Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2020**
Policy Number: PA.CP.PHAR.11	**Effective Date: 01/2020** **Revision Date: 07/2020**
Policy Name: Burosumab-twza (Crysvita)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2020 annual review: clarified weight-based dosing limits in initial and continued approval criteria; removed the requirement for a prior trial of calcitriol plus oral phosphates based on updated clinical trial data demonstrating superiority of Crysvita over calcitriol plus oral phosphates; updated FDA approved pediatric age extension to ≥ 6 months from ≥ 1 year; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Burosumab-twza (Crysvita)

Reference Number: PA.CP.PHAR.11
Effective Date: 10.17.18
Last Review Date: 07.20

Coding Implications
Revision Log

Description
Burosumab (Crysvita®) is a fibroblast growth factor 23 (FGF23) blocking antibody.

FDA Approved Indication(s)
Crysvita is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness that Crysvita is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. X-Linked Hypophosphatemia (must meet all)**:**

1. Diagnosis of XLH confirmed by one of the following (a or b):
   a. DNA testing confirms the presence of mutations in the *PHEX* gene;
   b. Elevated serum fibroblast growth factor 23 (FGF23) levels;
2. Prescribed by or in consultation with an endocrinologist or metabolic disease specialist;
3. Age ≥ 6 months;
4. Current (within the last 30 days) serum phosphorus level is below the reference range for age and gender (*use laboratory-specific reference ranges if available; otherwise, see Appendix D for ranges*);
5. For age ≥ 18 years: presence of clinical signs and symptoms of the disease (e.g., rickets, growth impairment, musculoskeletal pain, bone fractures);
6. Dose does not exceed one of the following (a or b):
   a. Age 6 months to < 18 years: 2 mg/kg up to 90 mg every two weeks:
   b. Age ≥ 18 years: 1 mg/kg up to 90 mg every four weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. X-Linked Hypophosphatemia (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by both of the following (a and b):
   a. An increase in serum phosphorus levels from baseline and/or maintenance within the normal range for age and gender, not to exceed the upper limit of that normal range (*use laboratory-specific reference ranges if available; otherwise, see Appendix D for ranges*);
   b. A positive clinical response including any of the following: enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Age 6 months to < 18 years: 2 mg/kg up to 90 mg every two weeks:
   b. Age ≥ 18 years: 1 mg/kg up to 90 mg every four weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
FGF23: fibroblast growth factor 23
XLH: X-linked hypophosphatemia

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications

- Do not use Crysvita with oral phosphate and active vitamin D analogs.
- Do not initiate Crysvita treatment if serum phosphorus is within or above the normal range for age.
- Crysvita is contraindicated in patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism.

Appendix D: General Information

- Laboratory-specific reference ranges for serum phosphorus levels should be used when available; otherwise, the age- and gender-based reference ranges found below may be used:

Females	Males
1-7 years: 4.3-5.4 mg/dL	1-4 years: 4.3-5.4 mg/dL
8-13 years: 4.0-5.2 mg/dL	5-13 years: 3.7-5.4 mg/dL
14-15 years: 3.5-4.9 mg/dL	14-15 years: 3.5-5.3 mg/dL
16-17 years: 3.1-4.7 mg/dL	16-17 years: 3.1-4.7 mg/dL
≥ 18 years: 2.5-4.5 mg/dL	≥ 18 years: 2.5-4.5 mg/dL

- For pediatric patients continuing on Crysvita therapy, if serum phosphorus is >5 mg/dL, it is recommended to withhold the dose until the serum phosphorus level falls below the reference range per age.
- For adult patients continuing on Crysvita therapy, if serum phosphorus is above the upper limit of the normal range, it is recommended to withhold the dose until the serum phosphorus level falls below the reference range.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
XLH	**Pediatric XLH** • Weight < 10 kg: 1 mg/kg rounded to the nearest 1 mg, SC every two weeks • Weight ≥ 10 kg: 0.8 mg/kg rounded to the nearest 10 mg, SC every two weeks Increase dose up to approximately 2 mg/kg, SC every two weeks to achieve normal serum phosphorus. **Adult XLH** 1 mg/kg body weight rounded to the nearest 10 mg SC every four weeks. Crysvita should only be administered by a healthcare professional.	Pediatric XLH: 2 mg/kg up to 90 mg every two weeks Adult XLH: 1 mg/kg up to 90 mg every four weeks

VI. Product Availability

Single-dose vials for injection: 10 mg/mL, 20 mg/mL, 30 mg/mL

VII. References

1. Crysvita Prescribing Information. Novato, CA: Ultragenyx Pharmaceutical Inc; September 2019. Available at: www.crysvita.com. Accessed April 27, 2020.
2. Carpenter TO, et al. A clinician's guide to X-linked hypophosphatemia. JBMR 2011; 26(7):1381-8. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1002/jbmr.340.

3. Haffner D, Emma F, Eastwood DM, et al. Clinical practice recommendations for the diagnosis and management of X-linked hypophosphataemia. Nature Reviews Nephrology 2019 May; 15: 435-455.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Injection, burosumab-twza, (# of units TBD)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07.17.19	
3Q 2020 annual review: clarified weight-based dosing limits in initial and continued approval criteria; removed the requirement for a prior trial of calcitriol plus oral phosphates based on updated clinical trial data demonstrating superiority of Crysvita over calcitriol plus oral phosphates; updated FDA approved pediatric age extension to ≥ 6 months from ≥ 1 year; references reviewed and updated.	07.20	