

STANDARD MEDICARE PART B MANAGEMENT

CRYSVITA (burosumab-twza)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Crysvita is indicated for the treatment for:

1. X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
2. 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. X-linked hypophosphatemia

At least one of the following for initial requests:

1. Genetic testing results confirming the member has a PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation
2. Genetic testing results confirming a PHEX mutation in a directly related family member with appropriate X-linked inheritance
3. Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is greater than 30 pg/ml

B. Tumor induced osteomalacia

All of the following information for initial requests:

1. Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is greater than 100 pg/ml
2. Fasting serum phosphorus levels less than 2.5 mg/dL
3. Ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) less than 2.5 mg/dL

III. CRITERIA FOR INITIAL APPROVAL

A. X-linked hypophosphatemia

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| Reference number(s) |
| 4234-A |

Authorization of 12 months may be granted for treatment of X-linked hypophosphatemia when one of the following criteria is met:

1. Genetic testing was conducted to confirm a PHEX mutation in the member.
2. Genetic testing was conducted to confirm a PHEX mutation in a directly related family member with appropriate X-linked inheritance.
3. Member's FGF23 level is greater than 30 pg/ml.

B. Tumor-induced osteomalacia (TIO)

Authorization of 12 months may be granted for treatment of tumor-induced osteomalacia (TIO) when the following criteria is met:

1. Member's diagnosis is confirmed by ALL of the following:
 - a. FGF23 level is greater than 100 pg/ml
 - b. Fasting serum phosphorus levels less than 2.5 mg/dL
 - c. Ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) less than 2.5 mg/dL
2. Member's disease is associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Crysvida.
- B. Crysvida is being used to treat an indication enumerated in Section III.
- C. The member is receiving benefit from therapy.

V. REFERENCES

1. Crysvida [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; June 2020.
2. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. <http://clinicaltrials.gov/ct2/show/NCT02163577>. Accessed October 24, 2018.
3. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. <http://clinicaltrials.gov/ct2/show/NCT02526160>. Accessed October 24, 2018.
4. Dieter, H., Emma, F., Eastwood, D.M., et.al. Clinical Practice Recommendations for the Diagnosis and Management of X-linked Hypophosphataemia. *Nature Reviews Nephrology* 15, 435-455 (2019).
5. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. <http://clinicaltrials.gov/ct2/show/NCT02304367>. Accessed June 30, 2020.
6. Chong WH, Molinolo AA, Chen CC, et.al Tumor-induced Osteomalacia. *Endocrine Related Cancer* 18:R53-R77 (2011).