POLICY Document for Crysvita

The overall objective of this policy is to support the appropriate and cost effective use of the medication, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

CareFirst Site of Care Criteria
Administration of Crysvita

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Crysvita in an outpatient hospital setting for 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Crysvita in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after drug administration.
B. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
C. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of drug administration AND the patient does not have access to a caregiver.
D. The member is less than 21 years of age or is 65 years of age or older.

For situations where administration of Crysvita does not meet the criteria for outpatient hospital administration, coverage for Crysvita is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after drug administration
B. Medical records supporting the member is medically unstable
C. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver

Section 2: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

CRYSVITA (burosumab-twza)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

At least one of the following information is necessary to initiate the prior authorization review:
A. Genetic testing results confirming the member has a PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation
B. Genetic testing results confirming a PHEX mutation in a directly related family member with appropriate X-linked inheritance
C. Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is greater than 30 pg/ml

III. CRITERIA FOR INITIAL APPROVAL

X-linked hypophosphatemia
Authorization of 12 months may be granted for treatment of X-linked hypophosphatemia when one of the following criteria is met:
A. Genetic testing was conducted to confirm a PHEX mutation in the member and genetic testing results were submitted confirming diagnosis.
B. Genetic testing was conducted to confirm a PHEX mutation in a directly related family member with appropriate X-linked inheritance and genetic testing results were submitted confirming diagnosis.
C. Member's FGF23 level is greater than 30 pg/ml and lab test results were submitted confirming diagnosis.

IV. CONTINUATION OF THERAPY

Authorization of 12 months will be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who are currently receiving the requested medication through a paid pharmacy or medical benefit and who are experiencing benefit from therapy as evidenced by disease improvement or disease stability.

REFERENCES:

SECTION 1

1. Crysvita [package insert]. Novato, CA: Ultragenyx Pharmaceutical Inc.; September 2018.
2. Insogna KL, Briot K, Imel EA, et al. A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial Evaluating the Efficacy of Burosumab, an Anti-FGF23 Antibody, in Adults With X-Linked Hypophosphatemia: Week 24 Primary Analysis. *J Bone Miner Res.* 2018;33(8):1383-1393

SECTION 2

1. Crysvita [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2018.
2. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. http://clinicaltrials.gov/ct2/show/NCT02163577. Accessed October 24, 2018.
3. NIH. U.S. National Library of Medicine. ClinicalTrials.gov website. http://clinicaltrials.gov/ct2/show/NCT02526160. Accessed October 24, 2018.