TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Nadofaragene firadenovec-vncg (Adstiladrin®)	**CRITERIA ID:** TX.CC.PHAR.31
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 01/01/2024	**PRODUCT(S):** STAR, STAR Plus, STAR Kids, STAR Health, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 4/3/2024, 3/25/2025	
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 nadofaragene firadenovec-vncg (Adstiladrin®).

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.

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

DEFINITIONS:
BCG = Bacillus Calmette-Guérin
NMIBC = non-muscle invasive bladder cancer
CIS = carcinoma in situ

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of nadofaragene firadenovec-vncg (Adstiladrin®); procedure code: J9029.

Description/Mechanism of Action:

Nadofaragene firadenovec-vncg (Adstiladrin®) is a non-replicating adenoviral vector-based gene therapy designed to deliver a copy of a gene encoding a human interferon-alfa (IFN-alfa) 2b to the bladder urothelium. Intravesical instillation results in cell transduction and transient local expression of the IFN-alfa 2b protein that is anticipated to have anti-tumor effects.

FDA Approved Indications:
Nadofaragene firadenovec-vncg (Adstiladrin®) is an adenoviral vector-based gene therapy indicated to treat adult clients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

PROCEDURE:

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

I. Initial Approval Criteria

A. Bladder Cancer (must meet all):

1. The client is 18 years of age or older.
2. The client has a confirmed diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
3. The client's disease is high-risk and BCG-unresponsive, defined as (a, b, or c):
    a. Persistent disease following adequate BCG therapy;
    b. Disease recurrence after an initial tumor-free state following adequate BCG therapy;
    c. T1 disease following a single induction course of BCG.
4. The client does not have any have metastatic urothelial carcinoma.
5. The client does not have a hypersensitivity to interferon alfa.
6. The client is not immunocompromised or immunodeficient.

Approval duration: 6 months

II. Continued Therapy (must meet all):

B. Bladder Cancer (must meet all):

1. The client continues to meet all initial criteria requirements and has been treated with no adverse reactions.
2. The client has no signs of unacceptable toxicity (e.g. risk of disseminated adenovirus) from Adstiladrin therapy.

Approval duration: 6 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook
Adstiladrin Prescribing Information. Kuopio, Finland: Ferring Pharmaceuticals; December 2022. Available at: https://www.ferringusa.com/wp-content/uploads/sites/12/2022/12/ADSTILADRIN_pi.pdf

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	01/01/2024
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement	4/3/2024
Annual review	No changes	3/25/2025