AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Vykat XR	Page:	1 of 2
Effective Date:	6/20/2025	Last Review Date:	5/22/2025
Applies to:	☒Illinois ☒Florida Kids	☒New Jersey ☒Pennsylvania Kids	☒Maryland ☒Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Vykat XR under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Vykat XR is indicated for treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Vykat

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Laboratory test results confirming diagnosis of Prader-Willi syndrome (i.e., deletion in chromosomal 15q11-q13 region, maternal uniparental disomy in chromosome 15, imprinting defects, translocations, or inversions involving chromosome 15).
- For continuation requests, chart notes or medical record documentation confirming benefit from therapy (e.g., reduction in hyperphagia, reduction in body fat mass, reduced levels of leptin).

Exclusions

Coverage will not be provided for members with the following:

- Hyperinsulinemic hypoglycemia
- Known hypersensitivity to diazoxide or thiazides.

Coverage Criteria

Hyperphagia with Prader-Willi syndrome (PWS)

Authorization of 12 months may be granted for treatment of hyperphagia with Prader-Willi syndrome (PWS) when all of the following criteria are met:

- Member has diagnosis of Prader-Willi syndrome (PWS) confirmed by genetic testing demonstrating any of the following:
  - Deletion in the chromosomal 15q11-q13 region.

  - Maternal uniparental disomy in chromosome 15.
  - Imprinting defects, translocations, or inversions involving chromosome 15.
- Member has hyperphagia (e.g., food obsession, aggressive food seeking behavior, lack of satiety).
- Member has been assessed for hyperglycemia prior to initiating treatment.
- Member does not have clinically significant renal or hepatic impairment.
- Member is 4 years of age and older with a weight greater than or equal to 20 kilograms (kg).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for hyperphagia with Prader-Willi syndrome (PWS) when the member has achieved or maintained a positive clinical response (e.g., reduction in hyperphagia, reduction in body fat mass, reduced levels of leptin).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Vykat XR [package insert]. Redwood City, CA: Soleno Therapeutics, Inc.; March 2025.
2. Butler MG, Miller JL, Forster JL. Prader-Willi Syndrome – Clinical Genetics, Diagnosis and Treatment Approaches: An Update. Current Pediatric Reviews. 2019;15(4):207-244.
3. Miller JL, Gevers E, Bridges N, et al. Diazoxide Choline Extended-Release Tablet in People with Prader-Willi Syndrome: A Double-Blind Placebo-Controlled Trial. J Clin Endocrinol Metab. 2023;108(7):1676-1685.
4. McCandless SE, et al. Clinical Report -Health Supervision for Children with Prader-Willi Syndrome. Pediatrics. 2011;127(1):195-204.