

Pharmacy Policy

Zeposia®

Policy Number: 9.234

Revision Number: 1.1

Version Effective Date: 3/1/2022

| | |
|---|---|
| Product Applicability <input type="checkbox"/> All Plan+ Products | |
| <p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p> | <p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p> |

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Zeposia® (ozanimod)

The Plan may authorize coverage of the above products for members meeting the following criteria:

| | |
|-------------------------------------|---|
| Covered Use | All FDA approved indications not otherwise excluded |
| Exclusion Criteria | None |
| Required Medical Information | <p>A diagnosis of one of the following:</p> <ol style="list-style-type: none"> 1. Relapsing multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; AND |

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
 Zeposia

| | |
|-------------------------------|--|
| | <ul style="list-style-type: none"> a. Prescribed by or in consultation with a neurologist; AND b. Member has tried and failed treatment with one or more of the following or the provider has indicated clinical inappropriateness with: <ul style="list-style-type: none"> i. One of the following: Avonex, Betaseron, glatiramer, Plegridy, or Rebif; AND ii. One of the following: Vumerity, or Aubagio; AND c. All of the following <ul style="list-style-type: none"> i. A recent CBC, including lymphocyte count, has been obtained (within the last 6 months or after discontinuation of previously MS therapy); AND ii. ECG was obtained and if preexisting conditions were found, advice from a cardiologist was sought; AND iii. Transaminase and bilirubin levels were obtained within the last 6 months; AND iv. Member has antibodies to varicella zoster virus (VZV) OR member received VZV vaccination at least a month prior to treatment with Zeposia. OR <p>2. Moderately to severely active ulcerative colitis. AND</p> <ul style="list-style-type: none"> a. Documentation* that member has had a trial of BOTH Humira and Stelara SC ; AND b. The medication is prescribed by or in consultation with a gastroenterologist. <p>* Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts</p> |
| Age Restriction | Member is 18 years of age or older. |
| Prescriber Restriction | Prescribed by or in consultation with a neurologist or gastroenterologist. |
| Coverage Duration | 12 months |
| Other criteria | Reauthorization criteria: <ul style="list-style-type: none"> 1. Patient has met initial criteria. 2. Clinical condition has improved or stabilized. |

⁺ Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Zeposia

Clinical Background Information and References

1. Cohan S, Lucassen E, Smoot K, Brink J, Chen C. Sphingosine-1-phosphate: its pharmacological regulation and the treatment of multiple sclerosis: a review article. *Biomedicines*. 2020;8(7):227
2. Feuerstein, JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158:1450–1461
3. Sandborn WJ, Feagan BG, Hanauer S, et al. Long-term efficacy and safety of ozanimod in moderate-to-severe ulcerative colitis: results from the open-label extension of the randomized, phase 2 touchstone study. *J Crohns Colitis*. 2021 Jul 5;15(7):1120-1129.
4. Scott FL, Clemons B, Brooks J, et al. Ozanimod (RPC1063) is a potent sphingosine-1-phosphate receptor-1 (S1P1) and receptor-5 (S1P5) agonist with autoimmune disease-modifying activity. *Br J Pharmacol*. 2016;173(11):1778-1792.
5. Zeposia (ozanimod) [prescribing information]. Summit, NJ: Celgene Corporation. September 2020. Accessed July 2021.

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|------------------------|-------------------------|---------------------|------------------------|
| 8/12/2021 | 11/1/2021 | Pharmacy Department | Pharmacy P&T Committee |

Policy Revisions History

| Review Date | Summary of Revisions | Revision Effective Date | Approved by |
|-------------|--|-------------------------|---------------|
| 8/12/2021 | P&T: New policy created | 11/1/2021 | P&T Committee |
| 1/20/2022 | Updated policy to realign with ESI ICCV policy | 3/1/2022 | P&T Committee |

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other

^{*} Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Zeposia

Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

^{*} *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Zeposia