Pharmacy Medical Necessity Guidelines: Crysvita® (burosumab-twza)

Effective: December 14, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT / MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

All plans except Tufts Health Public Plans:
PRECERT: 617.972.9409

Tufts Health Public Plans:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

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 in adults and pediatric patients 6 months of age and older.

Crysvita (burosumab-twza) is also indicated for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

Via inhibition of FGF23 activity, Crysvita (burosumab-twza) restores renal phosphate reabsorption and increases serum concentrations of 1,25 dihydroxyvitamin D.

COVERAGE GUIDELINES

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

X-linked Hypophosphatemia

Initial Therapy

1. Documented diagnosis of X-linked hypophosphatemia confirmed by at least one of the following:
    a. Genetic testing
    b. Elevated serum fibroblast growth factor 23 (FGF23) level >30 pg/mL

AND

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

AND

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

AND

4. For adults (Members >18 years of age), documentation of symptomatic disease supported by at least one 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 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 Therapy

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

AND

2. Member is at least 2 years of age

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 with oral phosphate and calcitriol therapy

Reauthorization Criteria

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

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 by the Plan will be limited to 6 months for all patients. Subsequent 12 month approvals will be granted for Members meeting Continuation of Therapy Coverage Criteria.
- Members new to the Plan stable on Crysvita (burosumab-twza) should be reviewed against Reauthorization Criteria.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0584	Injection, burosumab-twza, 1 mg

REFERENCES

1. American College of Rheumatology. Western Ontario and McMaster Universities osteoarthritis index (WOMAC). 2015. URL: 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 clinicaltrials.gov/ct2/home. Accessed 2018 May 8.
4. Crysvita (burosumab-twza) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; 2019 September.
5. Food and Drug Administration. FDA approves first therapy for rare inherited form of rickets, x-linked hypophosphatemia. 2018b URL: 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: 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 week, 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: 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: nice.org.uk. Available from Internet. Accessed 2018 April 24.
12. National Organization for Rare Disorders. Familial hypophosphatemia. 2016. URL: 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: asbmr.org/education/AbstractDetail?aid=e8810682-38f5-4b6a-83dd-c3f6c5490661. Available from Internet. Accessed 2018 May 4

APPROVAL HISTORY

July 10, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 1, 2019: Administrative update: added new J code (J0584) to Medical Necessity Guideline.
2. August 13, 2019: No changes
3. December 8, 2020: Added coverage criteria for the supplemental indication of Tumor-induced osteomalacia. Removed the following from the Reauthorization Criteria for X-linked hypophosphatemia " Updated the Limitation section to have Members new to the Plan stable on Crysvita (burosumab-twza) should be reviewed against Reauthorization Criteria.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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