SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Crysvita® (burosumab-twza) **Injection (J0584) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Height: _____ **Date:** _____

☐ **Standard Review**. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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❑ **Diagnosis: Treatment of X-linked Hypophosphatemia (XLH)**
Initial Authorization: 6 months

Recommended Dose:

Pediatric XLH (6 months and older)	▪ For patients who weigh less than 10 kg, starting dose regimen is 1 mg/kg of body weight rounded to the nearest 1 mg, administered every two weeks. ▪ For patients who weigh 10 kg and greater, starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg. ▪ **NOTE:** Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus.
Adult XLH	▪ Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks.
Crysvita Dosing Strategy for Suboptimal Response in Adult XLH	▪ Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks. ▪ If serum phosphorus levels are below normal range after initial treatment period (3 months): Transition to 0.5 mg/kg, not to exceed 90 mg, once every 2 weeks. ▪ If further dosage increase is needed after 4 weeks at 0.5 mg/kg every 2 weeks: Increase to 1 mg/kg, not to exceed 90 mg, administered every 2 weeks.

- ❑ Member is at least 6 months of age or older
- ❑ Prescribed by or in consultation with a nephrologist or endocrinologist or specialist experienced in the treatment of metabolic bone disorders
- ❑ Member must have a documented diagnosis of X-linked Hypophosphatemia (XLH) **(submit chart notes and labs to confirm diagnosis)**
- ❑ Member's diagnosis has been confirmed by identifying at least **ONE** of the following:
  - ❑ Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
  - ❑ Genetic Testing: Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the member
- ❑ Provider must submit progress notes to document **ALL** the following:
  - ❑ Skeletal deformities: _____
  - ❑ Number of fractures: _____
  - ❑ Generalized bone pain score: _____

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- ❑ Member must meet **ONE** of the following:
  - ❑ Member's epiphyseal plates have **NOT** fused, and member has tried and failed or has experienced an intolerable life endangering adverse event with therapy **(i.e., anaphylaxis; submit chart notes to document intolerance)** with calcitriol in combination with an oral phosphate agent (e.g., OTC K-Phos Neutra, OTC phospho-trin 250 neutral) **[failure is defined as abnormal phosphate levels despite compliance with calcitriol therapy in combination with an oral phosphate agent for at least 2 months]**
  - ❑ Member meets **ALL** the following:
    - ❑ Member's epiphyseal plates have fused
    - ❑ Member is experiencing clinical signs and symptoms of the disease **(e.g., limited mobility; musculoskeletal pain; bone fractures)**
    - ❑ Member has tried and failed or has experienced an intolerable life endangering adverse event with therapy **(i.e., anaphylaxis; submit chart notes to document intolerance)** with calcitriol in combination with an oral phosphate agent (e.g., OTC K- Phos Neutra, OTC phospho-trin 250 neutral) **[failure is defined as abnormal phosphate levels despite compliance with calcitriol therapy in combination with an oral phosphate agent for at least 2 months]**
- ❑ Member's baseline fasting serum phosphorus level obtained within the last 30 days demonstrates current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range for the member's age **(submit current labs with level)**
- ❑ Member has **NOT** received oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy
- ❑ Member does **NOT** have severe renal impairment, defined as an estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m^2

❑ Diagnosis: X-linked Hypophosphatemia (XLH)

Reauthorization: 6 months. Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has previously received treatment with burosumab
- ❑ Member has experienced normalization of serum phosphate while on therapy **(submit current labs with level)**
- ❑ Provider has submitted chart notes to confirm member has experienced a positive clinical response to burosumab therapy (e.g., enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain)

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❑ **Diagnosis: Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO)**
Initial Authorization: 6 months

Recommended Dose:

Pediatric TIO (2 years and older)	▪ Starting dose is 0.4 mg/kg of body weight rounded to the nearest 10 mg every 2 weeks. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every two weeks.
Adult TIO	▪ Starting dose is 0.5 mg/kg every four weeks. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every two weeks.

- ❑ Member is at least 2 years of age or older
- ❑ Prescribed by, or in consultation with, an oncologist, endocrinologist, or specialist experienced in the treatment of tumor-induced osteomalacia (TIO)
- ❑ Member has a diagnosis of fibroblast growth factor 23 (FGF-23)-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors (PMT) that cannot be curatively resected or localized **(must submit chart notes documenting the reason that first-line therapy with surgical resection may not be performed)**
- ❑ Member's diagnosis of TIO associated with PMT has been confirmed by **BOTH** of the following:
  - ❑ Serum fibroblast growth factor-23 (FGF-23) level ≥ 100 pg/mL or iFGF23 level ≥ 100 pg/mL by Kainos assay
  - ❑ Tumor biopsy results or entire body functional imaging (SSTR octreo-SPECT, ^{68}Ga DOTATATE PET/CT, 18 FDG PET/CT) with follow-up CT, MRI or US confirms diagnosis of PMT **(must submit results)**
- ❑ Other causes of FGF-23 elevations, such as X-linked hypophosphatemia, autosomal dominant or recessive hypophosphatemic rickets, or Fanconi syndrome have been ruled out
- ❑ Member is experiencing clinical signs and symptoms of the disease (e.g., osteomalacia, musculoskeletal pain, bone fractures)
- ❑ Member has tried and failed or has experienced an intolerable life endangering adverse event with therapy **(i.e., anaphylaxis; submit chart notes to document intolerance)** with calcitriol in combination with an oral phosphate agent (e.g., OTC K- Phos Neutra, OTC phospho-trin 250 neutral) **[failure is defined as abnormal phosphate levels despite compliance with calcitriol therapy in combination with an oral phosphate agent for at least 2 months]**
- ❑ A baseline bone biopsy has been performed and osteoid volume/bone volume (OV/BV) and osteoid thickness results have been submitted with request

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- ❑ Member's baseline fasting serum phosphorus level obtained within the last 30 days demonstrates current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range for the member's age **(submit current labs with level)**
- ❑ Member has **NOT** received oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy
- ❑ Member does **NOT** have severe renal impairment, defined as an estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m^2
- ❑ Crysvita will be discontinued if member undergoes additional treatment of the underlying tumor, such as radiation therapy or surgical excision; Crysvita dose will be adjusted for re-initiation according to phosphate levels after treatment is completed

❑ **Diagnosis: Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO)**

Reauthorization: 6 months. Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Current bone biopsy documents decrease in osteoid volume/bone volume (OV/BV) and osteoid thickness, or maintenance of OV/BV and osteoid thickness below baseline level, since last approval of burosumab **(must submit biopsy report with OV/BV and osteoid thickness results)**
- ❑ Member has experienced normalization of serum phosphate while on therapy **(submit current labs with level)**
- ❑ Provider has submitted chart notes to confirm member has experienced a positive clinical response to burosumab therapy (e.g., radiographic evidence of healing of bone lesions, reduction of fractures, reduction of generalized bone pain)
- ❑ Member is **NOT** experiencing any contraindications to therapy, including hyperphosphatemia or progression of neoplasm

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~10/17/2018;~~ **8/16/2023**
REVISED/UPDATED/REFORMATTED: ~~12/11/2018; 4/30/2019; 7/6/2019; 9/20/2019; 9/7/2023; 10/28/2023;~~ **7/28/2026**