Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Crysvita (burosumab-twza)

Effective: September 15, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) - Approved Indications

Crysvita (burosumab-twza) is a fibroblast growth factor 23 blocking antibody indicated for the treatment of:

X-linked Hypophosphatemia

- X-linked hypophosphatemia in adults and pediatric patients 6 months of age and older

Tumor-induced Osteomalacia

- FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Crysvita (burosumab-twza) for Members when **ALL** of the following criteria are met:

X-Linked Hypophosphatemia

Initial Authorization Criteria

1. Documented diagnosis of X-linked hypophosphatemia confirmed by at least **one (1)** of the following:
    a. Genetic testing
    b. Elevated serum fibroblast growth factor 23 level of greater than 30 pg/mL

AND

2. Documented baseline serum phosphorus level that is below the normal range for age

AND

3. Prescribed by an endocrinologist, nephrologist, or a specialist with experience in the treatment of metabolic bone disorders

AND

4. For Members greater than 18 years of age, documentation of symptomatic disease evidenced by at least **one (1)** of the following:
    a. Significant/disabling skeletal pain
    b. Impaired mobility

c. Pending or recent orthopedic surgery or significant dental surgery
d. Recent fracture

Reauthorization Criteria

1. Prescribed by an endocrinologist, nephrologist, or a specialist with experience in the treatment of metabolic bone disorders

AND

2. Documentation of an increase in baseline phosphorus levels

AND

3. Documentation (e.g., chart notes) of a clinical benefit as evidenced by a reduction in skeletal pain, enhanced mobility, fracture reduction/healing, or improvement of skeletal deformities

Tumor-induced Osteomalacia

Initial Authorization Criteria

1. Documentation of a mesenchymal tumor that cannot be curatively resected or identified/localized

AND

2. Member is at least 2 years of age or older

AND

3. Documentation the Member is experiencing at least one sign or symptom of tumor-induced osteomalacia (e.g., bone pain, impaired mobility, muscle weakness, fatigue)

AND

4. Prescribed by or in consultation with an endocrinologist or nephrologist

AND

5. Documentation of a baseline serum phosphorus level that is below the normal range for age

AND

6. Documented inadequate response to or clinical inappropriateness of treatment with oral phosphate and calcitriol therapy

Reauthorization Criteria

1. Prescribed by an endocrinologist, nephrologist, or a specialist with experience in the treatment of metabolic bone disorders

AND

2. Documentation of an increase in baseline phosphorus levels

AND

3. Documentation of a clinical benefit as evidenced by a reduction in skeletal pain, enhanced mobility, fracture reduction/healing, or improvement of skeletal deformities

Limitations

- Initial approval of Crysvita will be authorized for six (6) months. Reauthorization of Crysvita will be provided in 12-month intervals.
- Members new to the plan stable on Crysvita should be reviewed against Reauthorization Criteria

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0584	Injection, burosumab-twza, 1 mg

References

1. American College of Rheumatology. Western Ontario and McMaster Universities osteoarthritis index (WOMAC). 2015. URL: https://www.rheumatology.org/I -Am- A/Rheumatologist/Research/Clinician-Researchers/Western-Ontario-McMaster-Universities- Osteoarthritis-Index-WOMAC. Available from Internet. Accessed 2018 April 30.
2. Carpenter TO, Imel EA, Holm IA et al. A clinician's guide to X -linked hypophosphatemia. *J Bone Miner Res*. 2011; 26(7):1381-8.
3. Clinicaltrials.gov. Available without subscription from https://clinic altrials.gov/ct2/home. Accessed 2018 May 8.
4. Crysvita (burosumab-twza) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; April 2026.
5. Food and Drug Administration. FDA approves first therapy for rare inherited form of rickets, x - linked hypophosphatemia. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604810.htm. Available from Internet. Accessed 2018 May 4.

6. Goldsweig BK and Carpenter TO. Hypophosphatemic rickets: lessons from disrupted FGF23 control of phosphorus homeostasis. *Curr Osteoporos Rep*. 2015; 13(2):88-97.
7. Imel E, Carpenter T, Gottesman GS et al. The effects of burosumab (KRN23), a fully human anti - FGF23 monoclonal antibody, on phosphate metabolism and rickets in 1 to 4 -year-old children with X-linked hypophosphatemia (XLH). *J Bone Miner Res 32* (Suppl 1); 2017. Abstract MO0695. URL: http://www.ultragenyx.com/file.cfm/22/docs/Phase%202%2040- week%20results%20in%20pediatric%20XLH%20patients%20%205%20years%20old%20 - %20ASBMR%202017.pdf. Available from Internet. Accessed 2018 May 4.
8. Insogna K, Briot K, Imel E et al. A phase 3 randomized, 24 weeks, double -blind, placebo-controlled study evaluating the efficacy of burosumab, an anti-FGF23 antibody, in adults with X-linked hypophosphatemia (XLH). J Bone Miner Res 32 (Suppl 1). Abstract LB-1159. URL: asbmr.org/education/AbstractDetail?aid=17f29fd1-0099-45a2-a072-f4f4df94a266. Available from the Internet. Accessed 2018 May 4.
9. Lee JY and Imel EA. The changing face of hypophosphatemic disorders in the FGF-23 era. Pediatr Endocrinol Rev. 2013; 10 Suppl 2:367-79.
10. National Institute of Health and Care Excellence (NICE). Burosumab for treating X -linked hypophosphataemia [ID1151]. 2017b December. URL: http://www.nice.org.uk. Available from Internet. Accessed 2018 April 24.
11. National Institute of Health and Care Excellence (NICE). Highly specialized technologies evaluation: burosumab for treating X-linked hypophosphataemia – final scope. 2017a December. URL: http://www.nice.org.uk. Available from Internet. Accessed 2018 April 24.
12. National Organization for Rare Disorders. Familial hypophosphatemia. 2016. URL: https://rarediseases.org/rare-diseases/familial-hypophosphatemia/. Available from Internet. Accessed 2018 April 24.
13. Whyte M, Portale A, Imel E et al. Burosumab (KRN23), a fully human anti-FGF23 monoclonal antibody for X-linked hypophosphatemia (XLH): final 64-week results of a randomized, open-label phase 2 study of 52 children. J Bone Miner Res 32 (Suppl 1); 2017. Abstract 1154. URL: http://www.asbmr.org/education/AbstractDetail?aid=e8810682-38f5-4b6a-83dd-c3f6c5490661. Available from Internet. Accessed 2018 May 4.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: No changes
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- September 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: No changes.
- September 15, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable,

and adherence to plan policies, plan procedures, and claims editing logic.