

**Clinical Policy: Potassium (Klor-Con)** 

Reference Number: HIM.PA.143

Effective Date: 10.31.17 Last Review Date: 02.18

Line of Business: Health Insurance Marketplace

**Revision Log** 

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

## **Description**

Potassium chloride (Klor-Con®) powder for oral solution is an oral potassium supplement.

## FDA Approved Indication(s)

Klor-Con is indicated:

- For therapeutic use in patients with hypokalemia with or without metabolic alkalosis; in digitalis intoxication and in patients with hypokalemic familial periodic paralysis
- For prevention of potassium depletion when the dietary intake of potassium is inadequate in the following conditions: patients receiving digitalis and diuretics for congestive heart failure; hepatic cirrhosis with ascites; states of aldosterone excess with normal renal function; potassium-losing nephropathy and certain diarrheal states.
- For treatment of severe cases of hypokalemia in patients receiving diurectics for uncomplicated essential hypertension.

#### Policy/Criteria

Provider must submit documentation (including 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<sup>®</sup> that Klor-Con is medically **necessary** when the following criteria are met:

# I. Initial Approval Criteria

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

- 1. Diagnosis of hypokalemia;
- 2. Failure of a trial of potassium chloride extended-release capsule or tablet unless contraindicated or clinically significant side effects are experienced;
- 3. Medical justification supports that member is not a candidate for oral capsule or tablet formulation of potassium salts;
- 4. Dose does not exceed 100 mEq/day.

**Approval duration: 12 months** 

#### B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### **II.** Continued Therapy



# CLINICAL POLICY Potassium Chloride

### 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 (e.g., labs, reduction in signs and symptom such as fatigue, muscle spasms, dysrythmias, etc.)
- 3. If request is for a dose increase, new dose does not 100 mEq/day.

Approval duration: 12 months

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

- 1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
  - Approval duration: Duration of request or 12 months (whichever is less); or
- 2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## 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 policy – HIM.PHAR.21 or evidence of coverage documents.

# IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Potassium	Varies	100 mEq/day
chloride	Potassium supplement dosing is	
	individualized according to the needs of	
	the patient.	

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

#### V. References

- 1. Klor-Con Prescribing Information. Maple Grove, MN: Upsher-Smith; August 2012. Available at: <a href="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bae3548f-40fe-4ef5-adb3-eb4cef6f735d">https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bae3548f-40fe-4ef5-adb3-eb4cef6f735d</a>. Accessed October 23, 2017.
- 2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <a href="http://www.clinicalpharmacology-ip.com/">http://www.clinicalpharmacology-ip.com/</a>. Accessed October 23, 2017.



# CLINICAL POLICY Potassium Chloride

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.31.17	02.18

#### **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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



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