CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Crysvita (burosumab-twza)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— up to 90 mg per month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Crysvita (burosumab-twza) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

X-LINKED HYPOPHOSPHATEMIA (XLH)

For **initial** authorization:

1. Member is 1 year old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist or nephrologist; AND
3. Member has diagnosis of XLH supported by ONE of the following:
   a) Confirmed Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX) mutation in the member or a directly related family member with appropriate X-linked inheritance;
   b) Serum fibroblast growth factor 23 (FGF23) level > 30 pg/mL by Kainos assay; AND
4. Member has baseline serum phosphorus concentration below the normal range for age; AND
5. Member has chart notes documentation of ONE of the following:
   a) Radiographic evidence of active bone disease including rickets in the wrists and/or knees, AND/OR femoral/tibial bowing;
   b) Rickets Severity Score (RSS) score in the knee of at least 1.5 as determined by central read; AND
6. Member does **not** have ANY of the following:
   a) Human immunodeficiency virus antibody, hepatitis B surface antigen, and/or hepatitis C antibody;
   b) History of recurrent infection or predisposition to infection, or of known immunodeficiency;
   c) Hypocalcemia or hypercalcemia, defined as serum calcium levels outside the age-adjusted normal limits; AND
7. Member does **not**:
   a) Use oral phosphate and active vitamin D analogs (contraindicated with Crysvita);
   b) Have severe renal impairment or end stage renal disease (contraindicated with Crysvita).
8. **Dosage allowed:** Adult XLH (18 years of age and older): Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks. Pediatric XLH (less than 18 years of age): Starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg. Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member's serum phosphorus concentration increased from baseline; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Crysvita (burosumab-twza) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/16/2018	New policy for Crysvita created.

References:

1. Crysvita [package insert]. Novato, CA: Ultragenyx Pharmaceutical Inc.; April, 2018.
2. ClinicalTrials.gov. Identifier: NCT 02163577. Study of KRN23, a Recombinant Fully Human Monoclonal Antibody Against FGF23, in Pediatric Subjects With X-linked Hypophosphatemia (XLH). Available at: https://clinicaltrials.gov/ct2/show/NCT02163577?term=02163577&rank=1.
3. ClinicalTrials.gov. Identifier: NCT 02750618. Study of the Safety, Pharmacodynamics (PD) and Efficacy of KRN23 in Children From 1 to 4 Years Old With X-linked Hypophosphatemia (XLH). Available at: https://clinicaltrials.gov/ct2/show/NCT02750618?term=02750618&rank=1.
4. ClinicalTrials.gov. Identifier: NCT 02526160. Study of KRN23 in Adults With X-linked Hypophosphatemia (XLH). Available at: https://clinicaltrials.gov/ct2/show/NCT02526160?term=02526160&rank=1.
5. ClinicalTrials.gov. Identifier: NCT 02537431. Open Label Study of KRN23 on Osteomalacia in Adults With X-linked Hypophosphatemia (XLH). Available at: https://clinicaltrials.gov/ct2/show/NCT02537431?term=02537431&rank=1.
6. Carpenter TO, Whyte MP, Imel EA, et al. Burosumab Therapy in Children with X-Linked Hypophosphatemia. N Engl J Med 2018; 378:1987-1998. DOI: 10.1056/NEJMoa1714641.

Effective date: 09/21/2018
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