



Medical Pharmacy Drug Prior Authorization Criteria

Drug Trade Name:	Crysvita®	Drug Generic Name:	Burosumab-twza
J Code:	Jo584 (SQ)	1 billable unit =	1 mg
Original Date of Review:	6/11/2025	Last Reviewed:	6/11/2025
Revision Date History			

Burosumab-twza, is a fibroblast growth factor 23 (FGF23) blocking antibody resulting in normalization of serum phosphatase.

Criteria:

- **Length of authorization (LOA):**
 - **Initiation:** 6 months.
 - **Renewal:** 12 months
- **Age:** At least 6 months of age
- **Diagnoses:**
 - X-linked hypophosphatemia (XLH)
 - Tumor-induced osteomalacia (TIO)
- **Quantity Limit:**
 - XLH:
 - Age ≥ 18 years: 90 mg every 4 weeks
 - Age < 18 years: 90 mg every 2 weeks
 - TIO: 180 mg every 2 weeks
- **Maximum Units:**
 - XLH:
 - Age ≥ 18 years: 90 units every 4 weeks
 - Age < 18 years: 90 units every 2 weeks
 - TIO: 180 units every 2 weeks
- **Initial Approval Criteria**
 - **Universal Criteria**
 - Recent laboratory results (obtained within the past 6 months) of baseline fasting serum phosphorus level demonstrating patient is below the lower limit of the laboratory reference range for age; **AND**
 - Clinical documentation of inadequate response, contraindication, or intolerance to oral phosphate therapy and/or vitamin D analog therapy; **AND**
 - **Indication Specific Criteria**
 - **X-linked hypophosphatemia (XLH)**
 - Patient must be age 6 months or older; **AND**

- Prescribed by, or in consultation with, a nephrologist, an endocrinologist or other specialist experienced in the treatment of metabolic bone disorders; **AND**
 - Clinical documentation of diagnosis confirmed by one of the following:
 - Genetic testing (PHEX-gene mutation); **OR**
 - Genetic testing (PHEX-gene mutation) in a directly related family member with appropriate x-linked inheritance; **OR**
 - Serum fibroblast growth factor-23 (FGF23) level above the upper limit of normal; **AND**
 - Clinical documentation confirming the patient is exhibiting clinical signs and symptoms of XLH (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures, etc.); **AND**
- **Tumor-induced osteomalacia (TIO)**
 - Patient must be age 2 years or older; **AND**
 - Prescribed by, or in consultation with, an oncologist, nephrologist, endocrinologist, or specialist experienced in the treatment of metabolic bone disorders; **AND**
 - Recent laboratory results (obtained within the past 6 months) of baseline tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) demonstrating patient is below the normal range for age and gender; **AND**
 - Clinical documentation of FGF23-related hypophosphatemia in tumor induced osteomalacia; **AND**
 - Clinical documentation of phosphaturic mesenchymal tumors that cannot be curatively resected or localized;
 - **Universal Renewal Criteria**
 - Recent fasting laboratory results (obtained within the past 6 months while receiving drug therapy) demonstrating improvement or normalization of serum phosphate; **AND**
 - Clinical documentation demonstrating patient experienced a positive clinical response to therapy (e.g. enhanced height velocity, improvement in skeletal deformities and/or skeletal pain, reduction in bone fractures, etc.).

- **Dosage/Administration**

Crysvita®	
Indication	Dose (Subcutaneous administration)
X-linked hypophosphatemia	<u>Adult Dose:</u> <ul style="list-style-type: none"> - 1 mg/kg body weight rounded to the nearest 10 mg every 4 weeks - Maximum dose of 90mg every 4 weeks <u>Pediatric Dose:</u> <ul style="list-style-type: none"> - Weight < 10 kg: 1 mg/kg rounded to the nearest 1 mg every 2 weeks - Weight ≥ 10 kg: 0.8 mg/kg rounded to the nearest 10 mg every two weeks. The minimum starting dose is 10 mg. - Dose may be increased up to approximately 2 mg/kg every 2 weeks to achieve normal serum phosphorus.

	<ul style="list-style-type: none"> - Maximum dose of 2 mg/kg (not to exceed 90 mg) every 2 weeks
Tumor-induced osteomalacia	<p><u>Adult Dose:</u></p> <ul style="list-style-type: none"> - 0.5 mg/kg body weight rounded to the nearest 10 mg every 4 weeks - Dose may be increased up to 2 mg/kg every 2 weeks - Maximum dose 2 mg/kg (not to exceed 180 mg) every 2 weeks <p><u>Pediatric Dose:</u></p> <ul style="list-style-type: none"> - 0.4 mg/kg of body weight rounded to the nearest 10 mg every 2 weeks. - Dose may be increased up to 2 mg/kg every 2 weeks - Maximum dose 2 mg/kg (not to exceed 180 mg) every 2 weeks.

NDC:

- Crysvida® 10 mg/ml single-dose vial (SDV): 42747-102-01
- Crysvida® 20 mg/ml single-dose vial (SDV): 42747-203-01
- Crysvida® 30 mg/ml single-dose vial (SDV): 42747-304-01

References:

1. Crysvida® [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical; June 2020.
2. Carpenter TO, Whyte MP, Imel EA, et al. A Clinician’s guide to X-linked hypophosphatemia. J Bone Miner Res. 2011; 26(7): 1381-1388.

Covered Diagnosis Codes:

ICD-10	ICD-10 Description
E83.31	Familial hypophosphatemia
E83.39	Other disorders of phosphorus metabolism
M83.8	Other adult osteomalacia