Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 19, 2018 March 13, 2020, June 29, 2020, July 1, 2024

Crysvita® (burosumab)

LENGTH OF AUTHORIZATION: Initial therapy: 6 months
Continuation of therapy: 1 year

INITIAL REVIEW CRITERIA:

- Patient is six months 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 (XLH) confirmed by identifying at least one of the following:
    - Serum fibroblast growth factor-23 (FGF23) level >30pg/mL in children; **OR**
    - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient.
- Low-serum phosphate concentration (baseline labs required, drawn within 30 days of prior authorization submission) **AND**
- Reduced tubular resorption of phosphate corrected for glomerular filtration rate.

    OR
- Patient is 2 years of age or older for the treatment of FGF23-related hypophosphatemia in tumor induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized.

CONTINUATION OF THERAPY REVIEW CRITERIA:

- Patient met initial review criteria; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia; **AND**
- Disease response as indicated by at least one of the following:
    - Increased serum phosphorus levels (official labs required).
    - 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 AND ADMINISTRTATION:

- Refer to product labeling https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 10 mg/mL, 20 mg/mL, or 30 mg/mL in a single-dose vials for injection