Medical Policy:

Adstiladrin® (nadofaragene firadenovec-vncg) intravesical suspension

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

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

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

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 meets ONE of the following (i **OR** ii):
      i. Patient has carcinoma *in situ* (CIS) with or without high-grade papillary Ta/T1 tumors; **OR**
      ii. Patient has high-grade papillary Ta/T1 tumors without CIS; **AND**
   D. Medication is used for ONE of the following (i **OR** ii):
      i. Initial treatment; **OR**
      ii. Cytology- and bladder-biopsy positive, imaging- and cystoscopy-negative, recurrent, or persistent disease; **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.

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
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	08/10/2023	New Policy

References

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