Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Ulcerative Colitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Ulcerative Colitis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Ulcerative Colitis Agent. See the Preferred Drug List (PDL) for the list of preferred Ulcerative Colitis Agents at: https://papdl.com/preferred-drug-list.

2. A prescription for a sphingosine 1-phosphate receptor (S1PR) modulator.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ulcerative Colitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an S1PR modulator, **one** of the following:

   a. For treatment of multiple sclerosis, see the Multiple Sclerosis Agents policy

   b. For treatment of ulcerative colitis (UC), **all** of the following:

      i. Is prescribed the requested drug for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication,

      ii. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

      iii. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

      iv. Is prescribed the requested drug by or in consultation with an appropriate specialist (e.g., a gastroenterologist),

      v. Does not have a contraindication to the requested drug,

      vi. Has **one** of the following:

         a) A diagnosis of moderate to severe UC,

         b) A diagnosis of mild UC that is associated with multiple poor prognostic factors,[1]

[1] Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

c) **Both** of the following:

(i) Has achieved remission with the requested drug
(ii) Will be using the requested drug as maintenance therapy to maintain remission,

vii. **One** of the following:

a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis
b) Has a current history (within the past 90 days) of being prescribed an S1PR modulator,

viii. For a non-preferred S1PR modulator, **one** of the following:

a) Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred S1PR modulators approved or medically accepted for treatment of ulcerative colitis
b) Has a current history (within the past 90 days) of being prescribed the same S1PR modulator (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

AND

2. For all other non-preferred Ulcerative Colitis Agents, **one** of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Ulcerative Colitis Agents approved or medically accepted for the beneficiary's diagnosis
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Ulcerative Colitis Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN S1PR MODULATOR: The determination of medical necessity of a request for renewal of a prior authorization for an S1PR modulator that was previously approved will take into account whether the beneficiary:

1. Experienced improvement in disease activity and/or level of functioning since starting the requested drug; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed the requested drug by or in consultation with an appropriate specialist (e.g., gastroenterologist); **AND**

4. Does not have a contraindication to the requested drug; **AND**

5. For a non-preferred S1PR modulator with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug;

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Ulcerative Colitis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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ULCERATIVE COLITIS AGENTS PRIOR AUTHORIZATION FORM *(form effective 1/5/2026)*

☐New request ☐Renewal request	total pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Dosage form:	Strength:	
Directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code *(required)*:	
Is the beneficiary currently being treated with the requested medication?	☐Yes – date of last dose: _____ *Submit documentation.* ☐No		

Complete all sections that apply to the beneficiary and this request.
Check all that apply and submit documentation for each item.

INITIAL requests

1. For a SPHINGOSINE 1-PHOSPHATE RECEPTOR (S1PR) MODULATOR (eg, VELSIPITY [etrasimod], ZEPOSIA [ozanimod]) for treatment of ulcerative colitis (UC):

☐Is prescribed the drug by or in consultation with an appropriate specialist (eg, a gastroenterologist)
☐Has moderate-to-severe UC
☐Has UC associated with multiple poor prognostic factors
☐Has achieved remission with the requested medication AND:
  ☐Will be using the requested medication as maintenance therapy to maintain remission
☐Tried and failed or has a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists that are FDA-approved or medically accepted for the treatment of UC. (*Refer to https://papdl.com/preferred-drug-list for a list of preferred Cytokine and CAM Antagonists.)*

☐**Request is for VELSIPITY (etrasimod) AND:**
  ☐Has a comorbid heart condition – describe: _____
  ☐Experienced any of the following in the past 6 months:
    ☐Myocardial infarction
    ☐Unstable angina
    ☐Stroke
    ☐Transient ischemic attack
    ☐Decompensated heart failure requiring hospitalization
    ☐Class III or IV heart failure

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☐ **Request is for ZEPOSIA (ozanimod) AND:**
- ☐ Has severe untreated sleep apnea
- ☐ Will be taking a monoamine oxidase (MAO) inhibitor while taking Zeposia (e.g., selegiline, phenelzine)
- ☐ Has a comorbid heart condition – describe: _____
- ☐ Experienced any of the following in the past 6 months:
  - ☐ Myocardial infarction
  - ☐ Unstable angina
  - ☐ Stroke
  - ☐ Transient ischemic attack
  - ☐ Decompensated heart failure requiring hospitalization
  - ☐ Class III or IV heart failure

2. For all other NON-PREFERRED Ulcerative Colitis Agents:

☐ Tried and failed or has a contraindication or an intolerance to the preferred Ulcerative Colitis Agents *(Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

RENEWAL requests

1. For a SPHINGOSINE 1-PHOSPHATE RECEPTOR (S1PR) MODULATOR (eg, VELSIPITY [etrasimod], ZEPOSIA [ozanimod]):

☐ Is prescribed the medication by or in consultation with an appropriate specialist (eg, a gastroenterologist)
☐ Experienced improvement in disease activity or level of functioning since starting the requested medication

☐ **Request is for VELSIPITY (etrasimod) AND:**
- ☐ Has a comorbid heart condition – describe: _____
- ☐ Experienced any of the following in the past 6 months:
  - ☐ Myocardial infarction
  - ☐ Unstable angina
  - ☐ Stroke
  - ☐ Transient ischemic attack
  - ☐ Decompensated heart failure requiring hospitalization
  - ☐ Class III or IV heart failure

☐ **Request is for ZEPOSIA (ozanimod) AND:**
- ☐ Has severe untreated sleep apnea
- ☐ Will be taking a monoamine oxidase inhibitor while taking Zeposia (e.g., selegiline, phenelzine)
- ☐ Has a comorbid heart condition – describe: _____
- ☐ Experienced any of the following in the past 6 months:
  - ☐ Myocardial infarction
  - ☐ Unstable angina
  - ☐ Stroke
  - ☐ Transient ischemic attack
  - ☐ Decompensated heart failure requiring hospitalization
  - ☐ Class III or IV heart failure

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**: