchitis only])? **ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including clinical reason to avoid therapy.** Yes No

Section D: Rheumatoid Arthritis and Reactive Arthritis

Continuation

33. *If the diagnosis is rheumatoid arthritis*, has the patient achieved or maintained positive clinical response since starting treatment with the requested drug? Yes No
34. *If diagnosis is reactive arthritis*, has the patient achieved or maintained positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, or pain)? **ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation supporting positive clinical response and no further questions.** Yes No
35. 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.

Initiation – for diagnosis of Reactive Arthritis, skip to #40

36. Is the requested medication being prescribed in combination with methotrexate or leflunomide?
 Yes No **If No, indicate clinical reason for not using methotrexate or leflunomide:** _____
-
37. 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 #40.** Yes No
38. 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 #40.**
 Yes No
39. 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
40. 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
41. 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
42. 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
43. Please indicate if the patient tested positive or negative for the erythrocyte sedimentation rate (ESR) biomarker, or if the test was not completed.

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- Positive for ESR
- Negative for ESR
- Test for ESR was not completed

44. 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. Indicate below and no further questions.*** Yes No
45. 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. Indicate below and no further questions.*** Yes No
46. Does the patient have a contraindication to methotrexate? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including clinical reason to avoid therapy.*** Yes No
If Yes, indicate the contraindication: _____

Section E: Ankylosing Spondylitis or Active Axial Spondyloarthritis

Continuation

47. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy and no further questions.***
- Functional status
 - Inflammation (e.g., morning stiffness)
 - Total spinal pain
 - None of the above

Initiation

48. Has the patient experienced an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least two NSAIDs? ***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 No

Section F: Psoriatic Arthritis

Continuation

49. Which of the following has the patient experienced an improvement in from baseline? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***
- Number of swollen joints
 - Number of tender joints
 - Dactylitis
 - Enthesitis
 - Skin and/or nail involvement
 - None of the above

Section G: Plaque Psoriasis

Continuation

50. Has the patient experienced a reduction in body surface area (BSA) affected from baseline? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of decreased body surface area affected.*** Yes No
51. Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of improvement in signs and symptoms.*** Yes No

Initiation

52. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? ***ACTION REQUIRED: If 'Yes', please attach chart notes or medical record documentation of affected areas and***

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body surface area affected. Yes No

53. What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? **ACTION REQUIRED: Please attach chart notes or medical record documentation of affected areas and body surface area affected.** _____% *If greater than or equal to 10% of BSA, no further questions.*
54. Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin? **ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.** Yes No
55. Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin? **ACTION REQUIRED: If 'Yes', please attach documentation of clinical reason to avoid therapy.** Yes No
If Yes, indicate the clinical reason: _____

Section H: Juvenile Idiopathic Arthritis

Continuation

56. 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)
 - Number of joints with limitation of movement
 - Functional ability
 - None of the above

Initiation

57. Has the patient experienced an inadequate response to ANY of the following? **ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.**
Indicate below and no further questions.
- At least 1 month trial of NSAIDs
 - At least 2 weeks of treatment with corticosteroids (e.g. prednisone, methylprednisolone)
 - At least 3 months of treatment with methotrexate
 - At least 3 months of treatment with leflunomide
 - No – No history of an inadequate response to any of the above

Section I: Behcet's Disease

58. Has the patient had an inadequate response to at least one nonbiologic medication for Behcet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine)? **ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy** Yes No

Section J: Granulomatosis with Polyangiitis (Wegener's Granulomatosis), Pyoderma Gangrenosum, Sarcoidosis, and Takayasu's Arteritis

59. Has the patient experienced ANY of the following with corticosteroids or immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)?
ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and documentation of clinical reason to avoid therapy. Indicate ALL that apply.
- Corticosteroids Inadequate response Intolerance Contraindication
 - Immunosuppressive therapy Inadequate response Intolerance Contraindication
- If immunosuppressive therapy, specify therapy:* _____
- None of the above

Section K: Hidradenitis Suppurativa

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Continuation

60. Which of the following has the patient experienced since starting treatment with the requested drug? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***
- Reduction in abscess and inflammatory nodule count from baseline
 - Reduced formation of new sinus tracts and scarring
 - Decrease in frequency of inflammatory lesions from baseline
 - Reduction in pain from baseline
 - Reduction in suppuration from baseline
 - Improvement in frequency of relapses from baseline
 - Improvement in quality of life from baseline
 - Improvement on a disease severity assessment tool from baseline
 - None of the above

Initiation

61. Has the patient experienced an inadequate response after at least 90 days of treatment with oral antibiotics? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.***
- Yes No
62. Has the patient experienced an intolerable adverse effect to oral antibiotics? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** Yes No
63. Does the patient have a contraindication to oral antibiotics? ***ACTION REQUIRED: If 'Yes', please attach documentation of clinical reason to avoid therapy.*** Yes No

Section L: Uveitis

Continuation

64. Which of the following has the patient experienced since starting treatment with the requested drug? ***ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.***
- Reduced frequency of recurrence compared to baseline
 - Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
 - Decreased reliance on topical corticosteroids
 - None of the above

Initiation

65. Has the patient experienced ANY of the following with corticosteroids or immunosuppressive therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate mofetil)? ***Indicate ALL that apply. ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy, or clinical reason to avoid therapy.***
- Corticosteroid Inadequate response Intolerance Contraindication
- Immunosuppressive therapy Inadequate response Intolerance Contraindication
- If immunosuppressive therapy, specify therapy: _____*
- None of the above

Section M: Immune Checkpoint Inhibitor Toxicity

66. Has the patient experienced an inadequate response to corticosteroids? ***ACTION REQUIRED: If 'Yes', please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** Yes No
67. Has the patient experienced an intolerance to corticosteroids? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy and no further questions.*** Yes No
68. Does the patient have a contraindication to corticosteroids? ***ACTION REQUIRED: If 'Yes', please attach documentation of clinical reason to avoid therapy and no further questions.*** Yes No

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69. Does the patient have cardiac toxicity? Yes No

Section N: Acute Graft Versus Host Disease

70. 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 and no further questions.*** Yes No

71. 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 not advisable, please attach documentation of clinical reason to avoid therapy.*** 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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