

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Crysvita (burosumab-twza)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Crysvita (burosumab-twza) subcutaneous injection

### APPROVAL CRITERIA

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

- I. Individual is using for the treatment of X-linked hypophosphatemia (XLH); **AND**
- II. The diagnosis has been confirmed by (Carpenter 2011, Carpenter 2018, 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; **OR**
  - C. Low-serum phosphate concentration **AND** reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR); **AND**
- III. Individual has a serum phosphorus level below the reference range for age; **AND**
- IV. 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);

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

- I. Individual achieved and sustained a clinically significant improvement in serum phosphate level **AND** clinical signs and symptoms of XLH.

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

- I. Individual will be utilizing Crysvita in combination with a phosphate supplement or vitamin D analog (for example, calcitriol); **OR**
- II. Individual has severe renal impairment or end stage renal disease.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**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. Accessed: June 19, 2018.
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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 19, 2018.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
7. 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: July 16, 2018.
8. Scheinman SJ, Drezner MK. Hereditary hypophosphatemic rickets and tumor-induced osteomalacia. Last updated Sept 26 2017. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 19, 2018.

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