Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: October 1, 2024

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
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and 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

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ 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

X-linked hypophosphatemia (XLH) is a genetic form of rickets or osteomalacia that results from a loss of function mutation in the PHEX gene. That mutation leads to overproduction by bone cells of fibroblast growth factor 23, causing increased phosphate excretion by the kidney and decreased absorption from the gut and, ultimately, defective mineralization and delayed ossification of bone. Approval of Crysvita is based on a placebo-controlled trial in which 94% of Crysvita-treated adults on a monthly basis achieved normal phosphorus levels compared with 8% of placebo-treated adults. Results in pediatrics demonstrate, 94% to 100% of Crysvita-treated patients receiving treatment every two weeks achieved normal phosphorus levels. In both pediatrics and adults, radiograph findings associated with XLH improved with Crysvita.

Tumor-induced osteomalacia (TIO), also known as oncogenic osteomalacia, is a rare acquired paraneoplastic syndrome in which the biochemical and bone mineralization abnormalities closely resemble those in genetic forms of hypophosphatemic rickets.Approval of Crysvita in TIO is based on two trials of patients with a confirmed diagnosis of TIO in which treatment with Crysvita increased mean serum phosphorus levels and improved bone mineralization as assessed by bone histomorphometry

Food and Drug Administration - 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 for Members when the following criteria are met:

X-Linked Hypophosphatemia (XLH)

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. Member is 6 months of age or older

Tumor-Induced Osteomalacia (TIO)

1. Documented diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia

AND

2. Documentation the tumor(s) is/are not amenable to surgical excision or cannot be located

AND

3. Member is 2 years of age or older

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

References

1. Crysvita [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; June 2020.
2. M CF, et al. Global consensus recommendations on prevention and management of nutritional rickets. J Clin Endocrinol Metab. 2016 Feb; 101(2):394-415.
3. F LJ, et al. Recommendations released on prevention management of rickets. AAP News, 2017 Feb.

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).
- December 12, 2023: Removed the Limitation All other indications are considered experimental/investigational and not medically necessary. Updated coverage criteria for XLH to confirm diagnosis by at least one of the following: Genetic testing or Elevated serum fibroblast growth factor 23 level of greater than 30 pg/mL. Separated out diagnosis and confirmation the tumor cannot be curatively resected or localized criteria for TIO. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule (eff 3/1/24).
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.