| Reference number(s) |
| --- |
| 7151-A |

# 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 Indication[1]

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 initate 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 hepatits C (HCV).

# References

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

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.