



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 19, 2018

### **CRYSVITA® (buosumab-twza)**

**LENGTH OF AUTHORIZATION:** Initial: SIX MONTHS                      Continuation: ONE YEAR

**INITIAL REVIEW CRITERIA:**

- Patient is one year of age or older.
- Patient has not received oral phosphate and/or active vitamin D analogs within a week prior to starting therapy.
- Prescribed by, or in consultation with a geneticist, nephrologist or endocrinologist.
- Diagnosis of X-linked hypophosphatemia confirmed by identifying at least one of the following:
  - Serum fibroblast growth factor-23 (FGF23) level >30pg/mL **OR**
  - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient **AND**
- Baseline fasting serum phosphorus level with current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range.

**CONTINUATION OF THERAPY REVIEW CRITERIA:**

- Disease response as indicated by one of the following:
  - Increased serum phosphorus levels.
  - A reduction in serum total alkaline phosphatase activity.
  - Improvement in symptoms (e.g. skeletal pain, linear growth).
  - Improvement in radiographic imaging of rickets/osteomalacia.

**DOSING:**

- Patients (1 to <18 years of age)
  - Recommended starting dose is 0.8mg/kg of body weight, rounded to the nearest 10mg every 2 weeks. The maximum dose is 90mg.
- Adults (18 years of age and older)
  - Recommended dosing regimen is 1mg/kg of body weight, rounded to the nearest 10mg every 4 weeks. The maximum dose is 90mg.