Neighborhood Health Plan OF RHODE ISLAND™
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Papzimeos (zopapogene imadenovec-drba) (Subcutaneous)

Effective Date: 02/01/2026
Review Date: 11/10/2025
Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for 6 months for four doses total and 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, week 2, week 6, and week 12 [max of one treatment cycle per lifetime]

III. Summary of Evidence:

Papzimeos is a non-replicating adenoviral vector-based immunotherapy approved for the treatment of adult patients with recurrent respiratory papillomatosis (RRP). Papzimeos was approved based on results from the PRGN-2012-201 trial, a Phase 1/2, single-arm, open-label study with 35 adults with RRP who required at least three debulking procedures in the last 12 months. Patients received four subcutaneous injections over a 12-week period following a debulking procedure. The primary endpoint was complete response, defined as remaining surgery-free for at least 12 months post-treatment. In the trial, 51% of participants (18 out of 35) achieved a complete response (95% CI: 34% to 69%). Injection site reactions, fatigue, chills, and fever were the most common adverse reactions (incidence >60%), while nausea and headache had an incidence of 26% and 11%, respectively.

IV. Initial Approval Criteria

Recurrent respiratory papillomatosis (RRP)† Φ

- Member is at least 18 years of age; AND
- Documentation that member has diagnosis of recurrent respiratory papillomatosis (RRP) that is histologically confirmed by CLIA-certified (or comparable) laboratory report; AND
- Documentation that member has HPV serotype 6 or 11; AND
- Member has presence of laryngotracheal papillomas; AND
- The member has required at least 3 interventions (e.g., surgery, systemic therapy [i.e., bevacizumab, cidofovir], etc.) for control of respiratory papilloma in the previous 12 months; AND
- Surgical debulking of any present visible papilloma will be performed prior to the initial, third and fourth Papzimeos injections; AND
- Documentation that member has received the HPV vaccination series when 9-45 years of age, or rationale if not appropriate.

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

V. Renewal Criteria

Coverage cannot be renewed.

VI. Dosage/Administration

Indication	Dose
Recurrent respiratory papillomatosis (RRP)	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. Additional Notes: • 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.

VII. Billing Code/Availability information

HCPCS Code:

- 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

VIII. References

1. Papzimeos [package insert]. Germantown, MD; Precigen, Inc; August 2025. Accessed October 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 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
D36.9	Benign neoplasm, unspecified site
J38.7	Other diseases of larynx
J39.2	Other diseases of pharynx
D10.5	Benign neoplasm of other parts of oropharynx

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

Policy Rationale:

Papzimeos was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Papzimeos according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual

consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.