

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 3182-3
Program	Step Therapy
Medications	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:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two self-administered injectable products before providing coverage for Velsipity (etrasimod) for ulcerative colitis. Infused medications are not part of the criteria.

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

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

Adalimumab) is indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.

Simponi (golimumab) is indicated in adult patients with moderate to severe ulcerative colitis with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.

Stelara (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

Rinvoq (upadacitinib) is indicated in adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.

Xeljanz/Xeljanz XR (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have an inadequate response or intolerance to one or more TNF blockers.

Entyvio (vedolizumab) is indicated in adults for the treatment of moderately to severely active ulcerative colitis.

OmvoH (mirikizumab-mrkz) is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Skyrizi is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Tremfya (guselkumab) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

Members will be required to meet the coverage criteria below.

## 2. Coverage Criteria<sup>a</sup>:

### A. Ulcerative Colitis (UC)

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

a. 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-

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

**Authorization will be issued for 12 months.**

<sup>a</sup> 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 and/or Notification may be in place.

## 4. References:

1. Velsipity [package insert]. New York, NY: Pfizer Inc.; November 2023.

2. Zeposia [package insert]. Summit, NJ: Celgene Corporation; August 2023.
3. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
4. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
4. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2022.
5. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; November 2023.
6. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
7. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; January 2024.
8. Omvoh [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2024.
9. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2024.
10. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; September 2024.

Program	Step Therapy – Velsipity (etrasimod)
<b>Change Control</b>	
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. Updated background and reference.