

Pharmacy Policy Bulletin: J-1339 Pokonza (potassium chloride) – Commercial and Healthcare Reform	
Number: J-1339	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-1339-002	Original Date: 12/06/2023
Effective Date: 12/20/2024	Review Date: 12/04/2024

Drugs Product(s):	Pokonza (potassium chloride for oral solution)
FDA-Approved Indication(s):	Treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient

Background:	- Potassium ions are involved in multiple essential physiological processes, including maintenance of intracellular tonicity, transmission of nerve impulses, contraction of skeletal, cardiac, and smooth muscles, and maintenance of normal renal function. Potassium chloride works by replacing lost potassium and preventing potassium deficiency. - Hypokalemia, defined as a serum potassium level < 3.6 mEq/L occurs in up to 21% of hospitalized patients and 2% - 3% of hospitalized patients. - Hypokalemia results from abnormal loss of potassium, transcellular shifts, or insufficient intake, with abnormal losses being the most common. - Diuretic use is a common cause of hypokalemia. For hypokalemia associated with diuretic use, stopping the diuretic, or reducing its dosage may be effective. If the diuretic cannot be changed, use of an angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, beta-blocker, or potassium-sparing diuretic can be beneficial since these products are associated with elevation in serum potassium. - In patients with low-normal and mild hypokalemia, increasing dietary potassium is appropriate, particularly in patients with a history of hypertension or heart disease. - For patients who are unable to swallow solid oral dosage forms, some formulations of potassium chloride tablets can be dissolved in a 4-ounce glass of water. Additionally, potassium chloride capsules can be opened, and the contents sprinkled onto a spoonful of soft food for administration. - Prescribing Considerations: - If serum potassium levels are < 2.5 mEq/L, intravenous potassium should be used instead of oral supplementation.
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	○ For treatment of hypokalemia in adults, the recommended daily dose of Pokonza ranges from 40 to 100 mEq; the total daily dose should not exceed 200 mEq in a 24-hour period. For treatment of hypokalemia in pediatric patients from birth to 16 years of age, the initial dose is 2 to 4 mEq/kg/day; maximum daily doses should not exceed 100 mEq. ○ For maintenance or prophylaxis of hypokalemia in adults, the typical dose is 20 mEq per day, though the dose should be individualized based upon serum potassium levels. For maintenance or prophylaxis of hypokalemia in pediatric patients from birth to 16 years of age, the typical dose is 1 mEq/kg/day; do not exceed 3 mEq/kg/day. ○ The contents of 1 pouch of Pokonza should be diluted in at least 4 oz. of cold water.
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Approval Criteria

I. Initial Authorization

When a benefit, coverage of Pokonza may be approved when all of the following criteria are met **(A. through D.)**:

- A.** The member meets one (1) of the following criteria **(1. or 2.)**:
 - 1.** The member is using Pokonza for treatment of hypokalemia. (ICD-10: E87.6, P74.32)
 - 2.** The member is using Pokonza for prophylaxis of hypokalemia. (ICD-10: E87.6, P74.32)
- B.** The member meets one (1) of the following **(1. or 2.)**:
 - 1.** The prescriber attests that dietary management with potassium-rich foods is insufficient.
 - 2.** If the member is receiving concomitant diuretics, the prescriber attests that diuretic dose reduction has been insufficient.
- C.** If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to all of the following plan-preferred products **(1. and 2.)**:
 - 1.** Potassium chloride oral tablets
 - 2.** Potassium chloride oral capsules
- D.** The member has an inability to swallow solid oral dosage forms.

II. Reauthorization

When a benefit, reauthorization of Pokonza may be approved when all of the following criteria are met **(A. and B.)**:

- A.** The member requires continued therapy with Pokonza.
- B.** The member continues to have an inability to swallow solid oral dosage forms.

- III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Pokonza [package insert]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC March 2024.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2024.
3. Kim MJ, Valerio C, Knobloch G. Potassium Disorders: Hypokalemia and Hyperkalemia. *Am Fam Physician*. 2023; 107(1):59-70.
4. Viera AJ, Wouk N. Potassium Disorders: Hypokalemia and Hyperkalemia. *Am Fam Physician*. 2015; 92(6): 487-495.
5. Mayo Clinic. Potassium Supplement (Oral Route, Parenteral Route). Available at: <https://www.mayoclinic.org/drugs-supplements/potassium-supplement-oral-route-parenteral-route/proper-use/drg-20070753>. Accessed November 8, 2024.
6. Memorial Sloan Kettering Cancer Center. Potassium Chloride. Available at: <https://www.mskcc.org/cancer-care/patient-education/medications/adult/potassium-chloride>. Accessed November 8, 2024.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.