Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 24, 2025

Vykat XR™ (diazoxide choline)

LENGTH OF AUTHORIZATION: Initial - 4 months
Continuation of Therapy - 1 year

REVIEW CRITERIA:

- Patient must be ≥ 4 years of age; **AND**
- Patient must have a diagnosis of Prader-Willi syndrome and diagnosis has been confirmed by genetic testing indicating mutation on chromosome 15 (medical records required); **AND**
- Patient must have documented hyperphagia; **AND**
- Prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted a specialist in the area of the patient's diagnosis.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Patient must have positive clinical response (e.g., reduction in hyperphagic and/or food-related behaviors); **AND**
- Patient has NOT experienced any treatment-restricting adverse effects (e.g., severe hyperglycemia); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 25 mg, 75 mg, and 150 mg extended-release tablets.