

Papzimeos™ (zopapogene imadenovec-drba)

When requesting Papzimeos™ (zopapogene imadenovec-drba), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

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

Coverage Guidelines

Recurrent Respiratory Papillomatosis

The individual must meet all of the following criteria for authorization:

- Is 18 years of age or older;
- Diagnosis of recurrent respiratory papillomatosis has been confirmed by biopsy;
- Has or will undergo debulking procedure prior to Papzimeos administration;
- Papzimeos is prescribed by, or in consultation with a pulmonologist, oncologist, thoracic surgeon, or otolaryngologist.

Approval Duration: 4 doses (3 months)

Dosing Recommendation

Papzimeos is for subcutaneous injection only.

The recommended dosage of Papzimeos is 5×10^{11} particle units (PU) per injection administered as subcutaneous injection four times over a 12-week interval. The recommended dosing schedule for Papzimeos is shown in Table 1.

Table 1: Recommended Treatment Schedule for Papzimeos

Administration	Administration Interval
Initial Dose	
Second Dose	2 weeks after initial administration
Third Dose	6 weeks after initial administration
Fourth Dose	12 weeks after initial administration

References

1. Papzimeos™ subcutaneous injection [prescribing information]. Germantown, MD: Precigen; August 2025.
2. Norberg SM, Valez J, Napier S, et al. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. *Lancet Respir Med*. 2025;13: 318-326.
3. Ivancic R, Iqbal H, DeSilva B, et al. Current and future management of recurrent respiratory papillomatosis. *Laryngoscope Investigative Otolaryngology*. 2018;3: 22-34.
4. Position statement: recurrent respiratory papillomatosis and Gardasil vaccination. American Academy of Otolaryngology – Head and Neck Surgery. Available at: <https://www.entnet.org/resource/position-statement-recurrent-respiratory-papillomatosis-and-gardasil-vaccination/>. Updated on April 5, 2021. Accessed on August 18, 2025.
5. Recurrent respiratory papillomatosis or laryngeal papillomatosis. National Institute on Deafness and Other Communication Disorders. Available at: <https://www.nidcd.nih.gov/health/recurrent-respiratory-papillomatosis>. Updated on November 28, 2017. Accessed on August 18, 2025.
6. Meites E, Szilagyi PG, Chesson HW, et al. Human papillomavirus vaccination for adults: updated recommendations of the advisory committee on immunization practices. *MMWR*. 2019;68(32): 698-702.
7. Best SR, Bock JM, Fowler NB, et al. A consensus statement on the administration of systemic bevacizumab in patients with recurrent respiratory papillomatosis. *Laryngoscope*. 2024;134:5041-5046.
8. Kohli N, Pai SI, Buckingham J, et al. A clinical consensus statement on pulmonary recurrent respiratory papillomatosis. *Laryngoscope*. 2025 Aug 1. [Online ahead of print].