UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3160-1
Program	Step Therapy
Medications	Zeposia® (ozanimod)
P&T Approval Date	12/2021
Effective Date	2/1/2022; Oxford only: N/A

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.

Humira (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.

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. <u>Ulcerative Colitis (UC)</u>

1. **Zeposia** will be approved based on **<u>both</u>** of the following criteria:

   a. Diagnosis of moderately to severely active UC

   -AND-

   b. **<u>One</u>** of the following:

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

(a) Humira (adalimumab)
(b) Simponi (golimumab)
(c) Stelara (ustekinumab)

-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; May 2021.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc..; February 2021.

3. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
4. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2020.

Program	Step Therapy – Zeposia® (ozanimod)
Change Control	
12/2021	New program.