CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Zeposia (ozanimod)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Zeposia was approved by the FDA in 2020 for the treatment of relapsing forms of multiple sclerosis (MS). MS is a chronic autoimmune disease of the central nervous system that disrupts communication in the brain and between the brain and body. Zeposia is a once-daily oral sphingosine-1-phosphate (S1P) receptor modulator with high affinity for S1P receptors 1 and 5. Unlike its in-class competitor products, first-dose monitoring is not required for Zeposia. However, a baseline ECG is still recommended, as well as other initial evaluations. Efficacy between products appears to be similar.
In 2021, Zeposia was approved for the treatment of ulcerative colitis (UC), becoming the first S1P receptor modulator approved for this indication. As an oral drug, it sets itself apart as most other UC drugs are injectable. Approval was based on the pivotal phase 3 trial, True North.

Zeposia (ozanimod) will be considered for coverage when the following criteria are met:

Multiple Sclerosis (MS)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of a relapsing form of MS (i.e., clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease); AND
4. The following baseline assessments have been completed (or are scheduled):
   a) A complete blood count (CBC)
   b) An ophthalmic evaluation
   c) Baseline liver function tests
   d) A cardiac evaluation by electrocardiogram (ECG)
5. Member has not experienced any of the following in the past 6 months: Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
6. Member does not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker; AND
7. Member does not have severe untreated sleep apnea; AND
8. Zeposia will not be used concomitantly with any other disease modifying drugs for MS.
9. **Dosage allowed/Quantity limit:** After titration, the recommended dose is 0.92 mg once daily. (30 capsules per 30 days).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing an improvement in signs and symptoms of disease (e.g., fewer relapses, slowed disability progression, reduced number or volume of brain lesions).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ulcerative Colitis (UC)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a documented diagnosis of moderately to severely active UC; AND
4. Member must have a documented trial and inadequate response with at least one of the following:
   a) 3 months of 6-mercaptopurine or azathioprine;
   b) 30 days of Corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
   c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.); AND
5. Trial and failure of two different preferred biologic drug indicated for UC (see Appendix); AND
6. The following baseline assessments have been completed (or are scheduled):
   a) A complete blood count (CBC)
   b) An ophthalmic evaluation
   c) Baseline liver function tests
   d) A cardiac evaluation by electrocardiogram (ECG)
7. Member has not experienced any of the following in the past 6 months: Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure; AND
8. Member does not have Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker; AND
9. Zeposia is not being prescribed in combination with biologic therapy for UC.
10. **Dosage allowed/Quantity limit:** After titration, the recommended dose is 0.92 mg once daily. (30 capsules per 30 days).

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing an improvement in signs and symptoms of disease such as clinical remission, reduced rectal bleeding, decreased stool frequency, or endoscopic-histologic mucosal healing.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Zeposia (ozanimod) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/07/2020	New policy for Zeposia created.
10/13/2021	Transferred to new template. Added new indication section for UC. MS section: Updated references. General changes to language and safety monitoring for consistency with related drugs. Removed baseline relapse and lesion count.
04/01/2022	Updated UC biologic trial to reference appendix; added appendix

References:

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14. Trigo-Vicente C, Gimeno-Ballester V, García-López S, López-Del Val A. Systematic review and network meta-analysis of treatment for moderate-to-severe ulcerative colitis. *Int J Clin Pharm*. 2018;40(6):1411-1419. doi:10.1007/s11096-018-0743-4

Effective date: 04/01/2022
Revised date: 10/13/2021

Appendix: Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Humira • Stelara
Approved for Ulcerative Colitis	• Humira • Stelara • Rinvoq