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.

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*

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*

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

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

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. 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)
   ❑ Immune checkpoint inhibitor-related diarrhea or colitis
   ❑ 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 anti-rheumatic drugs (DMARD) (e.g., Xeljanz)? ❑ Yes ❑ No
4. Is the patient currently receiving Entyvio? ❑ Yes ❑ No
5. What is the prescribed dose? Indicate mg and frequency.
   ❑ Loading dose (if applicable) _____
   ❑ Maintenance dose _____
6. Is this request for continuation of therapy with the requested drug? ❑ Yes ❑ No *If No, skip to diagnosis section.*
7. 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
8. Has the patient achieved or maintained remission? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission.*** *If Yes, no further questions* ❑ Yes ❑ No
9. Has the patient achieved or maintained 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 ❑ No

10. *If diagnosis is ulcerative colitis (UC) or Crohn's disease (CD),* 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.***
Indicate ALL that apply.
❑ Stool frequency
❑ Rectal bleeding
❑ Urgency of defecation
❑ C-reactive protein (CRP)
❑ Fecal calprotectin (FC)
❑ Endoscopic appearance of the mucosa
❑ Improvement on a disease activity scoring tool (e.g., Ulcerative colitis Endoscopic Index of Severity [UCEIS], Mayo Score)
❑ None of the above

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

Section A: Ulcerative Colitis

11. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic disease modifying drug (e.g., Xeljanz) indicated for the treatment of moderately to severely active ulcerative colitis? ***ACTION REQUIRED: If Yes, please attach patient's chart notes, medical record documentation, or claims history of previous medications tried.*** *If Yes, no further questions* ❑ Yes ❑ No

12. Has the patient been hospitalized for acute, severe ulcerative colitis (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia)? ***ACTION REQUIRED: If Yes, please attach supporting chart notes or medical record documentation of hospitalization due to acute, severe ulcerative colitis.***
If Yes, no further questions ❑ Yes ❑ No

13. Has the patient tried and had an inadequate response to at least one conventional therapy option? ***ACTION REQUIRED: If Yes, please attach patient's chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy.***
If Yes, indicate below and no further questions.
❑ Yes - Azathioprine (Azasan, Imuran)
❑ Yes - Corticosteroid (e.g., budesonide [Entocort, Uceris], hydrocortisone [Cortifoam, Colocort, Solu-Cortef, Cortef], methylprednisolone [Medrol, Solu-Medrol], prednisone)
❑ Yes - Cyclosporine (Sandimmune)
❑ Yes - Mesalamine (e.g., Asacol, Lialda, Pentasa, Canasa, Rowasa)), balsalazide, olsalazine
❑ Yes - Mercaptopurine (Purinethol)
❑ Yes - Sulfasalazine
❑ Yes - Tacrolimus (Prograf)
❑ Yes - Metronidazole (Flagyl) or ciprofloxacin (Cipro) (for pouchitis only)
❑ No

14. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], corticosteroid [e.g., hydrocortisone [Entocort, Uceris], methylprednisolone, prednisone, cyclosporine [Sandimmune], mesalamine [Asacol, Lialda, Pentasa, Canasa, Rowasa], balsalazine, 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 response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy.*** ❑ Yes ❑ No

Section B: Crohn's Disease

15. Has the patient ever received (including current utilizers) a biologic (e.g., Humira) indicated for the treatment of moderately to severely active Crohn's disease? ***ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried.***
If Yes, no further questions ❑ Yes ❑ No

16. Does the patient have fistulizing Crohn's disease? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting diagnosis.*** *If Yes, no further questions* ❑ Yes ❑ No

17. Has the patient tried and had an inadequate response to at least one conventional therapy option? ***ACTION REQUIRED: If Yes, please attach patient's chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy.***
If Yes, indicate below and no further questions.
❑ Yes - Sulfasalazine (Azulfidine, Sulfazine)
❑ Yes - Metronidazole (Flagyl)
❑ Yes - Ciprofloxacin (Cipro)
❑ Yes - Prednisone
❑ Yes - Budesonide (Entocort EC)
❑ Yes - Azathioprine (Azasan, Imuran)
❑ Yes - Mercaptopurine (Purinethol)
❑ Yes - Methotrexate intramuscular (IM) or subcutaneous (SC)
❑ Yes - Methylprednisolone (Solu-Medrol) (IV)
❑ Yes - Rifaximin (Xifaxan)
❑ Yes - Tacrolimus
❑ No

18. Does the patient have a contraindication or intolerance to at least one conventional therapy option (e.g., azathioprine [Azasan, Imuran], budesonide [Entocort EC], ciprofloxacin [Cipro], mercaptopurine [Purinethol], methylprednisolone [Solu-Medrol], methotrexate, metronidazole [Flagyl], prednisone, sulfasalazine [Azulfidine, Sulfazine], rifaximin [Xifaxan], tacrolimus)? ***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 C: Immune Checkpoint Inhibitor-Related Diarrhea or Colitis

19. Has the patient experienced an inadequate response, 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 ❑ 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