Commercial PA Criteria

Effective: May 8, 2025

Prior Authorization: Vykat XR

Products Affected: Vykat XR (diazoxide choline extended release) oral tablets

Medication Description: 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). The exact mechanism of action of diazoxide choline in the treatment of hyperphagia in patients with PWS is not fully understood but believed to be related to reducing the synthesis and secretion of the appetite stimulatory neuropeptides Y (NPY) and agouti-related protein (AgRP).

Covered Uses: 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).

Exclusion Criteria:

1. Hyperphagia in a patient without Prader-Willi syndrome.

Required Medical Information:

1. Diagnosis

Prescriber Restriction: The medication has been prescribed by or in consultation with an endocrinologist.

Age Restriction: 4 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval 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 ≥ 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.

Renewal Criteria

1. Member has responded positively to therapy according to the prescriber; AND
2. Member has not experienced unacceptable toxicity from the medication

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 April 28, 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.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/08/2025