AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Vykat™ XR (diazoxide choline)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Requested Medication is ONE of the following:

- ❑ New Start
- ❑ Continuation of therapy – provide therapy start date: _____

Recommended Dosing:

Weight	Starting Dosage	Titration Dosage	Titration Dosage	Target Maintenance Dosage
	Weeks 1 and 2	Weeks 3 and 4	Weeks 5 and 6	
20 to < 30 kg	25 mg	50 mg	75 mg	100 mg
30 to < 40 kg	75 mg	150 mg	150 mg	150 mg
40 to < 65 kg	75 mg	150 mg	225 mg	225 mg
65 to < 100 kg	150 mg	225 mg	300 mg	375 mg
100 to < 135 kg	150 mg	300 mg	375 mg	450 mg
≥ 135 kg	150 mg	300 mg	450 mg	525 mg

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Quantity Limits:

- 25 mg – 4 tablets per day
- 75 mg – 7 tablets per day
- 150 mg – 3 tablets per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is > 4 years of age
- ❑ Member weighs > 20 kg
- ❑ Prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, neurologist, pediatric cardiologist or a physician who specializes in the treatment of Prader-Willi syndrome [**NOTE**: Pediatric cardiology consultation is recommended, and careful consideration should be given when a member has pulmonary hypoplasia, pulmonary hypertension, cardiomyopathy, or significant structural heart disease.]
- ❑ Member has a confirmed diagnosis of Prader-Willi syndrome as established by a genetic test showing **ONE** of the following **(submit documentation)**:
  - ❑ Deletion 15q11-q13 or Maternal disomy
  - ❑ Imprinting genes on chromosome 15
- ❑ Member has moderate to severe hyperphagia
- ❑ Provider must submit **ONE** of the following baseline assessments **(submit documentation)**:
  - ❑ Hyperphagia questionnaire
  - ❑ Clinical Global Impression of Improvement (CGI-I)
  - ❑ Caregiver Global Impression of Change (GI-C)
  - ❑ Body fat measured
- ❑ Provider must submit documentation of fasting plasma glucose and HbA1c, with optimization of blood glucose in those with hyperglycemia prior to initiating treatment
- ❑ Prescriber agrees to monitor for signs and symptoms of hyperglycemia and edema or fluid overload during treatment and as clinically indicated
- ❑ Provider must submit documentation to confirm the member does **NOT** have clinically significant renal or hepatic impairment

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has experienced a positive clinical response to Vykat™ XR therapy (e.g., improved behavior, metabolism improvement, reduced hyperphagia) or disease has stabilized in response to treatment

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- ❑ Provider must submit documentation to confirm the member is tolerating therapy (including repeat fasting glucose testing of HbA1c, evidence of no clinically significant renal or hepatic impairment, and absence of cardiac abnormalities)
- ❑ Provider must submit documentation of member's current weight **(within last 30 days)**

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: ~~5/22/2025;~~ **9/24/2026**
REVISED/UPDATED/REFORMATTED: ~~6/4/2025;~~ **10/16/2026**