

## PHARMACY POLICY STATEMENT Indiana Medicaid

DRUG NAME	Zeposia (ozanimod)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 30 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Zeposia (ozanimod) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### RELAPSING MULTIPLE SCLEROSIS

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a confirmed diagnosis of relapsing multiple sclerosis, including clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS), and active secondary progressive disease (SPMS); AND
4. Member's relapse rate and/or number of lesions prior to starting treatment are documented in chart notes; AND
5. Member does NOT have any of the following:
  - a) Primary progressive MS;
  - b) Myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months;
  - c) Severe untreated sleep apnea;
  - d) Concurrent use with another disease-modifying agent for MS.
6. **Dosage allowed:** 1 capsule (0.23mg to 0.92mg) once per day for 7 days of titration (see package insert for details). Maintenance dose is 1 capsule (0.92 mg) once daily.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing an improvement or stabilization in signs and symptoms of disease (e.g., fewer relapses, slowed disability progression, reduced number or volume of brain lesions).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Zeposia (ozanimod) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE

ACTION/DESCRIPTION

## References:

1. Zeposia [package insert]. Summit, NJ; Celgene Corporation, March 2020.
2. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology* 2018;90:789-800.
3. Cohen JA, Comi G, Arnold DL, et al. Efficacy and safety of ozanimod in multiple sclerosis: Dose-blinded extension of a randomized phase II study. *Multiple Sclerosis Journal* 2019;25(9):1255-1262. doi: 10.1177/1352458518789884.
4. Cohen JA, Comi G, Selmaj KW, et al. Safety and efficacy of ozanimod versus interferon beta-1a in relapsing multiple sclerosis (RADIANCE): a multicenter, randomized, 24-month, phase 3 trial. *Lancet Neurol* 2019, doi: 10.1016/S1474-4422(19)30238-8.
5. Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). *Neurology*. 1983 Nov;33(11):1444-52.
6. ClinicalTrials.gov. Identifier NCT02294058. Phase 3 study of RPC1063 in relapsing MS. Available at <https://clinicaltrials.gov/ct2/show/NCT02294058>.
7. ClinicalTrials.gov. Identifier NCT02047734. Efficacy and safety study of ozanimod in relapsing multiple sclerosis (Radiance study). Available at <https://clinicaltrials.gov/ct2/show/NCT02047734>.
8. Finkelsztejn A. Multiple sclerosis: overview of disease-modifying agents. *Perspect Medicin Chem*. 2014;6:65-72. Published 2014 Oct 5.
9. Swallow E, Patterson-Lomba O, Yin L, et al. Comparative safety and efficacy of ozanimod versus fingolimod for relapsing multiple sclerosis. *J Comp Eff Res*. 2020;9(4):275-285.

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