BlueCross BlueShield Federal Employee Program

CRYSVITA (burosumab-twza)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody. X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D. Crysvita binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D (1).

Regulatory Status

FDA approved indications: Crysvita is indicated for: (1)

1. The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
2. The treatment of FGF23-related hypophosphatemia 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.

Crysvita is contraindicated for patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism. It is also contraindicated if serum phosphorus is within or above the normal range for the patient's age and should not be used with oral phosphate or active vitamin D analogs. Oral phosphate and active vitamin D analogs should be discontinued one week prior to initiation of treatment (1).

Pediatric Patients with X-linked Hypophosphatemia (6 months to less than 18 years of age): After initiation of treatment, fasting serum phosphorus should be measured every four weeks for the first three months of treatment, and thereafter as appropriate (1).

Adult Patients with X-linked Hypophosphatemia (18 years of age and older): After initiation of treatment, assess fasting serum phosphorus on a monthly basis, measured two weeks post-dose, for the first three months of treatment, and thereafter as appropriate (1).

Pediatric Patients with Tumor-induced Osteomalacia (2 years to less than 18 years of age): After initiation of treatment, assess fasting serum phosphorous on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate (1).

Adult Patients with Tumor-induced Osteomalacia (18 years of age or older): After initiation of treatment, assess fasting serum phosphorous on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate (1).

The safety and effectiveness for Crysvita in pediatric patients with XLH less than 6 years of age have not been established. The safety and effectiveness for Crysvita in pediatric patients with TIO less than 2 years of age have not been established (1).

Summary

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody. X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D. Crysvita binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Crysvita while maintaining optimal therapeutic outcomes.

References

1. Crysvita [package insert]. Princeton, NJ: Kyowa Kirin, Inc.; March 2023.