Crysvita (burosumab-twza)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Approval Duration: 6 months Continuation Approval Duration: 1 year

Medications	Quantity Limit
Crysvita (burosumab-twza) subcutaneous injection 10 mg/mL	2 vials per 28 days
Crysvita (burosumab-twza) subcutaneous injection 20 mg/mL	8 vials per 28 days
Crysvita (burosumab-twza) subcutaneous injection 30 mg/mL*	6 vials per 28 days

*For individuals using Crysvita (burosumab-twza) to treat tumor-induced osteomalacia, may approve up to 360 mg [twelve (12) 30 mg/mL vials] per 28 days.

APPROVAL CRITERIA

Initial requests for Crysvita (burosumab-twza) for X-linked hypophosphatemia may be approved if the following criteria are met:

I. Individual is using for the treatment of X-linked hypophosphatemia (XLH); **AND**
II. Documentation is provided that diagnosis has been confirmed by (Carpenter 2018; Haffner 2019; Ruppe 2017):
    A. Genetic testing (in the individual or a directly related family member);
    OR
    B. Fibroblast growth factor 23 (FGF-23) greater than 30 pg/mL;

    AND
    C. Reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR);

AND

III. If 18 years of age or older, individual is experiencing clinical signs and symptoms of XLH (including but not limited to bone pain, fractures, limited mobility in adults) (Carpenter 2011, Ruppe 2017); **AND**
IV. Documentation is provided that individual has a serum phosphorus level below the reference range for age.

Continuation requests for Crysvita (burosumab-twza) for X-linked hypophosphatemia may be approved if the following criteria are met:

I. Documentation is provided that individual achieved and sustained a clinically significant improvement in serum phosphate level; **AND**
II. Individual has achieved and sustained clinically significant improvement of clinical signs and symptoms of XLH.

Initial requests for Crysvita (burosumab-twza) for tumor-induced osteomalacia may be approved if the following criteria are met:

I. Individual has a diagnosis of tumor-induced osteomalacia; **AND**
II. The tumor(s) cannot be curatively resected or localized; **AND**
III. The diagnosis is supported by (NCT02722798, NCT02304367):
    A. Fibroblast growth factor 23 (FGF-23) greater than or equal to 100 pg/mL, and documentation is provided; **AND**
    B. Reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR); **AND**
IV. Documentation is provided that individual has a serum phosphate level below the reference range for age.

Continuation requests for Crysvita (burosumab-twza) for tumor-induced osteomalacia may be approved if the following criterion is met:

I. Documentation is provided that individual achieved and sustained a clinically significant improvement in serum phosphate level; **AND**
II. Individual achieved and sustained clinically significant improvement of clinical signs and symptoms of osteomalacia.

Crysvita (burosumab-twza) may not be approved for any of the following:

I. All other indications not included above; **OR**
II. Individual will be utilizing Crysvita in combination with an oral phosphate supplement or active vitamin D analog (for example, calcitriol); **OR**
II. Individual has severe renal impairment or end stage renal disease.

Key References:

1. Carpenter TO, Imel EA, Holm IA, Jan de Beur SM, Insogna KL. A clinician's guide to X-linked hypophosphatemia. *J Bone Miner Res.* 2011 Jul;26(7):1381-8.
2. Carpenter TO, Whyte MP, Imel EA, et al. Burosumab Therapy in Children with X-Linked Hypophosphatemia. *N Engl J Med.* 2018; 378: 1987-98.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 26, 2021.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Haffner D, Emma F, Eastwood DM, et al. Clinical practice recommendations for the diagnosis and management of X-linked hypophosphataemia. *Nat Rev Nephrol*. 2019;15(7):435-455.

6. Kyowa Kirin Co., Ltd. A Study of KRN23 in Subjects With Tumor-Induced Osteomalacia or Epidermal Nevus Syndrome. NLM Identifier: NCT02722798. Last updated: September 3, 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT02722798?term=02722798&draw=2&rank=1. Accessed: June 26, 2021.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
8. Ruppe MD. X-Linked Hypophosphatemia, Synonyms: XLHR, X-Linked Hypophosphatemic Rickets, X-Linked Vitamin D-Resistant Rickets. GeneReviews [Internet]. Updated: April 13, 2017. Available at: https://www.ncbi.nlm.nih.gov/books/NBK83985/ Accessed: June 26, 2021.
9. Scheinman SJ, Carpenter T, Drezner MK. Hereditary hypophosphatemic rickets and tumor-induced osteomalacia. Last updated: February 16, 2021. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 26, 2021.
10. Ultragenyx Pharmaceutical Inc. Study of Burosumab (KRN23) in Adults With Tumor-Induced Osteomalacia (TIO) or Epidermal Nevus Syndrome (ENS). NLM Identifier: NCT02304367. Last updated: February 12, 2021. Available at: https://clinicaltrials.gov/ct2/show/study/NCT02304367?term=NCT02304367&draw=2&rank=1. Accessed: June 26, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.