Crysvita (burosumab-twza)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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 Indications

Crysvita (burosumab-twza) is indicated for the treatment of:

1. X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age or older.
2. Serum fibroblast growth factor (FGF) 23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

POLICY

Required Documentation

X-linked hypophosphatemia

Submission of the following information is necessary to initiate the prior authorization review for X-linked hypophosphatemia (XLH):

1. Initial requests
    A. Genetic testing results confirming at least one of the following:
        1) Member has a PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation
        2) A directly related family member with appropriate X-linked inheritance to the member has a PHEX mutation

B. Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level (if applicable)
C. Medical records documenting clinical finding and radiographic features supporting XLH
D. Serum phosphorus levels
E. Creatinine clearance

2. Continuation requests
   A. Medical records documenting clinical benefit
   B. Lab test results confirming the member's serum FGF23 level (if applicable)
   C. Serum phosphorus levels
   D. Creatinine clearance

Tumor Induced Osteomalacia (TIO)
Submission of the following information is necessary to initiate the prior authorization review for tumor induced osteomalacia:

1. Initial requests
   A. Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level
   B. Medical records documenting clinical finding and radiographic features supporting FGF23-related hypophosphatemia in TIO
   C. Medical records documenting ratio of renal tubular reabsorption of phosphate for glomerular filtration rate (TmP/GFR)
   D. Serum phosphorus levels
   E. Creatinine clearance

2. Continuation requests
   A. Medical records documenting clinical benefit
   B. Lab results confirming the member's FGF23 level
   C. Serum phosphorus level
   D. Creatinine clearance

Criteria for Initial Approval
Crysvita (burosumab-twza) may be considered **medically necessary** for the treatment of X-linked hypophosphatemia in adult and pediatric patients 6 months of age and older when ALL of the following criteria are met:

1. Diagnosis of X-linked hypophosphatemia is confirmed by one of the following:
   A. Genetic testing was conducted to confirm a PHEX mutation in the member
   B. Genetic testing was conducted to confirm a PHEX mutation in a directly related family member with appropriate X-linked inheritance
   C. FGF23 level is greater than 30 pg/mL
2. Diagnosis must be made by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders such as Endocrinologist, Nephrologist, Rheumatologist, or Orthopedist
3. Serum phosphorus is below the normal range for age
4. Creatinine clearance (CrCl) ≥30 mL/min
5. The patient has clinical signs and/or symptoms of the disease (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures)

Approval will be for **12 months**

Crysvita (burosumab-twza) may be considered **medically necessary** for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older when ALL of the following criteria are met:

1. Diagnosis of TIO associated with phosphaturic mesenchymal tumors is confirmed by one of the following:
    A. Functional imaging (fluorodeoxyglucose-positron emission tomography [FDG-PET]/computed tomography [CT] AND Octreoscan/CT)
    B. Anatomical imaging (magnetic resonance imaging [MRI] AND/OR CT
    C. Venous sampling
2. Diagnosis must be made by, or in consultation with, an Oncologist or a specialist experienced in the treatment of metabolic bone disorders such as Endocrinologist, Nephrologist, Rheumatologist, or Orthopedist
3. Serum FGF23 level is greater than 100 pg/mL
4. Serum phosphorus is below the normal range for age
5. Creatinine clearance (CrCl) ≥ 30 mL/min
6. The patient has clinical signs and/or symptoms of the disease (e.g rickets, growth retardation, musculoskeletal pain, bone fractures)
7. Tumors cannot be curatively resected or localized
8. Tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) is below the normal range for age

Approval will be for **12 months**

Continuation of Therapy

Crysvita (burosumab-twza) may be considered **medically necessary** for the continuation of treatment of X-linked hypophosphatemia OR FGF 23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized when ALL of the following criteria are met:

1. Patient meets criteria for initial approval above for both diagnosis and prescriber specialty requirements
2. Tumors cannot be curatively resected or localized [for FGF23-related hypophosphatemia in TIO ONLY]
3. Patient has experienced an improvement in serum phosphorus levels while on therapy
4. The patient has responded to therapy with Crysvita with documentation supporting improvement and/or stabilization (upon subsequent renewals) in clinical signs and/or symptoms of disease, as demonstrated by enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain, or enhanced mobility
5. Creatinine clearance (CrCl) ≥30 mL/min

Approval will be for **12 months**

Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0584 - Injection, burosumab-twza 1 mg

REFERENCES

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POLICY HISTORY

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