Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Papzimeos (zopapogene imadenovec-drba)

Effective: May 1, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together- MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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

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 patients 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 is 18 years of age or older

AND

4. Patient has presence of laryngotracheal papillomas

AND

5. Documentation that patient has undergone at least three surgical debulking of laryngotracheal papillomas in the previous 12 months

AND

6. Papzimeos will be used as monotherapy

AND

7. Prescribed by, or in consultation with a pulmonologist, oncologist, thoracic surgeon or otolaryngologist

Limitations

- Authorization of Papzimeos will be limited to one 12-week course of treatment (4 doses) per lifetime. Any members (including members new to the plan) who have 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

February 10, 2026: Reviewed by the Pharmacy & Therapeutics Committee. Medical Necessity Guideline effective April 1, 2026.

Subsequent endorsement date(s) and changes made:

- April 14, 2026: Clarified that Papzimeos approval duration is limited to one 12-week course of treatment (4 doses) per lifetime.
- April 2026: Administrative update: Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans”.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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