# A Step-by-Step Guide

# **How to Order**

The FIRST and ONLY FDA-approved intravesical non-replicating gene therapy for high-risk NMIBC



LOCALLY. QUARTERLY. CONFIDENTLY.

**INDICATION:** ADSTILADRIN® (nadofaragene firadenovec-vncg) 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.

Please see Important Safety Information on page 4 and full Prescribing Information at adstiladrinHCP.com.

# Ferring Pharmaceuticals Is Committed to Ensuring a Seamless ADSTILADRIN Ordering Experience

#### **STEP**

## Patient identification and submission of Patient Enrollment Form



- **Submit a completed Patient Enrollment Form:** Once a patient has been identified, submit the form by fax to 1-888-322-5233 or online via <a href="ferringaccesssupport.com">ferringaccesssupport.com</a>. You will receive a notification via email that your form has been successfully submitted
- Ferring Access Support will conduct a benefits investigation.\* Upon completion, Ferring Access Support will contact you via phone and/or fax with a benefits investigation summary, which will include details regarding the patient's coverage:
  - Support options may be available for the patient
- Results may include notifying your office of prior authorization requirements

For assistance, call 1-844-NADOnow (1-844-623-6669) Monday to Friday, 9 AM to 6 PM ET.

Eligible, commercially insured patients may pay as little as \$100<sup>†</sup> for each ADSTILADRIN prescription

Create an account, register and enroll patients, and submit claims on <a href="https://example.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopay.com/hcp.ferringcopa

ADSTILADRIN has confirmed 99% coverage for commercial and government-insured patients<sup>1</sup>

#### **STEP**

## Account setup and ordering ADSTILADRIN



- Please validate that your practice location has an active account set up with either Besse Medical or Optum Frontier Therapies
- Account setup: If there is not an active account, please set up an account with Besse Medical by phone at 1-800-252-8759 or by email at <a href="mailto:advancedtherapies@amerisourcebergen.com">advancedtherapies@amerisourcebergen.com</a> or with Optum Frontier Therapies by email at <a href="mailto:oft-specialtydistribution@optum.com">oft-specialtydistribution@optum.com</a>
  - Note: Account setup may take 3 to 5 business days provided that all information and documentation submitted are complete
- Ordering ADSTILADRIN: Once benefits coverage is confirmed, you can proceed to order
  - To order through the specialty distributor, contact Besse Medical at 1-800-252-8759 or Optum Frontier Therapies at 1-833-754-6457
  - If ordering through the specialty pharmacy, Ferring Access Support will triage your prescription to Optum Frontier Therapies (1-855-768-9727), and the patient and practice will be contacted by both Optum Frontier Therapies and Ferring Access Support

Flexible payment terms: Ferring offers 120-day payment terms<sup>‡</sup>

Product information <sup>2</sup>		
Name	ADSTILADRIN	
Generic name	nadofaragene firadenovec-vncg	
Package presentation	Carton of four 20 mL vials (1 dose)	
Wholesale acquisition cost <sup>3</sup>	\$60,000 per dose <sup>5</sup>	
Dosage form	Sterile, clear to opalescent suspension single-use vials	
National Drug Code (NDC)	Carton, 4-vial package: <b>NDC</b> 55566-1050-01	
Specialty distributors <sup>¶</sup>	• Besse Medical (1-800-252-8759)	
	Optum Frontier Therapies (1-833-754-6457)	
Specialty pharmacy	Optum Frontier Therapies (1-855-768-9727)	

**Effective April 1, 2024, ADSTILADRIN has established an average sales price** in accordance with the guidelines set forth by the Centers for Medicare & Medicaid Services Part B. This determination is a significant milestone for Ferring Uro-Oncology and represents our commitment to providing transparency and value to our customers

<sup>\*</sup>Only commercially insured patients will go through a benefits verification.

<sup>&</sup>lt;sup>†</sup>Available only for patients who meet eligibility requirements. Program does not cover the cost of administration, office visits, or any associated costs. Terms and conditions apply. Offer expires 12/31/24.

Ferring offers approximately 120-day payment terms to its specialty distribution network. Payment terms offered from specialty distributor to HCP may vary.

Wholesale acquisition cost as of 4/1/2024.

It is recommended that provider sites and offices establish accounts with the specialty distributors, Besse Medical and Optum Frontier Therapies, to ensure access to ADSTILADRIN.

# **Account setup and ordering ADSTILADRIN (continued)**

## Coding

	ICD-10-CM codes <sup>3</sup>				
C67.0-C67.9	D09.0	Z85.51			
Malignant neoplasm of bladder	Carcinoma in situ of bladder	Personal history of malignant neoplasm of bladder			

HCPCS code⁴			CPT code⁵
J9029	Instillation, nadofaragene firadenovec-vncg, per therapeutic dose	51720	Bladder instillation of anticarcinogenic agent (including retention time)  (Catheterization is not separately billable for bladder instillation of ADSTILADRIN)

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

## Ordering timeline and day-of-delivery expectations

All accounts must be set up and active for the below time frames to apply.

For order to be received at site of care by*	Order must be placed at specialty distributor within time frame
10:30 AM Tuesday	Thursday 2 pm - Monday 2 pm
10:30 AM Wednesday	Monday 2 рм – Tuesday 2 рм
10:30 AM Thursday	Tuesday 2 рм – Wednesday 2 рм
10:30 AM Friday	Wednesday 2 pm - Thursday 2 pm

Exceptions to the ordering time line will be reviewed upon request

### DAY OF DELIVERY

Expect to receive a call from AeroSafe Global (1-585-760-2830) for shipper return instructions

#### **STEP**

# Storage and instillation of ADSTILADRIN



Schedule the instillation appointment with your patient. ADSTILADRIN is administered intravesically

**QUARTERLY: ONCE EVERY 3 MONTHS<sup>2</sup>** 

## ADSTILADRIN has specific storage and handling requirements to preserve the quality of the viral particles

Upon receipt, cartons of ADSTILADRIN can be stored as indicated below<sup>2</sup>:

- In a freezer ≤-60°C (≤-76°F) until expiry date printed on the carton
- In a freezer between -25°C to -15°C (-13°F to 5°F) up to 3 months, without exceeding the original expiry date printed on the vial and outer carton
  - When stored in freezer, the date of placement in freezer should be noted
- Protect the vials from light

<sup>\*</sup>Shipment receipt times listed as local times at the site of care, if available in that geography.
†Order placement times are listed in central standard time to account for Ferring distribution center customer service.

# **Access Important Resources**



Patient Enrollment Form <u></u>



ADSTILADRIN
Copay Program
Leave Behind



Instructions for Use 🕹



ADSTILADRIN

Pass-Through

Leave Behind



ADSTILADRIN
Average Sales
Price (ASP)
Leave Behind



ADSTILADRIN Ordering Walk-Through •

# **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 <u>www.FDA.gov/medwatch</u> or call 1-800-332-1088. You may also contact Ferring Pharmaceuticals at 1-888-FERRING.

#### Please see full Prescribing Information at <u>adstiladrinHCP.com</u>.

References: 1. Ferring Access Support benefits investigations for commercial and government-insured patients through March 15, 2024. 2. ADSTILADRIN. Package insert. Ferring Pharmaceuticals, Inc; 2023. 3. Data on file. ADSTILADRIN CSR, Ferring Pharmaceuticals, Inc. Parsippany, NJ. 4. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations: First Quarter, 2023 HCPCS Coding Cycle. Centers for Medicare & Medicaid Services, US Dept of Health and Human Services; 2023:6. 5. Atlas SJ, Touchette DR, Beinfeld M, et al. Nadofaragene Firadenovec and Oportuzumab Monatox for BCG-Unresponsive, Non-Muscle Invasive Bladder Cancer: Effectiveness and Value. Institute for Clinical and Economic Review; 2020. Accessed April 5, 2024. https://icer.org/wp-content/uploads/2020/08/ICER\_Bladder-Cancer\_Final-Report\_053122.pdf



