OPTIMA HEALTH PLAN

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 1-844-723-2094**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **Incomplete form will delay authorization process**.

Drug Requested: Crysvita (burosumab-twza) Injection (J3590) (Medical)

DRUG INFORMATION: Complete information below or authorization will be delayed.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code**: _____

Baseline Height: _____

Please submit progress notes: skeletal deformities; number of fractures _____; **generalized pone pain score**: _____

CLINICAL CRITERIA: Check boxes below to qualify. If **not** checked, authorization will be delayed.

Initial Approval Criteria - All of the following criteria **MUST** be met for approval.

- ❑ Patient is at least 1 year of age; **AND**
- ❑ Patient has not received oral phosphate and/or active vitamin D analogs within 1 weeks prior to the start of therapy; **AND**
- ❑ Must be prescribed by or in consultation with a nephrologist or endocrinologist or specialist experienced in the treatment of metabolic bone disorders; **AND**
- ❑ Patient must have documented diagnosis of X-linked Hypophosphatemia (XLH)—Chart notes and labs must be submitted for the following:
  - ❑ Diagnosis is confirmed by identifying at least one of the following:
    - ❑ Serum fibroblast growth factor-23 (FGF23) level > 30 pg/ml; **AND**
    - ❑ Genetic Testing: Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient; **AND**
  - ❑ **ONE** of the following:
    - ❑ Patient epiphyseal plate has NOT fused; and Failure (define compliant on calcitriol in combination with an oral phosphate agent monthly and levels are still abnormal for 2 months) to therapy with calcitriol in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra) **OR**
  - ❑ **ALL** of the following:
    - ❑ Patients epiphyseal plate has fused; **AND**
    - ❑ Patient is experiencing clinical signs and symptoms of the disease (e.g. limited mobility, musculoskeletal pain, bone fractures); **AND**
    - ❑ Failure (define compliant on calcitriol in combination with an oral phosphate agent monthly and levels are still abnormal for 2 months), contraindication (needs to send progress notes of incident), or intolerance (anaphylaxis reaction) to therapy with calcitriol in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra)

AND

- ❑ Fasting serum phosphorus is below the normal range for age: **AND**
- ❑ Dosing is in accordance with the United States Food and Drug Administration approved labeling;

AND

- ❑ Initial authorization with be for no more than 12 months

AND

- ❑ Baseline fasting serum phosphorus level within the last 90 days demonstrates current hypophosphatemia, defined as a phosphate level below the lower limit of the laboratory normal reference range; **AND**
- ❑ Patient does not have severe renal impairment, defined as a glomerular filtration rate (GFR) < 30 mL/min/1.73 m^2

Renewal Criteria - All of the following criteria **MUST** be met for approval:

- ❑ Patient has previously received treatment with burosumab; **AND**
- ❑ Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders; **AND**
- ❑ Patient has experienced normalization of serum phosphate while on therapy; **AND**
- ❑ Patient has experienced a positive clinical response to burosumab (e.g., enhanced height velocity;
- ❑ improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain); **AND**
- ❑ Dosing is in accordance with the United States Food and Drug Administration approved labeling; **AND**
- ❑ Reauthorization will be for no more **than 12 months**.

Medication being provided by (check applicable box below):

❑ **Physician's Office** **OR** ❑ **Specialty Pharmacy: PropriumRx**

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.*

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 10/17/2018
REVISED/UPDATED: 12/11/2018