SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

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 Name/Form/Strength: _____

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

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

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

❑ 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.

❑ **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 pharmacy department ❑ Yes ❑ No

(Continued on next page)

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.

- ❑ 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

(Continued on next page)

❑ **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

(Continued on next page)

❑ **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 – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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; 10/25/2023, 4/24/2024; 6/28/2024;~~ **6/8/2026**