

Request for Prior Authorization for Crysvida (burosumab-twza)
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030.

All requests for Crysvida (burosumab-twza) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Crysvida (burosumab-twza) Prior Authorization Criteria:

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 > 30 pg/mL
- 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 Crysvida 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 normal range lab; 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 or oncologist
- **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 normal range lab; 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 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.

**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 Health Options Pharmacy Services. **FAX: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: 1-844-325-6251 Mon – Fri 8 am to 7 pm**

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:		
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No		

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE:	
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other	

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:
<p>For X-Linked Hypophosphatemia:</p> <p>How was the member's diagnosis confirmed? (please submit documentation)</p> <input type="checkbox"/> genetic test <input type="checkbox"/> serum fibroblast growth factor 23 level > 30 pg/ml <p>Will Crystvita be used in combination with oral phosphate or vitamin D analogs? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Baseline fasting serum phosphorus concentration: _____ reference range _____</p> <p>For members <18 years of age please provide at least one of the following:</p> <p>Baseline recumbent length/standing height z score: _____</p> <p>Baseline serum alkaline phosphatase activity: _____</p> <p>Baseline Thacher Rickets Severity Score (RSS) _____</p> <p>For members ≥ 18 years of age please provide at least one of the following:</p> <p>Is the member experiencing skeletal pain? <input type="checkbox"/> Yes <input type="checkbox"/> No Total healing fracture amount: _____</p> <p>Baseline osteoid volume/bone volume: _____</p> <p>For Tumor-Induced Osteomalacia</p> <p>Does the member have a phosphaturic mesenchymal tumor that cannot be resected or localized? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Baseline fasting serum phosphorus concentration: _____ reference range _____</p>	

CURRENT or PREVIOUS THERAPY

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

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

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MEMBER INFORMATION

Member Name:	DOB:
Member ID:	Member weight: Height:

REAUTHORIZATION

Baseline fasting serum phosphorus concentration _____ reference range _____ date taken _____
Current fasting serum phosphorus concentration: _____ reference range _____ date taken _____

For members <18 years of age please provide at least one of the following:

Baseline recumbent length/standing height z score _____ date taken _____
Current recumbent length/standing height z score _____ date taken _____
Baseline serum alkaline phosphatase activity _____ date taken _____
Current serum alkaline phosphatase activity _____ date taken _____

Baseline Thacher Rickets Severity Score (RSS) _____ date taken _____
Current Thacher Rickets Severity Score (RSS) or Radiographic Global Impression of Change Score _____ date taken _____

For members ≥ 18 years of age with X-linked Hypophosphatemia or all members with Tumor-induced 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 _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date

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