CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Velsipity (etrasimod)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Velsipity (etrasimod), initially approved by the FDA in 2023, is a sphingosine 1-phosphate (S1P) receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults. The mechanism of Velsipity in UC is unknown but may involve the reduction of lymphocyte migration into the intestines.
Ulcerative colitis is a type of inflammatory bowel disease (IBD) in which the colon becomes inflamed. Symptoms include abdominal pain, frequent bowel movements, and bloody or pus-filled diarrhea. The pattern of disease activity is characterized by periods of active inflammation alternating with periods of remission.

Velsipity (etrasimod) will be considered for coverage when the following criteria are met:

Ulcerative Colitis (UC)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a diagnosis of moderately to severely active UC; AND
4. Member must have a documented trial and inadequate response with **ONE** of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of a corticosteroid (e.g., budesonide, prednisone, methylprednisolone);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
5. Member has a documented trial and failure of Zeposia; AND
6. Chart notes must show **ALL** of the following baseline assessments have been completed (or are scheduled):
   a) Complete blood count (CBC);
   b) Ophthalmic evaluation;
   c) Liver function tests;
   d) Cardiac evaluation by electrocardiogram (ECG);
   e) Skin examination; AND
7. Member has **NOT** experienced any of the following in the past 6 months: myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
8. Member does **NOT** have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker.
9. **Dosage allowed/Quantity limit:** 2 mg orally once daily. Quantity Limit: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing an improvement in signs and symptoms of disease such as clinical remission, reduced rectal bleeding, decreased stool frequency, or endoscopic-histologic mucosal healing.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Velsipity (etrasimod) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/31/2023	New policy for Velsipity created.

References:

1. Velsipity [prescribing information]. New York, NY: Pfizer, INc.; 2023.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114(3):384-413
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158(5):1450-1461
4. Sands BE, Schreiber S, Blumenstein I, Chiorean MV, Ungaro RC, Rubin DT. Clinician's Guide to Using Ozanimod for the Treatment of Ulcerative Colitis [published online ahead of print, 2023 Jul 12]. *J Crohns Colitis.* 2023;jjad112. doi:10.1093/ecco-jcc/jjad112
5. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on Therapeutics in Ulcerative Colitis: Medical Treatment. *J Crohns Colitis.* 2022;16(1):2-17. doi:10.1093/ecco-jcc/jjab178

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