

PAPZIMEOS™ (zopapogene imadenovec-drba) Sample Letter of Appeal

Instructions

[The following is a sample letter of appeal, 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 Appeal should be sent with the initial rejection notification.]

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]. [Patient Name] has recently been prescribed PAPZIMEOS™ (zopapogene imadenovec-drba). [Insurance provider name] denied coverage for PAPZIMEOS on [date of denial letter] due to [insert reason for denial from denial letter]. I am requesting this denial be reconsidered in light of [Patient Name]'s past and current medical circumstances as noted below.

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.¹

Patient Clinical History and Diagnosis

- [Insert explanation as to why the drug is medically necessary for the patient and meets treatment criteria (policy-specific prior authorization criteria from the patient's payer, aged 18 years or older, and diagnosis of RRP²)]
- [Relevant medical records and clinical notes, including:]
 - [Patient's diagnosis and medical history]
 - Diagnostic test results, including histological confirmation of HPV 6 or 11 (ie, low-risk HPV infection) infection (if available in chart)
 - [Healthcare provider notes]
 - [Explanation of previous treatments (# of total prior clinically indicated interventions and medical treatments {including, # of in-office scoping, laser, and/or surgical procedures})]
 - [Explanation of how previous off-label medications (bevacizumab, cidofovir, pembrolizumab) were ineffective, if applicable]
 - Relevant laboratory, endoscopy, or radiologic testing reports

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.²

Please call my office at [telephone number], if you require additional information. I look forward to receiving your timely response.

Sincerely,

[Physician Name]

[NPI]

[Title, Institution]

[Email/Phone Number]

Attachments:

- Copy of the health plan's denial letter (Explanation of Benefits)
- Appeal forms required by the health plan
- [Supporting clinical evidence]
 - [Pertinent peer-reviewed journal articles]
 - [Clinical studies supporting the use of the requested drug]
 - [FDA approval letter/prescribing information for PAPZIMEOS]
 - *Lancet Respiratory Medicine* Pivotal Trial Journal Article
 - *Laryngoscope* Position Statement

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 or FDA at 1-800-FDA-1088 or 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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