labCVS Caremark®

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| Reference number(s) |
| 6921-A |

# 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 Indication1

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.

## Documentation2

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)1-4

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 Therapy1-3

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. 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.