



PROVIDER POLICIES & PROCEDURES

PAPZIMEOS™ (zopapogene imadenovec-drba)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for PAPZIMEOS (zopapogene imadenovec-drba). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Recurrent respiratory papillomatosis (RRP) is a rare neoplastic disorder caused by chronic infection with human papilloma virus (HPV) types 6 or 11. RRP is characterized by recurrent papillomatous growths in the aerodigestive tract — predominantly the larynx, trachea, and occasionally the lungs which can lead to significant voice disturbance and airway obstruction. Historically, management for RRP has consisted of repeated laser ablation and surgical excision of papillomas to alleviate symptoms, however this is not typically a permanent solution. PAPZIMEOS is designed to target the root cause by generating an immune response to HPV 6 and 11 proteins in patients with RRP.

PAPZIMEOS is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of recurrent respiratory papillomatosis in adults.

CLINICAL GUIDELINE

Coverage guidelines for the use of Papzimeos will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage guidelines are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Initial Requests

A full course of treatment (four doses over the course of 12 weeks) with Papzimeos (zopapogene imadenovec-drba) may be considered medically necessary for adult patients with recurrent respiratory papillomatosis when ALL of the following criteria are met:

- A. The individual is 18 years of age or older; **AND**
- B. The individual has a clinical diagnosis of RRP defined by BOTH the following:
 - a. Histological diagnosis of papilloma confirmed by pathology report; **AND**
 - b. Documented human papillomavirus (HPV) serotype 6 or 11; **AND**
- C. This medication is prescribed by or in consultation with a provider who specializes in the treatment of RRP (e.g., otolaryngologist, pulmonologist, oncologist); **AND**
- D. The individual has a history of 3 or more surgical debulking procedures in the last 12 months for control of RRP; **AND**
- E. The individual has not previously received Papzimeos; **AND**
- F. The treating provider will follow all FDA-approved labeling for dosing, administration, and additional monitoring for Papzimeos including surgical debulking guidelines before and during treatment.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the Benefit Grid summaries on www.ct.gov/husky by clicking on *For Providers* followed by *Benefit Grids* under the *Medical Management* sub-menu. For a definitive list of benefits and service limitations, CMAP providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

Reauthorization Requests

N/A

Investigational and Not Medically Necessary

Papzimeos for all other indications is considered investigational and not medically necessary as there is insufficient evidence in the peer reviewed medical literature to support its clinical efficacy and safety.

Repeat treatment with Papzimeos has not been clinically evaluated and is considered investigational and not medically necessary.

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of Papzimeos is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for Papzimeos:

1. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Papzimeos Prior Authorization Request form (to include physician's order and signature);
2. Clinical documentation supporting the medical necessity of treatment with Papzimeos should include the following:
 - a. Medical record documentation confirming:
 - i. Clinical diagnosis of RRP; **AND**
 - b. Signed provider attestation confirming the following:
 - i. The individual has a history of 3 or more surgical debulking procedures in the last 12 months for control of RRP; **AND**
 - ii. The individual has not previously received Papzimeos; **AND**
 - iii. The treating provider will follow all FDA-approved labeling for dosing, administration, and additional monitoring for Papzimeos including surgical debulking guidelines before and during treatment; **AND**
3. Other information as requested.

Initial Authorization

If the above criteria are met, authorization will be given for one course of treatment (four doses). Authorization will be valid for six months.

Reauthorization

N/A

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EFFECTIVE DATE

This Policy for the prior authorization of Papzimeos for individuals covered under the HUSKY Health Program is effective November 1, 2026.

LIMITATIONS

Not Applicable

CODE:

Code	Definition
J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose

DEFINITIONS

1. **Current Procedural Terminology (CPT):** The most recent edition of a listing, published by the American Medical Association, of descriptive terms and identifying codes for reporting medical services performed by providers.
2. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
3. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
4. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
5. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
6. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
7. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
8. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

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9. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- Adjuvant PRGN-2012 in Adult Patients With Recurrent Respiratory Papillomatosis. ClinicalTrials.gov identifier: NCT04724980. Updated June 11, 2025. <https://clinicaltrials.gov/study/NCT04724980>
- Best SR, Friedman AD, Rosen CA, et al. Recurrent Respiratory Papillomatosis Foundation Position Statement on the Management of Adults With RRP. *Laryngoscope*. Published online January 16, 2026. doi:10.1002/lary.70379
- 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
- Papzimeos [package insert]. Germantown, MD; Precigen, Inc.; Revised August 2025.
- Shepherd W, Radchenko C. Presentation and diagnostic evaluation of non-life-threatening and nonmalignant subglottic and tracheal stenosis in adults. In: UpToDate, Feller-Kopman DJ, Muller NL, Finlay G (Eds.). Wolters Kluwer. Updated October 6, 2025.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	June 2026	Approved at the June 24, 2026 CHNCT Medical Reviewer Meeting. Approved by the CHNCT Clinical Quality Subcommittee on September 21, 2026. Approved by DSS on October 9, 2026.

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