Mass General Brigham
Health Plan

Crysvita (burosumab-twza)
Effective 09/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for treatment of:

- X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older
- FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in pediatric patients at least 2 years of age and adults

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

Authorization may be granted when all of the following diagnosis-specific criteria have been met:

X-linked hypophosphatemia

1. Documented diagnosis of X-linked hypophosphatemia supported by at least ONE of the following: :
    a. Genetic testing
    b. Serum fibroblast growth factor 23 level greater than 30pg/ml
2. Prescriber is an endocrinologist, nephrologist or specialist in metabolic bone disorders.
3. Documentation the member's baseline serum phosphorous level is below normal range for age
4. **For members > 18 years of age**: documentation of symptomatic disease as evidenced by at least ONE of the following:
    a. Severe disabling skeletal pain
    b. Impaired mobility
    c. Recent fracture

Tumor-induced osteomalacia

1. Documentation of a mesenchymal tumor which cannot be curatively resected or localized
2. Member is 2 years of age or older
3. Prescriber is an endocrinologist, nephrologist or specialist in metabolic bone disorders
4. Documentation the member's baseline serum phosphorous level is below normal range for age
5. Documentation the member is experiencing at least ONE of the following sign or symptoms of tumor-induced osteomalacia:
    a. Bone pain
    b. Impaired mobility
    c. Muscle weakness
    d. Fatigue
6. Documentation member has had an inadequate response with or has a contraindication to therapy with oral phosphate and calcitriol.

<u>Continuation of Therapy</u>

Requests for reauthorization will be approved when all of the following criteria are met:

1. Prescribed by or in consultation with an endocrinologist or nephrologist
2. Documentation of an increase in baseline phosphorus levels
3. Member has had a positive response to therapy as evidenced by a reduction in skeletal pain, enhanced mobility, fracture reduction/healing, or improvement of skeletal deformities

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months.

References

1. Crysvita (burosumab-twza) [prescribing information]. Princeton, NJ: Kyowa Kirin, Inc; March 2023.
2. Drezner MK, Whyte MP. Heritable renal phosphate wasting disorders. In: Genetics of bone biology and skeletal disease, 2nd ed, Thakker RV, Whyte MP, Eisman JA, Igarashi T (Eds), Academic Press, Amsterdam 2017.
3. He Q, Zhang B, Zhang L, et al. Diagnostic efficiency of 68Ga-DOTANOC PET/CT in patients with suspected tumour-induced osteomalacia. Eur Radiol 2021; 31:2414
4. Imel EA, Glorieux FH, Whyte MP, et al. Burosumab versus conventional therapy in children with X-linked hypophosphataemia: a randomised, active-controlled, open-label, phase 3 trial. Lancet 2019; 393:2416
5. Insogna KL, Briot K, Imel EA, et al. A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial Evaluating the Efficacy of Burosumab, an Anti-FGF23 Antibody, in Adults With X-Linked Hypophosphatemia: Week 24 Primary Analysis. J Bone Miner Res 2018; 33:1383.
6. Jan de Beur SM, Miller PD, Weber TJ, et al. Burosumab for the Treatment of Tumor-Induced Osteomalacia. J Bone Miner Res 2021; 36:627
7. Verge CF, Lam A, Simpson JM, et al. Effects of therapy in X-linked hypophosphatemic rickets. N Engl J Med 1991; 325:1843.

Review History

02/20/2019 – Reviewed
07/22/2020 – Reviewed and Updated July P&T Mtg; started and stabilized statement added; references updated. Effective 10/01/2020.

09/22/2021- Reviewed and Updated Sept. P&T; updated new FDA age requirement for X-linked hypophosphatemia: Added new FDA indication and criteria for osteomalacia; Updated reauthorization criteria for both indications. Effective 01/01/2022.
06/11/2025 - Reviewed and updated at June P&T. Updated language for members who are new to the Plan. Clarified documentation requirements. Effective 09/01/2025.