

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.

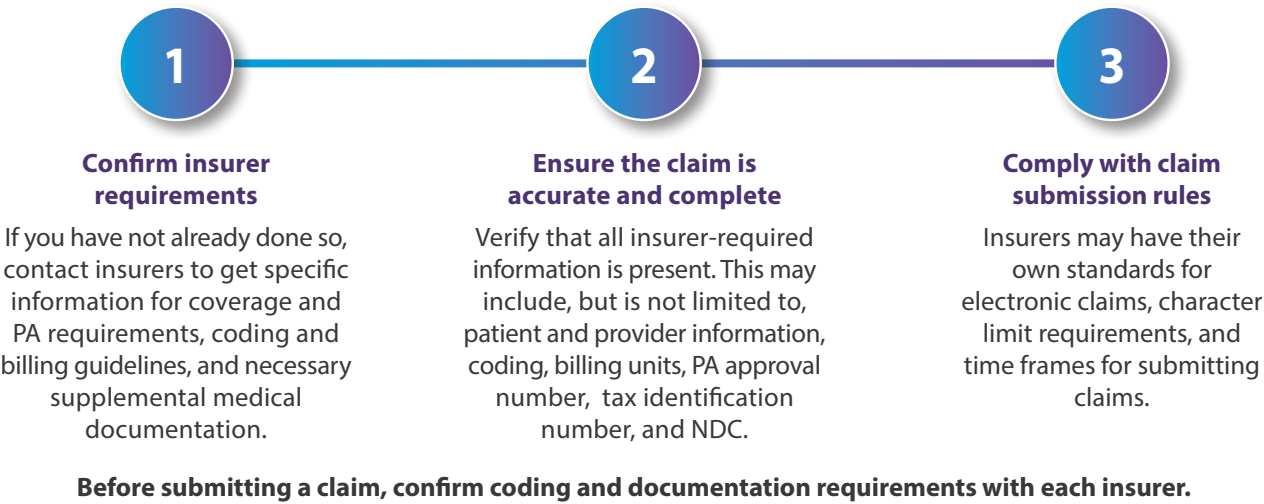
Thrombotic Events: Thrombotic events may occur following administration of adenoviral vector-based therapies. Monitor patients for signs and symptoms of thrombotic events and treat events according to clinical practice.

Submitting a Claim for PAPZIMEOS

PAPZIMEOS is administered as a subcutaneous injection by a healthcare provider. 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 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



Papzimeos SUPPORT

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

10-Digit Code	11-Digit Code	Description
84768-511-01	84768-0511-01	1 carton containing zopapogene imadenovec-drba 1 mL single-dose vial



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

Typically, CMS assigns a product-specific HCPCS J-code that becomes effective 7 to 9 months after FDA approval. In the interim, a miscellaneous J-code is used to submit reimbursement claims. CMS may also issue a temporary C-code to be used for outpatient setting reimbursement claims.

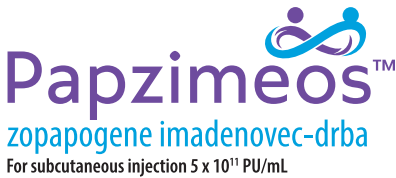
When using unclassified codes, ensure the NDC, drug name, strength, route, and dosage are included in the claim notes.

Relevant HCPCS Billing Codes for PAPZIMEOS²

Code	Description	Sites of Care
J3490	Unclassified drugs	Most care settings for most insurers
J3590	Unclassified biologics	Most care settings for most insurers
C9399	Unclassified drugs or biologics	Outpatient settings for most insurers

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CMS=Centers for Medicare & Medicaid Services; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System.



Summary of Relevant Codes for PAPZIMEOS (cont.)

Diagnosis Codes

There is currently no ICD-10 code for RRP; however, you can use a combination of RRP-related ICD-10 codes and laryngoscopy procedure codes depending on context, primarily based on severity and location of lesions.

Additionally, while ICD-10 diagnostic codes such as D14.1 are commonly used to diagnose RRP, some D10/D14 codes can be used to indicate other non-recurrent forms of respiratory papillomatosis. Because RRP is recurrent, multiple patient admissions with a specified ICD-10 code, potentially combined with CPT codes representing laryngoscopy, may indicate RRP.

Example ICD-10-CM Diagnosis Codes³

Code	Description
D10.5	Benign neoplasm of other parts of oropharynx
D10.6	Benign neoplasm of nasopharynx
D10.9	Benign neoplasm of pharynx, unspecified
D14.0	Benign neoplasm of middle ear, nasal cavity, and accessory sinuses
D14.1	Benign neoplasm of larynx
D14.2	Benign neoplasm of trachea
D14.3	Benign neoplasm of bronchus and lung
D14.30	Benign neoplasm of unspecified bronchus and lung
D14.31	Benign neoplasm of right bronchus and lung
D14.32	Benign neoplasm of left bronchus and lung
D14.4	Benign neoplasm of respiratory system, unspecified
D36.9	Benign neoplasm, unspecified site
J38.7	Other diseases of larynx
J39.2	Other diseases of pharynx

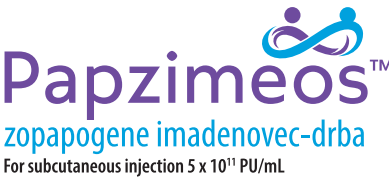
CPT=Current Procedural Terminology; ICD-10=International Classification of Diseases, Tenth Revision; RRP=recurrent respiratory papillomatosis.

Diagnostic Procedure CPT Codes⁴

Code	Description
<i>Diagnostic</i>	
31525	Laryngoscopy direct, with or without tracheoscopy; diagnostic, except newborn
31526	Laryngoscopy direct, with or without tracheoscopy; diagnostic, with operating microscope or telescope
31575	Laryngoscopy, flexible; diagnostic
<i>Operative</i>	
31540	Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis
31541	Laryngoscopy, direct, operative, with excision of tumor and/or stripping of vocal cords or epiglottis; with operating microscope or telescope
31545	Laryngoscopy, direct, operative, with operating microscope or telescope, with submucosal removal of non-neoplastic lesion(s) of vocal cord; reconstruction with local tissue flap(s)
<i>Administration</i>	
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic
31571	Laryngoscopy, direct, with injection into vocal cords, therapeutic; with operating microscope or telescope
<i>Diagnostic + Operative</i>	
31535	Laryngoscopy, direct, operative, with biopsy
31536	Laryngoscopy, direct, operative, with biopsy; with operating microscope or telescope
31572	Laryngoscopy, flexible; diagnostic with ablation or destruction of lesion(s) with laser, unilateral
31578	Laryngoscopy, flexible; diagnostic with removal of lesion(s), non-laser
<i>Miscellaneous</i>	
31529	Laryngoscopy direct, with or without tracheoscopy; with dilation, subsequent
31579	Laryngoscopy, flexible or rigid telescopic, with stroboscopy
31599	Unlisted procedure, larynx

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.

Diagnosis codes used in the submission of claims should be chosen based on the individual patient's medical diagnosis.



Summary of Relevant Codes for PAPZIMEOS (cont.)

Administration Codes

PAPZIMEOS is administered by a healthcare provider 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 initial administration.¹

Primary Administration CPT Code⁴

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

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 Codes⁵

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)

Hospital Outpatient Billing

Example AHA Revenue System Codes⁶

Code	Description
0260	Intravenous therapy, general
0636	Drugs requiring detailed coding

Example Claim Scenario

A patient has a confirmed clinical diagnosis of RRP from their provider. Due to the lack of a specific ICD-10 code, their provider has utilized **ICD-10 D14.1 (benign neoplasm of larynx)**, given their findings on **laryngoscopy (CPT 31525)**. The provider orders PAPZIMEOS and the patient receives a **subcutaneous injection** of PAPZIMEOS in an **outpatient infusion center**.

Relevant Coding for Submission:

Code Type	Code
Diagnosis Code	ICD-10: 14.1
	CPT: 31525
Administration Code	CPT: 96372
Product Package Code	HCPCS: J3590 (accompanied by biologic prescription and NDC)
Place of Service Code	Place of Service Code: 22
Hospital Outpatient Billing	AHA Revenue Systems Code: 0636

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AHA=American Hospital Association.



Indication and Important Safety Information

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WARNINGS AND PRECAUTIONS

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ADVERSE REACTIONS

The most commonly reported adverse reactions (≥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.

Notes

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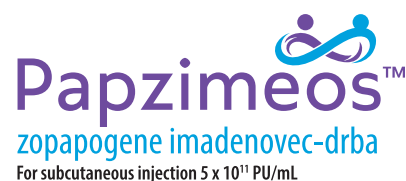
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References: **1.** PAPZIMEOS. Package insert. Precigen, Inc; 2025. **2.** HCPCS quarterly update. Centers for Medicare & Medicaid Services. Updated May 13, 2025. Accessed June 9, 2025. <https://www.cms.gov/files/zip/july-2025-alpha-numeric-hcpcs-file.zip> **3.** 2025 ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services. Accessed April 9, 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.** 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> **6.** Medicare intermediary manual. Department of Health & Human Services. Updated July 1, 2003. Accessed June 9, 2025. <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r1875a3.pdf>



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