

SPECIALTY GUIDELINE MANAGEMENT

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 AND CONTINUATION OF THERAPY

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

III. CRITERIA FOR INITIAL APPROVAL

For all indications:

1. Member is free of any clinically important active infection, including clinically important localized infections; AND
2. Member will not receive live vaccines during therapy; AND
3. Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
4. Member has obtained an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present.; AND
5. Velsipity will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), Simponi (golimumab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Wezlana etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Omvoh (mirikizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)

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
2. Velsipity must be prescribed by or in consultation with a gastroenterologist
3. Documented moderate to severe UC
4. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses
Member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

CONTINUATION OF THERAPY

A. Moderately to severely active ulcerative colitis

1. Authorization of 12 months may be granted for treatment of 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.
2. Authorization of 12 months 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:
 - i. Stool Frequency
 - ii. Rectal bleeding
 - iii. Urgency of defecation
 - iv. C-reactive protein (CRP)
 - v. Fecal calprotectin (FC)
 - vi. Endoscopic appearance of the mucosa (e.g., computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound)
 - vii. 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. REFERENCES

1. VELSIPTITY [prescribing information]. New York, NY: Pfizer Inc.; October 2023.

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

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.