Original Effective Date: 03/07/2024
Current Effective Date: 12/17/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C27181-A

Velsipity (etrasimod)

PRODUCTS AFFECTED

Velsipity (etrasimod)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Ulcerative colitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ULCERATIVE COLITIS:
   1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
      AND

2. (a) Documentation of treatment failure, serious side effects or clinical contraindications to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently
   NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC
   OR
   (b) Member has severe disease indicated by one or more of the following: > 6 stools per day, frequent bloody stools, frequent urgency or incontinence, laboratory abnormalities (i.e., anemia, elevated CRP, low albumin), severe indicators on endoscopy or imaging (i.e., mucosal inflammation, extensive colitis)
   OR
   (c) Documentation the member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid, enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. Documentation of a pre-treatment assessment as recommended by FDA label which includes: CBC including lymphocyte counts, baseline bilirubin and transaminase levels, ECG (baseline), heart rate, blood pressure, ophthalmologic exam, vaccination status (varicella, etc.), skin examination
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review. [Contraindications to Velsipity (etrasimod) include: In the last 6 months, member has experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure; History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the member has a functioning pacemaker.]
   AND
6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary /PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

CONTINUATION OF THERAPY:

A. ULCERATIVE COLITIS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests to continued monitoring as required per FDA labeling

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified gastroenterologist or colorectal surgeon. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
2mg once daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Sphingosine-1-phosphate (S1P) Receptor Modulators (GI)

FDA-APPROVED USES:
Indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Ulcerative Colitis (UC) is a chronic, immune-mediated disease that is characterized by diffuse mucosal inflammation. It is characterized by relapsing and remitting mucosal inflammation, starting in the rectum and extending to proximal segments of the large intestine, also known as the colon. The ulcers produce pus and mucous, which cause abdominal pain and the need to frequently empty the colon. Other common signs and symptoms of UC include but are not limited to, diarrhea, blood in stool, and mucus discharge. Although several risk factors are not yet well understood, genetics, environmental factors, and even abnormal immune response can contribute to UC. The peak age of disease onset of UC is between the ages of 30 to 40 years of age. UC has a prevalence that equates to over 1.2 million people in the United States per year. It is the most common form of inflammatory bowel disease worldwide. 8-14% patients with UC have a family history of inflammatory bowel disease and first-degree relatives have four times the risk of developing the disease.

2020 AGA guidelines recommend prescribing outpatient adults with moderate to severe UC with infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment for the induction and maintenance of remission. 2019 American college of gastroenterology guidelines recommend patients with moderately active UC, non-systemic corticosteroids such as budesonide MMX before the use of systemic therapy. Patients with severely active UC, consider systemic corticosteroids rather than topical corticosteroids.

The approval of Velsipity, a sphingosine 1-phosphate (S1P) receptor modulator, was based on a data from 2 phase 3 double blind, placebo controlled, clinical trials to evaluate the safety and efficacy of etrasimod vs placebo in patients with active moderate-to-severe UC with an inadequate or loss of response or tolerance to at least 1 approved UC therapy. In ELEVATE UC 12, clinical remission was achieved among 26% of patients in Velsipity group compared to 15% of patients receiving placebo at week 12 ($P<0.05$). In ELEVATE UC 52, clinical remission was 27% for Velsipity group compared to 7% for placebo group at week 12 ($P<0.0001$). At week 52 in UC 52, clinical remission was 32% Velsipity group compared to 7% placebo group ($P<0.0001$). Results showed that in both trials, Velsipity treatment resulted in statistical significance for clinical remission. Key secondary endpoints such as symptomatic remission and endoscopic improvement proved statistical significance. The most common adverse reactions were headache, elevated liver tests, and dizziness.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Velsipity (etrasimod) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Velsipity (etrasimod) include: In the last 6 months, member

has experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure; History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the member has a functioning pacemaker, avoid use of live attenuated vaccines, avoid concomitant administration of immunosuppressive therapies.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Velsipity TABS 2MG

REFERENCES

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3. Sandborn, W. J., Vermeire, S., Peyrin-Biroulet, L., Dubinsky, M. C., Panes, J., Yarur, A., … Feagan, B.G. (2023). Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo-controlled, phase 3 studies. The Lancet, 401(10383). https://doi.org/10.1016/S0140-6736(23)00061-2
4. Rubin DT et al. ACG clinical guideline: Ulcerative colitis in adults. Am J Gastroenterol 2019 Mar; 114:384. Available at: https://journals.lww.com/ajg/Fulltext/2019/03000/ACG_Clinical_Guideline_Ulcerative_Colitis_in.10.asp x# pdf-link
5. Feuerstein, J., Isaacs, K., Schneider, Y., Siddique, S., Falck-Ytter, Y., & Singh, S. et al. (2020). AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology, 158(5), 1450-1461. doi: 10.1053/j.gastro.2020.01.006
6. Rubin, D. T., Ananthakrishnan, A. N., Siegel, C. A., Barnes, E. L., & Long, M. D. (2025). ACG Clinical Guideline Update: Ulcerative Colitis in Adults. The American Journal of Gastroenterology, 120(6), 1187–1224. https://doi.org/10.14309/ajg.0000000000003463

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable revisions: Required Medical Information Appendix References	Q4 2025
REVISION-Notable revisions: Coding/Billing Information Template Update Required Medical Information Contraindications/Exclusions/Discontinuation	Q4 2024
NEW CRITERIA CREATION	Q1 2024