



THE STANDARD OF
CARE FOR RRP IS CLEAR^{1,2}

Recommended as first-line treatment per the RRP Foundation position statement^{1,2}

PAPZIMEOS is the first FDA-approved therapy to treat recurrent respiratory papillomatosis (RRP) in adults.^{1,3}

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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

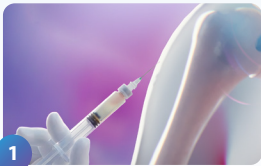
PAPZIMEOS is changing the treatment landscape^{1,3}

PAPZIMEOS is the first immunotherapy that targets the root cause, helping to reduce the need for frequent surgeries^{1-3*}

Patients with RRP are unable to clear the papillomas, suggesting an immunologic deficiency may be involved in the development of the disease. As an immunotherapy administered as a subcutaneous injection, PAPZIMEOS is designed to activate the patient's immune system to elicit a T-cell response against HPV 6- or HPV 11-infected papilloma cells.^{1,4}

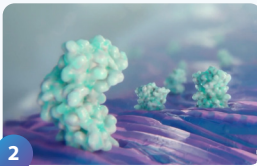
PAPZIMEOS works differently than the preventative HPV vaccine. Vaccination aims at prevention, whereas PAPZIMEOS was developed to activate T-cells to target the underlying disease and papillomas that have grown as a result of chronic HPV infection.^{1,5}

PAPZIMEOS is designed to generate an immune response against papilloma cells infected with HPV 6 or HPV 11.¹



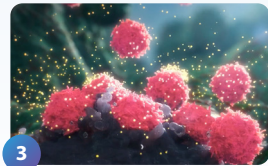
1

PAPZIMEOS administered as a subcutaneous injection.



2

Non-replicating adenoviral vector expresses a fusion antigen comprising selected regions from HPV 6 and 11 proteins.



3

T-cell mediated immune response is generated against papilloma cells expressing HPV 6- or HPV 11-associated proteins.



Watch PAPZIMEOS in action at papzimeosHCP.com/MOA.

*Prior to the initial administration of PAPZIMEOS, perform a surgical debulking of visible papilloma to establish MRD. PAPZIMEOS is administered as a subcutaneous injection 4 times over a 12-week interval. To maintain MRD during treatment with PAPZIMEOS, you may choose to remove visible papilloma, if present, prior to the third and fourth administration of PAPZIMEOS.¹

MRD=minimal residual disease.

Select Important Safety Information

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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

CLEAR the way for a different type of RRP treatment^{1,3}

Study design

PAPZIMEOS was evaluated in an open-label, single-arm study of 38 adult patients with RRP in the United States. 35/38 patients received the recommended dosage of 5×10^{11} PU per injection.¹

Primary endpoint: complete response

51% OF PATIENTS

(n=18/35) did not require any surgical interventions for 1 year post treatment (95% CI: 34%-69%)¹

Durability of complete response

15 out of 18 COMPLETE RESPONDERS

evaluated at 2 years demonstrated continued complete response¹

Complete responses are ongoing, with most remaining durable at a median follow-up of 3 years (n=15/18)⁶

Over a 36-month median follow-up period (range, 27-37 months), a majority of patients (n=15/18) have maintained a complete response. No new safety events were observed. Complete responders are in a 5-year long-term follow-up.^{6,7*}

*Based on the data cutoff of September 19, 2025.

PU=particle injection.

Please see full [Prescribing Information](#) for full study design.

Select Important Safety Information

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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#).


Papzimeos™
zopapogene imadenovec-drba
For subcutaneous injection 5×10^{11} PU/mL

Summary of adverse reactions (ARs)

ARs occurring in $\geq 5\%$ of patients treated with PAPZIMEOS (N=38)^{1,7}

Preferred term	Grade 1* n (%)	Grade 2* n (%)
Injection site reaction	37 (97)	0
Fatigue	28 (74)	2 (5)
Chills	25 (66)	0
Pyrexia	24 (63)	0
Myalgia	9 (24)	2 (5)
Nausea	10 (26)	0
Headache	4 (11)	0
Tachycardia	3 (8)	0
Diarrhea	2 (5)	0
Vomiting	2 (5)	0
Hyperhidrosis	2 (5)	0

*Graded per NCI CTCAE v5.0.¹

NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

Other clinically significant ARs occurring in $< 5\%$ of patients included blurred vision (3%), injection site bruising (3%), dizziness (3%), dyspnea (3%), and pruritus (3%).¹

PAPZIMEOS has been shown to be well-tolerated. There were no Grade > 2 ARs in the pivotal trial.^{1,3}

In the clinical trial, there were no treatment discontinuations due to ARs. All patients received 4 doses of PAPZIMEOS. There were no dose-limiting toxicities or treatment-related serious adverse events.^{1,3}



No new safety events were observed during long-term follow-up.^{6†}

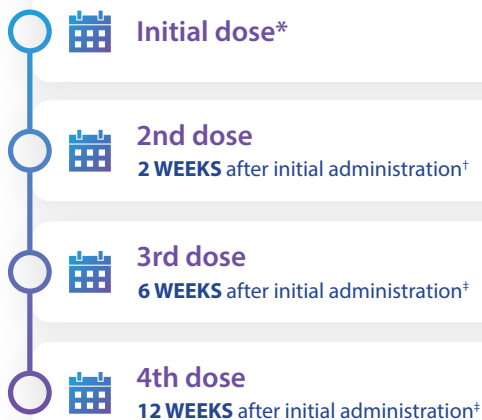
[†]Median duration 36 months; range, 27 to 37 months.⁶

Please see additional **Important Safety Information** throughout and full **Prescribing Information**.

Papzimeos™
zopapogene imadenovec-drba
For subcutaneous injection 5 x 10¹¹ PU/mL

PAPZIMEOS dosing & administration

PAPZIMEOS is for subcutaneous injection provided as a suspension in a single-dose vial¹



The recommended dose of PAPZIMEOS is 5×10^{11} PU per injection administered subcutaneously 4 times over a 12-week interval.¹

*Prior to the initial administration of PAPZIMEOS, perform a surgical debulking of visible papilloma to establish MRD.¹

†The second administration should occur no less than 11 days after the initial administration.¹

‡To maintain minimal residual disease during treatment with PAPZIMEOS, remove visible papilloma, if present, prior to the third and fourth administration of PAPZIMEOS.¹

In RRP, the papilloma microenvironment suppresses HPV clearance to perpetuate a chronic infection. Decreasing the disease burden through surgical interventions prior to treatment establishes MRD and may reduce the immunosuppression associated with the papilloma microenvironment to maximize the potential for clinical benefit.^{3,8}

- ✓ PAPZIMEOS carton should be stored in an appropriate freezer at $\leq -60^{\circ}\text{C}$ [$\leq -76^{\circ}\text{F}$] until ready to thaw and administer.¹
- ✓ PAPZIMEOS MUST BE RAPIDLY thawed before use and prepared for immediate administration.¹
- ✓ Once thawed, DO NOT place the PAPZIMEOS vial in a refrigerator, freezer, or on dry ice. Protect PAPZIMEOS from light. DO NOT shake the vial.¹
- ✓ DO NOT hold PAPZIMEOS at room temperature for more than 60 minutes after thawing.¹

Please see full [Prescribing Information](#) for complete information on DOSAGE AND ADMINISTRATION.

Select Important Safety Information

USE IN SPECIFIC POPULATIONS (cont'd)

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

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

It's time to advance the standard of care^{1,2}

Explore more at papzimeosHCP.com.

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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.

References: **1.** PAPZIMEOS. Package insert. Precigen, Inc; 2025. **2.** 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 **3.** Norberg SM, Valdez J, Napier S, et al. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. *Lancet Respir Med*. 2025;13(4):318-326. doi:10.1016/S2213-2600(24)00368-0 **4.** Ivancic R, Iqbal H, deSilva B, Pan Q, Matrka L. Current and future management of recurrent respiratory papillomatosis. *Laryngoscope Investig Otolaryngol*. 2018;3(1):22-34. doi:10.1002/lio2.132 **5.** Ovcinnikova O, Engelbrecht K, Verma M, Pandey R, Morais E. A systematic literature review of the epidemiology, clinical, economic and humanistic burden in recurrent respiratory papillomatosis. *Respir Res*. 2024;25(1):430. doi:10.1186/s12931-024-03057-w **6.** Norberg S, Giridhar PV, Semnani R, Bonifacio G, Lankford A, Allen C. Zopapogene imadenovec-drba, a novel adenoviral vector-based immunotherapy, induces complete and durable responses in adults with recurrent respiratory papillomatosis (RRP). Presented at: AAO-HNSF 2025 Annual Meeting & OTO Expo; October 11-14, 2025; Indianapolis, IN. **7.** Data on file. Precigen, Inc. **8.** Ramos ML, Ueha R, Goto T, Matsumoto N, Kondo K. Pathogenesis of recurrent respiratory papillomatosis and potential novel treatment strategies. *Auris Nasus Larynx*. 2025;52(4):381-387. doi:10.1016/j.anl.2025.05.011

Please see full [Prescribing Information](#).

PRECIGEN

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