Updated: 07/2023
DMMA Approved: 07/2023

Request for Prior Authorization for Crysvita (burosumab-twza)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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

Crysvita (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 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 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.

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.

HIGHMARK HEALTH OPTIONS

Updated: 07/2023
DMMA Approved: 07/2023

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:** (855) 476-4158

If needed, you may call to speak to a Pharmacy Services Representative.

PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

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? ☐ Yes ☐ 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? ☐ Yes ☐ No

BILLING INFORMATION

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a 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)

Member's Diagnosis: ☐ X-Linked Hypophosphatemia ☐ Tumor- Induced Osteomalacia ☐ Other _____

For X-Linked Hypophosphatemia:
How was the member's diagnosis confirmed? (please submit documentation)
☐ genetic test ☐ serum fibroblast growth factor 23 level > 30 pg/ml
Will Crysvita be used in combination with oral phosphate or vitamin D analogs? ☐ Yes ☐ No
Baseline fasting serum phosphorus concentration: _____ reference range _____

For members <18 years of age please provide at least 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 of age please provide at least one of the following:
Is the member experiencing skeletal pain? ☐ Yes ☐ No Total healing fracture amount: _____
Baseline osteoid volume/bone volume: _____

Updated: 07/2023
DMMA Approved: 07/2023

Member Name:	DOB:
Member ID	

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 _____

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 _____

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

HIGHMARK HEALTH OPTIONS

Updated: 07/2023
DMMA Approved: 07/2023