SmartPA Criteria Proposal

Drug/Drug Class:	Crysvita Clinical Edit
First Implementation Date:	April 11, 2019
Proposed Date:	July 18, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

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

Why Issue Selected: Crysvita®, FDA approved in April 2018, is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in patients 6 months of age and older. XLH is an inherited disorder characterized by low levels of phosphate in the blood, due to abnormal phosphate processing in the kidneys, leading to loss of phosphate in the urine and soft, weak bones (rickets). XLH is present in about 3,000 children and 12,000 adults in the US. In children, XLH treatment is usually started at the time of diagnosis and continues until bones stop growing. The conventional treatment goal for adults with XLH is to help improve pain. XLH is caused by excess fibroblast growth factor 23 (FGF23) which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D; Crysvita binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D. Crysvita is a major advance for patients with XLH; prior to Crysvita, therapy for XLH involved supplementation with phosphate and calcitriol. The drug leads to sustained improvement in phosphate metabolism with concurrent repair of the skeleton, even following prior treatment with conventional therapies.

In June 2020, the FDA approved Crysvita for the treatment of FGF23-related hypophosphatemia in tumor induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

Due to the possible adverse events and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Crysvita.

Program-Specific Information:

Date Range FFS 4-1-22 to 3-31-23			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
CRYSVITA 10 MG/ML VIAL	75	$619,976.70	$8,266.36
CRYSVITA 20 MG/ML VIAL	130	$2,847,932.90	$21,907.18
CRYSVITA 30 MG/ML VIAL	37	$1,742,923.20	$47,106.03

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Preferred Drug List**

	☒ **Appropriate Indications**	☒ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Crysvita® (burosumab-twza)
- Age range: All appropriate MO HealthNet participants aged 6 months or older

Approval Criteria

Initial Therapy:

- Prescribed by or in consultation with a nephrologist, endocrinologist, or other specialist in the treated disease state **AND**
- Documented diagnosis of X-linked hypophosphatemia in the past year **OR**
- Documented diagnosis of FGF23-related hypophosphatemia in tumor induced osteomalacia:
  - Participant aged ≥ 2 years **AND**
  - Documentation that participant has a phosphaturic mesenchymal tumor that cannot be resected or localized
- Documented baseline fasting serum phosphorus levels below the normal range for age **OR**
- Requests for participants with baseline fasting serum phosphorus levels in the normal range will be referred to clinical review
- Initial approval for 4 months

Continuation of Therapy:

- Renewal of prior authorization may be given following documentation of:
  - normalization of serum phosphorus levels **AND**
  - recent normal 25-hydroxy vitamin D levels **AND**
  - lack of oral phosphate or calcitriol therapy in the past 3 months **AND**
  - for participants aged ≥ 18 years & with normal baseline phosphorus levels: documentation of benefit of therapy (examples include but are not limited to: maintenance of reduced pain complaints, improved mobility, stamina, or improving rickets on radiographic evaluation when compared to baseline)
- Continued approval for 12 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met.
- Documented diagnosis of severe renal impairment or end stage renal disease

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

4 months

References

- CRYSVITA® (burosumab-twza) injection, [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; March 2023.
- IPD Analytics. New Drug Approval: Crysvita (burosumab). May 2018.
- IPD Analytics. Endocrine and Metabolic Agents: Rickets/Osteomalacia.
- Genetic and Rare Diseases (GARD) Information Center. X-linked hypophosphatemia. https://rarediseases.info.nih.gov/diseases/12943/x-linked-hypophosphatemia. Accessed May 24, 2023.
- Haffner D, Emma F, Eastwood DM, et al. Clinical practice recommendations for the diagnosis and management of X-linked hypophosphataemia. Nat Rev Nephrol. 2019;15(7):435-455. doi:10.1038/s41581-019-0152-5