Effective Date: 5/24
Reviewed: 2/2024, 1/2025, 7/2026 Scope: Medicaid

VELSIPITY (etrasimod)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active ulcerative colitis (UC) in adults

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Velsipity will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.); AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; AND
- Member has not experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack, or heart failure requiring hospitalization in the last 6 months OR has/has had a history of arrhythmia that is not corrected by a pacemaker; AND

A. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active UC when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active UC; AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

III. CONTINUATION OF THERAPY

A. Moderately to severely active ulcerative colitis (UC)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and documentation is submitted indicating one of the following:

1. Member has achieved or maintained remission; OR
2. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition from baseline (e.g., stool frequency, rectal bleeding, urgency of defecation, C-reactive protein (CRP), fecal calprotectin (FC), endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound), improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score).

IV. QUANTITY LIMIT

1. Velsipity 2mg tablet: 1 tablet per day

V. DOSING

1. The recommended dosage is 2mg orally once daily

VI. REFERENCES

1. VELSIPITY [prescribing information]. New York, NY: Pfizer Inc.; August 2025.
2. Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo-controlled, phase 3 studies [published correction appears in *Lancet*. 2023;401(10381):1000]. *Lancet*. 2023;401(10383):1159-1171.

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.