burosumab-twza (Crysvita)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

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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.; April 2026.
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

Review History

Date of Last Annual Review: 3Q2026
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