burosumab-twza (Crysvita)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Fibroblast growth factor 23 (FGF23) blocking antibody
HCPCS:
J0584:Injection, burosumab-twza 1 mg
How Supplied:
10 mg/mL, 20 mg/mL, or 30 mg/mL (single-dose vials)

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

- Tumor-Induced Osteomalacia
- X-Linked Hypophosphatemia

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** 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.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

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

1. Patient is initiating therapy (allowed for the first two infusions) on 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.*

OR

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

2. Patient has experienced a previous severe adverse event on Crysvita based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on 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.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Tumor-Induced Osteomalacia

Meets medical necessity if all the following are met:

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

Covered Doses:
Up to 180 mg given subcutaneously every 2 weeks

Coverage Period:
Indefinite

ICD-10:
E55.0, M83.8

X-Linked Hypophosphatemia

Meets medical necessity if all the following are met:

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

- Pediatric (< 18 years): up to 90 mg given subcutaneously every 2 weeks
- Adults (≥ 18 years): up to 90 mg given subcutaneously every 4 weeks

Coverage Period:
Yearly, based on continued response to therapy

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

References

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

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee