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VykatXRHCP.com

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## SAMPLE LETTER OF MEDICAL NECESSITY

Dear Healthcare Provider,

Included below is language you may want to consider when preparing a letter of medical necessity for your patient's insurance plan when appealing a previous denial or seeking medical exception for coverage. This is only an example of what some insurance plans may consider to be relevant information when making a coverage determination.

Please create your own letter on your letterhead and do not submit this template itself. You should always use your professional judgment, provide accurate clinical information, and consider the specific requirements of the patient's plan when preparing letters of medical necessity and other appeal requests.

Please note that insurance plans vary and may require different or additional information when considering access to VYKAT™ XR (diazoxide choline) extended-release tablets.

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[Today's Date]

[Prescriber Full Name]

[Site Address]

[Site City], [Site State] [Site Zip Code]

**Attn:** [Medical Director or Contact]

[Insurance Company]

[Address]

[City], [State] [Zip Code]

**Subject:** Letter of Medical Necessity for VYKAT XR (diazoxide choline) extended-release tablets

**Insured:** [Patient First and Last Name]

Date of Birth: [MM/DD/YYYY]

Policy Number: [ID Number]

Group Number: [Group Number]

Dear [Medical Director or Contact Name],

I am a specialist in [Prescriber's specialty] writing on behalf of my patient [Patient First and Last Name] to request approval for coverage of VYKAT XR which is the first and only FDA-approved treatment for hyperphagia in Prader-Willi syndrome (PWS). This patient has been in my care since [MM/DD/YYYY].

The patient's plan does not currently cover VYKAT XR, however, I am requesting coverage as it is my professional opinion as a clinician that this treatment is medically necessary.

Please review my clinical rationale and the attached documentation to assist with your coverage decision.

*\*Consider including:*

- rationale for why this is medically necessary
- reason to overturn a previous authorization denial (stated in the denial letter if appealing previous decision)
- any pertinent diagnostic results
- previous or current therapies which may be relevant
- reasons to substantiate why this is the next logical step in your medical judgment to help the patient manage their disease
- any applicable medical records which support your decision to prescribe VYKAT XR
- published data you feel supports the use of VYKAT XR for the patient's condition
- any other relevant considerations

Primary Diagnosis: [ICD-10 and description]

Secondary Diagnosis: [ICD-10 and description]

Weight: [Patient's weight in kgs]

Prescribed Dosing Schedule (Insurer, please note multiple NDCs may be requested):

*[consider including the patient's dosing schedule, examples following]*

Should anything further be needed for the approval of this request, please contact me directly at [Prescriber's phone number] to discuss. Thank you in advance for your immediate attention to this request so I may move forward with treating this patient as I deem necessary for their health.

Sincerely,

[Prescriber Name and Credentials]

**Example Dosing Schedules based on PI for VYKAT<sup>™</sup> XR (diazoxide choline) extended-release:**

VYKAT XR Dosing Schedule	Month 1		Month 2		Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance (Week 7 and 8)	Target Maintenance
20 kg to <30 kg	Once Daily Dose: 25 mg  NDC: 25 mg: 83860-0025-01	Once Daily Dose: 50 mg  NDC: 25 mg: 83860-0025-01	Once Daily Dose: 75 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 100 mg  NDC: 25 mg: 83860-0025-01 75 mg: 83860-0075-01	Once Daily Dose: 100 mg  NDC: 25 mg: 83860-0025-01 75 mg: 83860-0075-01

VYKAT XR Dosing Schedule	Month 1		Month 2		Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance (Week 7 and 8)	Target Maintenance
≥30 kg to <40 kg	Once Daily Dose: 75 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 150 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 150 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 150 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 150 mg  NDC: 150 mg: 83860-0150-01

VYKAT XR Dosing Schedule	Month 1		Month 2		Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance (Week 7 and 8)	Target Maintenance
≥40 kg to <65 kg	Once Daily Dose: 75 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 150 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 225 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01	Once Daily Dose: 225 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01	Once Daily Dose: 225 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01

VYKAT XR Dosing Schedule	Month 1		Month 2		Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance (Week 7 and 8)	Target Maintenance
≥65 kg to <100 kg	Once Daily Dose: 150 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 225 mg  NDC: 75 mg: 83860-0075-01	Once Daily Dose: 300 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 375 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01	Once Daily Dose: 375 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01



VYKAT XR Dosing Schedule	Month 1		Month 2		Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance (Week 7 and 8)	Target Maintenance
≥100 kg to <135 kg	Once Daily Dose: 150 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 300 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 375 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01	Once Daily Dose: 450 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 450 mg  NDC: 150 mg: 83860-0150-01

VYKAT XR Dosing Schedule	Month 1		Month 2		Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance (Week 7 and 8)	Target Maintenance
≥135 kg	Once Daily Dose: 150 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 300 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 450 mg  NDC: 150 mg: 83860-0150-01	Once Daily Dose: 525 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01	Once Daily Dose: 525 mg  NDC: 75 mg: 83860-0075-01 150 mg: 83860-0150-01

Example Dosing Chart to communicate tailored dosing for VYKAT™ XR (diazoxide choline) extended-release:

VYKAT XR Dosing Schedule	Month 1		Month 2	Month 3 Onward
Weight (kg)	Titration Step 1 (Weeks 1 and 2)	Titration Step 2 (Weeks 3 and 4)	Titration Step 3 (Weeks 5 and 6)	Target Maintenance
_____ kg	Daily Dose: _____ mg  NDC:	Daily Dose: _____ mg  NDC:	Daily Dose: _____ mg  NDC:	Daily Dose: _____ mg  NDC: