Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 29, 2024

Velsipity™ (etrasimod)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of moderately to severely active ulcerative colitis (UC) confirmed by endoscopy and/or an objective score (e.g., modified Mayo score [MMS], Truelove and Witts criteria); **AND**
- The prescribing physician is in consultation with or a related clinical specialist; **AND**
- Patient has a documented history of inadequate response, loss of response, or intolerance of ≥ 1 of the following:
    - Oral aminosalicylate (e.g., sulfasalazine, mesalamine)
    - Corticosteroid (e.g., budesonide, prednisone)
    - Thiopurine (e.g., azathioprine, mercaptopurine)
    - Janus kinase (JAK) inhibitor (e.g., tofacitinib)
    - Biologic therapy (e.g., tumor necrosis factor [TNF] blocker [e.g., adalimumab]); **AND**
- Patient has NOT experienced any of the following within the last 6 months: myocardial infarction (MI), unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or Class III or IV HF; **AND**
- Patient does NOT have a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless they have a functioning pacemaker; **AND**
- Prescriber has performed an electrocardiogram (ECG) and attests to consult a cardiologist if any of the following are true:
    - Significant QT prolongation: QTcF ≥ 450 msec (males) or QTcF ≥ 470 msec (females)
    - Arrhythmias requiring treatment with Class Ia (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) anti-arrhythmic drugs or other QT-prolonging drugs
    - Unstable ischemic heart disease, Class I or II HF, history of cardiac arrest, cerebrovascular disease, or uncontrolled hypertension
    - Resting heart rate (HR) < 50 bpm
    - History of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnea
    - History of Mobitz type I second-degree AV block, unless patient has a functioning pacemaker; **AND**
- Patient does NOT have an active infection; **AND**
- Prescriber has obtained a complete blood count (CBC), including lymphocyte count, within the last 6 months or after discontinuation of prior UC therapy; **AND**

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- Prescriber has obtained transaminase and bilirubin levels within the last 6 months; **AND**
- Patient will have baseline ophthalmic evaluation of the fundus, including the macula, near the start of treatment; **AND**
- Prescriber attestation to perform a skin examination prior to or shortly after initiation of therapy; **AND**
- Patient has been tested for antibodies to varicella zoster virus (VZV) if no confirmed history of varicella or if no documentation of full VZV vaccination; **AND**
- Females of reproductive potential have been counseled on the potential for serious fetal risks and the need for effective contraception during treatment and for 1 week following the last dose.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of positive clinical response (e.g., clinical remission according to an objective measure such as MMS, Truelove and Witts criteria); **AND**
- Patient has NOT experienced any treatment-restricting adverse effects (e.g., serious infection, progressive multifocal leukoencephalopathy [PML], cryptococcal meningitis [CM], significant liver injury, macular edema, suspected posterior reversible encephalopathy syndrome [PRES]); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 2 mg tablet