Effective Date: 5/24
Reviewed: 2/2024 Scope: Medicaid

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. DOCUMENTATION

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

A. Ulcerative colitis (UC):
   a. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   b. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

IV. 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 a recent (i.e., within the last 6 months or after discontinuation of prior UC therapy) complete blood count (CBC), including lymphocyte count; AND
5. Member has obtained an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present.; AND
6. Member has obtained recent (i.e., within the last 6 months) transaminase and bilirubin levels; AND
7. Member has obtained a baseline evaluation of the fundus, including the macula, near the start of treatment; AND
8. Member will obtain a skin examination prior to or shortly after the start of treatment

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 (e.g., Mayo Clinical Score 6-12, with Mayo Endoscopic Subscore 2 or 3)
4. 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), Stelara (ustekinumab), 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.)
5. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of one conventional therapy option (e.g., mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine) at maximum tolerated doses; AND
6. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab 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)

V. QUANTITY LIMIT

1. Velsipity 2mg tablet: 1 tablet per day

VI. REFERENCES

1. VELSIPITY [prescribing information]. 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 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.