Gateway Health℠ It's Wholecare.

Updated: 09/2020
PARP Approved: 09/2020

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 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, 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 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
        - 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 Gateway Health℠ 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? ☐ Yes ☐ 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: _____ ☐ Tumor- Induced Osteomalacia ICD-10 Code: _____ ☐ Other: _____ ICD-10 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: _____

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): _____

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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 _____

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 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

Prescribing Provider Signature	Date

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