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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	May 2, 2025
Subject:	Vykat XR	**Page:**	1 of 4

Last Review Date: September 19, 2025

Vykat XR

Description

Vykat XR (diazoxide choline)

Background
Vykat XR (diazoxide choline) is indicated for the treatment of hyperphagia in patients with Prader-Willi syndrome (PWS). The exact mechanism of action is unknown (1).

Regulatory Status
FDA-approved indication: Vykat XR is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi Syndrome (PSW) (1).

Vykat XR has been associated with hyperglycemia and risk of fluid overload. Fasting blood glucose and hemoglobin A1c (HbA1c) should be monitored. Based on severity of hyperglycemia, Vykat XR may require dosage interruption, reduction, or discontinuation to avoid progression into ketoacidosis. Monitor for signs and symptoms of edema or fluid overload and consider appropriate clinical management, which may include Vykat XR dosage reduction or treatment interruption, if clinically significant (1).

The safety and effectiveness of Vykat XR in pediatric patients less than 4 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vykat may be considered **medically necessary** if the conditions indicated below are met.

Vykat may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 4 years of age or older

Diagnosis

Patient must have the following:

Moderate to Severe Hyperphagia with Prader-Willi syndrome (PWS)

AND ALL of the following:

1. Diagnosis has been confirmed by genetic testing demonstrating **ONE** of the following:
   a. Deletion in the chromosomal 15q11-q13 region
   b. Maternal uniparental disomy in chromosome 15
   c. Imprinting defects, translocations, or inversions involving chromosome 15
2. Patient has hyperphagia (e.g., food obsession, aggressive food seeking behavior, lack of satiety)
3. Fasting blood glucose and HbA1c will be tested prior to initiation
4. Prescriber agrees to monitor for signs and symptoms of hyperglycemia and edema or fluid overload during treatment and as clinically indicated
5. Prescribed by or recommended by an endocrinologist

Prior – Approval *Renewal* Requirements

Age 4 years of age or older

Diagnosis

Patient must have the following:

Moderate to Severe Hyperphagia with Prader-Willi syndrome (PWS)

AND ALL of the following:

1. Improvement in symptoms of hyperphagia
2. Prescriber agrees to monitor for signs and symptoms of hyperglycemia and edema or fluid overload during treatment and as clinically indicated

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 525 mg per day

Duration 12 months

Prior - Approval *Renewal* Limits

Same as above

Rationale

Summary

Vykat XR is indicated for the treatment in hyperphagia in adults and pediatric patients 4 years and older with Prader-Willi syndrome (PWS). Vykat XR has been associated with hyperglycemia and risk of fluid overload. The safety and effectiveness of Vykat XR in pediatric patients less than 4 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Vykat XR while maintaining optimal therapeutic outcomes.

References

1. Vykat XR [package insert]. Redwood City, CA: Soleno Therapeutics, Inc.; March 2025.

Policy History

Date	Action

Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
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May 2025	Addition to PA
June 2025	Annual review
September 2025	Annual review. Per SME, added requirement of moderate to severe hyperphagia. Per FEP, added requirements for genetic confirmation, hyperphagia symptoms, and endocrinologist

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.