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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Anti-Infective Agents	**Original Policy Date:**	October 24, 2025
Subject:	Papzimeos	**Page:**	1 of 3

Last Review Date: December 12, 2025

Papzimeos

Description

Papzimeos (zopapogene imadenovec-drba)

Background
Papzimeos is a non-replicating adenoviral vector-based immunotherapy designed to express a fusion antigen of selected regions of human papillomavirus (HPV) proteins expressed in HPV 6- and HPV 11-infected cells. Papzimeos is designed to generate an immune response directed against HPV 6 and HPV 11 proteins in patients with recurrent respiratory papillomatosis (1).

Regulatory Status
FDA-approved indication: Papzimeos is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of adults with recurrent respiratory papillomatosis (1).

Papzimeos contains warnings regarding injection-site reactions and thrombotic events. Patients should be monitored for local site reactions for at least 30 minutes after the initial treatment and managed accordingly. Patients should also be monitored for signs and symptoms of thrombotic events and treated according to clinical practice (1).

The safety and effectiveness of Papzimeos in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Papzimeos may be considered **medically necessary** if the conditions indicated below are met.

Papzimeos may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Recurrent respiratory papillomatosis

AND ALL of the following:

1. Histological diagnosis of papilloma confirmed by pathology report
2. Presence of laryngotracheal papillomas
3. Patient has a history of 3 or more debulking procedures to remove laryngotracheal papillomas in the last 12 months
4. Prescriber agrees to monitor for injection-site reactions and thrombotic events

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 vials (only one PA approval for four injections per lifetime)

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Papzimeos is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of adults with recurrent respiratory papillomatosis. The safety and effectiveness of Papzimeos in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Papzimeos while maintaining optimal therapeutic outcomes.

References

1. Papzimeos [package insert]. Germantown, MD: Precigen, Inc.; August 2025.

Policy History

Date	Reason
October 2025	Addition to PA
December 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.