MEDICAL COVERAGE POLICY	
SERVICE: Medicaid Burosumab-twza (Crysvita)	
Policy Number:	**276**
Effective Date:	**11/01/2020**
Last Review:	**09/24/2020**
Next Review Date:	**09/24/2021**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Burosumab-twza (Crysvita)

PRIOR AUTHORIZATION: Required

POLICY: For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM. Burosumab-twza (Crysvita) may be medically necessary for the treatment of X-linked hypophosphatemia (XLH) when the following criteria are met:

For initial therapy, the following criteria must be met:

- Member is six months of age or older
- Must be prescribed by or in consultation with a nephrologist or endocrinologist
- Member has a diagnosis of X-linked hypophosphatemia (XLH) (diagnosis code E8330 or E8331) that is supported by one of the following:
  - Confirmed phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutation
  - Serum fibroblast growth factor-23 (FGF23) level >30 pg/ml
- Prescriber discontinues any oral phosphate or active vitamin D analog supplementation at least one week prior to starting burosumab-twza (Crysvita) therapy
- Prescriber agrees to measure serum phosphate throughout therapy and withhold medication when serum phosphorus is above 5 mg/dl

For renewal or continuation therapy, the following criteria must be met:

- Member has previously received treatment with burosumab-twza (Crysvita)
- Documentation from prescriber confirming one of the following:
  - Member has achieved normal level of serum phosphate
  - Member has demonstrated a positive clinical response to burosumab-twza (Crysvita) (e.g., enhanced height velocity, improvement in askeletal deformity, reduction of fractures, and reduction of generalized bone pain)
- Prescriber continues to monitor serum phosphate level

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Burosumab-twza (Crysvita) may be medically necessary for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors when all of the following criteria are met:

Initial requirements for FGF23-related hypophosphatemia in tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors must include the following:

- Member is two years of age or older
- Member has a diagnosis of FGF23-related hypophosphatemia produced by an underlying tumor unable to be localized or is not amenable to surgical excision
- Prescriber discontinues any oral phosphate or vitamin D analog supplement at least two weeks before starting burosumab-twza (Crysvita) therapy
- Prescriber agrees to measure serum phosphate throughout therapy

Burosumab-twza (Crysvita) may be approved for a duration of every 12 months per prior authorization request.

Burosumab-twza (Crysvita) is not a benefit for the following:

- Members who currently use oral phosphates and active vitamin D analogs
- Members whose serum phosphorus is within or above the normal range for client's age
- Members with severe renal impairment or end stage renal disease

OVERVIEW:

X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 (FGF23) which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D.

Tumor-induced osteomalacia (TIO) is a rare disease characterized by slow-growing tumors that release excess levels of FGF23, which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D.

Burosumab-twza binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D.

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
ICD10 codes:	E83.31 – Familial hypophosphatemia
HCPCS Codes	J0584 - Injection, burosumab-twza 1 mg

POLICY HISTORY:

Status	Date	Action
New	09/24/2020	New policy

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. The health plan will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to the health plan so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Texas Medicaid Provider Procedures Manual: http://www.tmhp.com/resources/provider-manuals/tmppm.
2. Crysvita (burosumab-twza) [prescribing information]. Bedminster, NJ: Ultragenyx Pharmaceutical Inc.; 2020.
3. Park. [2020, June 22]. Crysvita Approved for Treatment of Tumor-Induced Osteomalacia. Retrieved from https://www.empr.com/home/news/crysvita-burosumab-twza-fibroblast-growth-factor-23-hypophosphatemia/.