SmartPA Criteria Proposal

Drug/Drug Class:	Crysvita Clinical Edit
First Implementation Date:	April 11, 2019
Proposed Date:	June 17, 2021
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 main 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. 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 4-1-2020 to 3-31-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
CRYSVITA 10 MG/ML VIAL	73	$458,996.50	$6,287.62
CRYSVITA 20 MG/ML VIAL	42	$708,545.00	$16,870.12
CRYSVITA 30 MG/ML VIAL	74	$1,551,810.85	$20,970.42

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 **AND**
- ~~**Documented adequate therapeutic trial of phosphate and calcitriol (defined as 90 days in the past 180 days for both) AND**~~
- Documentation of baseline fasting serum phosphorus levels below the normal range for age
- Initial approval of prior authorization is 4 months

Continuation of Therapy:

- Renewal of prior authorization may be given following documentation of:
  - recent serum phosphorus level remains below the normal range for age **AND**
  - recent 25-hydroxy vitamin D levels **AND**
  - lack of oral phosphate or calcitriol therapy in the past 3 months
  - for participants aged ≥ 18 years: documentation of benefit of therapy (i.e. decreased pain, enhanced mobility)

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.; June 2020.
- IPD Analytics. New Drug Approval: Crysvita (burosumab). May 2018.
- IPD Analytics. Endocrine and Metabolic Agents: Rickets/Osteomalacia. Accessed May 17, 2021.

- Genetic and Rare Diseases (GARD) Information Center. X-linked hypophosphatemia. https://rarediseases.info.nih.gov/diseases/12943/x-linked-hypophosphatemia. Accessed May 17, 2021.
- 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