

DRUG POLICY

Papzimeos™ (zopapogene imadenovec-drba)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Papzimeos policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Chart notes, medical record documentation, or laboratory results of all the following:
 - A. Presence of laryngotracheal papillomas
 - B. Histological diagnosis of papilloma confirmed by pathology report
 - C. Member has documented human papillomavirus (HPV) serotype 6 or 11

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Otolaryngologist
2. Pulmonologist
3. Specialist in the treatment of recurrent respiratory papillomatosis

Criteria for Initial Approval

Recurrent Respiratory Papillomatosis

Authorization of 6 months [for a one-time treatment course of 12 weeks (4 doses)] may be granted for treatment of recurrent respiratory papillomatosis (RRP) in adult members when all of the following criteria are met:

1. Member has a clinical diagnosis of recurrent respiratory papillomatosis defined by all of the following:
 - A. Presence of laryngotracheal papillomas
 - B. Histological diagnosis of papilloma confirmed by pathology report
 - C. Member has documented HPV serotype 6 or 11
2. Member has had 3 or more debulking procedures to remove laryngotracheal papillomas in the 12 months prior to treatment with Papzimeos
3. Prescriber attests to both of the following criteria:
 - A. Surgical debulking of visible papilloma will be performed prior to initial administration to establish minimal residual disease
 - B. If present, visible papillomas will be removed to maintain minimal residual disease prior to the third and fourth administration of Papzimeos
4. Member has not received more than 4 doses (one-treatment course) of Papzimeos
5. Papzimeos will not be used in combination with other medications used for the treatment of RRP (e.g., bevacizumab, cidofovir)
6. Member has a negative serology test for hepatitis B (HBV) and hepatitis C (HCV)

Continuation of Therapy

Repeat treatment with Papzimeos for any indication is considered investigational, as the safety and efficacy beyond one treatment course has not been studied. The evidence is insufficient to determine the effect on net health outcomes.

Other

Papzimeos (zopapogene imadenovec-drba) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Papzimeos (zopapogene imadenovec-drba) 5x10 ¹¹ particle units (PU)/1 mL suspension single-dose vial	4 vials per 84 days	Administer 5x10¹¹ particle units (PU) per injection as a subcutaneous injection four times over a 12-week interval. 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. Initial administration – Day 1 Second administration – 2 weeks after initial administration (The second administration should occur no less than 11 days after the initial administration)

		Third administration – 6 weeks after initial administration Fourth administration – 12 weeks after initial administration
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PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3490 – unclassified drugs
- J3590 – unclassified biologics
- J3404 – Injection, zopapogene imadenovec-drba suspension, per therapeutic dose

REFERENCES

- Amiling R, Meites E, Querec TD, et al. Juvenile-onset recurrent respiratory papillomatosis in the United States, epidemiology and HPV types-2015-2020. J Pediatric Infect Dis Soc. 2021;10(7):774-781. doi:10.1093/jpids/piab016
- Benedict JJ, Derkay CS. Recurrent respiratory papillomatosis: a 2020 perspective. Laryngoscope Investig Otolaryngol. 2021;6(2):340-345. doi:10.1002/lio2.545
- Derkay CS, Bluher AE. Update on recurrent respiratory papillomatosis. Otolaryngol Clin North Am. 2019;52(4):669- 679. doi:10.1016/j.otc.2019.03.011
- Papzimeos. Prescribing information. Precigen Inc.; August 2025.
- Recurrent respiratory papillomatosis. National Organization for Rare Disorders. June 2023. <https://rarediseases.org/rare-diseases/recurrent-respiratory-papillomatosis/>
- Recurrent respiratory papillomatosis or laryngeal papillomatosis. National Institute on Deafness and Other Communication Disorders. No. 10-4307. September 2017. <https://www.nidcd.nih.gov/health/recurrent-respiratory-papillomatosis>. Accessed October 7, 2025.

POLICY HISTORY

Policy #: 05.06.07

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Reviewed: August 2026

Revised:

Current Effective Date: December 3, 2025