

Billing and Coding Guide

Information to assist with PAPZIMEOS claims submissions

This resource is provided for informational purposes only. It is always the healthcare provider's (HCP) responsibility to determine details specific to individual patients and to submit factual and accurate claims for the products and services rendered. HCPs should contact third-party insurers for specific information on their coding, coverage, payment policies, and fee schedules. Precigen makes no guarantee regarding reimbursement for any service or item. **This resource is not intended as reimbursement advice, legal advice, medical advice, or a substitute for an HCP's independent professional judgment.**

These codes are only provided for informational purposes. It is the responsibility of the provider to make all coding decisions and submit true and accurate information to the patient's insurance plan. Use of provided codes is not a guarantee of coverage or reimbursement.

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.

Submitting a claim for PAPZIMEOS

PAPZIMEOS is administered as a subcutaneous injection by an HCP. Once a patient has received a PAPZIMEOS injection, your facility may submit a claim to the patient's insurance plan(s). A new claim can be submitted for each injection of PAPZIMEOS. It is important to review claims before submitting to help ensure accurate submission of claims and avoid coverage denials.

Although PAPZIMEOS is a subcutaneous injection, it may be administered in outpatient infusion settings. Providers should select the appropriate procedural code that reflects the route of administration, and ensure that the place of service code aligns with the site of care. Claims for subcutaneous injections should include documentation specifying the injection site and route of administration, and that the procedure was performed under appropriate supervision.

Steps for submitting a claim



1 Confirm insurer requirements

If you have not already done so, contact insurers to get specific information for coverage and PA requirements, coding and billing guidelines, and necessary supplemental medical documentation.

2 Ensure the claim is accurate and complete

Verify that all insurer-required information is present. This may include, but is not limited to, patient and provider information, coding, billing units, PA approval number, tax identification number, and NDC.

3 Comply with claim submission rules

Insurers may publish a companion guide as to how to populate certain data fields and time frames for claims submission.

Before submitting a claim, confirm coding and documentation requirements with each insurer.

Papzimeos SUPPORT

To begin your patient's PAPZIMEOS treatment, submit the Papzimeos SUPPORT Enrollment Form at papzimeosSUPPORT.com. The Papzimeos SUPPORT HUB, provided by Biologics, is available to support patients and HCPs with navigating the access journey. Papzimeos SUPPORT provides resources (including sample letters of medical necessity and requests for appeal) as well as live support for the claim submission and appeal processes. You can reach the Papzimeos SUPPORT team by calling (866) 827-8180, 8 AM to 8 PM ET, Monday to Friday.

NDC=National Drug Code; PA=prior authorization.

Summary of relevant codes for PAPZIMEOS

Product package codes

National Drug Codes¹

Codes	Description ²
84768-511-01 (10-Digit Code)	1 carton containing 1 single-dose vial of zopapogene imadenovec-drba
84768-0511-01 (11-Digit Code)	



State and insurer guidelines for reporting the NDC may vary and should be reviewed prior to submitting a claim.

Billing code

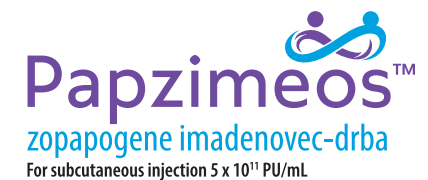
Effective April 1, 2026, PAPZIMEOS has a permanent, product-specific HCPCS Level II J-code that can be used to submit reimbursement claims.

HCPCS billing code for PAPZIMEOS²

Code	Description
J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose

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HCPCS=Healthcare Common Procedure Coding System.



Summary of relevant codes for PAPZIMEOS (cont.)

Diagnosis codes

There is currently no ICD-10-CM Diagnosis Code for RRP; therefore, you may provide clinical documentation in lieu of a diagnosis code when submitting a claim for PAPZIMEOS.

While payer requirements may differ, accepted clinical documentation may include:

- Histological diagnosis confirmed by pathology report
- Test results confirming low-risk HPV serotype 6 or 11
- Presence of laryngotracheal papillomas

Administration codes

PAPZIMEOS is administered by an HCP as a subcutaneous injection. PAPZIMEOS consists of 4 doses, with 1 dose given on Day 1, and the subsequent doses at 2 weeks, 6 weeks, and 12 weeks, after the initial administration. Prior to the initial administration of PAPZIMEOS, perform a surgical debulking of visible papilloma to establish minimal residual disease. To maintain minimal residual disease during treatment with PAPZIMEOS, remove visible papilloma, if present, prior to the third and fourth administration of PAPZIMEOS.¹

Primary administration CPT code⁴

Code	Description
96372	Injection of drug or substance under skin or into muscle

Revenue codes

Example NUBC revenue system codes⁵

Code	Description
0940	Other therapeutic services-general
0636	Drugs requiring detailed coding

Place of service codes

Place of services codes used in the submission of claims should be chosen based on the location that PAPZIMEOS was administered for each individual patient.

Commonly used place of service codes⁶

Code	Location	Description
11	Office	Location, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off Campus—Outpatient Hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)
22	On Campus—Outpatient Hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016)

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

Example claim scenario

A patient has a confirmed clinical diagnosis of RRP from their provider. Due to the lack of a specific ICD-10-CM code, their provider has utilized **a pathology report to confirm a histological diagnosis of RRP**. The provider orders PAPZIMEOS and the patient receives a **subcutaneous injection** of PAPZIMEOS in an **outpatient infusion center**.

Hospital outpatient infusion center Medicare claim

Code Type	Code
Proof of RRP Diagnosis (in lieu of ICD-10-CM code) ³	Histological diagnosis of RRP confirmed by pathology report
Administration Code ⁴	CPT: 96372
Product Code ²	HCPCS: J3404
Revenue Codes ⁵	Administration: 0940
	Drug: 0636

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Indication and Important Safety Information

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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.


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

References: **1.** PAPZIMEOS. Package insert. Precigen, Inc; 2025. **2.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding determinations. Centers for Medicare & Medicaid Services. January 20, 2026. Accessed February 11, 2026. <https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-4-2025-drugs-biologicals.pdf> **3.** 2025 ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services. Accessed December 12, 2025. <https://www.cms.gov/files/zip/2025-code-tables-tabular-and-index.zip> **4.** Jagmin CL, et al. *CPT 2024 Professional Edition*. 4th ed. American Medical Association; 2024:215-217. **5.** Medicare intermediary manual. Centers for Medicare & Medicaid Services. Updated July 1, 2003. Accessed December 12, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r1875a3.pdf> **6.** Place of service code set. Centers for Medicare & Medicaid Services. Updated May 2, 2024. Accessed June 9, 2025. <https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets>

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For subcutaneous injection 5 x 10¹¹ PU/mL

Please see Important Safety Information on page 7 and full Prescribing Information.