Pharmacy Policy

Crysvita

Policy Number: 9.324
Version Number: 2.0
Version Effective Date: 9/1/2021

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:

- **Crysvita (burosumab-twza)**

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

Covered Use	All medically excepted indications unless otherwise excluded
Exclusion Criteria	Concurrent use with oral phosphate and/or active vitamin D analogs Severe renal impairment End stage renal disease
Required Medical	1. Diagnosis of X-linked hypophosphatemia; ***AND*** a. Confirmation of diagnosis by 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.

Information	i. Genetic testing; ***OR*** ii. Elevated serum fibroblast growth factor 23 (FGF23) level >30pg/mL; ***AND*** b. Documentation of baseline serum phosphorus level that is below the normal range for age; ***AND*** c. For members 18 years and older: documentation of symptoms related to mobility, skeletal pain or recent fractures; ***OR*** 2. Diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia; ***AND*** a. Documentation of a phosphaturic mesenchymal tumor that cannot be curatively resected or localized; ***AND*** b. Documentation that the member is experiencing at least one sign or symptom of tumor-induced osteomalacia, such as fatigue, impaired mobility, bone pain, or muscle weakness ; ***AND*** c. Member has tried and failed oral phosphate and calcitriol therapy OR documentation has been provided of a clinical rationale why treatment with oral phosphate and calcitriol therapy is not appropriate for the member; ***AND*** d. Documentation of baseline serum phosphorus level that is below the normal range for age
Age Restrictions	X-linked hypophosphatemia: 6 months and older FGF23-related hypophosphatemia in tumor-induced osteomalacia: 2 years and older
Prescriber Restriction	Prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	12 months
Other criteria	Reauthorization a. Documentation of improvement in symptoms (e.g. skeletal pain, enhanced mobility, linear growth, etc.); ***AND*** b. Documentation of increased serum phosphorus levels from baseline

Clinical Background Information and References

1. Crysvita (burosumab-twza) injection [prescribing information]. Ultragenyx 2018
2. Scheinman, SJ. Hereditary hypophosphatemic rickets and tumor-induced osteomalacia. UptoDate. Last updated October 2, 2019

Applicable Coding:

J -Code	Medication
J0584	Injection, burosumab-twza, 1 mg

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			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.999 Crysvita Policy retired, new policy created. Removed baseline tubular reabsorption of phosphorus corrected for glomerular filtration rate that was below the normal range for age and gender	1/1/2021	P&T Committee
5/13/2021	P&T annual review. Added diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia. Updated reauthorization language.	9/1/2021	P&T Committee

Next Review Date

5/2022

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 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.