UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2335-1
Program	Prior Authorization/Medical Necessity
Medication	Velsipity™ (etrasimod)* *Velsipity is excluded from coverage for the majority of our benefits
P&T Approval Date	4/2024
Effective Date	7/1/2024

1. Background:

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

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Velsipity** will be approved based on **all** of the following criteria:

   a. Diagnosis of moderately to severely active ulcerative colitis (UC)

   -AND-

   b. **One** of the following:

      (1) Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

      -OR-

      (2) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi (golimumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

   -AND-

   c. History of failure, contraindication, or intolerance to **three** of the following preferred products (document drug, date, and duration of trial):

      (1) One of the preferred adalimumab products[b]
      (2) Simponi (golimumab)
      (3) Stelara (ustekinumab)
      (4) Xeljanz/Xeljanz XR (tofacitinib)
      (5) Rinvoq (upadacitinib)

-AND-

d. History of failure, contraindication, or intolerance to Zeposia (ozanimod) (document date and duration of trial):

-AND-

e. Patient is not receiving Velsipity in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

-AND-

f. Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Velsipity** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response to Velsipity therapy

   -AND-

   b. Patient is not receiving Velsipity in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For a list of preferred adalimumab products please reference drug coverage tools.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Exclusion: Velsipity is excluded from coverage for the majority of our benefits
- Supply limits may be in place.

4. References:

1. Velsipity [package insert]. New York, NY: Pfizer Inc.; November 2023.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

Program	Prior Authorization/Medical Necessity – Velsipity (etrasimod)
Change Control	
4/2024	New program.