ANNOUNCING

ADSTILADRIN®
(nadofaragene firadenovec-vncg)
suspension, for intravesical use / 3 x 10^{11} viral particles/mL

ADSTILADRIN established an Average Sales Price (ASP)

Great news! As of April 1, 2024, ADSTILADRIN established an ASP. Per Centers for Medicare and Medicaid Services (CMS), the allowable amount of reimbursement for products under Part-B is ASP + 6%.

ASP	Medicare Reimbursement	Billing Unit
ASP information can be found within the CMS ASP Pricing File.[1]	**Allowable amount of reimbursement for products under Part-B is ASP + 6%.**	**1 therapeutic dose** (4 single-dose vials, 20 mL per single-dose vial, 80 mL total)

Coding for ADSTILADRIN

HCPCS code[2]	Description
J9029	Instillation, nadofaragene firadenovec-vncg, per therapeutic dose

ICD-10-CM codes[3]	Description
C67.0–C67.9	Malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder

CPT code[4]	Description
51720	Bladder instillation of anticarcinogenic agent

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*.

References: 1. Centers for Medicare & Medicaid Services. ASP Pricing Files. Accessed April 1, 2024. https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files **2.** Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations Fourth Quarter, 2023 HCPCS Coding Cycle. Accessed March 13, 2024. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-4-2023-drugs-and-biologicals-posted-01/26/2024-updated-03/04.pdf **3.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM: 2024 code tables and index. ICD-10-CM tabular list of diseases and injuries. Accessed March 13, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **4.** Institute for Clinical and Economic Review. Nadofaragene firadenovec and oportuzumab monatox for BCG-unresponsive, non-muscle invasive bladder cancer: effectiveness and value. Accessed January 4, 2024. https://icer.org/wp-content/uploads/2020/08/ICER_Bladder-Cancer_Final-Report_053122.pdf

Please see Important Safety Information on page 2 and click here for full Prescribing Information.

FERRING PHARMACEUTICALS

Indication and Important Safety Information

INDICATION

ADSTILADRIN is a non-replicating adenoviral vector-based gene therapy 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: ADSTILADRIN is contraindicated in patients with prior hypersensitivity reactions to interferon alfa or to any component of the product.

WARNINGS AND PRECAUTIONS

- ***Risk with delayed cystectomy:*** Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after 3 months or if CIS recurs, consider cystectomy.

- ***Risk of disseminated adenovirus infection:*** Persons who are immunocompromised or immunodeficient may be at risk for disseminated infection from ADSTILADRIN due to low levels of replication-competent adenovirus. Avoid ADSTILADRIN exposure to immunocompromised or immunodeficient individuals.

DOSAGE AND ADMINISTRATION: Administer ADSTILADRIN by intravesical instillation only. ADSTILADRIN is not for intravenous use, topical use, or oral administration.

USE IN SPECIFIC POPULATIONS: Advise females of reproductive potential to use effective contraception during ADSTILADRIN treatment and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during ADSTILADRIN treatment and for 3 months after the last dose.

ADVERSE REACTIONS: The most common (>10%) adverse reactions, including laboratory abnormalities (>15%), were glucose increased, instillation site discharge, triglycerides increased, fatigue, bladder spasm, micturition (urination urgency), creatinine increased, hematuria (blood in urine), phosphate decreased, chills, pyrexia (fever), and dysuria (painful urination).

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact Ferring Pharmaceuticals at 1-888-FERRING.

Please click here for full Prescribing Information.

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