BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Zeposia – Unified Formulary

Policy Number: 9.234
Version Number: 1.0
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

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

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Zeposia® (ozanimod)	

Approval Criteria:

Zeposia® (ozanimod)	1. Diagnosis of multiple sclerosis; **AND** a. Documentation of **ONE** of the following:

+ 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.

	i. Clinically isolate syndrome (CIS); **OR** ii. Relapse-remitting multiple sclerosis (RRMS); **OR** iii. Active secondary-progressive multiple sclerosis (SPMS) **AND** b. Prescriber is a neurologist or consult notes from a neurology office are provided; **AND** c. Documentation of medical necessity for use instead of Gilenya® d. Documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents (*History of claims is sufficient for all failed trials*): i. Aubagio® (teriflunomide) ii. glatiramer acetate therapy iii. interferon therapy iv. Ocrevus® (ocrelizumab) v. Tecfidera® (dimethyl fumarate) or Vumerity® (diroximel fumarate) 2. Documented diagnosis of moderate-to-severe ulcerative colitis; **AND** a. Prescriber is a gastroenterologist or consult notes from a gastroenterology office are provided; **AND** b. Documentation of **ONE** of the following: i. Inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for ulcerative colitis (*History of claims is sufficient for all failed trials*) ; **OR** ii. Contraindication to **ALL** anti-TNF agents **AND** c. Documented inadequate response, adverse reaction, or contraindication to Entyvio®; **AND** d. Documentation member is not currently receiving concomitant therapy with immunomodulators or biologic agents
Duration/Quantity of Authorization:	Ulcerative colitis: Prior authorization may be issued for **6 months** Multiple sclerosis: Prior authorization may be issued for **1 year**

References

1. Zeposia (ozanimod) [prescribing information]. Summit, NJ: Celgene Corporation; March 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
11/5/2021	1/1/2022	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
11/5/2021	Moved into drug specific policy to capture criteria from Targeted Immunomodulators and Multiple Sclerosis MH UPPL policies for drug	1/1/2022	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

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 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.