

## Crysvita® (burosumab-twza)

When requesting Crysvita® (burosumab-twza) for non-oncology use, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

### FDA-Approved Non-Oncology Indication

Crysvita is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.

### Coverage Guidelines

#### X-Linked Hypophosphatemia (XLH)

The individual must meet **all** of the following criteria for initial authorization:

- Had a baseline (i.e., prior to any XLH treatment [e.g., Crysvita®, oral phosphate, or vitamin D]) serum phosphorus level that was below the normal range for age;
- Meets one of the following:
  - Had a baseline (i.e., prior to any XLH treatment [e.g., Crysvita®, oral phosphate, or vitamin D]) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender; OR
  - Had a genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX mutation;
- Meets BOTH of the following (*applies to patients 18 years of age and older*):
  - Is currently exhibiting one or more signs or symptoms of X-linked hypophosphatemia (e.g., fractures/pseudofractures, bone and joint pain, muscle weakness, and impaired mobility); AND
  - Has tried oral phosphate and calcitriol therapy unless contraindicated to oral phosphate therapy, calcitriol therapy, or both;
- Crysvita is prescribed by or in consultation with an endocrinologist or nephrologist;

The individual must meet the following criteria for reauthorization:

- Is continuing to benefit from Crysvita (e.g., increased phosphorus levels, radiographic improvement in deformities, healing of fractures/pseudofractures, or reduction in the incidence of new fractures/pseudofractures).

**Approval duration (initial and renewal): 12 months**

## Dosing Recommendations

### **Adult XLH (18 years of age and older)**

The recommended dose regimen is 1 mg/kg body weight, rounded to the nearest 10 mg up to a maximum dose of 90 mg, administered subcutaneously every 4 weeks.

### **Pediatric XLH (6 months to less than 18 years of age)**

For patients who weigh less than 10 kg, the recommended starting dose is 1 mg/kg of body weight, rounded to the nearest 1 mg, administered subcutaneously every 2 weeks.

For patients who weigh 10 kg and greater, the recommended starting dose regimen is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, administered subcutaneously every 2 weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.

## References

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12. Weber TJ, Imel EA, Carpenter TO, et al. Long-term burosumab administration is safe and effective in adults with X-linked hypophosphatemia. *J Clin Endocrinol Metab.* 2022;108(1):155-165.
13. Kamenicky P, Briot K, Brandi ML, et al. Benefit of burosumab in adults with X-linked hypophosphatemia (XLH) is maintained with long-term treatment. *RMD Open.* 2023;9(1):e002676.