

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: _____

Recommended Dosing:

Weight	Starting 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: 12 months

- Member is > 4 years of age
- Member weighs > 20 kg
- Prescribed by or in consultation with a geneticist, endocrinologist, metabolic disorder subspecialist, neurologist, or a physician who specializes in the treatment of Prader-Willi syndrome
- 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

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)

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.****