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Last P&T Approval/Version: 01/31/2024
Next Review Due By: 10/2024
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

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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) 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 intolerance 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).

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

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

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requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

2mg once daily

Maximum Quantity Limits – 30 tablets/30 days

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 Modulator

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

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.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Drug and Biologic Coverage Criteria

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Velsipity TABS 2MG

REFERENCES

1. Velsipity (etrasimod) tablets [prescribing information]. New York, NY: Pfizer Labs; November 2023.
2. Lynch, W. D., & Hsu, R. (2023, June 5). Ulcerative colitis. Retrieved November 20, 2023, from Nih.gov website: <https://www.ncbi.nlm.nih.gov/books/NBK459282/>
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](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.aspx#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

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2024