Reference number(s)
7156-A

Standard Medicare Part B Management Papzimeos

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Papzimeos	zopapogene imadenovec-drba

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Papzimeos is indicated for the treatment of adults with recurrent respiratory papillomatosis.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- Chart notes, medical record documentation, or laboratory results of all of the following:
  - Presence of laryngotracheal papillomas
  - Histological diagnosis of papilloma confirmed by pathology report

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- Member has documented human papillomavirus (HPV) serotype 6 or 11

Coverage Criteria

Recurrent Respiratory Papillomatosis (RRP)[1-3]

Authorization of 16 weeks (for a one-time treatment course of 12 weeks [4 doses]) may be granted for treatment of recurrent respiratory papillomatosis (RRP) in adult members when all of the following criteria are met:

- Member has a clinical diagnosis of recurrent respiratory papillomatosis defined by all of the following:
  - Presence of laryngotracheal papillomas
  - Histological diagnosis of papilloma confirmed by pathology report
  - Member has documented HPV serotype 6 or 11
- Member has had 3 or more debulking procedures to remove laryngotracheal papillomas in the 12 months prior to treatment with Papzimeos.
- Prescriber attests to both of the following criteria:
  - Surgical debulking of visible papilloma will be performed prior to initial administration to establish minimal residual disease
  - If present, visible papillomas will be removed to maintain minimal residual disease prior to the third and fourth administration of Papzimeos
- Member has not received more than 4 doses (one-treatment course) of Papzimeos.
- Papzimeos will not be used in combination with other medications used for the treatment of RRP (e.g., bevacizumab, cidofovir).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Papzimeos.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs

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    - Clinical Pharmacology
- National Institute on Deafness and Other Communication Disorders – Recurrent Respiratory Papillomatosis or Laryngeal Papillomatosis
- National Organization for Rare Disorders – Recurrent Respiratory Papillomatosis

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Papzimeos are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

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

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