



Smart

PA

Clinical Edit Criteria

Drug/Drug Class: **Crysvita® (burosumab-twza) Clinical Edit**

Date: **April 11, 2019**

Prepared for:

Prepared by: **MO HealthNet**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Crysvita® (burosumab).

Why was this Issue Selected:

Crysvita® is the first drug indicated for adults and children aged 1 year and older with X-linked hypophosphatemia (XLH), which is a rare, inherited form of rickets. About 3,000 children and 12,000 adults in the US have XLH, a progressive and lifelong skeletal disorder characterized by renal phosphate wasting caused by excess fibroblast growth factor 23 production. In children, XLH causes rickets that leads to lower extremity deformity, delayed growth and decreased height. Adults with XLH have an increased risk for fractures. Crysvita® is a major advance for patients with X-linked hypophosphatemia. The drug leads to sustained improvement in phosphate metabolism with concurrent repair of the skeleton, even following prior treatment with conventional therapies.

Program-specific information:	Drug	Approximate cost per year (depending on weight)
	<ul style="list-style-type: none"> • Crysvita® 	\$160,000-\$200,000

Setting & Population: All patients 1 year of age and older

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

Data Sources:

<input type="checkbox"/> Only administrative databases	<input checked="" type="checkbox"/> Databases + Prescriber-supplied
---	--

Setting & Population

- Drug for review: Crysvita® (burosumab-twza)
- Age range: All patients age 1 year of age and older
- Gender: Male and female

Approval Criteria

- Diagnosis of X-linked hypophosphatemia
- Documented trial on phosphate and calcitriol
- Approve for four months, then confirm improvement in phosphorus concentration

Denial Criteria

- Therapy will be denied if approval criteria is not met

References

1. Crysvita (Prescribing Information). Novato, CA. Ultragenyx Pharmaceutical Inc; 2018.
2. IPD Analytics Rx Insights_New Drug Approval Review_Crysvita_05 2018.pdf