ALASKA MEDICAID
Prior Authorization Criteria

Crysvita®
(burosumab-twza)

FDA INDICATIONS AND USAGE[1]

CRYSVITA is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

APPROVAL CRITERIA[1,2]

1. Patient is 1 year of age or older **AND**;
2. Being prescribed by or in consultation with nephrologist or endocrinologist **AND;**
3. Patient has the diagnosis of X-linked hypophosphatemia confirmed by genetic testing (I.E. PHEX gene mutation in the patient) **and** baseline serum fibroblast growth factor 23 level **AND**;
4. Documentation that patients baseline fasting serum phosphorus is below the normal range for the patients age **AND;**
5. Trial of at least 2 months, has a contraindication, or an intolerance to therapy with calcitriol in combination with an oral phosphate agent (I.E.- K-Phos®, K-Phos Neutra®) with phosphate levels documented before and after supplementation **AND:**
6. Patient has discontinued any oral phosphate or vitamin D analog for a period of at least one week prior to therapy **AND**;
7. Prescriber agrees to monitor and document serum phosphorus levels throughout therapy.

DENIAL CRITERIA[1,2]

1. Patient is less than 1 year of age **OR**;
2. Has not been prescribed by or in consultation with nephrologist or endocrinologist **OR;**
3. Patient does not have a diagnosis of X-linked hypophosphatemia confirmed by genetic testing (I.E. PHEX gene mutation in the patient) and baseline serum fibroblast growth factor 23 level has not been obtained **OR**;
4. Documentation that patients baseline fasting serum phosphorus is within the normal range for the patients age **OR;**
5. Patient has not trialed, has no contraindications, or intolerances to therapy with calcitriol in combination with an oral phosphate agent (I.E.- K-Phos®, K-Phos Neutra®) with phosphate levels not documented before and after supplementation **OR;**
6. Patient has not discontinued any oral phosphate or vitamin D analog for a period of at least one week prior to therapy **OR**;
7. Prescriber does not agree to monitor and document serum phosphorus levels throughout therapy.

CAUTIONS[1]

- Do not use CRYSVITA with oral phosphate and active vitamin D analogs.
- Do not initiate CRYSVITA if serum phosphorus is within or above the normal range for age.
- CRYSVITA is contraindicated in patients with severe renal impairment or end stage renal disease.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months with documentation that the patient's phosphorus levels improved and the patient has experienced a positive clinical response (I.E. decreased bone pain or improvement in skeletal deformities)

QUANTITY LIMITS

- 10 mg/ml vial – 2 per 28 days
- 20 mg/ml vial – 2 per 28 days
- 30 mg/ml vial – 6 per 28 days

REFERENCES / FOOTNOTES:

1. Crysvita [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical, Inc., April 2018.
2. Carpenter TO, Imel EA, Holm IA, et al. Aclinician's guide to x-linked hypophosphatemia. J Bone Miner Res. 2011;26(7):1381-1388.