Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Papzimeos

Professional / Institutional
Original Effective Date: December 26, 2025
Latest Review Date: April 1, 2026
Current Effective Date: February 24, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

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.*	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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 is at least 18 years of age; **AND**
- Member has a confirmed histological diagnosis of recurrent respiratory papillomatosis; **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 interventions (e.g., surgery, systemic therapy, etc.) 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*)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS Code(s):

- J3404 – Injection, zopapogene imadenovec-drba suspension, per therapeutic dose
- 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

REVISIONS	
Posted: 11-26-2025 Effective: 12-26-2025	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.
02-24-2026	Policy updates: ▪ Editorial changes made to Initial Approval Criteria
	Policy maintained by Prime Therapeutics LLC.
04-01-2026	Updated Coding Section ▪ Removed J3590 ▪ Added J3404 (Eff. 04-01-2026)

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