Vykat XR™ (diazoxide choline ER)

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 policy 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 covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Vykat XR is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Laboratory test results confirming diagnosis of Prader-Willi syndrome (i.e., deletion in chromosomal 15q11-q13 region, maternal uniparental disomy in chromosome 15, imprinting defects, translocations, or inversions involving chromosome 15).
2. For continuation requests, chart notes or medical record documentation confirming benefit from therapy (e.g., reduction in hyperphagia, reduction in body fat mass, reduced levels of leptin).

Exclusions

Coverage will not be provided for members with the following:

1. Hyperinsulinemic hypoglycemia
2. Known hypersensitivity to diazoxide or thiazides

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Endocrinologist
2. Psychiatrist
3. Other prescriber with expertise in the treatment of Prader-Willi Syndrome

Criteria for Initial Approval

Hyperphagia with Prader-Willi syndrome (PWS)

Authorization of 6 months may be granted for treatment of hyperphagia with Prader-Willi syndrome (PWS) when all of the following criteria are met:

1. Patient has diagnosis of PWS confirmed by genetic testing demonstrating any of the following:
    A. Deletion in the chromosomal 15q11-q13 region
    B. Maternal uniparental disomy in chromosome 15
    C. Imprinting defects, translocations, or inversions involving chromosome 15
2. Patient has moderate to severe hyperphagia (e.g., food obsession, aggressive food seeking behavior, lack of satiety)
3. Patient has been assessed for hyperglycemia prior to initiating treatment
4. Patient has been assessed for ability to swallow tablets whole prior to initiating treatment
5. Patient does not have clinically significant renal or hepatic impairment
6. Patient is 4 years of age and older
7. Patient has a recent (within 30 days) weight documented to ensure appropriate dose
8. Patient's caregiver has implemented and will continue to establish a food-secure environment

Continuation of Therapy

Hyperphagia with Prader-Willi syndrome (PWS)

Authorization of 12 months may be granted for treatment of hyperphagia with Prader-Willi syndrome (PWS) when all of the following criteria are met:

1. Patient has achieved or maintained a positive clinical response (e.g., reduction in hyperphagia, reduction in body fat mass, reduction in leptin levels)
2. Patient is adherent to therapy and able to swallow tablets whole
3. Patient has a recent (within 30 days) weight documented to ensure appropriate dose

Other

Vykat XR (diazoxide choline) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

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

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Vykat XR (diazoxide choline) 25 mg tablet	2 tablets per day	Administer orally once daily. Recommended starting dosage and titration schedule is based on patient's body weight.
Vykat XR (diazoxide choline) 75 mg tablet	1 tablet per day	

<table>
<tr>
<td>Vykat XR (diazoxide choline) 150 mg tablet</td>
<td>3 tablets per day</td>
<td>Maximum recommended dosage is 5.8 mg/kg/day or 525 mg per day.
<table>
<tr><th>Weight</th><th>Target Maintenance Dose</th></tr>
<tr><td>20 to <30 kg</td><td>100 mg</td></tr>
<tr><td>30 to <40 kg</td><td>150 mg</td></tr>
<tr><td>40 to <65 kg</td><td>225 mg</td></tr>
<tr><td>65 to <100 kg</td><td>375 mg</td></tr>
<tr><td>100 to <135 kg</td><td>450 mg</td></tr>
<tr><td>≥135 kg</td><td>525 mg</td></tr>
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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.

N/A

REFERENCES

Vykat XR [package insert]. Redwood City, CA: Soleno Therapeutics, Inc.; March 2025.

Butler MG, Miller JL, Forster JL. Prader-Willi Syndrome – Clinical Genetics, Diagnosis and Treatment Approaches: An Update. Current Pediatric Reviews. 2019;15(4):207-244.

Miller JL, Gevers E, Bridges N, et al. Diazoxide Choline Extended-Release Tablet in People with Prader-Willi Syndrome: A Double-Blind Placebo-Controlled Trial. J Clin Endocrinol Metab. 2023;108(7):1676-1685.

McCandless SE, et al. Clinical Report -Health Supervision for Children with Prader-Willi Syndrome. Pediatrics. 2011;127(1):195-204.

POLICY HISTORY

Policy #: 05.05.90

Original Effective Date: July 31, 2025

Reviewed: June 2025

Revised:

Current Effective Date: July 31, 2025