Effective Date: 12/2019
Reviewed: 9/2019 Scope: Medicaid

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 Indication
Crysvita is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

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

II. CRITERIA FOR INITIAL APPROVAL

X-linked hypophosphatemia
A 6 month authorization may be granted for treatment of X-linked hypophosphatemia when all of the following criteria are met:

1. Diagnosis of XLH confirmed by:
   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
   b. Serum fibroblast growth factor 23 (FGF23) level is greater than 30 pg/ml.
2. Member is at least 1 year of age
3. Member will not receive oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy.
4. One of the following is met:
   a. Member's epiphyseal plates have not fused OR
   b. Member's epiphyseal plates have fused AND
      i. Member is experiencing severe, persistent clinical symptoms of the disease (e.g. bone pain that interferes with daily activities), OR radiographic evidence of osteomalacia-related fractures provided, AND
      ii. Member has failed, is intolerant to, or contraindicated to standard therapy with oral phosphate supplements and calcitriol.
5. For adults, dose requested is 1 mg/kg, rounded to nearest 10mg, every 4 weeks and dose does not exceed 90mg [Member's weight must be provided].
6. For pediatric members, dose requested is 0.8 mg/kg, rounded to nearest 10mg, every 2 weeks and dose does not exceed 90mg [Member's weight must be provided].

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III. CONTINUATION OF THERAPY

A 6 month authorization may be granted to:

1. All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.
2. For pediatric patients whose epiphyseal plates have not fused, documentation provided that phosphorus levels within normal range.
3. For adults and pediatric patients whose epiphyseal plates have fused, documentation provided that member has had a clinically significant reduction in bone pain and/or reduction in osteomalacia-related fractures.
4. For adults, dose requested is 1 mg/kg, rounded to nearest 10mg, every 4 weeks and dose does not exceed 90mg [Member's weight must be provided].
5. For pediatric members, dose requested is up to 2mg/kg, rounded to nearest 10mg, every 2 weeks and dose does not exceed 90mg [Member's weight must be provided].

IV. REFERENCES

1. Crysvita [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2018.
2. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. http://clinicaltrials.gov/ct2/show/NCT02163577. Accessed October 24, 2018.
3. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. http://clinicaltrials.gov/ct2/show/NCT02526160. Accessed October 24, 2018.

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