Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Vykat XR (diazoxide choline extended-release)

Effective: August 11, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Vykat XR (diazoxide choline extended-release) is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Vykat XR (diazoxide choline extended-release) for Members when **ALL** of the following criteria are met:

Initial Authorization:

1. Documented diagnosis of Prader-Willi syndrome (PWS) confirmed by presence of a mutation in chromosome 15

AND

2. Member is ≥4 years of age or older

AND

3. Prescribed by or in consultation with an endocrinologist or geneticist

AND

4. Documentation of baseline hyperphagia questionnaire for clinical trials (HQ-CT) score ≥13

AND

5. Prescriber attests that member experiences moderate to severe symptoms of hyperphagia related to PWS and provides documentation of associated symptoms (e.g., food-seeking behaviors)

AND

6. Caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g., locked food storage)

AND

7. Recent weight documentation (within 30 days) to ensure appropriate dose

Reauthorization:

1. One of the following:
   a. Member has experienced 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
   b. For adult members, prescriber has determined that member is likely to still benefit from therapy (i.e., member has not entered the phase of symptom improvement sometimes observed in adulthood)

AND

2. Member is adherent to therapy and able to successfully swallow the prescribed number of tablets daily

AND

3. Improvement in hyperphagia questionnaire for clinical trials (HQ-CT) score

AND

4. Recent weight documentation (within 30 days) to ensure appropriate dose

Limitations:

1. Duration of approval for initial authorization is limited to 6 months.
2. Additional reauthorizations will be limited to 12 months.
3. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception.

Codes:

None

References:

1. Vykat XR (diazoxide choline extended-release) [prescribing information]. Redwood City, CA: Soleno Therapeutics; March 2025.
2. Driscoll, D., Miller, J., and Cassidy, S. Prader-Willi Syndrome. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1330/. Accessed April 14, 2025.
3. Soleno Therapeutics Announces U.S. FDA Approval of VYKAT™ XR to Treat Hyperphagia in Prader-Willi Syndrome. Available at: https://investors.soleno.life/news-releases/news-release-details/soleno-therapeutics-announces-us-fda-approval-vykattm-xr-treat. Accessed April 14, 2025.
4. VYKAT XR Start Form, Available at: https://www.vykatxrhcp.com/. Accessed April 14, 2025.
5. Prader-willi syndrome. Available at: https://rarediseases.info.nih.gov/diseases/5575/prader-willi-syndrome. Accessed April 14, 2025.

Approval And Revision History

August 12, 2025: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 11, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.