Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 19, 2018 March 13, 2020, June 29, 2020

CRYSVITA® (burosumab)

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

- 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:

- Pediatrics XLH patients: (<10 kg)
  - Recommended starting dose is 1mg/kg of body weight, rounded to the nearest 1mg every 2 weeks subcutaneously.
- Pediatric XLH patients (>10kg)
  - Starting dose is 0.8mg/kg of body weight rounded to the nearest 10mg, administered every 2 weeks subcutaneously. 90mg per dose is the maximum.
- Adults XLH patients (18 years of age and older)
  - Recommended dosing regimen is 1mg/kg of body weight, rounded to the nearest 10mg every 4 weeks subcutaneously. 90mg per dose is the maximum.

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- Pediatric TIO (2 years and older):
  - Starting dose is 0.4 mg/kg of body weight rounded to the nearest 10 mg every 2 weeks subcutaneously. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every two weeks.
- Adult TIO patients (18 years of age and older):
  - Starting dose is 0.5 mg/kg every four weeks subcutaneously. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every two weeks.