blue california
Promise Health Plan

zopapogene imadenovec-drba (Papzimeos)

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:
J3404:Injection, zopapogene imadenovec-drba suspension, per therapeutic dose
How Supplied:
5×10^11 PU in 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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

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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: 4Q2025
Changes from previous policy version:

- HCPCS: Added J3404, effective 4/1/26

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