Crysvita (burosumab-twza)
Effective 01/01/2022

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for X-linked hypophosphatemia and works by restoring renal phosphate reabsorption and by increasing serum concentrations of 1,25 dihydroxy vitamin D for pediatric patients at least 6 months of age and adults. Crysvita is also indicated for tumor-induced Osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in pediatric patients at least 2 years of age and adults

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Crysvita, excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

<u>X-linked hypophosphatemia</u>

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Documented diagnosis of X-linked hypophosphatemia is supported by either:
    a. Genetic testing or
    b. Serum fibroblast growth factor 23 level greater than 30pg/ml
2. The prescriber is an Endocrinologist, Nephrologist or specialist in metabolic bone disorders.
3. The member's baseline serum phosphorous level is below normal range for age
4. **For adults > 18 years of age**, symptomatic disease as evidenced by at least ONE of the following:
    a. Severe disabling skeletal pain
    b. Impaired mobility
    c. Recent fracture

Tumor-induced osteomalacia

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. Documentation of a mesenchymal tumor which cannot be curatively resected or localized
2. The member is at least 2 years of age
3. The prescriber is and Endocrinologist, Nephrologist or specialist in metabolic bone disorders
4. The member's baseline serum phosphorous level is below normal range for age
5. The Member is experiencing at least ONE of the following sign or symptoms of tumor-induced osteomalacia:
   a. Bone pain
   b. Impaired mobility
   c. Muscle weakness
   d. Fatigue
6. The Member has had an inadequate response with or has a contraindication to therapy with oral phosphate and calcitriol.

Continuation of Therapy

Reauthorization for both diagnoses may be granted for members when physician documentation of ALL the following information is submitted:

1. Prescribed by or in consultation with an endocrinologist or nephrologist
2. Documentation of an increase in baseline phosphorus levels
3. Physician attestation of a clinical benefit as evidenced by a reduction in skeletal pain, enhanced mobility, fracture reduction/healing, or improvement of skeletal deformities

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months.

References

1. Crysvita (burosumab-twza) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc; June 2020.
2. Verge CF, Lam A, Simpson JM, et al. Effects of therapy in X-linked hypophosphatemic rickets. N Engl J Med 1991; 325:1843.
3. FDA News Release: FDA approves first therapy for rare inherited form of rickets, x-linked hypophosphatemia. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604810.htm
4. Insogna KL, Briot K, Imel EA, et al. A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial Evaluating the Efficacy of Burosumab, an Anti-FGF23 Antibody, in Adults With X-Linked Hypophosphatemia: Week 24 Primary Analysis. J Bone Miner Res 2018; 33:1383.
5. Drezner MK, Whyte MP. Heritable renal phosphate wasting disorders. In: Genetics of bone biology and skeletal disease, 2nd ed, Thakker RV, Whyte MP, Eisman JA, Igarashi T (Eds), Academic Press, Amsterdam 2017.
6. He Q, Zhang B, Zhang L, et al. Diagnostic efficiency of 68Ga-DOTANOC PET/CT in patients with suspected tumour-induced osteomalacia. Eur Radiol 2021; 31:2414
7. Jan de Beur SM, Miller PD, Weber TJ, et al. Burosumab for the Treatment of Tumor-Induced Osteomalacia. J Bone Miner Res 2021; 36:627

8. Imel EA, Glorieux FH, Whyte MP, et al. Burosumab versus conventional therapy in children with X-linked hypophosphataemia: a randomised, active-controlled, open-label, phase 3 trial. Lancet 2019; 393:2416

Review History

02/20/2019 – Reviewed
07/22/2020 – Reviewed and Updated July P&T Mtg; started and stabilized statement added; references updated. Effective 10/01/2020.
09/22/2021- Reviewed and Updated Sept. P&T; updated new FDA age requirement for X-linked hypophosphatemia: Added new FDA indication and criteria for osteomalacia; Updated reauthorization criteria for both indications. Effective 01/01/2022

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