HIGHMARK WHOLECARE

Updated: 07/2025
PARP Approved:07/2025

Prior Authorization Criteria

# Crysvita (burosumab-twza)

All requests for Crysvita (burosumab-twza) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of X-linked hypophosphatemia (XLH) and the following criteria is met:

- Confirmation of the diagnosis by at least one of the following:
  - Genetic test showing a PHEX gene mutation (phosphate regulating gene with homology to endopeptidase on the X chromosome)
  - Serum fibroblast growth factor 23 (FGF23) level above the upper limit of normal for the reference range for the member's age (reference range must be provided)
- Member must be 6 months or older
- Must be prescribed by or in consultation with a physician who is experienced in the management of patients with metabolic bone disease.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- An attestation from the provider the Crysvita will not be used together with oral phosphate and active vitamin D analogs
- Baseline fasting serum phosphorus concentration that is below the reference range for the member's age (reference range must be provided)
- For members under 18 years of age documentation of one of the following:
  - Baseline recumbent length/standing height z score
  - Baseline serum alkaline phosphatase activity
  - Baseline Thacher Rickets Severity Score (RSS)
- For members 18 years and older documentation of one of the following:
  - An attestation from the provider that the member is experiencing skeletal pain
  - Total healing fracture amount
  - Baseline osteoid volume/bone volume

- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - For members under 18 years of age
    - An increase in fasting serum phosphorus from baseline taken within last 12 months but not greater than 5.0mg/dL
    - Documentation the member has a positive clinical response or stabilization in their disease demonstrated by one of the following
      - An increase in height z score from baseline
      - A decrease in serum alkaline phosphatase activity from baseline
      - A decrease in the RSS score from baseline or a positive Radiographic Global Impression of Change (RGI-C) score.
  - For members 18 years and older

    - An increase in fasting serum phosphorus from baseline taken within last 12 months (the level must also be below the upper limit of normal for the lab range; reference range must be provided)
    - Documentation the member has a positive clinical response or stabilization in their disease demonstrated by one of the following:
        - An attestation there has been improvement in the member's pain
        - Total fractures healing after starting therapy
        - A decrease in osteoid volume/bone volume from baseline
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of FGF23-related hypophosphatemia in Tumor Induced Osteomalacia and the following criteria is met:

- Member must be 2 years of age or older
- Documentation member has a phosphaturic mesenchymal tumor that cannot be resected or localized
- Baseline fasting serum phosphorus concentration that is below the reference range for the member's age (reference range must be provided)
- Must be prescribed by or in consultation with a hematologist, oncologist, or endocrinologist
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - An increase in fasting serum phosphorus from baseline taken within last 12 months (the level must also be below the upper limit of normal range for the lab range; reference range must be provided)
    - Documentation the member has a positive clinical response or stabilization in their disease demonstrated by one of the following:
        - An attestation there has been improvement in the member's pain
        - Total fractures healing after starting therapy
        - A decrease in osteoid volume/bone volume from baseline
        - Improved growth velocity
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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# CRYSVITA (BUROSUMAB-TWZA) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

## PROVIDER INFORMATION

| | |
|---|---|
| Requesting Provider: | Provider NPI: |
| Provider Specialty: | Office Contact: |
| State license #: | Office NPI: |
| Office Address: | Office Phone: |
| | Office Fax: |

## MEMBER INFORMATION

| | | |
|---|---|---|
| Member Name: | DOB: | |
| Member ID: | Member weight: | Height: |

## REQUESTED DRUG INFORMATION

| | | |
|---|---|---|
| Medication: | Strength: | |
| Directions: | Quantity: | Refills: |
| Is the member currently receiving requested medication? ☐ Yes ☐ No | Date Medication Initiated: | |

## Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

## Place of Service Information

| | |
|---|---|
| Name: | NPI: |
| Address: | Phone: |

## MEDICAL HISTORY (Complete for ALL requests)

| | |
|---|---|
| Diagnosis:<br>☐ X-linked hypophosphatemia (XLH)<br>☐ Tumor- Induced Osteomalacia<br>☐ Other: | ICD Code: |

**For X-Linked Hypophosphatemia:**

Has the diagnosis been confirmed by at least one of the following? *Please select all that are applicable* ☐ Yes ☐ No

☐ Genetic test showing a PHEX gene mutation (phosphate regulating gene with homology to endopeptidase on the X chromosome)

☐ Serum fibroblast growth factor 23 (FGF23) level > 30pg/mL

Is the medication prescribed by, or in consultation with, a physician who is experienced in the management of patients with metabolic bone disease? ☐ Yes ☐ No

Baseline fasting serum phosphorus concentration: _____ Reference range: _____

**CRYSVITA (BUROSUMAB-TWZA)**
**PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 3**

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**MEMBER INFORMATION**

| | | |
|---|---|---|
| Member Name: | DOB: | |
| Member ID: | Member weight: | Height: |

**MEDICAL HISTORY (Complete for ALL requests)**

Will Crysvita be used in together with oral phosphate and active vitamin D analogs? ☐ Yes ☐ No

**For Members under 18 years of age:**
Please provide one of the following:

- Baseline recumbent length/standing height z score: _____
- Baseline serum alkaline phosphatase activity: _____
- Baseline Thacker Rickets Severity Score (RSS): _____

**For Members 18 years of age and older:**
Please provide one of the following:

- Attestation from the provider that the member is experiencing skeletal pain: _____
- Total healing fracture amount: _____
- Baseline osteoid volume/bone volume:_____

**For Tumor-Induced Osteomalacia**

Does the member have a phosphaturic mesenchymal tumor that cannot be resected or localized? ☐ Yes ☐ No
Baseline fasting serum phosphorus concentration: _____ reference range _____

☐ Yes ☐ No

**CURRENT or PREVIOUS THERAPY**

| Medication Name | Strength/ Frequency | Dates of Therapy | Status (Discontinued & Why/Current) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**REAUTHORIZATION**

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

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**CRYSVITA (BUROSUMAB-TWZA)**
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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

**MEMBER INFORMATION**

| | | |
|---|---|---|
| Member Name: | DOB: | |
| Member ID: | Member weight: | Height: |

**REAUTHORIZATION**

Has the member's fasting serum phosphorus concentration increased from baseline? ☐ Yes ☐ No
Fasting serum phosphorus concentration: _____ Date collected: _____

**For X-linked Hypophosphatemia:**
**For Members under 18 years of age:**
Please provide documentation of one of the following:

- An increase in height z score from baseline: _____
- A decrease in serum alkaline phosphatase activity from baseline: _____
- A decrease in the RSS score from baseline or a positive Radiographic Global Impression of Change (RGI-C) score:_____

**For Members 18 years of age and older:**

- Attestation from the provider that there has been improvement in the member's pain: _____
- Total fractures healing after starting therapy: _____
- A decrease in osteoid volume/bone volume from baseline: _____

**For Tumor Induces Osteomalacia:**
please provide at least one of the following:

Total healing fracture amount before starting therapy: _____ date taken _____
Current healing fracture amount after starting therapy:_____ date taken _____
Has the member had an improvement in skeletal pain from baseline? ☐ Yes ☐ No
Baseline osteoid volume/bone volume _____ date taken _____
Current osteoid volume/bone volume_____ date taken _____
Current growth velocity _____ date taken _____ baseline growth velocity _____

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

| |
|---|
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| **Prescribing Provider Signature** | Date |
|---|---|
| | |