Crysvita (burosumab-twza)

Effective Date: January 1, 2021
Number: MG.MM.PH.307

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Definitions

Crysvita, a fibroblast growth factor 23 (FGF23) blocking antibody, is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients ≥ 6 months of age.1 Crysvita is a recombinant human immunoglobulin G subclass 1 (IgG1) anti-FGF antibody. FGF23 reduces renal tubular phosphate reabsorption and suppresses renal production of 1,24 dihydroxyvitamin D. Via inhibition of FGF23 activity, Crysvita restores renal phosphate reabsorption and increases serum concentrations of 1,25 dihydroxyvitamin D.

Dosing

X-Linked Hypophosphatemia (XLH)
- For adult patients (≥ 18 years of age), approve up to a maximum dose of 90 mg administered subcutaneously (SC) not more frequently than once every 4 weeks; OR
- For pediatric patients (< 18 years of age), approve up to a maximum dose of 90 mg administered SC not more frequently than once every 2 weeks.

Tumor-Induced Osteomalacia
- Approve up to a maximum dose of 180 mg administered subcutaneously not more frequently than once every 2 weeks.

Length of Coverage
X-Linked Hypophosphatemia (XLH)
Coverage will be provided for 12 months and may be renewed.

Tumor-Induced Osteomalacia
Initial authorization will be for no more than 6 months and reauthorization will be for no more than 12 months.

Guideline

X-Linked Hypophosphatemia (XLH)
- The medication is prescribed by or in consultation with an endocrinologist or nephrologist; AND
- The patient has had a baseline (prior to any XLH treatment) serum phosphorus level that was below the normal range for age; AND
  Note: Examples of XLH treatment include Crysvita, oral phosphate/vitamin D therapy.
- The patient meets ONE of the following:
  - The patient has had a baseline (i.e., prior to any XLH treatment [e.g., Crysvita, oral phosphate/vitamin D]) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender; OR
  Note: Examples of XLH treatment include Crysvita, oral phosphate/vitamin D therapy.
  - The patient has had a genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX mutation; AND
- If the patient is ≥ 18 years of age, the patient meets BOTH of the following:
  - Per the prescriber, the patient is currently exhibiting one or more signs or symptoms of XLH; AND
  Note: Examples of signs and symptoms of XLH in patients ≥ 18 years of age include fractures/pseudofractures, bone and joint pain, muscle weakness, and impaired mobility.
  - The patient meets ONE of the following:
    - The patient has tried oral phosphate and calcitriol therapy; OR
    - Per the prescriber the patient has a contraindication to oral phosphate therapy, calcitriol therapy, or both.

Coverage for Crysvita may be renewed when the following criteria are met:
- The patient is continuing to derive benefit from Crysvita as determined by the prescriber.
  Note: Examples of a response to Crysvita therapy are increased phosphorus levels, radiographic improvement in deformities, healing of fractures/pseudofractures, reduction in the incidence of new fractures/pseudofractures.

Tumor-Induced Osteomalacia
- Patient is ≥ 2 years of age; AND
- Patient has a mesenchymal tumor that cannot be curatively resected or identified/localized; AND
• Per the prescriber, the patient is currently exhibiting one or more signs or symptoms of tumor-induced osteomalacia (Note: Examples of signs and symptoms of tumor-induced osteomalacia include bone pain, impaired mobility, muscle weakness, and fatigue); AND

• Patient has had a baseline (prior to any tumor-induced osteomalacia treatment) serum phosphorus level that was below the normal range for age (Note: Examples of tumor-induced osteomalacia treatment include Crysvita, oral phosphate/vitamin D therapy); AND

• Patient has had a baseline (prior to any tumor induced osteomalacia treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender (Note: Examples of tumor-induced osteomalacia treatment include Crysvita, oral phosphate/vitamin D therapy); AND

• Patient meets ONE of the following (i or ii):
  i. Patient has tried oral phosphate and calcitriol therapy; OR  
  ii. Per the prescriber the patient has a contraindication to oral phosphate therapy, calcitriol therapy, or both; AND

• The medication is prescribed by or in consultation with an endocrinologist or nephrologist.

Coverage for Crysvita may be renewed when the following criteria are met:

• The patient is continuing to derive benefit from Crysvita as determined by the prescriber. Note: Examples of a response to Crysvita therapy are increased phosphorus levels, decreased symptoms of bone pain and/or muscle weakness, and increased mobility.

Limitations/Exclusions

• Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease  
• Epidermal Nevus Syndrome (ENS)  

Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

Applicable Procedure Codes

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Applicable Diagnosis Codes

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<tr>
<td>E83.31</td>
<td>Familial hypophosphatemia</td>
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<td>E83.39</td>
<td>Other disorders of phosphorus metabolism</td>
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<td>M83.8</td>
<td>Tumor-induced osteomalacia</td>
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Applicable NDC Codes

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Revisions
Criteria apply to Commercial, Medicare, and Medicaid members.

- Added new indication: Tumor-Induced Osteomalacia. Added criteria for new indication. Added dosing for Tumor-Induced Osteomalacia: Approve up to a maximum dose of 180 mg administered subcutaneously not more frequently than once every 2 weeks. Added diagnosis code M83.8 Tumor-induced Osteomalacia.

REFERENCES