

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 > 30 pg/mL
- Member must be 1 year of age 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 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 Gateway HealthSM Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date Medication Initiated:

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)

Diagnosis: X-linked hypophosphatemia (XLH) ICD-10 Code: _____
 Other: _____ ICD-10 Code: _____

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:

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: _____

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PRIOR AUTHORIZATION FORM – Page 2 of 2**

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MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____ pounds or _____ kg

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:

Has the member's fasting serum phosphorus concentration increased from baseline? Yes No

- Fasting serum phosphorus concentration: _____ Date collected:

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: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature

Date