MASSACHUSETTS

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Gene Therapies for Bladder Cancer - Prior Authorization Request Form for Adstiladrin (nadofaragene firadenovec-vncg), #193

Medical Policy #159 Gene Therapies for Bladder Cancer

CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for Adstiladrin must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration) explaining why an exception is justified.

Requesting Prior Authorization Using Authorization Manager
Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources
Refer to our Authorization Manager page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for Adstiladrin (nadofaragene firadenovec-vncg) (193) using Authorization Manager.

For out of network providers: Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient ❒ Inpatient ❒ Distributor:

Physician Information	**Facility Information**
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient has the following diagnosis:	
Bladder Cancer	❒

Initial Approval Criteria

INITIAL APPROVAL: For up to 6 months

Please check off that the patient meets ALL the following criteria:	
1. Patient has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (*with or without papillary tumors*); **AND**	❒
2. Patient has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG) defined as: a. Persistent disease following adequate BCG therapy of at least five (5) of six (6) doses of an initial induction course of BCG followed by at least two (2) of three (3) doses of maintenance therapy or two (2) of six (6) doses of an additional induction course; **OR** b. Disease recurrence after an initial tumor-free state following adequate BCG therapy of at least five (5) of six (6) doses of an initial induction course of BCG followed by at least two (2) of three (3) doses of maintenance therapy or two (2) of six (6) doses of an additional induction course; **OR** c. Stage T1 disease following a single induction course of BCG; **AND**	❒
3. Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components); **AND**	❒
4. Patient does NOT have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma; **AND**	❒
5. Individual is not currently receiving systemic therapy for bladder cancer; **AND**	❒
6. Individual has not received any prior treatment with adenovirus-based therapies; **AND**	❒
7. Patient does not have a hypersensitivity to interferon alfa; **AND**	❒
8. Patient is not immunosuppressed or immunodeficient.	❒

Renewal Criteria

CONTINUED APPROVAL – 12 months

Please check off that the patient meets ALL the following criteria:	
CONTINUED APPROVAL – 12 months Due to the increased risk of developing muscle-invasive or metastatic bladder cancer with delay in cystectomy, if patients with CIS do not have a complete response to treatment with Adstiladrin (Nadofaragene firadenovec-vncg) after 3 months or if CIS recurs, consider cystectomy.	
1. 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 such as but not limited to disseminated adenovirus infection; **AND** a. For first renewal request, the patient had a complete response (CR) to initial therapy defined as a negative result for cystoscopy [with TURBT/biopsies as applicable] and urine cytology; **OR** b. For subsequent renewals the patient has not experienced a high-grade or CIS recurrence.	❒

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

Providers should enter the relevant diagnosis code(s) below:

Code	Description	
		❒
		❒

Providers should enter <u>other relevant code(s)</u> below:

Code	Description	
		❒
		❒