Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Papzimeos® (zopapogene imadenovec-drba)

Effective: April 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Recurrent respiratory papillomatosis (RRP) is a rare disease caused by chronic human papillomavirus (HPV) infection, leading to the growth of benign tumors in the respiratory tract, most commonly in the larynx, and is typically managed with repeat surgical procedures.

The approval of Papzimeos was supported by data from a Phase 1/2 open-label, single-arm study that included adult patients with RRP who required three or more debulking surgeries in the 12 months prior to treatment. Eighteen out of 35 patients (51%) in the efficacy population achieved a complete response (CR), defined as requiring no surgical intervention in the 12 months after treatment. Among the patients who achieved a CR, 15 maintained a CR at 24 months, for an overall CR rate of 43% at 24 months.

Food and Drug Administration - Approved Indications

Papzimeos (zopapogene imadenovec-drba) is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of adults with recurrent respiratory papillomatosis.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of **Papzimeos** for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of recurrent respiratory papillomatosis confirmed by tissue biopsy

AND

2. Documented HPV serotype 6 or 11

AND

3. Patient has presence of laryngotracheal papillomas

AND

4. Documentation that patient has undergone at least three clinically indicated interventions (defined as surgical resection of disease or laser ablation aimed at reducing voice and airway symptoms caused by the papilloma) in the past 12 months

AND

5. Papzimeos will be used as monotherapy

AND

6. Prescribed by, or in consultation with, a pulmonologist, oncologist, or otolaryngologist

Limitations

- Authorization of Papzimeos will be limited to one course of treatment (4 doses) per lifetime. Any members (including members new to the plan) who has previously completed 4 doses of Papzimeos will not be approved for a repeat course of treatment. There is no clinical evidence to support treatment with Papzimeos beyond 4 doses.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose

References

1. Papzimeos (zopapogene imadenovec-drba) [prescribing information]. Germantown, MD: Precigen Inc; August 2025.

Approval And Revision History

March 10th, 2026: Reviewed by Pharmacy and Therapeutics Committee (P&T) effective 4/1/26

Subsequent endorsement date(s) and changes made:

- March 2026: Joint Medical Policy and Health Care Services UM Committee review

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.