

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>
- Crysvida® (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.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*