TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Zopapogene imadenovec-drba (Papzimeos®)	**CRITERIA ID:** TX.CC.PHAR.55
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 4/14/2026	**PRODUCT(S):** STAR, STAR+PLUS, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for zopapogene imadenovec-drba (Papzimeos®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:

It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of zopapogene imadenovec-drba (Papzimeos®); procedure code: J3404.

Description/Mechanism of Action:
Zopapogene imadenovec (Papzimeos) is a nonreplicating adenoviral vector-based immunotherapy indicated for the treatment of individuals with recurrent respiratory papillomatosis (RRP). It works by expressing a fusion antigen derived from selected regions of human papillomavirus (HPV) types 6 and 11 proteins, thereby generating an immune response targeted against HPV 6 and 11 infected cells.

FDA Approved Indications:
PAPZIMEOS™ is a non-replicating adenoviral vector-based immunotherapy indicated for the treatment of adults with recurrent respiratory papillomatosis.

Formulations:
PAPZIMEOS is supplied in a single-dose vial that contains 5×1011 PU in an extractable volume of 1 mL of suspension.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Approval Criteria

A. Respiratory papillomatosis (must meet all):

1. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
2. Client is 18 years of age or older.
3. Client has a confirmed diagnosis of recurrent respiratory papillomatosis (diagnosis code: D14.1).
4. Client has documented human papillomavirus (HPV) serotype 6 or 11.
5. Prescriber attests to perform a surgical debulking of visible papilloma prior to the initiation of Papzimeos treatment (Day 1) to establish minimal residual disease.
6. Prescriber attests to remove visible papilloma prior to the third and fourth Papzimeos administration to maintain minimal residual disease during treatment.
7. Prescriber attests to monitor for signs and symptoms of thrombotic events (e.g., shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms, including severe or persistent headaches or blurred vision).

Approval duration: 6 months (total of four doses per lifetime)

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		04/14/2026

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