

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: Commercial (Traditional) Commercial (Individual/Optimized)

Medicaid

This request is: Urgent (life threatening) Non-Urgent (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Crysvita[®] (buosumab-twza)

Member

Last Name: _____ First Name: _____
 ID #: _____ DOB: _____ Gender: _____
 Primary Care Physician: _____
 Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____
 Provider Address: _____
 Provider NPI: _____ Contact Name: _____
 Date: _____

Product Information

New request Continuation request

Drug product: Crysvita 10 mg/mL **Start date** (or date of next dose): _____
 Crysvita 20 mg/mL **Date of last dose** (if applicable): _____
 Crysvita 30 mg/mL **Date of next dose** (if applicable): _____
Dose: _____ **Dose Frequency:** _____

Place of administration: Physician's office
 Outpatient infusion
 Facility: _____ NPI: _____ Fax: _____
 Home infusion
 Facility: _____ NPI: _____ Fax: _____

Billing: Physician to buy and bill
 Facility to buy and bill
 Specialty Pharmacy
 Pharmacy: _____ NPI: _____ Fax: _____

ICD-10 Diagnosis code(s): _____

Drug cost information

The wholesale acquisition cost for Crysvita[®] is up to \$10,200.00 per vial. Annual treatment costs will vary depending on the patient's weight, but can approach \$795,600.00.

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Must be used for the treatment of X-linked hypophosphatemia (XLH)
 Diagnosis must be confirmed by:
 - Genetic testing (PHEX-gene mutation), OR
 - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
2. Must be age 1 or older
3. Must have baseline serum phosphorus level below lower limit of laboratory reference range with current hypophosphatemia
4. Must have clinical signs and symptoms of XLH (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures, etc.)

When the above criteria is met, initial approval of Crysvisa® will be for 12 months.

For continuation, patient must meet the following requirements:

1. The patient is compliant in taking the medication as scheduled
2. Must have experienced normalization of serum phosphate while on therapy (documentation of laboratory levels must be submitted to Priority Health)
3. Must have experience a positive clinical response to therapy (e.g. enhanced height velocity, improvement in skeletal deformities, reduction in bone fractures)

When the above continuation criteria is met, approval of Crysvisa® will be granted for no more than 12 months.

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

X-linked hypophosphatemia

Which of the following is provided to confirm the diagnosis (documentation must be submitted to Priority Health)?

Genetic testing

FGF23 serum level > 30 pg/mL

Neither; Rationale for use: _____

Other – the patient's condition is: _____
 Rationale for use: _____

B. What is the patient's serum phosphate level? _____ (lab report will reference range must be submitted to Priority Health)

C. Documentation of clinical signs and symptoms of XLH must be submitted to Priority Health.

**Request to continue a previously authorized approval
 Priority Health Precertification Documentation**

A. Has the patient been compliant with therapy?

Yes

No; rationale for continued use: _____

B. Documentation of normalized serum phosphate levels must be submitted to Priority Health

C. Documentation of improved clinical outcomes must be submitted to Priority Health

Additional information

When approved, the amount of Crysvida[®] allowed is limited to the FDA-approved dose and frequency.

Pediatrics

- Starting dose is 0.8 mg/kg of body weight, rounded to the nearest 10 mg, administered every two weeks.
- The minimum starting dose is 10 mg up to a maximum dose of 90 mg.
- Measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is above the lower limit of the reference range for age and below 5 mg/dL, continue treatment with the same dose.

Adults

- Starting dose is 1 mg/kg body weight, rounded to the nearest 10 mg up to a maximum dose of 90 mg, administered every four weeks.
- Assess fasting serum phosphorus on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate. If serum phosphorus is within the normal range, continue with the same dose.

Dosing of Crysvida[®] should not be adjusted more frequently than every 4 weeks and must be administered by a healthcare professional.