AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Velsipity (etrasimod)	Page:	1 of 2
Effective Date:	5/1/2024	Last Review Date:	01/08/2024; 4/2024
Applies to:	☐Illinois ☒Maryland ☐Michigan	☐Florida ☒Florida Kids ☐ Virginia	☒New Jersey ☒Pennsylvania Kids ☐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 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.; 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.