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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

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 has not received oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy
- ❑ Member has a baseline fasting serum phosphorus level showing current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range
- ❑ Member has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- ❑ Other causes of hypophosphatemia (e.g., autosomal dominant or recessive hypophosphatemic rickets) have been ruled out
- ❑ Must be prescribed by, or in consultation with, a nephrologist or endocrinologist
- ❑ Will not be used concomitantly with oral phosphate and/or active vitamin D analogs
- ❑ Member does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of <30 mL/min
- ❑ Member 25-hydroxy vitamin D levels will be monitored at baseline and intermittently and patient will be supplemented with cholecalciferol or ergocalciferol to maintain levels in the normal range for age
- ❑ Member is at least 6 months of age
- ❑ Diagnosis is confirmed by identifying at least **ONE** of the following:
  - ❑ Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL (>230 RU/mL in children 3 months-17 years; >180 RU/mL in adults using EDTA plasma)
  - ❑ Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEXgene) mutations in the patient
- ❑ Adult members must have had an inadequate response from oral phosphate and active vitamin D analogs

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❑ **Diagnosis: X-linked Hypophosphatemia (XLH)**
Reauthorization: 12 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 the relevant criteria identified in the initial criteria;
- ❑ Member has an absence of unacceptable toxicity from the drug
- ❑ Member is being continuously monitored for a beneficial response to therapy

❑ **Diagnosis: 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 has not received oral phosphate and/or active vitamin D analogs within 1 week prior to the start of therapy
- ❑ Member has a baseline fasting serum phosphorus level showing current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range
- ❑ Member has a reduced tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- ❑ Other causes of hypophosphatemia (e.g., autosomal dominant or recessive hypophosphatemic rickets) have been ruled out
- ❑ Must be prescribed by, or in consultation with, a nephrologist or endocrinologist
- ❑ Will not be used concomitantly with oral phosphate and/or active vitamin D analogs
- ❑ Member does not have severe renal impairment, defined as a glomerular filtration rate (GFR) of <30 mL/min
- ❑ Member 25-hydroxy vitamin D levels will be monitored at baseline and intermittently and patient will be supplemented with cholecalciferol or ergocalciferol to maintain levels in the normal range for age
- ❑ Member is at least 2 years of age or older
- ❑ Must have a diagnosis of tumor-induced osteomalacia associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized
- ❑ Diagnosis is confirmed by identifying excessive serum FGF23 (i.e., level ≥ 100 pg/mL) that is not amenable to cure by surgical excision of the offending tumor/lesion

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❑ **Diagnosis: Tumor-induced osteomalacia (TIO)**
Reauthorization: 12 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 the relevant criteria identified in the initial criteria
- ❑ Member has an absence of unacceptable toxicity from the drug
- ❑ Member is being continuously monitored for a beneficial response to therapy

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/REFORMATTED: ~~12/11/2018; 4/30/2019; 7/6/2019; 9/20/2019;07/11/2023; 11/8/2023; 4/24/2024;~~ **6/4/2026**