ALASKA MEDICAID Prior Authorization Criteria

Vykat™ XR (diazoxide choline)

FDA INDICATIONS AND USAGE¹

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

APPROVAL CRITERIA^{1,2}

- 1. Patient meets FDA labeled age **AND**;
- 2. Prescribed by or in consultation with an endocrinologist or geneticist AND;
- 3. Patient has the diagnosis of Prader Willi Syndrome confirmed by genetic testing indicating chromosome 15 mutation <u>AND</u>;
- 4. Hyperphagia is present.

DENIAL CRITERIA¹

- 1. Failure to meet approval criteria **OR**;
- 2. Patient has a history of hypersensitivity to diazoxide or thiazides

CAUTIONS¹

- Hemoglobin A1C(HbA1c) and fasting glucose should be monitored prior to and throughout treatment.
- Dose adjustment may be necessary in patients receiving strong CYP 1A2 inhibitors.
- Edema, including severe reactions associated with fluid overload, has been reported.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

QUANTITY LIMIT¹

- 25 mg tablets: 120 tablets/30 days*
- 75 mg tablets: 210 tablets/30 days*
- 150 mg tablets: 90 tablets/30 days*

REFERENCES / FOOTNOTES:

- Vykat™ XR (diazoxide choline) [prescribing information]. Redwood City, CA; Soleno Therapeutics; March 2025
- 2. Miller JL, Gevers E, Bridges N, et al. Diazoxide choline extended-release tablet in people with Prader-Willi syndrome: results from long-term open-label study. Obesity. 2024;32(2):252-261.

VykatTM XR Criteria Version: 1

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^{*}Total cumulative dose not to exceed FDA label recommended weight-based target dose.