Crysvita

**Description**

Crysvita (burosumab-twza)

**Background**

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH), also known as vitamin D-resistant rickets. X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D. Crysvita binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D (1).

**Regulatory Status**

**FDA approved indication:** Crysvita is indicated for the treatment of X-linked hypophosphatemia in adult and pediatric patients 6 months of age and older (1).

Crysvita is contraindicated for patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism. It is also contraindicated if serum phosphorus is within or above the normal range for the patient’s age, and should not be used with oral phosphate or active vitamin D analogs. Oral phosphate and active vitamin D analogs should be discontinued one week prior to initiation of treatment (1).

Pediatric Patients with X-linked Hypophosphatemia (6 months to less than 18 years of age): After initiation of treatment, fasting serum phosphorus should be measured every four weeks for the first three months of treatment, and thereafter as appropriate (1).
Adult Patients with X-linked Hypophosphatemia (18 years of age and older): After initiation of treatment, assess fasting serum phosphorus on a monthly basis, measured two weeks post-dose, for the first three months of treatment, and thereafter as appropriate (1).

The safety and effectiveness of Crysvita has been established in pediatric patients 6 months of age and older.

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Crysvita may be considered medically necessary in patients 6 months of age and older for the treatment of X-linked hypophosphatemia (XLH) and when the conditions indicated below are met.

Crysvita is considered investigational for patients less than 6 months of age and for all other indications.

Prior-Approval Requirements

Age 6 months of age or older

Diagnosis

Patient must have the following:

X-linked hypophosphatemia (XLH) (also called X-linked dominant hypophosphatemic rickets, X-linked vitamin D-resistant rickets)

AND ALL of the following:

1. Confirmed diagnosis by genetic testing of PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation in the patient
2. Patient will discontinue any oral phosphate or active vitamin D analog supplementation at least one week prior to starting therapy with Crysvita.

3. Prescriber agrees to measure serum phosphorous throughout therapy and withhold medication when serum phosphorus is above 5 mg/dL.

4. Administered by healthcare provider

**AND NONE** of the following:

1. Fasting serum phosphorus is within or above the normal range for age
2. Severe renal impairment or end stage renal disease (ESRD), defined as eGFR < 30 mL/min/1.73 m²

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**Prior–Approval Renewal Requirements**

**Age**  6 months of age or older

**Diagnosis**

Patient must have the following:

X-linked hypophosphatemia (XLH) (also called X-linked dominant hypophosphatemic rickets, X-linked vitamin D-resistant rickets)

**AND** the following:

1. Prescriber agrees to measure serum phosphorous throughout therapy and withhold medication when serum phosphorus is above 5 mg/dL
2. Administered by healthcare provider

**AND NONE** of the following:

1. Severe renal impairment or end stage renal disease (ESRD), defined as eGFR < 30 mL/min/1.73 m²

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**Policy Guidelines**

**Pre–PA Allowance**

None
Prior–Approval Limits

Duration  12 Months

Prior–Approval Renewal Limits
Same as above

Rationale

Summary
Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older. X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D. Crysvita binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Crysvita while maintaining optimal therapeutic outcomes.

References

Policy History

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<tbody>
<tr>
<td>May 2018</td>
<td>Addition to PA</td>
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<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
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<tr>
<td></td>
<td>Addition of a requirement: Confirmed diagnosis by genetic testing of PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation in the patient; and administered by healthcare provider per SME</td>
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<tr>
<td>October 2019</td>
<td>Age requirement reduced to 6 months and older from 1 year and older</td>
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<tr>
<td>December 2019</td>
<td>Annual review</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.