CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Crysvita (burosumab-twza)
BILLING CODE	J0584
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 6 months 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 confirmed by ONE of the following:
   a) Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX) mutation;
   b) Family history of XLH (i.e., a directly related family member with appropriate X-linked inheritance); 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 (e.g., chart notes from provider confirming previous radiological assessment, radiographic images, radiologist's interpretation of images, etc.);
   b) Clinical findings such as:
      i) For pediatric members: rickets, osteomalacia, short stature/loss of growth potential, progressive skeletal deformity, lower-extremity deformity, bone pain joint pain and stiffness, Chiari malformation, craniosynostosis, tooth abscesses, excessive dental caries, delayed walking, gait abnormalities, etc.;
      ii) For adult members: short stature, lower-extremity deformity, osteomalacia, bone pain, joint pain and stiffness, muscle pain, muscle weakness, fractures (including pseudofractures & Looser zones), osteoarthritis, extraosseous calcifications including: enthesopathy, spinal stenosis, Chiari malformation, hearing loss, tooth abscesses, excessive dental caries, gait abnormalities, etc.; AND
6. Member does **not** have any of the following:
   a) Hepatitis B or Hepatitis C (member must be treated prior to initiating Crysvita);
   b) History of recurrent infection or predisposition to infection, or of known immunodeficiency;
   c) Use oral phosphate and active vitamin D analogs (contraindicated with Crysvita). *Note: oral phosphate and active vitamin D analogs should be discontinued 1 week prior to initiation of treatment*;

d) Severe renal impairment or end stage renal disease (i.e., pediatric patients with eGFR 15-29 mL/min/1.73m^2 or end stage renal disease eGFR < 15 mL/min/1.73m^2; adult patients with creatinine clearance (CrCl) 15 - 29 mL/min or end stage renal disease CrCl < 15 mL/min).

7. **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 SQ every four weeks.

   Pediatric XLH (6 months and older): For members who weigh < 10 kg, starting dose regimen is 1 mg/kg of body weight rounded to the nearest 1 mg, administered SQ every two weeks. For members who weigh > 10 kg, starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered SQ 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.
09/26/2019	Kainos assay requirement for XLH diagnosis was removed. RSS score requirement was replaced with clinical finding requirement. Criteria about HIV presence, presence of hypocalcemia or hypercalcemia were removed.

References:

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