Payers may require prior authorization or supporting documentation to process and cover a claim for the requested therapy. A prior authorization allows the payer to review the reason for the requested therapy and to determine medical appropriateness. A patient-specific letter of medical necessity will help to explain the physician's rationale and clinical decision making in choosing a therapy. The following is a sample letter of medical necessity that can be customized based on your patient's medical history and physical examination. Please note that some payers may have specific forms that must be completed in order to request prior authorization or to document medical necessity.

Please see Full Prescribing Information for KEVEYIS® (dichlorphenamide) at www.KEVEYIS.com/PI.

Sample Format: Letter of Medical Necessity

[Insert physician letterhead]

[Insert Name of Medical Director]
[Insurance Company]
[Insurance Company Address]
[Insurance Company City, State, Zip]

RE: Patient Name: [_____]
Policy Number: [_____]
Claim Number: [_____]

Dear **[Insurance Company]**:

I am writing to provide additional information to support my claim for the treatment of **[insert patient name]** with KEVEYIS® (dichlorphenamide) 50mg tablets for **[insert diagnosis]**. In brief, treatment of **[insert patient name]** with KEVEYIS is medically appropriate and necessary and should be a covered and reimbursed treatment.

Below, this letter outlines **[insert patient name]**'s relevant medical history, prognoses, treatment history, and treatment rationale.

Summary of Patient's History

[You may want to include]:

- Patient's diagnosis, condition, and history – including the type of Primary Periodic Paralysis: hyperkalemic, hypokalemic or a related variant (e.g. paramyotonia congenita)
- Confirmation that the patient does not have hepatic insufficiency or severe pulmonary obstruction
- Confirmation that the patient does not have a hypersensitivity or allergy to sulfonamides or use high-dose aspirin concurrently
- Documentation that lifestyle modifications have been reviewed and conservative measures implemented by the patient to alleviate potential triggers (i.e. dietary and exercise restrictions)
- List the name and dosage of prior medication(s) with a brief description of the patient's inadequate response or intolerance to the therapy
- Brief overview of the patient's recent symptoms and conditions
- Recent lab values and results of diagnostic tests
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with KEVEYIS

[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment
Level I evidence supports the use of dichlorphenamide in the management of HypoPP and HyperPP.[1] Given KEVEYIS is the only FDA-approved treatment for hyperkalemic, hypokalemic and related variants of Primary Periodic Paralysis, the published data supporting use of KEVEYIS, and the patient's history and condition, I believe treatment of **[insert patient name]** with KEVEYIS is warranted, appropriate, and medically necessary.

Please call my office at **[insert telephone number]** if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,
[Insert Doctor Name and Participating Provider Number]

[Mandatory Enclosures]
[Supporting Documentation]
[Clinical Notes]

[Suggested Enclosures]
[Peer Reviewed Literature]
[Package Insert]

References: 1. KEVEYIS Prescribing Information, Feasterville-Trevose, PA: Strongbridge Biopharma; 2019.