

Clinical Oversight Review Board (CORB) Criteria for Prescribing/  
Criteria-Based Consultation (CBC) Criteria for Coverage

# Nadofaragene Firadenovec(Adstiladrin)

**Notes:**

- Quantity Limits: Yes, 4 doses or 12 months total duration
- \* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **Nadofaragene Firadenovec (Adstiladrin)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria:** Non-formulary **Nadofaragene Firadenovec (Adstiladrin)** will be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Prescribed by Urology
- Patient is at least 18 years old and has a diagnosis of non-muscle invasive bladder cancer with carcinoma in situ.  
-AND-
- Patient has failed adequate trial of BCG, or is considered unresponsive to BCG (defined as administration of five of six doses of initial induction course plus either two of three doses of maintenance therapy or at least two of six doses of second induction course)  
-AND-
- Failed adequate trial of either alternative intravesical chemotherapy -OR - immunotherapy.  
-AND-
- Patient has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease. And does NOT have extra-vesical (e.g., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma.  
-AND-
- Does not have a hypersensitivity to interferon alfa.  
-AND-
- Patient is not immunocompromised or immunodeficient.

**Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-formulary **Nadofaragene Firadenovec (Adstiladrin)** will be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Prescribed by Urology

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All plans offered and underwritten by  
Kaiser Foundation Health Plan of the Northwest

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- Patient has a diagnosis of non-muscle invasive bladder cancer with carcinoma in situ  
-AND-
- Has no evidence of tumor progression must be assessed prior to each dose.

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary **Nadofaragene Firadenovec (Adstiladrin)** will be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Prescribed by Urology
- Patient has a diagnosis of non-muscle invasive bladder cancer with carcinoma in situ  
-AND-
- Has no evidence of tumor progression must be assessed prior to each dose.

**Continued use criteria (3 months after initiation):** Non-formulary **Nadofaragene Firadenovec (Adstiladrin)** will be covered on the prescription drug benefit for 3 months when the following criteria are met:

- Prescribed by Urology
- Patient has a diagnosis of non-muscle invasive bladder cancer with carcinoma in situ  
-AND-
- Has no evidence of tumor progression must be assessed prior to each dose.