RX.PA.060.MPC Crysvita® (burosumab-twza)

The purpose of this policy is to define the prior authorization process for non-oncologic indications for Crysvita®(burosumab-twza).

Eviti reviews prior authorization requests for all oncology related indications for Crysvita®(burosumab-twza) products.

Crysvita® (burosumab-twza).) is indicated for:

- X-linked hypophosphatemia (XLH)
- Tumor Induced Osteomalacia (TIO)

The drug, Crysvita® (burosumab-twza), is subject to the prior authorization process.

PROCEDURE

1. X-linked Hypophosphatemia (XLH)

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be 6 months of age or older
- Must have a diagnosis of X-linked hypophosphatemia (XLH) confirmed 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 above the upper limit of normal for the reference range for the member's age (reference range must be provided)
- Must be prescribed by an endocrinologist, nephrologist, or physician who is experienced in the management of patients with metabolic bone disease
- Member must discontinue any oral phosphate or active vitamin D analog supplementation at least 1 week prior to starting therapy with Crysvita
- Must provide baseline fasting serum phosphate concentration that is below the reference range for the member's age (labs must be within 30 days)
- Prescriber must agree to monitor member's serum phosphorus levels throughout therapy
- Must not be initiated in patients with severe renal impairment (GFR < 30 mL/min) or end stage renal disease
- Member must have a documented history of failure, contraindication, or intolerance to oral phosphate and calcitriol therapy

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Crysvita will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

MPC Renewal:

- Chart documentation from the prescriber that the member's condition has improved or stabilized based upon the prescriber's assessment while on therapy
- Documentation of at least one of the improved clinical measures such as decrease in bone and joint pain, reduction in fractures, improvement in skeletal deformities
- Documentation of member's increase in fasting serum phosphate from baseline
- Must be prescribed by an endocrinologist, nephrologist, or physician who is experienced in the management of patients with metabolic bone disease
- Must not be used concurrently with oral phosphate and active vitamin D analogs
- Prescriber must agree to monitor member's serum phosphorus levels throughout therapy
- Must not be used in patients with severe renal impairment or end stage renal disease

Non-MPC Renewal:

- Members who have previously been taking Crysvita and are requesting a non-MPC renewal should be considered under criterion 1A (X-linked hypophosphatemia, Initial Authorization Criteria)
- Member has not been receiving medication samples for Crysvita; AND
- Provider has a documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	6 months
Reauthorization	1 year

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J0584	Injection, burosumab-twza, 1 mg

REFERENCES

1. Crysvita (burosumab-twza) [prescribing information]. Bedminster, NJ: Kyowa Kirin, Inc.; June 2020.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2023*
New Policy	*10/2022*