PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Papzimeos (imadenovec-drba)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Papzimeos, approved by the FDA in 2025, is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of adults with recurrent respiratory papillomatosis (RRP). It mounts an immune response directed at both HPV 6 and HPV 11 proteins.
Respiratory papillomatosis is caused by chronic human papillomavirus (HPV) infection leading to benign tumors in the respiratory tract. HPV 6 and HPV 11 are the most common subtypes. In rare cases, the lesions can spread to the lungs causing pulmonary RRP. Treatment consists of repeat surgical procedures.

Papzimeos (imadenovec-drba) will be considered for coverage when the following criteria are met:

Recurrent Respiratory Papillomatosis (RRP)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an otolaryngologist or pulmonologist; AND
3. Member has a diagnosis of RRP confirmed by the presence of laryngotracheal papillomas; AND
4. Member has documentation of HPV serotype of 6 or 11; AND
5. Member has had 3 or more surgeries to remove laryngotracheal papillomas in the previous 12 months; AND
6. Provider attests that surgical debulking of visible papilloma will occur prior to starting therapy and if present, prior to the third and fourth dose.
7. **Dosage allowed/Quantity limit:** administer 5×10^{11} particle units (PU) per injection administered by subcutaneous injection four times over a 12-week interval per package insert. Quantity limit: 4 injections per 12 weeks

If all the above requirements are met, the medication will be approved for 12 weeks.

For **reauthorization**:
1. Papzimeos will not be reauthorized.

CareSource considers Papzimeos (imadenovec-drba) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/29/2025	New policy for Papzimeos created.

References:

1. Papzimeos [prescribing information]. Precigen, Inc.; 2025.

2. Balai E, Dronkers EA, Yaghchi CA, Gujral D, Sandhu G, Iacovidou A. Adjuvant treatments for recurrent respiratory papillomatosis: a descriptive review and proposed management guideline in adults. *J Laryngol Otol.* 2024;138(12):1133-1143. doi:10.1017/S0022215124001026
3. Norberg SM, Valdez J, Napier S, et al. PRGN-2012 gene therapy in adults with recurrent respiratory papillomatosis: a pivotal phase 1/2 clinical trial. *Lancet Respir Med.* 2025;13(4):318-326. doi:10.1016/S2213-2600(24)00368-0

Effective date: 04/01/2026
Revised date: 09/29/2025