JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP079
		Effective Date	05/01/2023
		Review Date	04/19/2023
	Subject **Crysvita**	*Revision Date*	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Crysvita

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I. POLICY

A. Crysvita (burosumab-twza) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Crysvita may be approved for patients who meet the following:
   1. X-linked hypophosphatemia (XLH)
      a. Documentation has been submitted showing both of the following
         I. Patient meets one of the following:
            i. Genetic testing was conducted to confirm a PHEX mutation in the patient, and genetic testing results were submitted confirming diagnosis
            ii. Genetic testing was conducted to confirm a PHEX mutation in a directly related family member with appropriate X-linked inheritance and genetic testing results were submitted confirming diagnosis.
            iii. Patient's FGF23 level is above the upper limit of normal or abnormal for the assay and lab test results were submitted confirming diagnosis.
         II. Patient has radiographic evidence of rickets or other bone disease attributed to XLH
   2. Tumor-induced osteomalacia (TIO)
      a. Documentation has been submitted showing the following:
         I. Patient's diagnosis is confirmed by ALL of the following, and lab test results were submitted confirming diagnosis:
            i. FGF23 level is above the upper limit of normal or abnormal for the assay
            ii. Fasting serum phosphorus levels are less than 2.5 mg/dL
            iii. Ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) is less than 2.5 mg/dL
         II. Patient's disease is associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy

B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient is continuing to have a clinical benefit from therapy, evidenced by disease stability, or improvement, such as the following;

1. increase or normalization in serum phosphate
2. improvement in bone and joint pain
3. reduction in fractures
4. improvement in skeletal deformities

IV. EXCLUSIONS

A. Crysvita will not be covered for the following:

1. Any indications that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, burosumab-twza 1 mg	J0584

VII. REFERENCES

1. Crysvita [prescribing information]. Bedminster, NJ: Kyowa Kirin, Inc.; June 2020.
2. 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).

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/19/2023	Policy Creation

Review Dates: 04/19/2023

Revision Dates: 04/19/2023

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