SmartPA Criteria Proposal

Drug/Drug Class:	Crysvita Clinical Edit
First Implementation Date:	April 11, 2019
Revised Date:	November 19, 2020
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.

In June of 2020, Crysvita was also FDA approved 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.

Program-Specific Information:

Date Range FFS 4-1-2019 to 3-31-2020				
Drug	**Claims**	**Spend**	**Cost per vial (MAC)**	**Cost per month (avg pediatric dose = 30mg every 2 weeks)**
CRYSVITA 10 MG/ML VIAL	46	$249,503.80	$3,485.00	$20,910.00
CRYSVITA 20 MG/ML VIAL	27	$368,817.85	$6,970.00	
CRYSVITA 30 MG/ML VIAL	29	$492,859.20	$10,455.00	

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

- **Prescribed by or in consultation with a nephrologist, endocrinologist, or other specialist in the treated disease state AND**
- **Documentation of baseline fasting serum phosphorus levels below the normal range for age AND**
- Documented adequate therapeutic trial of **oral** phosphate and calcitriol (defined as 90 days in the past 180 days for both) **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**
- Initial approval of prior authorization is 4 months
- Renewal of prior authorization may be given following documentation of:
  - ~~**improvement in phosphorus concentration AND**~~
  - **recent serum phosphorus level remaining below or within 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 with diagnosis of X-linked hypophosphatemia: documentation of benefit of therapy (i.e. decreased pain, enhanced mobility)**

Denial Criteria

- Therapy will be denied if no approval criteria are 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]. Place of publication: Publisher; June 2020.
- IPD Analytics. New Drug Approval: Crysvita (burosumab). May 2018.
- IPD Analytics. Endocrine and Metabolic Agents: Rickets/Osteomalacia. Accessed May 7, 2020.
- Genetic and Rare Diseases (GARD) Information Center. X-linked hypophosphatemia. https://rarediseases.info.nih.gov/diseases/12943/x-linked-hypophosphatemia. Accessed May 7, 2020.
- 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
- Kinoshita Y, Fukumoto S. X-Linked Hypophosphatemia and FGF23-Related Hypophosphatemic Diseases: Prospect for New Treatment. Endocr Rev. 2018 Jun 1;39(3):274-291. doi: 10.1210/er.2017-00220. PMID: 29381780.