Mass General Brigham
Health Plan

Crysvita (burosumab-twza)
Effective 07/31/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for X-linked hypophosphatemia and works by restoring renal phosphate reabsorption and by increasing serum concentrations of 1,25 dihydroxy vitamin D for pediatric patients at least 6 months of age and adults. Crysvita is also indicated for tumor-induced Osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in pediatric patients at least 2 years of age and adults

No PA	Drugs that require PA
calcitriol injection	Crysvita (burosumab-twza)
K-phos® M.F. (potassium phosphate/sodium phosphate)	
K-phos® Neutral (potassium phosphate/dibasic sodium phosphate/monobasic sodium phosphate)	
K-phos® No.2 (potassium phosphate/sodium phosphate/phosphorus)	
potassium phosphate *	
Rocaltrol® # (calcitriol)	
sodium phosphate *	

This is a brand-name drug with FDA "A"-rated generic equivalents. Prior authorization is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without prior authorization

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:
X-linked hypophosphatemia

1. Diagnosis of X-linked hypophosphatemia (XLH) supported by genetic testing, elevated FGF23 levels, decreased serum phosphorus levels or radiographic evidence
2. Member is ≥ 6 months of age
3. Appropriate dosing (weight required)

FGF23-related hypophosphatemia in tumor-induced osteomalacia

1. Diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)
2. Documentation that phosphaturic mesenchymal tumor cannot be resected or localized
3. Member is ≥ 2 years of age
4. Appropriate dosing (weight required)

Continuation of Therapy
Reauthorization requires physician documentation of a positive response to therapy (defined as either improved patient serum phosphorus concentration and/or radiographic improvement).

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

References

1. Crysvita® [package insert] Novato (CA): Ultragenyx Pharmaceuticals; 2019 Sep.
2. FDA approves first therapy for rare inherited form of rickets, x-linked hypophosphatemia [press release on internet]. Silver Spring (MD): Food and Drug Administration. 2018 April 17 [cited 2019 Nov 17]. Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604810.htm
3. Ultragenyx nabs blockbuster FDA nod for $200k-per-year Crysvita [press release from the internet] Newton (MA): Fierce Pharma: 2018 April 18 [cited 2019 Nov 17]. Available from: https://www.fiercepharma.com/regulatory/ultragenyx-nabs-fda-nod-for-200-000-per-year-crysvita-a-potential-blockbuster.
4. Ultragenyx and Kyowa Kirin announce topline phase 3 study results demonstrating superiority of Crysvita® (burosumab) treatment to oral phosphate and active vitamin D in children with X-linked hypophosphatemia (XLH) [press release on the internet]. Novato (CA): Ultragenyx Pharmaceuticals; 2018

May 17 [cited 2019 Nov 17]. Available from: http://ir.ultragenyx.com/news-releases/news-release-details/ultragenyx-and-kyowa-kirin-announce-topline-phase-3-study.
5. Familial Hypophosphatemia. Danbury (CT): National Organization for Rare Disorders. 2019 [cited 2019 Nov 17]. Available from: https://rarediseases.org/rare-diseases/familial-hypophosphatemia/.
6. Scheinman SJ, Carpenter T, Drezner MK. Hereditary hypophosphatemic rickets and tumor-induced osteomalacia. In Scheinman SG (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 21]. Available from: http://www.utdol.com/utd/index.do.
7. Linglart A, Biosse-Duplan M, Briot K, et al. Therapeutic management of hypophosphatemic rickets from infancy to adulthood. Endocrine Connections. 2014;3(1):R13-R30. doi:10.1530/EC-13-0103.
8. 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) 26(7):1381–8.10.1002/jbmr.340.
9. Gaucher, C., Walrant-Debray, O., Nguyen, TM. et al. Hum Genet (2009) 125: 401. https://doi.org/10.1007/s00439-009-0631-z.
10. Ultragenyx and Kyowa Kirin Announce U.S. FDA Approval of Crysvita® (burosumab) for the Treatment of Tumor-Induced Osteomalacia (TIO) [press release on the internet]. Ultragenyx Pharmaceutical; 2020 Jun 18 [cited 2020 Oct 30]. Available from: https://ir.ultragenyx.com/news-releases/news-release-details/ultragenyx-and-kyowa-kirin-announce-us-fda-approval-crysvitar#.

Review History

02/20/2019 – Reviewed

07/22/2020 – Reviewed and Updated July P&T Mtg; started and stabilized statement added; references updated. Effective 10/01/2020.

09/22/2021- Reviewed and Updated Sept. P&T; updated new FDA age requirement for X-linked hypophosphatemia: Added new FDA indication and criteria for osteomalacia; Updated reauthorization criteria for both indications. Effective 01/01/2022

01/11/23 - Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Added an overview table listing drugs that require PA vs without PA. Requirement of ≥ 6 months of age for diagnosis of X-linked hypophosphatemia. Removed requirement of symptoms and prescriber specialty. Updated references. Effective 4/1/23.

07/12/23 – Reviewed and updated for P&T. Admin update: It was determined by MH that Crysvita be opened to pharmacy benefit access and remain open to medical benefit access. Agent will require PA through both benefits. Brand preferred and mandatory generic language was added under Limitations. Effective 07/31/23.