

Clinical Oversight Review Board (CORB) Criteria for Prescribing Burosumab-twza (Crysvita)

Notes:

- Burosumab-twza (Crysvita) vials for injection requires administration by a healthcare professional and is not approved for self-injection.

Non-Formulary **burosumab-twza (Crysvita)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **burosumab-twza (Crysvita)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders;
- Diagnosis of either (TIO or XLH):
 - Serum fibroblast growth factor 23 (FGF23) level >30 pg/m in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.
- **-OR-**
 - X-linked hypophosphatemia (XLH), at least 6 months of age, supported by at least one of the following:
 - Genetic testing (PHEX mutation) OR
 - Family member with X-linked inheritance OR
 - Serum fibroblast growth factor 23 (FGF23) level >30 pg/mL
- Patient meets either of the following based on age group:
 - Pediatric patients (epiphyseal growth plates are open), at least one of the following:
 - i. Radiographic evidence of active bone disease (rickets in wrists and/or knees and/or femoral/tibial bowing) OR
 - ii. Documented abnormal growth velocity OR
 - iii. 1-2 years of age without radiographic evidence or abnormal growth velocity; but with confirmed genetic testing or family history, and low fasting serum phosphorus; consider treatment per clinical judgement
 - Adults and adolescents at final adult height (epiphyseal growth plates are closed) have presence of non-healing fractures (e.g., visible fracture lines)
- Fasting serum phosphorus below the reference range for age
- Patient does not have any either: Chronic Kidney Disease (CKD) Stage 2 or greater, tertiary hyperparathyroidism
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use this medication

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