Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Burosumab-Twza (Crysvita)
PAGE: 1 of 4	**REPLACES DOCUMENT:**
APPROVED DATE: 4/8/2019	**RETIRED:**
EFFECTIVE DATE: 4/8/2019	**REVIEWED/REVISED:** 4/17/2019, 3/15/20
PRODUCT TYPE: Star, Star Health, Star Kids, Star Plus, Chip, Chip Prenate	**REFERENCE NUMBER:** TX.PHAR.55

SCOPE:

Superior Health PlanPharmacy Department, Medical Directors

PURPOSE:

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

BACKGROUND:

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 1 year of age and older.

Policy and Procedure

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PAGE: 2 of 4	**REPLACES DOCUMENT:**
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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. Medication is prescribed by or in consultation with a nephrologist or endocrinologist.
3. Member is one year of age or older.
4. 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.
5. 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.
6. Documentation that the prescriber agrees to measure serum phosphate throughout therapy and withhold medication when serum phosphorus is above 5 mg/dl.
7. 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.

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

Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Burosumab-Twza (Crysvita)
PAGE: 3 of 4	**REPLACES DOCUMENT:**
APPROVED DATE: 4/8/2019	**RETIRED:**
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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 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; September 2018.

ATTACHMENTS:

DEFINITIONS/ABBREVIATIONS:

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PAGE: 4 of 4	**REPLACES DOCUMENT:**
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REVISION LOG

REVISION	DATE
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

POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations — Approval on file

Dr. David Harmon, Sr. V.P., Chief Medical Officer — Approval on file

Pharmacy & Therapeutics Committee: — Approval on file

NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.