CareSource

# PHARMACY POLICY STATEMENT
## Marketplace

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| DRUG NAME | Crysvita (burosumab-twza) |
| BILLING CODE | J0584 |
| BENEFIT TYPE | Medical |
| SITE OF SERVICE ALLOWED | Office |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>QUANTITY LIMIT— see "dosage allowed" sections |

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, nephrologist, or rheumatologist; AND
3. Member has a diagnosis of XLH confirmed by **at least one** of the following:
   a) PHEX (Phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation per genetic testing;
   b) Family history positive for XLH (first-degree relative);
   c) Elevated plasma levels of intact fibroblast growth factor 23 (FGF23); AND
4. Lab results show fasting serum phosphorus level BELOW the reference range for age; AND
5. Member has chart notes documenting the following:
   a) Pediatric: Radiographic evidence of active bone disease including rickets and/or lower extremity bowing;
   b) Adult: Persistent bone and/or joint pain due to XLH and/or osteomalacia that limits daily activities; pseudofractures or osteomalacia-related fractures; AND
6. Member is refractory to or develops complications from conventional treatment with phosphate and active vitamin D (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol); AND
7. Member does not have ANY of the following:
   a) Concurrent use of oral phosphate and active vitamin D analogs;
   b) Severe renal impairment or ESRD.
8. **Dosage allowed:** Adult XLH (18 years of age and older): 1 mg/kg to the nearest 10 mg up to a maximum dose of 90 mg subQ every four weeks.

   Pediatric XLH (6 months to 17 years): For members who weigh < 10 kg, starting dose is 1 mg/kg to the nearest 1 mg, subQ every two weeks. For members who weigh 10 kg or greater, starting dose is 0.8 mg/kg to the nearest 10 mg, subQ 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), every two weeks.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:
1. Lab results show an improved serum phosphorus level compared to baseline; AND
2. Chart notes have been provided that show the member has improvement of signs and symptoms of disease (e.g. severity of rickets, linear growth, reduced pain/stiffness, fracture healing, physical function [6MWT]); AND
3. Member is not taking oral phosphate or active vitamin D analogs; AND
4. Member does not have severe renal impairment or ESRD.

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

## TUMOR-INDUCED OSTEOMALACIA (TIO)

For **initial** authorization:
1. Member is 2 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist, nephrologist, or rheumatologist; AND
3. Member has chart notes showing a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO); AND
4. The tumor is not amenable to surgical excision or cannot be located; AND
5. Chart notes show elevated fibroblast growth factor 23 (FGF23); AND
6. Lab results show fasting serum phosphorus level BELOW the reference range for age; AND
7. Member does not have ANY of the following:
   a) Concurrent use of oral phosphate and active vitamin D analogs (eg, calcitriol, paricalcitol, doxercalciferol, calcifediol);
   b) Severe renal impairment or ESRD.
8. **Dosage allowed:** See package insert for titration details. Adult= Starting dosage: 0.5 mg/kg, rounded to nearest 10 mg, up to a max of 180mg subQ every 4 weeks; Maximum dosage: 2 mg/kg not to exceed 180 mg every 2 weeks. Pediatric= Starting dosage: 0.4 mg/kg, rounded to nearest 10 mg, up to 180mg subQ every 2 weeks; Maximum dosage: 2 mg/kg not to exceed 180 mg every 2 weeks.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:
1. Lab results show an improved serum phosphorus level compared to baseline; AND
2. Chart notes demonstrate improvement of signs and symptoms of disease compared to baseline (e.g. bone pain, muscle weakness, fractures); AND
3. Member is not taking oral phosphate or active vitamin D analogs; AND
4. Member does not have severe renal impairment or ESRD.

***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 |
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| **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. |
| **09/21/2020** | Added criteria for new indication of TIO.<br>Revised XLH criteria: added rheumatology as an acceptable specialist, edited diagnostic confirmation to match clinical guideline by Haffner et al (added FGF23), |

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| | simplified/summarized the section on radiologic and clinical findings, added trial of conventional therapy per guideline, changed exclusions to match TIO section, simplified and made slight correction to dosing, changed initial auth duration to be 6 months, modified the re-auth criteria to more closely match TIO. |

References:


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