POLICY AND PROCEDURE

POLICY NAME: Burosumab-twza (Crysvita)	**POLICY ID:** TX.PHAR.55
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	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of burosumab (Crysvita).

PURPOSE:
This medication is a pass through drug (non-risk based 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 Superior 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:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of burosumab (Crysvita).

Description/Mechanism of Action:
Burosumab (Crysvita) 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:
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 (Crysvita) is approved for the treatment of:

- X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
- FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be localized or is 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. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Member is 6 months of age or older.
3. Member has a diagnosis of XLH (ICD-10: 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.
    b. Serum fibroblast growth factor-23 (FGF23) level greater than 30 pg/ml.
4. Documentation that the prescriber will discontinue any oral phosphate or active vitamin D analog supplementation at least one week prior to starting burosumab (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.
6. Burosumab (Crysvita) will not be approved for members who currently use oral phosphates and active vitamin D analogs; whose serum phosphorus is within or above the normal range for member's age; or for members with severe renal impairment or end stage renal disease.

B. FGF23- Related Tumor Induced Osteomalacia associated with phosphaturic mesenchymal tumors

a. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director
b. Member is 2 years of age or older
c. Diagnosis of FGF23-related hypophosphatemia produced by an underlying tumor unable to be localized or is not amenable to surgical excision
d. Prescriber discontinues any oral phosphate or vitamin D analog supplement at least two weeks before starting burosumab (Crysvita) therapy
e. Prescriber agrees to measure serum phosphate throughout therapy

Note: Documentation of the member's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units per injection, and the dosage calculation must be submitted.

Approval duration: 12 months

I. Continued Therapy

A. X-linked hypophosphatemia (XLH)

1. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
2. All approvals or denials for continued therapy will be reviewed by a Superior Medical Director to continue coverage.
3. Documentation that the physician continues to monitor serum phosphate level.
4. Documentation from physician confirming one of the following:
    a) The member has achieved normal level of serum phosphate.
    b) The member has demonstrated a positive clinical response to burosumab (Crysvita) (e.g., enhanced height velocity, improvement in askeletal deformity, reduction of fractures, and reduction of generalized bone pain).

B. FGF23- Related Tumor Induced Osteomalacia associated with phosphaturic mesenchymal tumors

1. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
2. All approvals or denials for continued therapy will be reviewed by a Superior Medical Director to continue coverage.
3. Documentation that the physician will continue monitoring serum phosphate levels.
4. Documentation from physician confirming one of the following:
    a) The member has achieved normal level of serum phosphate.
    b) The member has demonstrated a positive clinical response to burosumab (Crysvita) (e.g., enhanced height velocity, improvement in askeletal deformity, reduction of fractures, and reduction of generalized bone pain).

Note: Documentation of the member's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units per injection, and the dosage calculation must be submitted.

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

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: 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

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company’s P&P management software, is considered equivalent to a signature.