UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2335-3
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, 10/2024, 11/2024
Effective Date	2/1/2025

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 (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
      (2) Entyvio (vedolizumab)
      (3) Omvoh (mirikizumab-mrkz)
      (4) Rinvoq (upadacitinib)

(5) Simponi (golimumab)
(6) Skyrizi (risankizumab)
(7) Stelara (ustekinumab)
(8) Tremfya (guselkumab)
(9) Xeljanz/Xeljanz XR (tofacitinib)

-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), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

-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), Omvoh (mirikizumab-mrkz), Entyvio (vedolizumab)]

   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.

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.
10/2024	Updated step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote. Added Entyvio, Omvoh and Skyrizi as step therapy agents.
11/2024	Added Tremfya as a step therapy agent.