Nadofaragene Firadenovec-vncg (ADTILADRIN)
Criteria for Use
September 2023

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive nadofaragene firadenovec.

- ☐ Hypersensitivity to interferon alpha
- ☐ Current or previous evidence if muscle-invasive or metastatic bladder cancer
- ☐ Upper tract urothelial carcinoma or urothelial carcinoma within the prostatic urethra
- ☐ Pregnancy in patients of reproductive potential

Inclusion Criteria

ALL of the following criteria must be met.

- ☐ Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) ^1
- ☐ Carcinoma in situ (CIS) with or without papillary tumors (Ta or T1 high-grade tumors)

Additional Inclusion Criteria

All of the following criteria must be met:

- ☐ Care is provided by a VA/VA Community Care urology provider or in consultation with a VA urology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Goals of care have been discussed and documented

Additional Inclusion Criteria- Select if applicable

- ☐ For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 6 months after stopping treatment

Other Justification

- ☐ _____

[1] BCG-unresponsive: Received 2 courses of BCG within 12 months (5 of 6 induction instillations and at least 2 of 3 maintenance doses OR at least 2 of 6 instillations of a second induction when maintenance not given)

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