

Policy Name:	Crysvita (burosumab)	Policy #:	2664P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Crysvita.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Crysvita under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for X-linked hypophosphatemia

- 1.1 Diagnosis confirmed by one of the following:
 - Genetic testing (e.g., confirmed *PHEX* gene mutation in patient or first-degree relative)
 - Elevated serum fibroblast growth factor 23 (FGF23) level > 30 pg/mL
- 1.2 Age 6 months or older
- 1.3 Prescribed by or in consultation with an endocrinologist (hormone doctor) or specialist experienced in the treatment of metabolic bone disorders
- 1.4 One of the following:
 - Patient's epiphyseal plate (growth plate) has not fused
 - Patient's epiphyseal plate has fused and patient is experiencing clinical signs and symptoms of the disease (e.g., limited mobility, musculoskeletal pain, bone fractures) and failure, intolerance or contraindication to therapy with calcitriol in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra)
- 1.5 Documented fasting serum phosphorus level that is below the normal range for age

2 Coverage Criteria for Tumor-Induced Osteomalacia

- 2.1 Diagnosis of fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia
- 2.2 Associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized
- 2.3 Age 2 years or older
- 2.4 Prescribed by or in consultation with an oncologist (cancer doctor), an endocrinologist (hormone doctor), or a specialist experienced in the treatment of metabolic bone disorders
- 2.5 Documented fasting serum phosphorus level that is below the normal range for age

3 Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Reapproval: 12 months with documentation that patient has experienced normalization of serum phosphate while on therapy and a positive clinical response (e.g., enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain)

CPT Codes

HCPCS Codes

J0584	Injection, burosumab-twza 1 mg
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References

1. Crysvita (burosumab-twza) [prescribing information]. Princeton, NJ: Kyowa Kirin Inc; March 2023.

2. 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.
3. 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.
4. Haffner D, Francesco E, Eastwood DM, et al. Clinical practice recommendations for the diagnosis and management of X-linked hypophosphatemia. *Nat Rev Nephrol.* 2019;15(7):435-455.
5. 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.
6. Imanishi Y, Ito N, Rhee Y, et al. Interim Analysis of a Phase 2 Open-Label Trial Assessing Burosumab Efficacy and Safety in Patients With Tumor-Induced Osteomalacia. *J Bone Miner Res* 2021; 36:262.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.