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Commercial PA Criteria Effective: March 28, 2024

Prior Authorization: Velsipity

Products Affected: Velsipity (Etrasimod) oral tablets

<u>Medication Description</u>: The agent is an S1P receptor modulator that binds with high affinity to S1P receptor subtypes 1, 4, and 5 which partially and reversibly blocks the capacity of lymphocytes to egress from lymph nodes. This ultimately reduces the number of lymphocytes in the blood.

Covered Uses: is indicated for the treatment of adults with moderate to severe ulcerative colitis (UC).

Exclusion Criteria:

- 1. In the last 6 months, have experienced a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure
- 2. Have a history or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- 3. Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis.

Required Medical Information:

- 1. Diagnosis
- 2. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with a gastroenterologist

Coverage Duration:

Initial: 6 months Continuation: 1 year

Other Criteria:

1. Ulcerative Colitis.

- Initial Therapy: Approve if the patient meets the following (A AND B)
 - A. Patient has had a trial of ONE systemic agent for ulcerative colitis; AND <u>Note</u>: Examples of systemic agents for ulcerative colitis include 6-mercaptopurine, azathioprine, cyclosporine,

<u>Note</u>: Examples of systemic agents for ulcerative collitis include 6-mercaptopurine, azathloprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of one biologic also counts as a trial of one systemic agent for ulcerative collitis.

B. Patient must have a trial and documented failure of, or intolerance to, TWO Step 1 or 2 products AND ONE Step 3b Product of the following medications



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Ulcerative Colitis				
Step 1	Step 2	Step 3b		
Adalimumab Product	Rinvoq	Zeposia		
Stelara SC	Simponi SC			
	Xeljanz/Xeljanz XR			
	Omvoh SC			

Renewal

- A. Patient meets all initial authorization criteria; AND
- B. Patient achieves or maintains a positive clinical response after at least 6 months of therapy as evidenced by low disease activity or improvement in signs and symptoms of the condition **AND**
- C. Member has not experienced unacceptable toxicity from the drug

References:

- 1. Velsipity[®] tablets [prescribing information]. New York, NY: Pfizer; October 2023.
- Pfizer. An Extension Study for Treatment of Moderately to Severely Active Ulcerative Colitis (ELEVATE UC OLE). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 October 14]. Available at: https://clinicaltrials.gov/study/NCT03950232. NLM Identifier: NCT 03950232.
- 3. VELSIPITY. IBM Micromedex[®] [database online]. Pfizer Labs (per FDA), New York, NY, 2023. Available at: https://www.micromedexsolutions.com. Updated December 14, 2023. Accessed January 10, 2024

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/28/2024

March 2024