UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3160-7
Program	Step Therapy
Medications	Zeposia® (ozanimod)
P&T Approval Date	12/2021, 5/2022, 1/2023, 4/2023, 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 Zeposia® (ozanimod) for ulcerative colitis. Infused medications are not part of the criteria.

Zeposia (ozanimod) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults and moderately to severely active ulcerative colitis (UC) 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 currently on Zeposia therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Ulcerative Colitis (UC)

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

   a. Diagnosis of moderately to severely active UC

   -AND-

   b. **One** of the following:

      (1) History of failure, contraindication, or intolerance to **two** of the following preferred products:

      (a) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
      (b) Entyvio (vedolizumab)
      (c) Omvoh (mirikizumab-mrkz)
      (d) Rinvoq (upadacitinib)
      (e) Simponi (golimumab)
      (f) Skyrizi (risankizumab)
      (g) Stelara (ustekinumab)
      (h) Tremfya (guselkumab)
      (i) Xeljanz/Xeljanz XR (tofacitinib)

      -OR-

      (2) **Both** of the following:

      (a) Patient is currently on Zeposia therapy

      -AND-

      (b) Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Bristol Myers Squibb sponsored Zeposia 360 Support Program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Zeposia*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Bristol Myers Squibb sponsored Zeposia 360 Support Program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Zeposia** will be approved

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:

- Supply limits and/or Notification may be in place.

4. References:

1. Zeposia [package insert]. Summit, NJ: Celegene Corporation; August 2023.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc..; February 2024.
3. 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 – Zeposia® (ozanimod)
Change Control	
12/2021	New program.
5/2022	Added Xeljanz and Rinvoq as preferred products for failure, contraindication, or intolerance for Ulcerative Colitis. Updated background and references.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated background and references.
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote "For a list of preferred adalimumab products please reference drug coverage tools." Updated references.
4/2024	Annual review with no change to coverage criteria. Updated references.
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.