Reference number(s)
2562-A

Specialty Guideline Management
Crysvita

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Crysvita	burosumab-twza

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
- Treatment of fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

X-linked hypophosphatemia (XLH)

Initial requests

- At least one of the following:
  - Genetic test results confirming the member has a pathogenic variant in the phosphate regulating endopeptidases X-linked (PHEX) gene
  - Genetic test results confirming a pathogenic variant in the PHEX gene in a directly related family member with appropriate X-linked inheritance
  - Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is above the upper limit of normal or abnormal for the assay
- Baseline fasting serum phosphate level
- Radiographic evidence of rickets or other bone diseases attributed to XLH

Continuation requests

- Chart notes or medical record documentation showing beneficial response to therapy

Tumor-induced osteomalacia (TIO)

Initial requests

- Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is above the upper limit of normal or abnormal for the assay
- Baseline fasting serum phosphorus level
- Ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR)
- Chart notes or medical record documentation of clinical signs or symptoms of TIO

Continuation requests

- Chart notes or medical record documentation showing beneficial response to therapy

Prescriber Specialties

This medication must be prescribed by or in consultation with an endocrinologist, nephrologist, or a physician specializing in the treatment of metabolic bone disorders.

Coverage Criteria

X-linked hypophosphatemia (XLH)[1-5]

Authorization of 12 months may be granted for treatment of X-linked hypophosphatemia (XLH) when all of the following criteria are met:

- Member meets one of the following criteria:
  - Genetic test confirming a pathogenic variant in the PHEX gene in the member.
  - Genetic test confirming a pathogenic variant in the PHEX gene in a directly related family member with appropriate X-linked inheritance.
  - Member's FGF23 level is above the upper limit of normal or abnormal for the assay.
- Member's baseline fasting serum phosphorus level is below the normal range for age.
- Member has radiographic evidence of rickets or other bone diseases attributed to XLH.

Tumor-induced osteomalacia (TIO)[1,6,7]

Authorization of 12 months may be granted for treatment of tumor-induced osteomalacia (TIO) when all of the following criteria are met:

- Member's diagnosis is confirmed by ALL of the following:
  - Member's FGF23 level is above the upper limit of normal or abnormal for the assay.
  - Member's baseline fasting serum phosphorus level is below the normal range for age.
  - Member's ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) is below the normal range for age.
- Member has clinical signs or symptoms of TIO (e.g., bone pain, fractures, muscle weakness, limb deformity, craniofacial anomaly, localized mass).
- Member's disease is associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit and who are experiencing benefit from therapy as evidenced by disease improvement or disease stability (e.g., increase or normalization in serum phosphate, improvement in bone and joint pain, reduction in fractures, improvement in skeletal deformities).

References

1. Crysvita [package insert]. Princeton, NJ: Kyowa Kirin, Inc.; August 2025.

2. Linglart A, Imel EA, Whyte MP, et al. Sustained Efficacy and Safety of Burosumab, a Monoclonal Antibody to FGF23, in Children With X-Linked Hypophosphatemia. J Clin Endocrinol Metab. 2022;107(3):813-824.
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(8):1383-1393.
4. Haffner D, Emma F, Seefried L, et al. Clinical Practice recommendations for the diagnosis and management of X-linked hypophosphataemia. Nat Rev Nephrol. 2025;21(5):330-354.
5. Khan AA, Ali DS, Appelman-Dijkstra et al. X-Linked hypophosphatemia management in adults: An International Working Group clinical practice guideline. J Clin Endocrinol Metab. 2025;110(8):2353-2370.
6. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02304367. Study of Burosumab (KRN23) in Adults with Tumor-Induced Osteomalacia (TIO) or Epidermal Nevus Syndrome (ENS). 2020 June 30. Available from: http://clinicaltrials.gov/ct2/show/NCT02304367.
7. Jan de Beur SM, Minisola S, Xia WB, et al. Global guidance for the recognition, diagnosis, and management of tumor-induced osteomalacia. J Intern Med. 2023;293(3):309-328.