MEDICATION POLICY:

Vykat™ XR

Generic Name: Diazoxide choline

Therapeutic Class or Brand Name: Vykat XR

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

Prior Authorization Criteria

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of Prader-Willi syndrome (PWS) with confirmation with genetic testing

II. Documentation patient experiencing moderate to severe symptoms of hyperphagia related to PWS and provides documentation of associated symptoms (e.g. food-seeking behaviors)

III. Documentation of fasting plasma glucose and HbA1c, with optimization of blood glucose in those with hyperglycemia prior to initiating treatment

IV. Minimum age requirement: 4 years old.

V. The medication is prescribed by or in consultation with an endocrinologist, psychiatrist, pediatrician, or provider with expertise in treatment of PWS

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

Exclusion Criteria

- Unable to swallow whole tablets

Other Criteria

- Not recommended in renal impairment or hepatic impairment
- Not recommended in those on CYP1A2 substrates

Quantity / Days Supply Restrictions

- Strengths available include the following: 25 mg, 75 mg, and 150 mg tablets
- Max 120 tablets per 30 day supply
    - Weight based dosing; Max dose 525 mg (three tablets of 150 + one tablet of 75 mg) daily

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective. Document tolerating therapy (including repeat fasting glucose testing or HbA1c) and response of disease stabilization to be obtained for renewal. Will additionally require weight documentation prior to each renewal

Appendix

NA

References

1. Vykat XR. Prescribing information. Soleno Therapeutics, Inc.; Accessed May 1, 2025. https://www.vykatxrhcp.com/prescribing-information.pdf 3/2205
2. Miller JL, Gevers E, Bridges N, et al. DESTINY PWS Investigators. 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.
3. Gevers EF, Miller JL, Bridges NA et al. 7519 Withdrawal of DCCR (Diazoxide Choline) Extended-Release Tablets Worsens Hyperphagia and Increases Weight and BMI in a 16-week Double-blind, Placebo-controlled, Randomized Withdrawal Period in Patients with Prader Willi Syndrome. J Endocr Soc. 2024;8(supp 1):bvae163.055