Commercial & Healthcare Exchange PA Criteria

Effective: September 2nd, 2020

Prior Authorization: Zeposia

Products Affected: Zeposia (ozanimod) oral capsules

Medication Description: Ozanimod is a sphingosine 1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5. Ozanimod blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood.

Covered Uses: Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. In addition, treatment of moderately to severely active ulcerative colitis (UC) in adults.

Exclusion Criteria:

1. Patients who in the last 6 months, have experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart
2. Patients with the presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
3. Patients with severe untreated sleep apnea
4. Patents taking a monoamine oxidase (MAO) Inhibitor

Required Medical Information:

1. Diagnosis

Age Restrictions: 18 years of age or older

Prescriber Restrictions:

- For MS: Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of multiple sclerosis.
- For UC: Prescribed by or in consultation with a gastroenterologist.

Coverage Duration: 12 months

Other Criteria:

1. **Multiple Sclerosis:**
   Patient has a diagnosis of any of the following relapsing forms of Multiple Sclerosis:
   a. Relapsing-remitting multiple sclerosis; **OR**
   b. Active secondary progressive disease; **OR**
   c. Clinically isolated syndrome.

2. **Ulcerative Colitis**
    a. Patient has been clinically diagnosed with moderate to severe active ulcerative colitis; **AND**
    b. Patient has had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine; **AND**
    c. Patient has documented failure of, or intolerance to Adalimumab products (Humira or Amjevita) **AND** Stelara SC.

References:

1. Zeposia [package insert]. Celgene Corporation. Summit, NJ 07901; May 2021.
2. Ozanimod. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. August 2021.
3. Ozanimod. IBM Micromedex® DRUGDEX®. IBM Watson Health, Greenwood Village, Colorado, USA. June 2020.
4. Treatment for MS. Multiple Sclerosis Foundation - Treatment for MS. https://msfocus.org/Get-Educated/Treatment-for-MS.aspx. Accessed 13 August 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/2/2020
2	Updated Policy	Added UC criteria including step (Humira and Stelara SC trial first)	All	8/3/2021
3	Updated Policy	Changed UC criteria c. from "Patient has documented failure of Humira AND Stelara" to "…Humira OR Stelara"	Other Criteria: Ulcerative Colitis	1/11/2023
4	Updated Policy	Other Criteria- Changed "Humira" to "Adalimumab"	Other Criteria	5/11/23
5	Updated Policy	Updated Ulcerative Colitis criteria "from documented failure of, or intolerance to Adalimumab products (Humira/Amjevita) **OR** Stelara SC" to "**AND** Stelara"	Other Criteria: Ulcerative Colitis	5/30/2023