Effective Date: 09/10/2025
Current Effective Date: 09/10/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 07/2026
Policy Number: C29622-A

Vykat XR (diazoxide choline)

PRODUCTS AFFECTED

Vykat XR (diazoxide choline)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Hyperphagia associated with Prader-Willi syndrome (PWS)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. HYPERPHAGIA ASSOCIATED WITH PRADER-WILLI SYNDROME:
   1. Documented diagnosis of Prader-Willi syndrome (PWS)
      AND

2. Documentation diagnosis of PWS confirmed by genetic testing. [DOCUMENTATION REQUIRED]
   AND
3. Documentation supporting that member has moderate to severe hyperphagia (e.g. food-seeking behaviors and preoccupation with food that interferes with normal daily activities)
   AND
4. Documentation member weighs at least 20 kg
   AND
5. Documentation member does not have hyperglycemia (based on fasting glucose and HbA1c)

CONTINUATION OF THERAPY:

A. HYPERPHAGIA ASSOCIATED WITH PRADER-WILLI SYNDROME:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation, or held for adverse reactions (hyperglycemia, edema)
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by an improvement in hyperphagic symptoms, such as a decrease in food-related aggression or manipulation, or lessened food preoccupation that interferes with normal daily activities, etc.
   AND
4. Documentation of current weight for dosing

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a psychiatrist, endocrinologist or neurologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

4 years of age and older

QUANTITY:

Recommended starting dosage and titration schedule is based on body weight. [See chart]

Weight	Once Daily Dosage			
	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

Maximum Quantity Limits:

5.8 mg/kg/day or 525 mg per day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
ATP-Sensitive Potassium Channel Activators

FDA-APPROVED USES:
Indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Prader-Willi syndrome (PWS) is a rare genetic neurodevelopmental disorder caused by an abnormality in the gene expression on chromosome 15. PWS occurs in approximately 1 in every 15,000 live births. The condition is characterized by hypotonia, neurocognitive problems, behavioral difficulties, endocrinopathies, and hyperphagia (persistent, pathologically excessive appetite), resulting in severe obesity if not controlled. The prevalence of PWS in the United States is estimated to be approximately 10,000 individuals.

Treatment of PWS consists of management of an individual patient's specific symptoms. Hyperphagia is a key manifestation of PWS and is potentially life-threatening. According to an international consensus paper (J Neurodev Disord, 2021), hyperphagia in PWS manifests as "an intense, persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety."

Vykat XR (diazoxide choline) received FDA approval in March 2025 for the treatment of hyperphagia in adults and children 4 years of age and older with PWS. Vykat XR is a potent activator of the adenosine triphosphate (ATP)-sensitive potassium (KATP) channel that is capable of crossing the blood-brain barrier. The exact mechanism of action of diazoxide choline in the treatment of hyperphagia in patients with PWS is not fully understood but believed to be related to reducing the synthesis and secretion of the appetite stimulatory neuropeptides Y (NPY) and agouti-related protein (AgRP).

The approval of Vykat XR was based on results from a double-blind, placebo-controlled randomized withdrawal study period that followed an open-label study period. In the study, patients who switched from Vykat XR to placebo experienced a statistically significant worsening in hyperphagia compared to those who remained on treatment. Prior to entering the withdrawal period, all patients received Vykat XR for a mean duration of 3.3 years.

Vykat XR did not meet its primary study endpoint of decreased hyperphagia as measured by a change in the Hyperphagia Questionnaire for Clinical Trials (HQ-CT) for the entire study population. Statistically significant improvements were seen in the subset of patients with severe hyperphagia. Coverage is limited to those patients with moderate or severe symptoms by physician report.

Vykat XR is a long-acting crystalline salt formulation of diazoxide, which facilitates once-per-day dosing with more stable concentrations of active drug compared with diazoxide. Diazoxide is available as an oral solution under the brand name Proglycem, indicated for hyperinsulinemic hypoglycemia due to certain conditions in adults.

Alternative treatment options for obesity, such as drugs that work via the incretin effect (GLP-1 RAs), have shown limited efficacy in the PWS population, do not address the behavioral component, are not approved for use in young children, and may pose safety concerns.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vykat XR (diazoxide choline) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Vykat XR include: known hypersensitivity to diazoxide, other components of Vykat XR, or to thiazides.

Exclusions/Discontinuation:
Discontinue or reduce the dose of Vykat XR for:

- Hyperglycemia (clinically significant elevations in fasting glucose or HbA1c)
- Edema (clinically significant fluid overload)

Vykat XR is not recommended for patients with renal impairment or hepatic impairment as it has not been studied in these patient populations.
Patient must be able to swallow tablets whole. Do not split, crush, or chew the extended-release tablets because doing so may compromise the extended-release characteristics, efficacy, or safety of Vykat XR.

OTHER SPECIAL CONSIDERATIONS:
Vykat XR is not substitutable with diazoxide oral solution due to the differences in pharmacokinetics.

Dosage modifications should be made for concomitant use of Vykat XR with strong CYP1A2 inhibitors. The daily dosage should not exceed 325 mg per day.

Dosage Modifications for Concomitant Use with Strong CYP1A2 Inhibitors				
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	25 mg	50 mg	75 mg
30 to <40 kg	50 mg	100 mg	100 mg	100 mg
40 to <65 kg	50 mg	100 mg	150 mg	150 mg
65 to <100 kg	100 mg	150 mg	200 mg	250 mg
100 to <135 kg	100 mg	200 mg	250 mg	300 mg
≥135 kg	100 mg	200 mg	300 mg	325 mg

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Vykat XR TB24 25MG
Vykat XR TB24 75MG
Vykat XR TB24 150MG

REFERENCES

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8. Butler MG, et al. Prader-Willi syndrome - clinical genetics, diagnosis and treatment approaches: an update. Current Pediatric Reviews. 2019; 15 (1): 207–244. doi.org/10.2174/1573396315666190716120925

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q2 2025