Crysvita (burosumab-twza)
Effective 03/01/19

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 hypophophoatemia and works by restoring renal phosphate reabsorption and by increasing serum concentrations of 1,25 dihydroxyvitamin D for children at least 1 year of age and adults.

Coverage Guidelines

Authorization may be granted for members with a diagnosis of X-linked hypophosphatemia 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. Prescriber is an Endocrinologist, Nephrologist or specialist in metabolic bone disorders.
3. Documentation that member's baseline serum phosphorous level is below normal for age is submitted.
4. **For adults > 18 years of age**, Symptomatic disease as evidenced by at least ONE of the following:
    a. Severe disabling skeletal pain
    OR
    b. Impaired mobility
    OR
    c. Recent fracture

Continuation of Therapy

Reauthorization may be granted for members when physician documentation of an increase in the member's baseline phosphorous level is submitted with ALL the following information:

1. For adults > 18 years of age, documentation of:
    a. Decrease in skeletal pain
    b. Improved mobility
    c. Fracture reduction or increased in fracture healing time

    OR
2. For children > 1 year of age, documentation of:
    a. Increase in linear growth
    b. Decrease in pain

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; September 2018.DDAVP Spray and DDAVP Rhinyl (desmopressin) [product monograph]. North York, Ontario: Ferring; April 2018
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.

Review History

02/20/19 – Reviewed

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