

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Velsipity under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Treatment of moderately to severely active ulcerative colitis in adults.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Velsipity

Policy/Guideline:

- Member cannot use the requested medication concomitantly with immunomodulators, biologic drugs, or targeted synthetic drugs.
- The patient is unable to take a preferred adalimumab product and Rinvoq due to a trial and inadequate treatment response or intolerance, or a contraindication.
 Documentation is required for approval

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

 Chart notes or medical record documentation supporting positive clinical response to therapy or remission

Prescriber Specialties

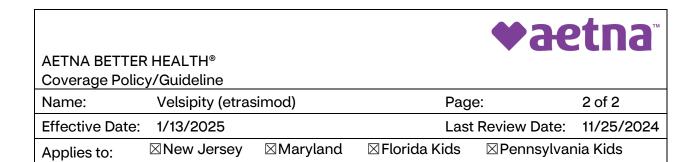
• This medication must be prescribed by or in consultation with gastroenterologist.

Criteria for Initial Approval:

 Authorization may be granted for adult members for treatment of moderately to severely active ulcerative colitis.

Criteria for Continuation of Therapy:

- Authorization may be granted for all adult members (including new members) who
 are using the requested medication for moderately to severely active ulcerative
 colitis and who achieve or maintain remission.
- Authorization may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative



colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY of the following from baseline:

- A. Stool frequency
- B. Rectal bleeding
- C. Urgency of defecation
- D. C-reactive protein (CRP)
- E. Fecal calprotectin (FC)
- F. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- G. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 Months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

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

References:

- 1. Velsipity [package insert]. New York, NY: Pfizer Inc.; June 2024.
- 2. Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomized, double-blind, placebo-controlled, phase 3 studies. Lancet. 2023; 410(10383):1159-71.
- 3. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114:384-413.
- 4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158:1450-1461.