### Overview

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for X-linked hypophosphatemia and works by restoring renal phosphate reabsorption and by increasing serum concentrations of 1,25 dihydroxy vitamin D for pediatric patients at least 6 months of age and adults. Crysvita is also indicated for tumor-induced Osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in pediatric patients at least 2 years of age and adults.

### Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Crysvita, excluding when the product is obtained as samples or via manufacturer’s patient assistance program. **OR**

**X-linked hypophosphatemia**

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Documented diagnosis of X-linked hypophosphatemia is supported by either:
   a. Genetic testing or
   b. Serum fibroblast growth factor 23 level greater than 30pg/ml
2. The prescriber is an Endocrinologist, Nephrologist or specialist in metabolic bone disorders.
3. The member’s baseline serum phosphorous level is below normal range for age
4. **For adults > 18 years of age**, symptomatic disease as evidenced by at least ONE of the following:
   a. Severe disabling skeletal pain
   b. Impaired mobility
   c. Recent fracture

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### Table

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
<th>Specialty Medications</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ MassHealth</td>
<td>☒ Prior Authorization</td>
<td>☐ Commercial/Exchange</td>
<td>☒ Medical Benefit (NLX)</td>
<td>Specialty Medications</td>
</tr>
<tr>
<td>☐ Pharmacy Benefit</td>
<td>☐ Quantity Limit</td>
<td>☒ MassHealth</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
</tr>
<tr>
<td>☒ Commercial/Exchange</td>
<td>☐ Step Therapy</td>
<td>☒ MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
</tr>
<tr>
<td>☒ Medical Benefit (NLX)</td>
<td>☐ Step Therapy</td>
<td>☒ MassHealth</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
</tr>
<tr>
<td>☐ Exchange</td>
<td>☐ Step Therapy</td>
<td>☒ MassHealth</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
</tr>
</tbody>
</table>

**Specialty Medications**

All Plans | Phone: 866-814-5506 | Fax: 866-249-6155

**Non-Specialty Medications**

MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569

Commercial | Phone: 800-294-5979 | Fax: 888-836-0730

Exchange | Phone: 855-582-2022 | Fax: 855-245-2134

**Medical Specialty Medications (NLX)**

All Plans | Phone: 844-345-2803 | Fax: 844-851-0882

**Exceptions**

N/A
Tumor-induced osteomalacia
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Documentation of a mesenchymal tumor which cannot be curatively resected or localized
2. The member is at least 2 years of age
3. The prescriber is an Endocrinologist, Nephrologist or specialist in metabolic bone disorders
4. The member’s baseline serum phosphorous level is below normal range for age
5. The Member is experiencing at least ONE of the following sign or symptoms of tumor-induced osteomalacia:
   a. Bone pain
   b. Impaired mobility
   c. Muscle weakness
   d. Fatigue
6. The Member has had an inadequate response with or has a contraindication to therapy with oral phosphate and calcitriol.

Continuation of Therapy
Reauthorization for both diagnoses may be granted for members when physician documentation of ALL the following information is submitted:

1. Prescribed by or in consultation with an endocrinologist or nephrologist
2. Documentation of an increase in baseline phosphorus levels
3. Physician attestation of a clinical benefit as evidenced by a reduction in skeletal pain, enhanced mobility, fracture reduction/healing, or improvement of skeletal deformities

Limitations
1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months.

References
3. FDA News Release: FDA approves first therapy for rare inherited form of rickets, x-linked hypophosphatemia. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604810.htm

Review History
02/20/2019 – Reviewed
09/22/2021- Reviewed and Updated Sept. P&T; updated new FDA age requirement for X-linked hypophosphatemia; Added new FDA indication and criteria for osteomalacia; Updated reauthorization criteria for both indications. Effective 01/01/2022

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