MVP Health Care Medical Policy

Medicare Part B: Zopapogene Imadenovex (Papzimeos)

Type of Policy: Medical Drug therapy (administered by the pharmacy department)
Prior Approval Date: N/A
Approval Date: 06/01/2026
Effective Date: 06/01/2026
Related Policies: CAR-T Cell Therapy, Amtagvi

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Drugs Requiring Prior Authorization under the medical benefit

J3404 Papzimeos (injection, zopapogene imadenovec-drba suspension, per therapeutic dose)

Overview

Recurrent respiratory papillomatosis (RRP) is a rare, benign neoplastic disease caused by chronic infection with human papillomavirus (HPV) types 6 or 11. It is characterized by recurrent growth of papillomas throughout the aerodigestive tract, predominantly in the larynx, trachea, and occasionally the lungs.

Zopapogene imadenovec (Papzimeos) is a nonreplicating adenoviral vector-based immunotherapy indicated for the treatment of individuals with recurrent respiratory papillomatosis (RRP). It is the first FDA-approved immunotherapy for adult RRP and is a novel therapeutic approach targeting the underlying HPV infection rather than just removing papillomas surgically. It works by expressing a fusion antigen derived from selected regions of human papillomavirus (HPV) types 6 and 11 proteins, thereby generating an immune response targeted against HPV 6 and 11 infected cells.

Indications/Criteria

A. Recurrent Respiratory Papillomatosis (RRP)

Papzimeos may be considered for coverage when all the following is provided:

- Chart notes are provided confirming a diagnosis of recurrent respiratory papillomatosis (RRP)
- Papzimeos is prescribed by or in consultation with an appropriate specialist (e.g. otolaryngologist, laryngologist, oncologist, pulmonologist).
- Confirmation that the member has not received a previous treatment course of Papzimeos
- Provider attestation that surgical debulking of visible papilloma is performed prior to the initial, third and fourth dose of Papzimeos.

Papzimeos will be for one (1) treatment course within a 6-month period. One treatment course is 4 doses over a 12-week interval.
Requests for extensions beyond one (1) completed treatment course are excluded from coverage.

Exclusions

The use of Papzimeos will not be covered in the following situations:

- More than one (1) treatment course (4 doses within a 12-week interval) per lifetime.
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

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References

1. Zopapogene Imadenovec (Papzimeos). Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier; 2017 [cited 2026 Mar 27]. Available from: www.clinicalpharmacology.com. Subscription required to view.

2. Papzimeos [package insert]. Germantown, MD: Precigen, Inc. Aug 2025. PAPZIMEOS United States Prescribing Information V1.0 Approved

3. Norberg SM, Valdez J, Napier S, Kenyon M, Ferraro E, Wheatley M, Parsons-Wandell L, Doran SL, Lankford A, Sabzevari H, Brough DE, Schlom J, Gulley JL, Allen CT. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. Lancet Respir Med. 2025 Apr;13(4):318-326. doi: 10.1016/S2213-2600(24)00368-0. Epub 2025 Jan 21. Erratum in: Lancet Respir Med. 2025 Apr;13(4):e22. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial - PubMed