

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Diazoxide Choline extended-release tablet (Vykat ER)

Notes:

- Quantity Limits: Yes
- Has not been studied in patients with renal or hepatic impairment or pregnant patients
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ^ Adequate trial of GLP-1 is defined as a 3-month treatment duration

Initiation (new start) criteria and criteria for new and current Kaiser Permanente members already taking the medication who have not been reviewed previously:

Non-formulary **Diazoxide Choline extended-release tablet (Vykat ER)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Pediatric Endocrinology OR Bariatric Medicine
- Patient is 4 years of age or older
- Patient has a diagnosis of severe hyperphagia unresponsive to behavioral therapy
- Patient has genetically confirmed Prader-Willi Syndrome
- Patient lives in stable care setting
- Patient is able to swallow tablets whole
- Patient does NOT have a diagnosis of:
 - Type 2 diabetes
 - Impaired fasting glucose
 - Impaired glucose tolerance
 - Compromised cardiac reserve or cardiac issues
- Patient does NOT have any of the following:
 - Renal or hepatic impairment
 - Hypersensitivity to thiazides
- Patient is not pregnant or planning to become pregnant
- Patient has documented contraindication, intolerance*, or treatment failure to an adequate^ trial of a glucagon-like peptide-1 (GLP-1) agonist (applies only for patients 18 years of age or older).

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **Diazoxide Choline extended-release tablet (Vykat ER)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Sustained improvement in hyperphagia from prior to starting the medication