

Navigating Access and Getting Started Guide

Important Information to Understand Coverage, Access, and the Reimbursement Process

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.**

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.

Getting Started With PAPZIMEOS: Access and Reimbursement Process

Precigen is committed to providing support to patients and HCPs for PAPZIMEOS. As part of this commitment, this guide will provide information to help you understand the administrative aspects of the access and reimbursement process.

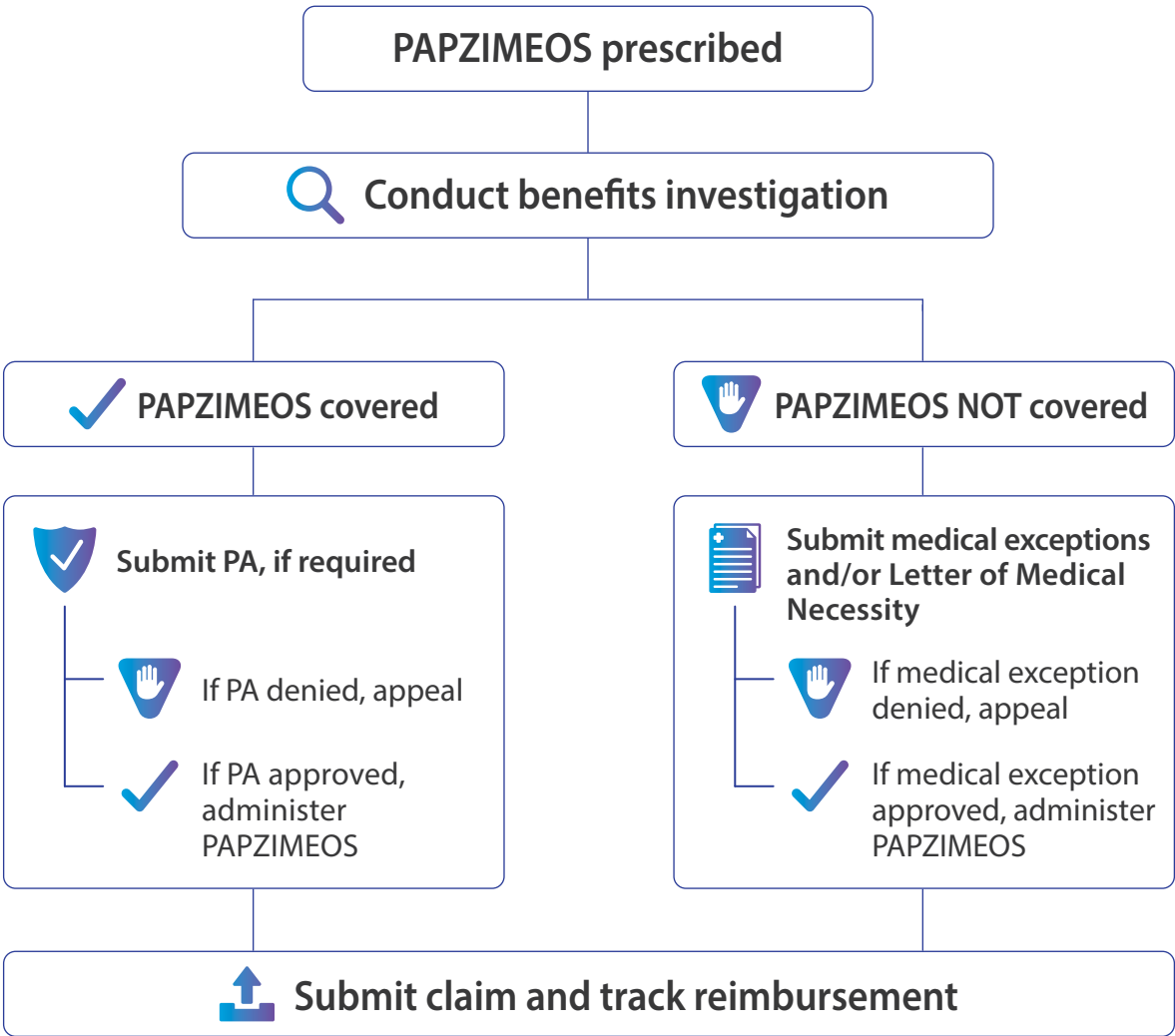
Within this guide, you will find an overview of the access process, including:

-  **Benefits Investigation**
-  **Prior Authorization (PA)**
-  **Medical Exceptions and Letter of Medical Necessity**
-  **Appeals**

Commercial and government insurers all have different coverage and payment policies for medications and services. Check directly with the patient’s insurer(s) to verify specific requirements for PAPZIMEOS.

Papzimeos SUPPORT can help your patients and care team throughout the access process. Download the enrollment form at PapzimeosSUPPORT.com. For questions or support, call (866) 827-8180, Monday to Friday, 8 AM to 8 PM ET.

From Prescription to Reimbursement: An Overview of the Access Process for PAPZIMEOS



Benefits Investigation

Understanding Your Patient’s Benefits

A benefits investigation is a key first step in determining a patient’s coverage for a particular medication. It helps identify the insurance plan’s coverage details and coding requirements. Insurers have different requirements for coverage, so it is important to complete a benefits investigation to determine the key clinical and coverage criteria that apply to each patient.

To support a thorough benefits investigation for PAPZIMEOS, all patient, HCP, coding, and site of care information should be readily available prior to contacting the insurance plan.



Patient Information

- ☐ Patient name
- ☐ Date of birth
- ☐ Phone number
- ☐ Address



Patient Insurance Information

- ☐ Policyholder name
- ☐ Policy start and end dates
- ☐ Policy ID number and group number
- ☐ Type(s) of plan(s) (eg, HMO, PPO, POS, EPO)
- ☐ Primary, secondary, and tertiary insurance information (eg, commercial, Medicare, Medicaid)



Prescriber Information

- ☐ Prescriber name
- ☐ Prescriber NPI number
- ☐ Tax ID number
- ☐ Site/facility name



Best Practice Considerations

- ✓ Call the HCP services phone number on the back of the patient’s medical insurance card
- ✓ Request a copy of the published PAPZIMEOS policy if one is available
- ✓ Determine which coverage and criteria apply to your patient

Benefits Investigation

Confirm Patient Benefits and Next Steps

Once the benefits investigation is complete and you have determined the patient’s insurance coverage for PAPZIMEOS:

- Identify whether a PA, precertification, referral, or any other specific documentation is necessary
- Confirm if you/the site is in network
- Check the patient’s policy effective date
- Confirm insurer-specific dispensing requirements
- Understand the patient out-of-pocket (OOP) costs such as annual deductible vs amount met to date, coinsurance and/or copay, and annual OOP maximum vs amount met to date
- Provide information about the Papzimeos SUPPORT Copay Program
- Prepare for future billing by confirming any insurer-specific billing requirements for PAPZIMEOS
- Verify coordination of benefits (who pays in what order)

If the patient has multiple insurance plans, repeat the benefits investigation process for each plan.

Communication Considerations



You may be communicating with your patient’s insurance plan(s) several times during the benefits investigation.

Consider documenting each exchange your site of care has with your patient’s insurance plan(s) and ensuring that notes are appropriately recorded in the patient’s medical records.

- ☐ Date and time of communication
- ☐ Communication preference (fax, email)
- ☐ Person(s) you spoke with
- ☐ Reference number for call
- ☐ Contact information (direct phone line, email)
- ☐ Summary of communication

Notes from the benefits investigation can be referred to throughout the billing and reimbursement process.



Prior Authorization

What If a PA Is Required Prior to Treatment With PAPZIMEOS

If the insurer requires that a PA must be obtained before the treatment will be approved, you will need to demonstrate the clinical rationale for PAPZIMEOS and that the patient meets the PA criteria.

Prior Authorization for PAPZIMEOS May Include:

- ☐ Clinical examination and tests used to diagnose recurrent respiratory papillomatosis (RRP)
- ☐ Current and previous RRP medications
- ☐ Relevant surgical history (eg, debulking) and dates of service
- ☐ Duration and magnitude of symptoms that affect activities of daily living
- ☐ Other supportive care management utilized to manage RRP

Submitting a PA



INDICATION

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of adults with recurrent respiratory papillomatosis.

Medical Exceptions and Appeals

How to Request Medical Exceptions and Appeal Denials

When a patient does not meet coverage requirements for PAPZIMEOS or no policy is in place, coverage may be obtained through the medical exception and/or appeal process, which vary by insurer.

If your prior authorization has been denied, follow the appeal process and timeline in the denial letter. If the process and/or timeline are not in the denial letter, contact the insurer for instructions.

Why Was the PA Denied?

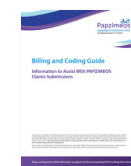
If the insurer reviewed the PA and denied it, you can request to learn if the reason for the denial was clerical, clinical, or benefit-driven

- If the denial was for clerical reasons, you can immediately resubmit the request with the proper information and/or process
- If the denial was for clinical reasons, determine what additional information may be required to demonstrate medical necessity
- If the denial was for benefit reasons, you can call the insurer to determine if an exception to the benefit is allowed and the process for such an exception (eg, no out-of-network benefits but the only experienced HCP is out of network)

Is the HCP/Site Out of Network?

Some patients may face restrictions because the HCP is out of network or out of state. In these instances, waivers or exceptions can be granted on the basis of medical necessity.

Find out if there is an exception process for patients seeking care out of state and/or out of network.



Review the Billing
& Coding Guide.

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

Writing Letters of Medical Necessity and Appeals

A **letter of medical necessity** allows the insurer to review requested medical services to determine whether the patient should receive coverage for the requested medication.

A **letter of appeal** includes similar information and can be used to respond to a denial letter.

Both Letters Typically Include:

- ☐ Patient's full name and date of birth
- ☐ Disease diagnosis (eg, RRP)
- ☐ Name of treatment (eg, PAPZIMEOS)
- ☐ Any diagnostic procedures (eg, laryngoscopy with biopsy) and dates of service
- ☐ Specific symptoms and their impact on the patient's life
- ☐ Previous treatments
- ☐ Clinical rationale for requested treatment
- ☐ Clinical studies that support the use of treatment



Review a Sample Letter of Medical Necessity.

If the Request for Treatment Is Denied, an Appeal Letter Generally Contains All Relevant Patient and HCP Information, As Well As:

- ☐ A clear statement that this is an appeal, and a concise explanation of why the drug is medically necessary for the patient's RRP
- ☐ Request for reconsideration of the denial
- ☐ Relevant medical records and clinical notes, including:
 - ☐ Patient's diagnosis and medical history
 - ☐ HCP notes
 - ☐ Diagnostic test results (eg, laryngoscopy reports, biopsy results)
 - ☐ Medication records
 - ☐ Relevant surgical history (eg, debulking) and dates of service
 - ☐ Relevant laboratory reports
 - ☐ Explanation of why alternative treatments are not suitable or have been ineffective
- ☐ Supporting clinical evidence:
 - ☐ Pertinent peer-reviewed journal articles
 - ☐ Clinical studies supporting the use of the drug for RRP
 - ☐ FDA approval information/Prescribing Information for the requested drug
- ☐ Copy of the health plan's denial letter (Explanation of Benefits)
- ☐ Any appeal forms required by the health plan



Review a Sample Letter of Appeal.

Indication and Important Safety Information

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 (≥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

☐

☐

☐

☐

☐

☐

☐

☐

☐

☐

☐

☐

☐

☐

☐

Reference: 1. PAPZIMEOS. Package insert. Precigen, Inc; 2025.



Precigen logo and PAPZIMEOS logo are trademarks of Precigen, Inc.
© 2025 Precigen, Inc. All Rights Reserved. PM-PAPZ-00003 V1 8/25



Please see Important Safety Information on page 10 and full Prescribing Information.