

## **PAPZIMEOS™ (zopapogene imadenovec-drba) Sample Letter of Medical Necessity**

### **Instructions**

[The following is a sample letter of medical necessity, which can be used to help support an insurer's coverage of PAPZIMEOS. This paragraph and other information within brackets are intended to provide additional guidance and should be omitted from the final letter. The magenta bracketed text is templated and should be replaced with pertinent information for the individual patient on whose behalf you are submitting the letter, and then made black. Black bracketed text has also been included throughout the letter, indicating suggested optional text to be included as appropriate.]

Before sending:

- Ensure that text is uniform and all relevant information is included
- Confirm that you have included your organization's official letterhead

The completed Letter of Medical Necessity should be sent with the completed prior authorization or medical exception form.]

### **Sample Letter Template**

[Date]

[Insurer Medical or Pharmacy Director/Contact Name]

[Insurer Organization Name]

[Insurer Street Address]

[Insurer City, State, ZIP Code]

RE: [Patient First and Last Name]

Date of Birth: [Patient's Date of Birth]

Policy ID Number: [Policy ID Number]

Policy Group Number: [Policy Group Number]

Policy Holder: [Policy Holder's Name]

Case ID Number: [Case ID Number]

Dear [Insurer Medical or Pharmacy Director/Contact Name/Insurer Organization Name],

I am [Physician Name, credentials, specialty, hospital/practice], and I am writing on behalf of my patient, [Patient Name], to document the medical necessity of PAPZIMEOS™ (zopapogene imadenovec-drba).

### **Indication**

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of recurrent respiratory papillomatosis in adults.

### **Recurrent Respiratory Papillomatosis (RRP) Foundation Position Statement**

The RRP Foundation position statement, published January 2026, states that patients with RRP, including patients being treated with systemic bevacizumab, should be offered a human papillomavirus (HPV)-specific immunotherapy to treat the underlying cause of RRP. HPV-specific immunotherapy is recommended as a first-line treatment by the RRP Foundation clinical algorithm. Additionally, the RRP Foundation does not recommend withholding the option of HPV-specific immunotherapy based on surgical or procedural thresholds. PAPZIMEOS is currently the only HPV-specific immunotherapy approved for the treatment of RRP.<sup>1</sup>

## Clinical Justification for Treatment

In brief, I have determined that [initiating/continuing] treatment with PAPZIMEOS for [Patient Name] is medically appropriate and necessary. Outlined below are [Patient Name]'s medical history, prognosis, and the clinical rationale for treatment with PAPZIMEOS. Please also see the attachments provided supporting the clinical rationale. The patient meets the following criteria for treatment:

- Aged 18 years or older<sup>2</sup>
- Confirmed diagnosis of RRP<sup>2</sup>
- [List additional medical policy specific criteria from the patient's payer, including previous clinical interventions]

## Patient Clinical History and Diagnosis

- [A summary of the patient's diagnosis, including date of diagnosis and current condition]
- [History of patient relationship, including length of time providing care and referring physician name]
- [Relevant medical records and clinical notes, including:]
  - [Explanation of previous treatments (# of total prior clinically indicated interventions and medical treatments {including, # of in-office scoping, laser and/or surgical procedures, and/or any previous adjuvant therapies})]
  - Histologic confirmation of HPV 6 or 11 (ie, low risk HPV infection) infection (if available in chart)
  - Previous endoscopy or radiologic testing reports
- [Clinical studies that support the use of treatment]

## Patient Treatment Plan

Per the FDA-approved label for PAPZIMEOS, a debulking procedure should be performed prior to the first dose of PAPZIMEOS to establish minimal residual disease. A total of 4 subcutaneous injections of PAPZIMEOS will be administered over a 12-week period.<sup>2</sup>

Therapy aligns with value-based care goals and can prevent progression of RRP, which may require further interventions.<sup>1-2</sup> Please call my office at [telephone number], if you require additional information. I look forward to receiving your timely response and approval of this authorization.

Sincerely,

[Physician Name]

[NPI]

[Title, Institution]

[Email/Phone Number]

## Attachments

- PAPZIMEOS full Prescribing Information
- Supporting clinical evidence
- [PAPZIMEOS FDA approval letter]
- *Lancet Respiratory* Pivotal Trial Journal Article
- *Laryngoscope* Position Statement
- *Lancet* Durability Journal Article

## INDICATION

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of recurrent respiratory papillomatosis in adults.

## Important Safety Information

### CONTRAINDICATIONS

None.

### WARNINGS AND PRECAUTIONS

**Injection-Site Reactions:** Injection-site reactions have occurred with PAPZIMEOS injection. Monitor patients for local site reactions for at least 30 minutes after the initial treatment.

**Thrombotic Events:** Thrombotic events may occur following administration of adenoviral vector-based therapies. Monitor patients for signs and symptoms of thrombotic events and treat events according to clinical practice.

### ADVERSE REACTIONS

The most commonly reported adverse reactions ( $\geq 5\%$  of patients) in PAPZIMEOS-treated patients were injection site reactions, fatigue, chills, pyrexia, myalgia, nausea, headache, tachycardia, diarrhea, vomiting, and hyperhidrosis.

### USE IN SPECIFIC POPULATIONS

**Pregnancy:** There are no available data with PAPZIMEOS in pregnant women.

**Lactation:** There is no information available on the presence of PAPZIMEOS in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PAPZIMEOS and any potential adverse effects on the breastfed child from PAPZIMEOS or from the underlying maternal condition.

**Pediatric Use:** The safety and effectiveness of PAPZIMEOS have not been established in pediatric patients.

**Geriatric Use:** Clinical studies of PAPZIMEOS did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger patients.

To report SUSPECTED ADVERSE REACTIONS, contact Precigen, Inc. at 1-855-PGE-NRRP (1-855-743-6777) or [medinfo@precigen.com](mailto:medinfo@precigen.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see full [Prescribing Information](#).

**References:** 1. Best SR, Friedman AD, Rosen CA, et al. Recurrent Respiratory Papillomatosis Foundation position statement on the management of adults with RRP. *Laryngoscope*. Published online January 16, 2026. doi:10.1002/lary.70379 2. PAPZIMEOS. Package insert. Precigen, Inc; 2025.

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