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Coverage Policy/Guideline								
Name:	Velsipity (etra	asimod)	Page:	1 of 2				
Effective D	Date: 3/26/2024		Last Review Date:	01/08/2024				
Applies to:	⊠Illinois	□Florida	⊠New Jersey					
	□Maryland	⊠Florida Kids	⊠Pennsylvania Kids					
	□Michigan	□ Virginia	☐Kentucky PRMD					

## 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 adalimumab 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.

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- 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.; October 2023.
- 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.