

Clinical Policy: Dichlorphenamide (Keveyis)

Reference Number: CP.CPA.56

Effective Date: 11.16.16

Last Review Date: 11.17

Line of Business: Medicaid – Medi-Cal

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Dichlorphenamide (Keveyis™) is an oral carbonic anhydrase inhibitor.

FDA approved indication

Keveyis is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

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

I. Initial Approval Criteria

A. Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants (must meet all):

1. Diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants;
2. Failure of acetazolamide unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 200 mg/day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Dose does not exceed 200 mg/day.

Approval duration: Length of Benefit

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 CP.PHAR.57 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 – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

N/A

Appendix B: General Information:

- Variants of periodic paralysis include paramyotonia congenita and Andersen syndrome.
- Dichlorphenamide was originally FDA approved for the treatment of elevated intraocular pressure but was voluntarily withdrawn from the market by the manufacturer in 2002.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/Maximum Dose
acetazolamide	250 to 375 mg/day PO in divided doses	375 mg/day

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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants	Initial dose of 50 mg PO BID; titrate based on individual response at weekly intervals up to a maximum recommended daily dose of 200 mg.	200 mg PO/day

VI. Product Availability

Tablet: 50 mg

VII. References

1. Keveyis Prescribing Information. Hawthorne, NY: Taro Pharmaceuticals U.S.A, Inc.; August 2015. Available at <https://keveyis.com/keveyis-prescribing-information.pdf>. Accessed on January 9, 2017.
2. Tawil R, McDermott MP, Brown R, et al. Randomized trials of dichlorphenamide in the periodic paralyses. *Ann Neurol* 2000;47:46-53.

3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Accessed January 12, 2017. Available at:<http://www.clinicalpharmacology-ip.com>
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 9, 2017.
5. Keveyis. American Hospital Formulary Service Drug Information. Available at:
<http://www.medicinescomplete.com/mc/ahfs.current/>. Accessed January 11,2017

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	1.17.17	11.17

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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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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