Burosumab-twza (Crysvita®)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Administration* [*Prior authorization required – see section (1)] HCPCS: J0584 per 1 mg

Condition listed in policy (*see criteria for details*)

- Tumor-induced osteomalacia
- X-linked hypophosphatemia

AHFS therapeutic class: Electrolytic, Caloric, and Water Balance Agents; Misc

Mechanism of action: Fibroblast growth factor 23 (FGF23) blocking antibody

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO/Shared Advantage/ HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF CRYSVITA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is receiving the initial two doses of Crysvita or is being re-initiated on Crysvita after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event to Crysvita based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events to Crysvita based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for burosumab-twza (Crysvita®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Tumor-induced osteomalacia

1. Recommended or prescribed by a specialist who is an expert in metabolic bone disorders (e.g., endocrinologist) or an oncologist

Covered Dose
Up to a maximum of 180 mg SC every 2 weeks

Coverage Period
Indefinite

ICD-10:
E55.0, M83.8

X-linked hypophosphatemia

1. Recommended or prescribed by a specialist who is an expert in metabolic bone disorders, (e.g., endocrinologist), **AND**
2. If for adult patients (≥ 18 years of age), attestation that patient has a current history of osteomalacia-related symptoms or complications [e.g., spontaneous unhealed insufficiency fractures, pending orthopedic procedures, biochemical evidence of osteomalacia (elevated serum bone ALP), or skeletal pain that impairs physical function and is not controlled with non-opioid analgesics, unless contraindicated]

Covered Dose
- Pediatric (< 18 years): up to a maximum of 90 mg SC every 2 weeks
- Adults (≥ 18 years): up to a maximum of 90 mg SC every 4 weeks

Coverage Period
Indefinite

ICD-10:
E55.0, E83.3, E83.31, E83.39

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for burosumab-twza (Crysvita®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 10 mg/mL, 20 mg/mL, or 30 mg/mL (single-dose vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Crysvita® (burosumab-twza) [Prescribing information]. Princeton, NJ: Kyowa Kirin, Inc.; 3/2023.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.
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BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee