Diazoxide Choline Extended-Release Tablets

Goals:

- Ensure appropriate utilization in people with hyperphagia due to Prader-Willi syndrome.
- Allow case-by-case review for members covered under the EPSDT program.

Length of Authorization:

- Up to 12 months

Requires PA:

- Vykat XR (diazoxide choline extended-release tablets)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for continuation of therapy in a patient previously approved by FFS?	**Yes:** Go to Renewal Criteria	**No:** Go to #3
3. Is this an FDA-approved indication?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical necessity.
5. Is the medication prescribed by an endocrinologist or in consultation with a provider that specializes in caring for patients with Prader-Willi syndrome?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
6. Has extent of baseline hyperphagia behavior been documented using the caregiver Hyperphagia Questionnaire for Clinical Trials (HQ-CT) assessment or a comparable assessment that is documented in the patient records?	**Yes:** Approve for 6 months Document care plan and treatment goals: _____	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Has hyperphagia behavior decreased since beginning therapy as assessed by improvement in the HQ-CT score or a comparable assessment that is documented in the patient record?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny for lack of treatment response.

P&T/DUR Review: 8/25; (DM)
Implementation: 9/15/25