AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Papzimeos™ (zopapogene imadenovec-drba) **(J3404) MEDICAL**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- Each single-dose vial delivers a minimum extractable volume of 1 mL
- 1 dose ($5x10^{11}$ particle units (PU)) on day 1, and then at week 2, week 6, and week 12

B. Max Units (per dose and over time):

- 4 doses (4 vials) per lifetime

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Length of Authorization: 6 months (180-days) for four doses total.

- ❑ Member is at least 18 years of age
- ❑ Requesting provider is a specialist in otolaryngology, oncology, and/or knowledgeable in disease management of respiratory papillomas
- ❑ Member has a confirmed diagnosis of recurrent respiratory papilloma (RRP) meeting **ALL** the following **(submit documentation)**:
  - ❑ Submission of medical chart history and documentation of the presence of laryngotracheal papillomas
  - ❑ Histological confirmation that papillomas are caused by human papillomavirus (HPV) serotype 6 or 11
  - ❑ Member has required 3 or more interventions (e.g., surgery, systemic therapy, etc.) in the last 12 months for control of respiratory papilloma **(NOTE: procedure record must be accompanied with request)**
- ❑ Requesting provider attests to plans for surgical debulking of any present visible papilloma performed prior to the initial, third and fourth injections in accordance with present guidelines and product labeling

Reauthorization: Prior authorization may NOT be renewed.

❑ **Medication being provided by (check applicable box(es) below):**

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee: 11/20/2025**
REVISED/UPDATED/REFORMATTED: ~~12/12/2025;~~ **4/16/2026**