Pharmacy Policy

Metabolic Bone Disease Agents

Policy Number: 9.318
Version Number: 1
Version Effective Date: 1/1/2021

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

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

Prior Authorization Policy

Products Affected:

- **Evenity (romosozumab-aqqg)**
- **Tymlos (abaloparatide)**
- **Xgeva (denosumab)**

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	Evenity: member has had a stroke or MI within the previous year
Required Medical Information	Tymlos, Evenity Documentation of the following: 1. A diagnosis of post-menopausal osteoporosis; AND 2. T-score is less than or equal to -2.5 as evidenced via a DXA bone density scan or T-score is between -1.0 and -2.5 as evidenced via a DXA bone density scan and multiple risk factors for fractures (must document risk factors*); 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.

	3. An inadequate response (defined as a declining T-score from baseline or a fragility fracture) or intolerance to one oral bisphosphonate; or contraindication (i.e., esophageal stricture, achalasia, etc) to oral bisphosphonates; AND 4. An inadequate response (defined as a declining T-score from baseline or a fragility fracture) or intolerance to one injectable bisphosphonate; or contraindication to injectable bisphosphonates Xgeva Documentation of the following: 1. Diagnosis of multiple myeloma or solid tumor with bone metastases; OR 2. Diagnosis of giant cell tumor of the bone; AND The tumor is unresectable or surgical resection is likely to result in severe morbidity; OR 3. Diagnosis of hypercalcemia of malignancy; AND An intolerance, contraindication, or treatment failure to a trial of zoledronic acid (Zometa)
Age Restriction	None
Prescriber Restriction	Evenity: prescribed by or in consultation with an endocrinologist
Coverage Duration	Evenity: 12 months Tymlos, Xgeva: 24 months
Other criteria	Continuation of therapy is clinically appropriate and does not exceed lifetime limit.

**Risk factors for fracture include advanced age, prior history of fragility fracture, chronic glucocorticoid use, low BMI, parental history of hip fracture, family history of osteoporosis, cigarette smoking, excess alcohol consumption, and presence of medical diseases that are associated with low BMD, such as rheumatoid arthritis, inflammatory bowel disease, type 1 diabetes, chronic liver disease.*

***Zometa® (zoledronic acid IV soln 4 mg) is covered without a PA*

Appendix A – Applicable HCPCs

Code	Medication
J0897	denosumab injection (Xgeva)
J3111	Romosozumab injection (Evenity)

Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.099 Metabolic Bone Disease Agents Policy retired, new policy created	1/1/2021	P&T Committee

Next Review Date

2021

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 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.