Papzimeos™ (zopapogene imadenovec-drba) (Subcutaneous)

Document Number: M-0807

Last Review Date: 01/06/2026
Date of Origin: 10/02/2024
Dates Reviewed: 10/2025, 01/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided for 6-months (180-days) for four doses total.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 dose ($5x10^{11}$ particle units (PU) per dose) on day 1, day 12, week 6, and week 12

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

Respiratory Papillomatosis † Φ [1-3]

Member must try and have an inadequate response, contraindication, or intolerance to bevacizumab or cidofovir; **AND**

- Member is at least 18 years of age; **AND**
- Member has a confirmed histological diagnosis of recurrent respiratory papillomatosis; **AND**
- Member has documented human papillomavirus (HPV) serotype 6 or 11; **AND**
- Surgical debulking of any present visible papilloma will be performed prior to the initial, third and fourth injections; **AND**

- Member has the presence of laryngotracheal papillomas; **AND**
- Member has required 3 or more surgical interventions in the last 12 months for control of respiratory papillomatosis

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded (*refer to Section I*)

V. Dosage/Administration [1]

Indication	Dose
Respiratory Papillomatosis	The recommended dose of Papzimeos is $5x10^{11}$ particle units (PU) per injection administered as subcutaneous injections four times over a 12-week interval. • *Initial dose: Day 1* • *Second dose: 2 weeks after initial administration but no less than 11 days after initial administration.* • *Third dose: 6 weeks after initial administration.* • *Fourth dose: 12 weeks after initial administration.*
– *Papzimeos is a non-replicating adenoviral vector-based immunotherapy. Follow universal biosafety precautions for handling.* – *Papzimeos is provided as a single-dose vial of sterile frozen suspension which must be rapidly thawed before use and prepared for immediate administration. Once thawed, do not place the vial in a refrigerator, freezer, or on dry ice.* – *Protect Papzimeos from light. Do not shake the vial.*	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals *(hospital outpatient use only)*

NDC:

- Papzimeos single-dose vial of sterile frozen suspension, formulated to contain an extractable dose of $5×10^{11}$ PU in a 1 mL suspension: 84768-0511-xx

VII. References

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

2. ClinicalTrials.gov. NCT04724980. A Phase 1/2 Study of Adjuvant PRGN-2012 in Adult Patients with Recurrent Respiratory Papillomatosis. | ClinicalTrials.gov.
3. Norberg S, Gulley JL, Schlom J, et al. PRGN-2012, a novel gorilla adenovirus-based immunotherapy, provides the first treatment that leads to complete and durable responses in recurrent respiratory papillomatosis patients. JCO 42, LBA6015-LBA6015(2024). DOI:10.1200/JCO.2024.42.17_suppl.LBA6015

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D10.5	Benign neoplasm of other parts of oropharynx
D10.6	Benign neoplasm of nasopharynx
D10.9	Benign neoplasm of pharynx, unspecified
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses
D14.1	Benign neoplasm of larynx
D14.2	Benign neoplasm of trachea
D14.30	Benign neoplasm of unspecified bronchus and lung
D14.31	Benign neoplasm of right bronchus and lung
D14.32	Benign neoplasm of left bronchus and lung
D14.4	Benign neoplasm of respiratory system, unspecified

ICD-10	ICD-10 Description
D36.9	Benign neoplasm, unspecified site
J38.7	Other diseases of larynx
J39.2	Other diseases of pharynx

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC