

Medical Policy:

Adstiladrin® (nadofaragene firadenovec-vncg) intravesical suspension

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.392	February 9, 2025	August 10, 2023

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Adstiladrin is indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. Adstiladrin is a non-replicating adenoviral vector-based gene therapy designed to deliver a copy of a gene encoding a human interferon-alfa 2b (IFNα2b) to the bladder urothelium. Intravesical instillation of Adstiladrin results in cell transduction and transient local expression of the IFNα2b protein that is anticipated to have anti-tumor effects.

Length of Authorization

Coverage will be provided for 12 months

Dosing Limits [Medical Benefit]

The dose is 75 mL of Adstiladrin at a concentration of 3×10^{11} viral particles (vp)/mL, instilled once every 3 months.

Guideline

I. INITIAL APPROVAL CRITERIA

1. **Non-Muscle Invasive Bladder Cancer.** Approve if the patient meets the following criteria (A, B, C, D, **AND E**):
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease; **AND**
 - C. Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); **AND**
 - D. Patient does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma **AND**
 - E. Medication is prescribed by or in consultation with a urologist or an oncologist.

Dosing. Approve 75 mL of Adstiladrin instilled into the bladder with a urinary catheter once every 3 months.

Limitations:

1. Patient does not have a hypersensitivity to interferon alfa; **AND**
2. Patient is not immunosuppressed or immunodeficient; **AND**
3. Therapy will be used for intravesical instillation only; **AND**
4. Used as a single agent

II. RENEWAL CRITERIA

1. Patient continues to meet INITIAL approval criteria **AND**
2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Absence of unacceptable toxicity from the drug **AND**
 - a. First Renewal: Patient has a complete response (CR) to initial therapy (after 3 months) defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; OR
 - b. Subsequent Renewals: Patient has not experienced a high-grade or CIS recurrence

Applicable Procedure Codes

Code	Description
J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose

Applicable NDCs

Code	Description
55566-1050-01	Adstiladrin suspension

ICD-10 Diagnoses

Code	Description
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder

C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder

Revision History

Company(ies)	DATE	REVISION																														
EmblemHealth & ConnectiCare	2/9/2025	<p>Removed from initial criteria Patient meets ONE of the following (i OR ii): i. Patient has carcinoma <i>in situ</i> (CIS) with or without high-grade papillary Ta/T1 tumors; OR ii. Patient has high-grade papillary Ta/T1 tumors without CIS; AND Medication is used for ONE of the following (i OR ii): Initial treatment; OR Cytology- and bladder-biopsy positive, imaging- and cystoscopy-negative, recurrent, or persistent disease. Addition of A. Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); AND B.Patient does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma</p> <p>Addition of Limitations: Patient does not have a hypersensitivity to interferon alfa; AND Patient is not immunosuppressed or immunodeficient; AND Therapy will be used for intravesical instillation only; AND Used as a single agent</p> <p>Addition of:</p> <table border="1"> <tr> <td>C67.0</td> <td>Malignant neoplasm of trigone of bladder</td> </tr> <tr> <td>C67.1</td> <td>Malignant neoplasm of dome of bladder</td> </tr> <tr> <td>C67.2</td> <td>Malignant neoplasm of lateral wall of bladder</td> </tr> <tr> <td>C67.3</td> <td>Malignant neoplasm of anterior wall of bladder</td> </tr> <tr> <td>C67.4</td> <td>Malignant neoplasm of posterior wall of bladder</td> </tr> <tr> <td>C67.5</td> <td>Malignant neoplasm of bladder neck</td> </tr> <tr> <td>C67.6</td> <td>Malignant neoplasm of ureteric orifice</td> </tr> <tr> <td>C67.7</td> <td>Malignant neoplasm of urachus</td> </tr> <tr> <td>C67.8</td> <td>Malignant neoplasm of overlapping sites of bladder</td> </tr> <tr> <td>C67.9</td> <td>Malignant neoplasm of bladder, unspecified</td> </tr> <tr> <td>D09.0</td> <td>Carcinoma in situ of bladder</td> </tr> <tr> <td>Z85.51</td> <td>Personal history of malignant neoplasm of bladder</td> </tr> </table> <p>Removal of:</p> <table border="1"> <tr> <td>C65.1</td> <td>Malignant neoplasm of right renal pelvis</td> </tr> <tr> <td>C65.2</td> <td>Malignant neoplasm of left renal pelvis</td> </tr> <tr> <td>C65.9</td> <td>Malignant neoplasm of unspecified renal pelvis</td> </tr> </table>	C67.0	Malignant neoplasm of trigone of bladder	C67.1	Malignant neoplasm of dome of bladder	C67.2	Malignant neoplasm of lateral wall of bladder	C67.3	Malignant neoplasm of anterior wall of bladder	C67.4	Malignant neoplasm of posterior wall of bladder	C67.5	Malignant neoplasm of bladder neck	C67.6	Malignant neoplasm of ureteric orifice	C67.7	Malignant neoplasm of urachus	C67.8	Malignant neoplasm of overlapping sites of bladder	C67.9	Malignant neoplasm of bladder, unspecified	D09.0	Carcinoma in situ of bladder	Z85.51	Personal history of malignant neoplasm of bladder	C65.1	Malignant neoplasm of right renal pelvis	C65.2	Malignant neoplasm of left renal pelvis	C65.9	Malignant neoplasm of unspecified renal pelvis
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EmblemHealth & ConnectiCare	4/29/2024	Annual Review: no changes																														
EmblemHealth & ConnectiCare	08/10/2023	New Policy																														

References

1. Adstiladrin® intravesical suspension [prescribing information]. Kastrup, Denmark: Ferring; December 2022.