

**VELSIPITY
(etrasimod)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Velsipity (etrasimod) is a sphingosine-1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1, 4, and 5 (S1P_{1,4,5}). Velsipity partially and reversibly blocks the capacity of lymphocytes to egress from lymphoid organs, reducing the number of lymphocytes in peripheral blood. The mechanism by which Velsipity exerts therapeutic effects in ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the intestines (1).

Regulatory Status

FDA-approved indication: Velsipity is a sphingosine 1-phosphate receptor modulator indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults (1).

Before initiation of treatment with Velsipity, the following should be assessed: (1)

- Complete blood count (CBC) – Obtain a recent CBC including lymphocyte count
- Cardiac evaluation – Obtain an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present
- Liver function tests – Obtain recent (i.e., within the last 6 months) transaminase and bilirubin levels
- Ophthalmic assessment – Obtain a baseline evaluation of the fundus, including the macula, near the start of treatment
- Vaccination – Test patients for antibodies to varicella zoster virus (VZV) before initiating Velsipity; VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with Velsipity. If live attenuated vaccine immunizations are required, administer at least 4 weeks prior to initiation of Velsipity.
- Skin examination – Obtain a skin examination prior to or shortly after initiation. Suspicious skin lesions should be promptly evaluated

Velsipity is contraindicated in patients who in the last 6 months experienced a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure (1).

Velsipity is also contraindicated in patients with Mobitz type II second-degree or third degree



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atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker (1).

The safety and effectiveness of Velsipity in pediatric patients less than 18 years of age have not been established (1).

Summary

Velsipity (etrasimod) is a sphingosine-1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1, 4, and 5. Velsipity blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which Velsipity exerts therapeutic effects in ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the intestines. The safety and effectiveness of Velsipity in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Velsipity while maintaining optimal therapeutic outcomes.

References

1. Velsipity [package insert], New York, NY: Pfizer Inc.; June 2024.