

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 <u>diagnosis</u> of X-linked hypophosphatemia (XLH) and the following criteria is met:

- Confirmation of the diagnosis by at least one of the following:
 - o Genetic test showing a PHEX gene mutation (phosphate regulating gene with homology to endopeptidase on the X chromosome)
 - o 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:
 - o Baseline recumbent length/standing height z score
 - o Baseline serum alkaline phosphatase activity
 - o 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
 - o Total healing fracture amount
 - o Baseline osteoid volume/bone volume
- **Initial Duration of Approval:** 12 months
- Reauthorization criteria
 - o 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.
- o 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 <u>diagnosis</u> 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)
 - O 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.

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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 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	y through Friday 8	:00am to 7:00pm		
	NFORMATION			
Requesting Provider:	NPI:			
Provider Specialty:	Office Co	Office Contact:		
Office Address:	Office Phone:			
	Office Fa	x:		
MEMBER IN	FORMATION			
Member Name:	DOB:			
Member ID:	Member weight:	Height:		
REQUESTED DRU	JG INFORMATI	ON		
Medication:	Strength:			
Directions:	Quantity:	Refills:		
Is the member currently receiving requested medicar	tion? Date N	Medication Initiated:		
Yes No				
Is this medication being used for a chronic or long-term cor	ndition for which the	medication may be necessary	for the	
life of the patient? Yes No				
	FORMATION			
This medication will be billed: at a pharmacy O		ICODE	,	
medically (if medically please provide a JCODE:) Place of Service: Hospital Provider's office Member's home Other				
PLACE OF SERVI		ION		
Name:	NPI:			
Address: Phone:				
MEDICAL HISTORY (Complete for ALL requests) Member's Diagnosis: X-Linked Hypophosphatemia Tumor- Induced Osteomalacia Other				
Member's Diagnosis.	umor- maucea Osteol			
For X-Linked Hypophosphatemia:				
How was the member's diagnosis confirmed? (please submit d				
genetic test serum fibroblast growth factor 23 level > 3 Will Crysvita be used in combination with oral phosphate or v		lvas		
Baseline fasting serum phosphorus concentration:				
	_ 6			
For members <18 years of age please provide at least one of the				
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	he following:			
Is the member experiencing skeletal pain? Yes No To	tal healing fracture ar	nount:		



Member Name:		DOB:			
Member ID					
For Tumor-Induced Osteomalacia					
Does the member have a phosphaturic mesenchymal tumor that cannot be resected or localized? Yes Saseline fasting serum phosphorus concentration: reference range					
REAUTHORIZATION					
Baseline fasting serum phosphorus of	oncentration	reference range	date taken		
Current fasting serum phosphorus co	oncentration:	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?					
Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why / Current)		
SUPPORTING INFORMATION or CLINICAL RATIONALE					
Prescribing Provider Signature Date					
Prescribing Pr	ovider Signature		Date		