

<b>ISSUE DATE</b> December 15, 2020	<b>EFFECTIVE DATE</b> January 5, 2021	<b>NUMBER</b> *See below
<b>SUBJECT</b>  Prior Authorization of Crysvida (burosumab) – Pharmacy Services		<b>BY</b>    Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of prescriptions for Crysvida (burosumab).
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Crysvida (burosumab) submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Crysvida (burosumab) to the appropriate managed care organization.

**BACKGROUND:**

*01-20-50	09-20-49	27-20-45	33-20-46
02-20-43	11-20-43	30-20-42	
03-20-43	14-20-44	31-20-50	
08-20-53	24-20-44	32-20-42	

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department's Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

**DISCUSSION:**

Crysvita (burosumab) is approved by the U.S. Food and Drug Administration for the treatment of X-linked hypophosphatemia and tumor-induced osteomalacia. During the October 21, 2020, meeting, the DUR Board recommended that the Department require prior authorization of Crysvita (burosumab) to ensure appropriate patient selection and drug utilization. The DUR Board recommended guidelines to determine medical necessity of prescriptions for Crysvita (burosumab) that were subject to public review and comment and subsequently approved for implementation by the Department.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Crysvita (burosumab) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Crysvita (burosumab)) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I  
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Crysvida (burosumab)**

A. Prescriptions That Require Prior Authorization

All prescriptions for Crysvida (burosumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Crysvida (burosumab), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Crysvida (burosumab) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed Crysvida (burosumab) by or in consultation with an appropriate specialist (e.g., endocrinologist, geneticist, nephrologist, oncologist, rheumatologist, or other specialist experienced in the treatment of patients with metabolic bone disease, etc.); **AND**
5. Does not have a contraindication to Crysvida (burosumab); **AND**
6. Has a baseline (before treatment) fasting serum phosphate level that is below the reference range for age; **AND**
7. Has laboratory evidence of renal phosphate wasting (i.e., low percent tubular reabsorption of phosphate [%TRP] and/or low fasting tubular maximum reabsorption of phosphate to glomerular filtration rate [TmP/GFR]); **AND**
8. Has a baseline (before treatment) fibroblast growth factor 23 (FGF23) level that is normal or above the assay-specific reference range for age; **AND**
9. For the treatment of X-linked hypophosphatemia (XLH), **both** of the following:
  - a. Has a diagnosis of XLH confirmed by at least **one** of the following:
    - i. Confirmed *PHEX* gene mutation,
    - ii. Positive family history of XLH,
    - iii. Presence of typical clinical features of XLH (e.g., abnormal gait, lower limb

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deformity, decreased growth velocity, etc. in children; short stature, osteomalacia, bone pain, osteoarthritis, pseudofractures, stiffness, enthesopathies, poor dental condition, etc. in adults)

- b. At least **one** of the following:
- i. Has open epiphyses
  - ii. Is experiencing clinical signs and/or symptoms of XLH (e.g., limited mobility, musculoskeletal pain and/or stiffness, bone fractures or pseudofractures, decreased physical function, renal calculi, etc.);

**AND**

10. For the treatment of tumor-induced osteomalacia (TIO), has a diagnosis of active TIO confirmed by at least **one** of the following:
- a. Identification and localization of the underlying tumor that is unresectable or pending resection
  - b. Other causes of genetic and acquired renal phosphate-wasting disorders have been reasonably ruled out;

**AND**

11. If a prescription for Crysvida (burosumab) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR CRYSVITA (BUROSUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Crysvida (burosumab) that was previously approved will take into account whether the beneficiary:

- 1. Experienced an increased fasting serum phosphate level from baseline; **AND**
- 2. **One** of the following:
  - a. For a beneficiary with open epiphyses, is experiencing clinical benefit from Crysvida (burosumab) based on the prescriber's assessment

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- b. For all other beneficiaries, experienced improvement of the signs and/or symptoms of the condition (e.g., decreased number of fractures, improved fracture healing, improved bone mineralization, decreased fatigue, pain, and/or stiffness, improved functional capacity, etc.);

**AND**

3. Is prescribed a dose to maintain serum phosphorus within the recommended range that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed Crysvida (burosumab) by or in consultation with an appropriate specialist (e.g., endocrinologist, geneticist, nephrologist, oncologist, rheumatologist, or other specialist experienced in the treatment of patients with metabolic bone disease, etc.); **AND**
5. Does not have a contraindication to Crysvida (burosumab) (NOTE: Continuation of treatment with Crysvida [burosumab] is not contraindicated when the fasting serum phosphorus level is within the reference range for age); **AND**
6. If a prescription for Crysvida (burosumab) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Crysvida (burosumab). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. Crysvida [package insert]. Novato, CA: Ultragenyx Pharmaceutical Inc. June 2020.

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9. Florenzano P, Hartley IR, Jimenez M, Roszko K, Gafni RI, Collins MT. Tumor-induced osteomalacia. *Calcif Tissue Int.* 2020. doi: 10.1007/s00223-020-00691-6.
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11. Jan de Beur SM. Tumor-induced osteomalacia. *JAMA.* 2005;294(10):1260-1267.