Reference number(s)
2562-A

SPECIALTY GUIDELINE MANAGEMENT

CRYSVITA (burosumab-twza)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Crysvita is indicated for the treatment of X-linked hypophosphatemia in adult and pediatric patients 1 year or older.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

X-linked hypophosphatemia
12 months of authorization may be granted for treatment of X-linked hypophosphatemia when either of the following criteria are met:

A. Genetic testing was conducted to confirm a PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation in the patient or a directly related family member with appropriate X-linked inheritance.
B. Serum fibroblast growth factor 23 (FGF23) level is greater than 30 pg/ml.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Crysvita [package insert]. Novato, CA: Ultragenyx Pharmaceutical; April 2018.