

# Specialty Guideline Management

## Vykat XR

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vykat XR	diazoxide choline

### Indications

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.

#### FDA-Approved Indication<sup>1</sup>

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.

### Documentation<sup>2</sup>

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

- 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).
- 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:

- Hyperinsulinemic hypoglycemia
- Known hypersensitivity to diazoxide or thiazides.

## Coverage Criteria

### Hyperphagia with Prader-Willi syndrome (PWS)<sup>1-4</sup>

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

- Member has diagnosis of Prader-Willi syndrome (PWS) confirmed by genetic testing demonstrating any of the following:
  - Deletion in the chromosomal 15q11-q13 region.
  - Maternal uniparental disomy in chromosome 15.
  - Imprinting defects, translocations, or inversions involving chromosome 15.
- Member has hyperphagia (e.g., food obsession, aggressive food seeking behavior, lack of satiety).
- Member has been assessed for hyperglycemia prior to initiating treatment.
- Member does not have clinically significant renal or hepatic impairment.
- Member is 4 years of age and older with a weight greater than or equal to 20 kilograms (kg).

## Continuation of Therapy<sup>1-3</sup>

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for hyperphagia with Prader-Willi syndrome (PWS) when the member has achieved or maintained a positive clinical response (e.g., reduction in hyperphagia, reduction in body fat mass, reduced levels of leptin).

## References

1. Vykate 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.

Reference number(s)
6921-A

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