

Crysvita® (burosumab-twza injection)



When requesting Crysvita® (burosumab-twa injection) for non-oncology use, the individual requiring treatment must be diagnosed with a 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).

Coverage Guidelines

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

- Crysvita is prescribed by or in consultation with an endocrinologist or nephrologist;
- The patient has had a baseline (i.e., prior to any XLH treatment [e.g., Crysvita, oral phosphate/vitamin D therapy]) serum phosphorus level below the normal range for age; AND
- The patient has had one of the following:
 - A baseline (i.e., prior to any XLH treatment [e.g., Crysvita®, oral phosphate/vitamin D]) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) below the normal range for age and gender; OR
 - A genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX mutation.
- If the patient is greater than or equal to 18 years of age, the patient meets BOTH of the following:
 - The patient is exhibiting one or more signs or symptoms of XLH (e.g., fractures/pseudofractures, bone and joint pain, muscle weakness, and impaired mobility); AND
 - Patient meets ONE of the following:
 - Patient has tried oral phosphate and calcitriol therapy; OR
 - The patient is contraindicated to oral phosphate therapy, calcitriol therapy, or both

Approval duration: 12 months

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 or reduction in the incidence of new fractures/pseudofractures).

Approval duration: 12 months

Dosing Recommendations

For adults (≥ 18 years of age), approve up to a maximum dose of 90 mg administered subcutaneously no more frequently than once every 4 weeks.

For pediatric patients (< 18 years of age), approve up to a maximum dose of 90mg administered subcutaneously no more frequently than once every 2 weeks.

References

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7. Carpenter TO, Whyte MP, Imel EA, et al. Burosumab therapy in children with X-linked hypophosphatemia. *N Engl J Med.* 2018;378(21):1987-1998.
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10. Portale AA, Carpenter TO, Brandi ML, et al. Continued beneficial effects of burosumab in adults with X-linked hypophosphatemia: results from a 24-week treatment continuation period after a 24-week double-blind placebo-controlled period. *Calcif Tissue Int.* 2019;105(3):271-284.
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