Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 182.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Crysvita (burosumab-twza)

I. Policy:
Crysvita (burosumab-twza)

II. Purpose/Objective:
To provide a policy of coverage regarding Crysvita (burosumab-twza)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Crysvita (burosumab-twza) is an anti-FGF23 monoclonal antibody that binds to and inhibits the activity of fibroblast growth factor 23 (FGF23), thereby restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Crysvita (burosumab-twza) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

X-linked hypophosphatemia

- Medical record documentation that the patient is at least 6 months of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, geneticist, or nephrologist **AND**
- Medical record documentation of a diagnosis of X-linked hypophosphatemia as evidenced by one of the following:
    - Reduced TmP/GFR ratio **AND** Reduced or normal plasma concentration of 1,25-dihydroxycholecalciferol (1,25-DHCC) or 25-hydroxyvitamin D [25(OH)D] **OR**
    - Genetic testing confirming a mutation in the PHEX (Phosphate regulating Endopeptidase on the X chromosome) gene

  AND
- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)

- Medical record documentation that the patient is at least 2 years of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, nephrologist, geneticist, or oncologist **AND**
- Medical record documentation of a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors **AND**
- Medical record documentation of an elevated serum level of FGF23 **AND**
- Medical record documentation that tumors cannot be curatively resected or localized **AND**
- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and the following criteria are met:

- Medical record documentation that patient is being followed regularly by and receiving medication from an endocrinologist, nephrologist, geneticist or oncologist **AND**
- Medical record documentation that Crysvita is improving patient's disease as evidenced by normalized or improved serum phosphorus levels **AND**
- Medical record documentation that the patient is not concurrently using active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) or phosphate supplements

Note: Per FDA labeling, supplementation with cholecalciferol or ergocalciferol is recommended to maintain 25-hydroxy vitamin D levels in the normal range for age.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/18/18

Revised: 11/7/18 (per DHS), 4/15/20 (age 6 months and older), 8/27/20 (TIO), 12/22/20 (FGF23 level), 10/5/22 (Medicaid PARP statement), 11/15/22 (active vit D analogs, note, LOB carve out, Medicaid business segment)

Reviewed: 8/29/19, 10/5/21