zopapogene imadenovec-drba (Papzimeos)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion
Hospital Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: non-replicating adenoviral vector-based immunotherapy
HCPCS:
C9399, J3490, J3590: zopapogene imadenovec-drba (Papzimeos):
How Supplied:

- 84768-511-99 (5×10^11 PU in single-dose vial)
- 84768-511-01: Carton that contains a pouch that holds the single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Recurrent Respiratory Papillomatosis (RRP)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Recurrent Respiratory Papillomatosis (RRP)
Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (18 years of age and older)
2. Patient has recurrent disease caused by human papillomavirus (HPV) serotype 6 or 11
3. Histological confirmation of RRP
4. Patient will undergo a debulking (surgical) procedure prior to receipt of the first dose

Covered Doses:
5×10^11 particle units (PU) given subcutaneously on Day 1, Week 2, Week 6, and Week 12

Coverage Period:
12-week treatment course; one time treatment course

ICD-10:
D10.5, D10.6, D10.9, D14.0, D14.1, D14.2, D14.3, D14.30, D14.31, D14.32, D14.4, D36.9, J38.7, J39.2

References

1. Papzimeos (zopapogene imadenovec-drba) Prescribing Information. Precigen, Inc., Germantown, MD: 8/2025.

Review History

Date of Last Annual Review: 12/01/2025
Changes from previous policy version:

- New policy

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee