

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

Reference Number: HIM.PA.143

Effective Date: 10.31.17

Last Review Date: 02.19

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. Medical justification supports that member is not a candidate for oral capsule or tablet formulation of potassium salts;
3. Dose does not exceed 200 mEq per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Hypokalemia (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 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.PHAR.21 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) <i>Capsule may be taken apart and sprinkled on food.</i>	Treatment of hypokalemia: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Adults: Typical dose range is 40-100 mEq per day Maintenance or prophylaxis of hypokalemia: <ul style="list-style-type: none"> • Adults: Typical dose range is 20 mEq per day 	Adults: 40 mEq/dose

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
potassium chloride ER tablet <i>micro-dispersible</i> (10/15/20 mEq) (Klor-Con [®] M10/15/20)	Treatment of potassium depletion: <ul style="list-style-type: none"> Adults: Doses of 40 to 100 mEq per day or more are used Prevention of hypokalemia: <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • 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 are severe or ongoing losses are great, consider IV therapy. 	Adults: 40 mEq/dose 200 mEq/day Pediatrics: 1 mEq/kg/dose or 40 mEq whichever is lower 100 mEq/day
Maintenance or prophylaxis of hypokalemia	<ul style="list-style-type: none"> • 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; June 2017. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e61a4522-b91d-400a-952c-6f035e4610dd>. Accessed December 7, 2018.
2. Klor-Con Extended-Release Tablet Prescribing Information. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; April 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019123s0361bl.pdf. Accessed December 10, 2018.
3. Klor-Con Sprinkle Extended Release Capsule Prescribing Information. Fort Lauderdale, FL: Actavis Laboratories FL, Inc.; May 2018. Available at

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ed5baaf6-270b-4dd3-b100-36030c0098fc>. Accessed December 10, 2018.

4. Klor-Con M Prescribing Information. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; December 2017. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c2bb5831-365b-4b0a-bfe5-4b55cd70b6d2>. Accessed December 10, 2018.
5. K-Tab Prescribing Information. North Chicago, IL: AbbVie LTD; April 2018. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6594df99-d8ce-49b9-3fbe-9ec7cdc9199b>. Accessed December 11, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	10.31.17	02.18
1Q 2019 annual review: indications edited to follow FDA package insert reorganization updates; maximum dosing is edited from 100 to 200 mEq/day; trial requirement removed and modified to only require medical justification why the other formulations are unsuitable, therapeutic alternative table is expanded to specify tablets versus micro-dispersible tablets and adds dosing for adults and pediatrics if for use in children; examples of positive responses are deleted given potassium's use as a maintenance drug; references reviewed and updated.	12.11.18	02.19

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.

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Note:

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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