Protocol for Crysvita® (burosumab-twza)

Approved October 2022

Background: *X-linked hypophosphatemia (XLH) is a rare, hereditary, progressive musculoskeletal disease that often causes pain and short stature, as well as decreased physical function, mobility, and quality of life.*

Crysvita *is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for:*

- *The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.*
- *The treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.*

Criteria for approval:

1. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence
2. Medication is prescribed by or in consultation with a geneticist, nephrologist, or endocrinologist
3. The patient does not have any contraindications to therapy:
    a. Concomitant use with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol)
    b. Serum phosphorus within or above the normal range for age
    c. Severe renal impairment or end stage renal disease, defined as an estimated glomerular filtration rate (GFR) of <30 mL/min in children or creatinine clearance (CrCl) < 30mL/min in adults

For X-linked Hypophosphatemia (XLH):

1. Patient has a diagnosis of X-linked hypophosphatemia (XLH) confirmed by one of the following:
    a. Genetic testing; OR
    b. Elevated levels of serum fibroblast growth factor 23
2. Patient is 6 months of age or older
3. Pediatric patients must have had an inadequate response from oral phosphate and active vitamin D analogs

For Tumor-induced Osteomalacia (TIO):

1. Patient has a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors confirmed by one of the following:
    a. Genetic testing; OR
    b. Elevated levels of serum fibroblast growth factor 23
2. The patient is 2 years of age or older
3. The tumor cannot be curatively resected or localized (located)

Initial approval: 6 months

Continuation of therapy:

1. Increase in serum phosphorus levels
2. Improvement in symptoms (e.g., skeletal pain, linear growth, etc.), and/or improvement in radiographic imaging
3. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Renewal approval: 12 months

References:

1. Crysvita [prescribing information]. Kyowa Kirin, Inc. Bedminster, NJ 07921 June 2020
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Dahir K, Roberts MS et al. X-Linked Hypophosphatemia: A New Era in Management. Journal of the Endocrine Society, Volume 4, Issue 12, December 2020, bvaa151. Accessed on September 6, 2022 at: https://doi.org/10.1210/jendso/bvaa151