TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Burosumab-twza (Crysvita®)	**CRITERIA ID:** TX.CC.PHAR.05
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 4/8/19	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 3/15/20, 10/27/20, 5/4/21, 8/1/22, 7/12/23, 2/27/2024, 6/28/2024, 5/14/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for burosumab-twza (Crysvita®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of burosumab-twza (Crysvita®); procedure code: J0584.

Description/Mechanism of Action:
Burosumab-twza (Crysvita®) is a fibroblast growth factor 23 (FGF23) blocking antibody which binds to and inhibits the activity of fibroblast growth factor 23 (FGF23), thereby restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D.

Formulations:
Burosumab-twza (Crysvita®) injection for subcutaneous administration is available as one single-dose vial per carton in the following strengths:

- 10 mg/mL
- 20 mg/mL
- 30 mg/mL

FDA Approved Indications:
Burosumab-twza (Crysvita®) is approved for the treatment of:

- X-linked hypophosphatemia (XLH, a rare, inherited form of rickets) in adult and pediatric clients 6 months of age and older.
- FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be localized or are not amenable by surgical excision in adult and pediatric clients who are two years of age and older.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. X-linked hypophosphatemia (XLH):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 6 months of age or older.
3. The client has a diagnosis of XLH (diagnosis codes: E83.30 or E83.31) supported by one of the following:
    a. Documentation of a confirmed phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutation; or
    b. Serum fibroblast growth factor-23 (FGF23) level greater than 30 pg/ml.
4. Prescriber attestation that any oral phosphate or active vitamin D analog supplementation will be discontinued at least one week prior to starting Crysvita therapy.
5. Documentation that the prescriber agrees to measure serum phosphate throughout therapy and withhold medication when serum phosphorus is above 5 mg/dl.

    Note: Crysvita will not be approved for clients who currently use oral phosphates and active vitamin D analogs; whose serum phosphorus is within or above the normal range for client's age; or for clients with severe renal impairment or end stage renal disease.

Approval duration: 12 months

B. FGF23 - Related Hypophosphatemia in Tumor-Induced Osteomalacia:

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 2 years of age or older.
3. The client has a diagnosis of FGF23-related hypophosphatemia produced by an underlying tumor that cannot be localized or is not amenable to surgical excision.
4. Prescriber attestation that any oral phosphate or vitamin D analog supplement will be discontinued at least two weeks prior to starting Crysvita therapy.
5. Documentation that the prescriber agrees to measure serum phosphate throughout therapy.

   Note: Crysvita will not be approved for clients who currently use oral phosphates and active vitamin D analogs; whose serum phosphorus is within or above the normal range for client's age; or for clients with severe renal impairment or end stage renal disease.

Approval duration: 12 months

I. Continued Therapy

A. X-linked hypophosphatemia (XLH):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client has previously received treatment with Crysvita.
3. Prescriber attestation confirming that the client has demonstrated a positive clinical response to Crysvita (e.g., enhanced height velocity, improvement in askeletal deformity, reduction of fractures, and reduction of generalized bone pain).
4. Documentation that the prescriber will continue to monitor serum phosphate level.

   Note: Crysvita will not be approved for clients who currently use oral phosphates and active vitamin D analogs; whose serum phosphorus is within or above the normal range for client's age; or for clients with severe renal impairment or end stage renal disease.

Approval duration: 12 months

B. FGF23 - Related Hypophosphatemia in Tumor-Induced Osteomalacia:

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client has previously received treatment with Crysvita.
3. Prescriber attestation confirming that the client has demonstrated a positive clinical response to Crysvita (e.g., enhanced height velocity, improvement in askeletal deformity, reduction of fractures, and reduction of generalized bone pain).
4. Documentation that the prescriber will continue to monitor serum phosphate level.

   Note: Crysvita will not be approved for clients who currently use oral phosphates and active vitamin D analogs; whose serum phosphorus is within or above the normal range for client's age; or for clients with severe renal impairment or end stage renal disease.

Approval duration: 12 months

REFERENCES:

Crysvita (burosumab-twza) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc; June 2020.

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	4/8/19
Annual Review	Added non-risk based payment drug to purpose section. Added applicable ICD-10 codes to #4 under Initial Approval Criteria. Added word "member" in #7 under Initial Approval criteria.	3/15/20
Ad Hoc Review	Updated XLH indication from 1 year and older to 6 months of age and older for approval. Added initial criteria and continued criteria for indication of FGF23- Related Tumor Induced Osteomalacia associated with phosphaturic mesenchymal tumors.	10/27/20
Ad Hoc Review	Updated continuation criteria for monitoring serum phosphate level to documentation shows provider continues to monitor vs provider will continue to monitor	5/4/21
Annual Review	Changed to new P&P template Updated FDA approved indications under policy section Updated references	4/25/22
Ad Hoc Review	Removed specialist requirement	8/1/22
Annual Review	Added -twza to burosumab for consistency across policy Reworded Initial Therapy Criteria for FGF23 sub-bullet point D to say prior instead of before Formatting changes	07/12/23
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement	02/27/24

Ad Hoc Review	Updated continuation criteria to remove criteria step requirement: The client has achieved normal level of serum phosphate.	6/28/2024
Annual Review	Formatting change to header and font and font size Updated section titles I.A. and I.B. to FGF23 - Related Hypophosphatemia in Tumor-Induced Osteomalacia to align with CAD Manual	5/14/2025