CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Vykat XR (diazoxide choline)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vykat XR, approved by the FDA in 2025, is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).
PWS is a rare genetic disorder that occurs due to the loss of function on chromosome 15 leading to disruption of the hypothalamus. Patients experience hypotonia and feeding difficulties in early life followed by hyperphagia and gradual development of obesity in early childhood. Hyperphagia often begins around 3 years of age and progress until teenage years. It is coupled with food-seeking behaviors such as hoarding and stealing food as well as attempting to consume inedible items. Thus, patients with PWS have a greater risk of choking and gastric distention. Both patients and caregivers carry a significant lifelong psychosocial burden.

Vykat XR (diazoxide choline) will be considered for coverage when the following criteria are met:

Hyperphagia in Prader-Willi Syndrome (PWS)

For **initial** authorization:

1. Member is at least 4 years of age; AND
2. Medication must be prescribed by or in consultation on with an endocrinologist; AND
3. Member has a diagnosis of PWS confirmed by genetic testing; AND
4. Provider attests that member has moderate to severe hyperphagia with documentation of associated symptoms such as food-seeking behaviors (hoarding, foraging, stealing, and attempting to consume garbage and inedible objects); AND
5. Member has documentation of a food-secure environment (such as locked food storage); AND
6. Patient is able to swallow tablets whole; AND
7. Member has documentation of recent weight in chart notes.
8. **Dosage allowed/Quantity limit:** administer orally once daily per table below. Maximum dose is 5.8 mg/kg/day or 525 mg per day.
    a) Quantity limit:
        i) 25 mg: 1 tablet per day
        ii) 75 mg: 1 tablet per day
        iii) 150 mg: 3 tablets per day

Weight	Starting Dosage Weeks 1 and 2	Titration Dosage Weeks 3 and 4	Titration Dosage 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

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must have been provided showing improvement or stabilized signs and symptoms of disease such as decrease in food-related behaviors, lessened food preoccupation that affects daily life, etc; AND
2. Provider attests that member continues to benefit from therapy; AND
3. Member has documentation of recent weight in chart notes.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vykat XR (diazoxide choline) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/23/2025	New policy for Vykat XR created.

References:

1. Vykat XR [prescribing information]. Soleno Therapeutics, Inc.; 2025.
2. Fermin Gutierrez MA, Daley SF, Mendez MD. Prader-Willi Syndrome. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; February 26, 2024.
3. McCandless SE; Committee on Genetics. Clinical report—health supervision for children with Prader-Willi syndrome. *Pediatrics*. 2011;127(1):195-204. doi:10.1542/peds.2010-2820
4. Shaikh MG, Barrett TG, Bridges N, et al. Prader-Willi syndrome: guidance for children and transition into adulthood. *Endocr Connect.* 2024;13(8):e240091. Published 2024 Jul 10. doi:10.1530/EC-24-0091
5. Beygo J, Buiting K, Ramsden SC, Ellis R, Clayton-Smith J, Kanber D. Update of the EMQN/ACGS best practice guidelines for molecular analysis of Prader-Willi and Angelman syndromes. *Eur J Hum Genet*. 2019;27(9):1326-1340. doi:10.1038/s41431-019-0435-0

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