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 Indication[1]

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[2]

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 Therapy[1-3]

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.