

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2420-1
Program	Prior Authorization/Medical Necessity
Medication	Vykat XR™ (diazoxide choline)
P&T Approval Date	5/2026
Effective Date	9/1/2026

1. Background:

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).

2. Coverage Criteria^a:

A. Initial Authorization

1. **Vykat XR** will be approved based on **all** of the following criteria:

a. Diagnosis of hyperphagia associated with Prader-Willi Syndrome

-AND-

b. Prader-Willi Syndrome is confirmed by genetic testing

-AND-

c. Patient is at least 4 years of age and older

Authorization will be issued for 12 months.

B. Reauthorization

1. **Vykat XR** will be approved based on the following criterion:

a. Documentation of positive clinical response to Vykat XR therapy

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim

logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

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

Program	Prior Authorization/Medical Necessity – Vykat XR
Change Control	
Date	Change
5/2026	Vykat XR moved out of program number 1114 to separate criteria.