

Specialty Guideline Management

Papzimeos

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Papzimeos	zopapogene imadenovec-drba

Indications

FDA-approved Indication¹

Papzimeos is indicated for the treatment of adults with recurrent respiratory papillomatosis.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

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

Prescriber Specialties

This medication must be prescribed by or in consultation with an otolaryngologist, pulmonologist, or a specialist in the treatment of recurrent respiratory papillomatosis.

Coverage Criteria

Recurrent Respiratory Papillomatosis (RRP)¹⁻³

Authorization of 16 weeks (for a one-time treatment course of 12 weeks [4 doses]) may be granted for treatment of recurrent respiratory papillomatosis (RRP) in adults members when all of the following criteria are met:

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

References

1. Papzimeos [package insert]. Germantown, MD: Precigen, Inc.; August 2025.

Reference number(s)
7151-A

2. 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.
3. Recurrent respiratory papillomatosis. National Organization for Rare Disorders. June 2023.
<https://rarediseases.org/rare-diseases/recurrent-respiratory-papillomatosis/>. Accessed October 7, 2025.