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Best Practices for the PAPZIMEOS Prior Authorization (PA) Process

Guide for office staff navigating the PA process and required documentation for 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.**

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.

Navigating the coverage determination process

To support appropriate utilization, payers often request clinical documentation for review before approving coverage for treatments such as PAPZIMEOS. This process confirms that prescribed patients meet the payer's criteria to receive treatment.

Documentation requirements and forms vary by payer and individual coverage policy. The following pages outline the prior authorization (PA) process and highlight the information and documentation that should be submitted to support the request for PAPZIMEOS coverage.

Below is an overview of the typical approval process for PAPZIMEOS.

STEP 1

HCP conducts benefits investigation

Verify coverage, PA requirements, and payer criteria.

STEP 2

HCP collects required information

Gather patient, insurance, and necessary clinical details.

STEP 3

HCP completes PA and letter of medical necessity (LOMN), if needed

Prepare payer forms and document the medical necessity for treatment.

Download a sample letter of medical necessity

STEP 4

HCP submits the PA to payer

Send the PA through the payer preferred channel and track status.

STEP 5

If the PA is denied, HCP requests a peer-to-peer review

Conduct a peer-to-peer review with prescribing HCP and payer medical director or peer clinician

STEP 6

If the peer-to-peer review is unsuccessful, HCP submits a letter of appeal (LOA)

Address denial reasons and submit an appeal with added support.

Download a sample letter of appeal

STEP 7

HCP confirms approval and schedules treatment

Verify approval and schedule next steps.

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Best practices for compiling required information

PA is a payer-required pre-approval process for specific treatments to prove medical necessity.

It's important that the information provided during the PA process is comprehensive and accurate—incomplete and incorrect details are a leading cause of denials and delayed patient care.

Review all payer requirements for PAPZIMEOS, including any specific forms or supporting documentation that must be completed. In addition to required forms, it is recommended to include an LOMN with the PA submission.

Key details and documentation to include

Patient information

Ensuring all patient insurance information is accurate may help prevent submission errors and support verification of coverage and benefits. It's also recommended to keep a photocopy of the patient's insurance card on file for future reference.

Prescriber information

The prescribing HCP's office will be the primary point of contact for any questions about the patient's diagnosis and medical history. Make sure that whoever is listed as the office contact is prepared to answer any payer questions that arise throughout the PA process.

Administration site

There are specific storage and handling requirements for PAPZIMEOS; therefore, the administration location may differ from the prescriber's office. Identifying the appropriate site of care early can support treatment planning and help prevent delays in treatment initiation.

Recurrent Respiratory Papillomatosis (RRP) diagnosis

PAPZIMEOS is indicated for adults 18 years and older with an RRP diagnosis.

There is currently no ICD-10-CM diagnosis code for RRP. There are 2 options for documenting an RRP diagnosis:

- Payers may accept proxy codes for RRP. Some proxy codes include:
  - **D14.1:** A benign neoplasm of the epiglottis or a polyp of the larynx
  - **J38.7:** Other diseases of the larynx, including abscess, cellulitis, necrosis, pachyderma, perichondritis, ulcer, or other diseases not specified
  - **J39.2:** Other diseases of the pharynx—including cyst and edema—excluding chronic or ulcerative pharyngitis
- Payers may also accept clinical documentation to document an RRP diagnosis. This may include:
  - Histological diagnosis confirmed by pathology report
  - Test results confirming low-risk HPV serotype 6 or 11
  - Presence of laryngotracheal papillomas

Medical history

A history of debulking interventions and/or off-label treatments may help further justify the clinical need for PAPZIMEOS by demonstrating the lack of effectiveness of previous treatments.

NOTE: There is no mandatory number of interventions prior to receiving PAPZIMEOS. Patients only need to have an initial debulking before their first dose to establish minimal residual disease.

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Best practices for compiling required information
(cont'd)

Key details and documentation to include (cont'd)

Recommended/approved treatment

Restating the recommended treatment helps reinforce that PAPZIMEOS is being prescribed in line with the FDA-approved indication. A single course of treatment of PAPZIMEOS treatment includes 4 subcutaneous injections over 12 weeks.

- Initial debulking is required before the first injection to establish minimal residual disease
- Patients may receive optional debulking prior to the third and fourth injection

Additional support

Clinical documentation may help further justify the patient's eligibility for treatment with PAPZIMEOS, such as:

- Medical chart notes and imaging results (x-rays, CT scans) to illustrate progression of a patient's disease and recurrence of papilloma
- Endoscopic records that help demonstrate how previous interventions were unsuccessful in managing a patient's disease

It may also be helpful to provide some resources to further educate the payer on PAPZIMEOS. These resources may include:

- **PAPZIMEOS Prescribing Information**
- **RRP Foundation Position Statement on RRP treatment** that supports first-line use of an HPV-targeted immunotherapy

Submitting and tracking PAs

When submitting the PA it's important to:

- ☐ **Review payer submission requirements** (email, fax, electronic PA portal, etc)
- ☐ **Confirm the turn-around time** for approval or response
- ☐ **Document and track** all communications with payers to support timely responses to questions
  - ☐ For conversations that take place over the phone, make sure to note the contact name, phone number, and the date that the call was made or received

PA approval should be confirmed prior to scheduling the first dose of PAPZIMEOS.

Letter of appeal

If a PA request is denied, an LOA may be submitted as the next step to request reconsideration of the coverage decision by providing specific clinical information that may not have been fully addressed in the initial determination.

Contact your Precigen Field Reimbursement Consultant for any additional questions about PA submissions.

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Indication and Important Safety Information

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Important Safety Information

CONTRAINDICATIONS

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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.

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Please see full Prescribing Information.