

GCHP Medi-Cal Clinical Guidelines Burosumab (CrysvitaTM)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	<ul style="list-style-type: none"> Treatment of fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized. Treatment of X-linked hypophosphatemia.
Exclusion Criteria	Concurrent use with oral phosphate and active vitamin D analogs (e.g., paricalcitol, doxercalciferol, calcifediol, or alfacalcidol).
Required Medical Information	<p>Initial:</p> <ul style="list-style-type: none"> Diagnosis of X-linked hypophosphatemia (XLH) confirmed by: <ul style="list-style-type: none"> Genetic testing (PHEX mutation) of patient or family member with X-linked inheritance; or Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL OR Diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized. <p>AND</p> <ul style="list-style-type: none"> Baseline fasting serum phosphorus level is below the reference range <p>AND</p> <ul style="list-style-type: none"> Does not have severe renal impairment (defined as glomerular filtration rate (GFR) of less than 30 mL/min AND Prescriber to monitor serum 25-hydroxy vitamin D levels; and supplement with cholecalciferol or ergocalciferol to maintain levels in the normal range for age as necessary. <p>Renewal:</p> <ul style="list-style-type: none"> Demonstrate clinically significant improvement in serum phosphate level AND Serum phosphorus level is not above the upper limit of the laboratory normal reference range AND Shown a positive clinical response or stabilization of disease.
Age Restriction	Osteomalacia, tumor-induced: 2 years of age and older X-linked hypophosphatemia: 6 months of age and older
Prescriber Restrictions	Endocrinologist, nephrologist, or prescribed by a physician who is experienced in the management of patients with metabolic bone disease.
Coverage Duration	Initial: Six months: Renewal: 12 months
Other Criteria/Information	Criteria adapted from DHCS March 2024.



	HCPCS	Description	Dosing, Units
	J0584	Injection, burosumab-twza, 1mg (Crysvita™)	Osteomalacia: 2mg/kg/dose (not to exceed 180mg/dose) X-linked hypophosphatemia: 90mg/dose

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025