

Drug Policy

Policy:	Prader-Willi Syndrome – Vykate XR Prior Authorization Policy Vykate™ XR (diazoxide choline extended-release tablets - Soleno)	Annual Review Date: 02/19/2026 Last Revised Date: 02/19/2026
----------------	----------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------

OVERVIEW

Vykate XR, a potent activator of the adenosine triphosphate-sensitive potassium channel², is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome.¹

Diazoxide increases blood glucose, primarily through inhibiting insulin release from the pancreas. The exact mechanism of action of diazoxide choline in the treatment of hyperphagia in patients with Prader-Willi syndrome is unknown.¹

POLICY STATEMENT

This policy involves the use of Vykate XR. Prior authorization is recommended for pharmacy benefit coverage of Vykate XR. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Vykate XR as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Vykate XR be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vykate XR is recommended in those who meet the following criteria:

1. **Prader-Willi Syndrome.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is \geq 4 years of age; AND
 - B) The diagnosis of Prader-Willi syndrome has been established by identification of abnormal DNA methylation of chromosome 15q11.2Q13*; AND
 - C) Patient has hyperphagia; AND
 - D) The medication has been prescribed by or in consultation with an endocrinologist.

Initial Approval/ Extended Approval.

- A) *Initial Approval:* 4 months
- B) *Extended Approval:* 1 year

This document is subject to the disclaimer found at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx> and is subject to change. <https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx>

Drug Policy

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vykat XR has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Hyperphagia in a patient without Prader-Willi syndrome.** Vykat XR tablets are only indicated for the treatment of hyperphagia in patients with Prader-Willi syndrome.¹ No data is available on the treatment of hyperphagia in patients without Prader-Willi.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vykat™ XR (diazoxide choline) extended-release tablets [prescribing information]. Redwood City, CA: Soleno; March 2025.
2. 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.
3. Driscoll DJ, Miller JL, Cassidy SB. Prader-Willi Syndrome. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReview® [Internet]. Updated December 5, 2024. Available at: www.ncbi.nlm.nih.gov/books/NBK1330/pdf/Bookshelf_NBK1330.pdf. Accessed on March 20, 2025.
4. Shaikh MG, Barrett TB, Bridges N, et al. Prader-Willi syndrome: guidance for children and transition into adulthood. *Endocr Connect.* 2024; 13(8):e240091.
5. Gevers EF, Miller JL, Bridges NA, et al. Withdrawal of DCCR (diazoxide choline) extended-release tablets worsens hyperphagia and increases weight and BMI in a 16-week double-blind, placebo-controlled, randomized withdrawal period in patients with Prader-Willi syndrome. *J Endocr Soc.* 2024;8(Suppl 1):bvae163.055.