

Dichlorphenamide (Keveyis, Ormalvi)

Override(s)	Approval Duration
Prior Authorization	Initial approval: 3 months
Quantity Limit	Continuation approval: 1 year

Medications	Quantity Limit
Keveyis (dichlorphenamide) – Brand and Generic	May be subject to quantity limit
Ormalvi (dichlorphenamide) - Generic	

APPROVAL CRITERIA

Requests for initiation of therapy with Keveyis (dichlorphenamide) or Ormalvi (dichlorphenamide) may be approved when the following criteria are met:

- I. Individual is using to treat primary hyperkalemic periodic paralysis; **OR**
- II. Individual is using to treat primary hypokalemic periodic paralysis; **OR**
- III. Individual is using to treat a periodic paralysis related variant (including, but not limited to paramyotonia congenita);

AND

- IV. Documentation is provided that individual experiences greater than or equal to one episode of muscle weakness per week.

Requests for continuation of therapy with Keveyis (dichlorphenamide) or Ormalvi (dichlorphenamide) may be approved when the following criteria are met:

- I. Individual is using to treat primary hyperkalemic periodic paralysis; **OR**
- II. Individual is using to treat primary hypokalemic periodic paralysis; **OR**
- III. Individual is using to treat a periodic paralysis related variant (including, but not limited to paramyotonia congenita);

AND

- IV. Documentation is provided that individual has achieved and sustained clinically significant improvement in the number of episodes of muscle weakness experienced per week.

Requests for **brand** Keveyis must meet the following, in addition to the above Prior Authorization criteria:

- I. Individual has failed an adequate trial of one chemically equivalent generic dichlorphenamide agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

- A. Generic dichlorphenamide had inadequate response; **OR**

- B. Generic dichlorphenamide caused adverse outcome; **OR**
- C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Keveyis (dichlorphenamide) or Ormalvi (dichlorphenamide) may not be approved for any of the following:

- I. Individual has a diagnosis of hepatic insufficiency; **OR**
- II. Individual has a severe pulmonary disease; **OR**
- III. Individual has a hypersensitivity to sulfonamides; **OR**
- IV. Used in combination with high-dose aspirin.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed November 28, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Primary Periodic Paralysis. Rochester, MN: American Association of Neuromuscular & Electrodiagnostic Medicine: 2022. URL: <https://www.aanem.org/Patients/Muscle-and-Nerve-Disorders/Primary-Periodic-Paralysis>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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