

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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. All other indications not included above; **OR**
- II. 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.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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: September 1, 2019.
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: September 1, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. 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: September 1, 2019.
7. Scheinman SJ, Carpenter T, Drezner MK. Hereditary hypophosphatemic rickets and tumor-induced osteomalacia. Last updated: July 12, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 1, 2019..

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.