

**Crysvita (burosumab-twza)**  
**Effective 06/01/2025**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange		<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit			
<b>Specialty Limitations</b>	N/A			
<b>Contact Information</b>	<b>Medical Benefit</b>	Phone: 833-895-2611	Fax: 888-656-6671	
	<b>Pharmacy Benefit</b>	Phone: 800-711-4555	Fax: 844-403-1029	
<b>Exceptions</b>	Crysvita is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.			

### 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

### 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  $\geq 6$  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  $\geq 2$  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.

## References

1. Crysvita [package insert] Novato (CA): Ultragenyx Pharmaceuticals; 2024 Nov.
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, Blosse-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. doi: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  $\geq 6$  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 Crysvida 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.  
05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting & references. Effective 6/1/25

