Clinical Policy: Potassium Chloride for Oral Solution (Klor-Con Powder)

Reference Number: HIM.PA.143
Effective Date: 10.31.17
Last Review Date: 02.24
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Potassium chloride for oral solution (Klor-Con® Powder) is a potassium salt supplement.

FDA Approved Indication(s)

Klor-Con Powder is indicated for the 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Klor-Con Powder is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hypokalemia (must meet all)**:**

1. Diagnosis of hypokalemia;
2. Member must use oral capsule and tablet formulation (*see Appendix B*) of potassium salts, unless clinically significant adverse effects are experienced or all are contraindicated;
3. Dose does not exceed 200 mEq per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Hypokalemia (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mEq per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ER: extended release
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
potassium chloride ER capsule (8/10 mEq) *Capsule may be taken apart and sprinkled on food.*	Treatment of hypokalemia: • Adults: Typical doses range from 40 to 100 mEq/day in 2 to 5 divided doses; limit doses to 40 mEq per dose • Pediatric patients: 2 to 4 mEq/kg/day in divided doses not to exceed 1 mEq/kg as a single dose or 20 mEq, whichever is lower; if deficits are severe or ongoing losses are great, consider intravenous therapy Maintenance or prophylaxis of hypokalemia: • Adults: Typical dose is 20 mEq per day • Pediatric patients: Typical dose is 1 mEq/kg/day	Adults: 40 mEq/dose Pediatrics: 1 mEq/kg/dose or 20 mEq/dose whichever is lower
potassium chloride ER tablet (8/10/20 mEq) (Klor-Con® ER - 8/10 mEq; K-Tab® ER - 8/10/20 mEq)	Treatment of hypokalemia: • Adults: Typical dose range is 40-100 mEq per day Maintenance or prophylaxis of hypokalemia: • Adults: Typical dose range is 20 mEq per day	Adults: 40 mEq/dose
potassium chloride ER tablet *micro-dispersible* (10/15/20 mEq) (Klor-Con® M10/15/20)	Treatment of potassium depletion: • Adults: Doses of 40 to 100 mEq per day or more are used Prevention of hypokalemia: • Adults: Doses are typically in the range of 20 mEq per day	Adults: 20 mEq/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): concomitant use with potassium sparing diuretics
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Dilute prior to administration. Monitor serum potassium and adjust dosage accordingly. If serum potassium concentration is < 2.5 mEq/L, use IV potassium instead of PO supplementation.		
Treatment of hypokalemia	• Adults: Initial doses range from 40 to 100 mEq/day in 2 to 5 divided doses. • Pediatrics (birth to 16 years old): 2 to 4 mEq/kg/day in divided doses; if deficits	Adults: 40 mEq/dose 200 mEq/day Pediatrics:

Indication	Dosing Regimen	Maximum Dose
	are severe or ongoing losses are great, consider IV therapy.	1 mEq/kg/dose or 40 mEq whichever is lower 100 mEq/day
Maintenance or prophylaxis of hypokalemia	• Adults: Typical dose is 20 mEq/day. • Pediatrics (birth to 16 years old): typical dose is 1 mEq/kg/day.	Adults: 200 mEq/day Pediatrics: 3 mEq/kg/day

VI. Product Availability

Packet: 1.5 g of potassium chloride providing potassium 20 mEq and chloride 20 mEq

VII. References

1. Klor-Con Powder Prescribing Information. Maple Grove, MN: Upsher-Smith; September 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e61a4522-b91d-400a-952c-6f035e4610dd. Accessed October 19, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.05.19	02.20
1Q 2021 annual review: amended medical justification criteria to require for both oral capsules and tablets; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.13.20	02.21
1Q 2022 annual review: revised medical justification language to "must use" alternative formulations; references reviewed and updated.	11.29.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.11.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.16.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.19.23	02.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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