



Entyvio

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

What is the ICD-10 code? _____

Site of Service Questions (SOS):

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
 No – This is a new therapy request (patient has not received requested medication in the last 6 months) *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, 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

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

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- D. 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
- E. Has the patient previously experienced a severe adverse event during or immediately after an infusion including but not limited to: anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures?
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 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

Criteria Questions:

1. Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz)?
 Yes, Continue to 2
 No, Continue to 2
2. What is the diagnosis?
 Ulcerative colitis, Continue to 3
 Crohn's disease, Continue to 10
 Immune checkpoint inhibitor-related diarrhea or colitis, Continue to 17
 Other, please specify. _____, No further questions
3. Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)?
 Yes, Continue to 4
 No, Continue to 4
4. Is the patient an adult (18 years of age or older)?
 Yes, Continue to 5
 No, Continue to 5
5. Is the requested drug being prescribed by or in consultation with a gastroenterologist?
 Yes, Continue to 6
 No, Continue to 6
6. Is this request for continuation of therapy with the requested drug?
 Yes, Continue to 7
 No, Continue to 23
7. Has the patient achieved or maintained remission? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission. **ACTION REQUIRED:** Submit supporting documentation

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- Yes, *Continue to 23*
- No, *Continue to 8*

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

- Yes, *Continue to 9*
- No, *Continue to 9*

9. 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.

- Stool frequency **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- Rectal bleeding **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- Urgency of defecation **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- C-reactive protein (CRP) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- Fecal calprotectin (FC) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
- None of the above, *Continue to 23*

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

- Yes, *Continue to 11*
- No, *Continue to 11*

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

- Yes, *Continue to 12*
- No, *Continue to 12*

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

- Yes, *Continue to 13*
- No, *Continue to 13*

13. Is this a request for continuation of therapy?

- Yes, *Continue to 14*
- No, *Continue to 23*

14. Has the patient achieved or maintained remission? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission. **ACTION REQUIRED:** Submit supporting documentation

- Yes, *Continue to 23*
- No, *Continue to 15*

15. 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?

- Yes, *Continue to 16*
- No, *Continue to 16*

16. 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.

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- Abdominal pain or tenderness **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- Diarrhea **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- Body weight **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- Abdominal mass **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- Hematocrit **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) **ACTION REQUIRED:** Submit supporting documentation, Continue to 23
- None of the above, Continue to 23

17. Is the requested drug being prescribed by or in consultation with a hematologist or oncologist?

- Yes, Continue to 18
- No, Continue to 18

18. Has the patient experienced an inadequate response to systemic corticosteroids or infliximab? **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 22
- No, Continue to 19

19. Has the patient experienced an intolerance to systemic corticosteroids or infliximab? **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 22
- No, Continue to 20

20. Does the patient have a contraindication to systemic corticosteroids or infliximab? **ACTION REQUIRED:** If Yes, please attach documentation of clinical reason to avoid therapy. **ACTION REQUIRED:** Submit supporting documentation

- Yes, Continue to 22
- No, Continue to 21

21. Does the patient have moderate or severe diarrhea or colitis?

- Yes, Continue to 22
- No, Continue to 22

22. 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 Further Questions
- No, No Further Questions

23. What is the diagnosis?

- Ulcerative colitis, Continue to 24
- Crohn's disease, Continue to 24

24. Is the patient currently receiving the requested drug?

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- Yes, *Continue to 28*
- No, *Continue to 25*

25. Is a loading dose prescribed?

- Yes, *Continue to 26*
- No, *Continue to 28*

26. Does the prescribed dose exceed a loading dose of 300 mg at weeks 0, 2, and 6, and a maintenance dose of 300 mg thereafter?

- Yes, *Continue to 27*
- No, *Continue to 27*

27. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

28. Does the prescribed dose exceed 300 mg?

- Yes, *Continue to 29*
- No, *Continue to 29*

29. Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks?

- Yes, *No Further Questions*
- No, *No Further Questions*

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

X _____

Prescriber or Authorized Signature

Date (mm/dd/yy)

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