SENTARA COMMUNITY PLAN
(MEDICAID)

PHARMACY 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 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

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

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight: _____ **Date:** _____

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.

❑ **Diagnosis: Treatment of X-linked Hypophosphatemia (XLH)**

Initial Authorization: 6 months

❑ Member Has the member been approved for Crysvita previously through the Sentara Health Plans medical department ❑ Yes ❑ No

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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.

- ❑ 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: _____
- ❑ 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)**

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- ❑ 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

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.

- ❑ **Diagnosis: X-linked Hypophosphatemia (XLH)**

- ❑ 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)

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.

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

Initial Authorization: 6 months

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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
- ❑ 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

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- ❑ 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

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.

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

- ❑ 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 – Proprium Rx**

*****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
REVISED/UPDATED: ~~12/11/2018; (Reformatted) 4/30/2019~~; ~~7/6/2019; 9/20/2019;07/11/2023~~; ~~11/8/2023~~**; 4/24/2024**