



Crysvita[®] (burosumab-twza)

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Definitions

Crysvita[®] (burosumab-twza) is a human immunoglobulin G subclass 1 (IgG1), anti-human fibroblast growth factor 23 (FGF23) antibody that binds to FGF23. FGF23 limits the reabsorption of phosphate in the renal tubules, which reduce the production of 1, 25-dihydroxy vitamin D in the kidneys. Burosumab-twza is indicated to treat patients ≥ 1 year of age who have X-linked hypophosphatemia (XLH).¹

Dosing and Administration

For subcutaneous use only.

- Pediatric XLH: Starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg. Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus.
- Adult XLH: Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks.

Initial Guideline

Initial coverage is provided for **6 months** when all of the following criteria are met:

- Patient is at least 1 year of age; AND
- Patient has not received oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy; AND

- Must be prescribed by, or in consultation with, a nephrologist or endocrinologist; AND
- Patient has a diagnosis of X-linked Hypophosphatemia (XLH) which is confirmed by at least one of the following:
 - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL; OR
 - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient; AND
 - Patient has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR); AND
- Baseline fasting serum phosphorus* level with current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range; AND
- Patient does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of <30 mL/min; AND
- Patient presents with clinical signs and symptoms of the disease (e.g., rickets, growth retardation, musculoskeletal pain, bone fractures)

**Note: Phosphorous levels should be obtained fasting 12 hours or more without food or drink except for water and after an adequate washout period after supplements; lab values (i.e. GFR, phosphorous, TmP/GFR) should be obtained within 28 days of the date of administration.*

Renewal Guideline

Coverage will be renewed for **12 months** when all of the following criteria are met:

- Patient continues to meet the criteria identified in the Initial Guideline section; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, hyperphosphatemia and/or nephrocalcinosis, severe injection site reactions, etc.; AND
- Patient has experienced normalization of serum phosphate within normal limits while on therapy; AND
- Disease response as indicated by increased serum phosphorus levels, a reduction in serum total alkaline phosphatase activity, improvement in symptoms (e.g., skeletal pain, linear growth, reduction of fractures, etc.), and/or improvement in radiographic imaging of Rickets/osteomalacia

Revisions

12/3/2018 – Added J0584 and removed J3590 from Applicable Procedure Codes.

Applicable Procedure Codes

J0584	Injection, burosumab-twza, 1 mg
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Applicable Diagnosis Codes

E83.30	Disorder of phosphorus metabolism, unspecified
E83.31	Familial hypophosphatemia

References

¹ Crysvita [Package Insert]. Novato, CA; Ultragenyx Pharmaceutical; May 2018.