Effective Date: 8/1/25
Reviewed: 05/2025, 04/2026
Scope: Medicaid

Vykat XR (diazoxide choline)

POLICY

I. INDICATION

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.

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

An authorization of 6 months may be granted when all the following criteria are met:

A. Member is 4 years of age or older with a weight greater than or equal to 20 kilograms; AND
B. Documentation of members weight within the past 30 days; AND
C. Documentation that the member is able to swallow tablets whole; AND
D. Drug is prescribed by or in consultation with an endocrinologist, psychiatrist, or other physician with expertise in the treatment of PWS; AND
E. Documentation confirming member has a diagnosis of Prader-Willi syndrome confirmed by any of the following:
    a. Deletion in chromosomal 15q11-q13 region
    b. Maternal uniparenteral disomy in chromosome 15
    c. Imprinting defects, translocations, or inversions involving chromosome 15; AND
F. Documentation that member experiences moderate to severe symptoms of hyperphagia (e.g., food obsession, aggressive food seeking behavior, lack of satiety); AND
G. Documentation that the member has been assessed for hyperglycemia prior to initiating treatment; AND
H. Fasting glucose will be monitored at least once every 4 weeks and HbA1c will be monitored every 3 months; AND
I. Documentation that caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g. locked food storage); AND
J. Documentation that the member does not have clinically significant renal or hepatic impairment; AND
K. Vykat XR is dosed according to FDA labeled dosing for PWS (see dosing table below)

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members when all of the following criteria are met:

A. Member has experienced an improvement in hyperphagic symptoms (e.g. decrease in food related aggression or manipulation, lessened food preoccupation interfering with normal daily activities); AND
B. For adult members, provider has determined that the patient is likely to still benefit from therapy (i.e. patient has not entered the phase of symptom improvement sometimes observed in adulthood); AND
C. Member is adherent to therapy and able to successfully swallow the prescribed number of tablets daily; AND
D. Documentation of member's current weight (within last 30 days); AND
E. Vykat XR is dosed according to FDA labeled dosing for PWS (see dosing table below)

IV. QUANTITY LIMIT

- 25 mg tablet: 4 tablets per day
- 75 mg tablet: 7 tablets per day
- 150 mg tablet: 3 tablets per day

FDA Recommended Dosing				
Weight	**Starting dosage Weeks 1 and 2**	**Titration Dosage Weeks 3 and 4**	**Titration Doasge Weeks 5 and 6**	**Target Maintenance Dosage**
20 to < 30 kg	25 mg	50 mg	75 mg	100 mg
30 to < 40 kg	75 mg	150 mg	150 mg	150 mg
40 to < 65 kg	75 mg	150 mg	225 mg	225 mg
65 to < 100 kg	150 mg	225 mg	300 mg	375 mg
100 to <135 kg	150 mg	300 mg	375 mg	450 mg
≥ 135 kg	150 mg	300 mg	450 mg	525 mg

V. REFERENCES

1. Vykat XR [package insert]. Redwood City, CA: Soleno Therapeutics, Inc.; March 2025.
2. 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.
3. 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.
4. McCandless SE, et al. Clinical Report- Health Supervision for Children with Prader-Willi Syndrome. Pediatrics. 2011;127(1):195-204.