

Medical Policy:

Adstiladrin - Non-Muscle Invasive Bladder Cancer (NMIBC)

Last review date: 7/1/25

Applicable Products:	
Adstiladrin (nadofaragene firadenovec)	Keytruda (pembrolizumab)
Anktiva (nogapendekin alfa inbakicept-pmIn)	Mitomycin
Gemcitabine	Valstar (valrubicin)

Initial Approval Criteria:

- Drug-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Adstiladrin, Anktiva, Keytruda, Valstar, Gemcitabine, Mitomycin

- Patient is 18 years of age or older; **AND**
- Patient has diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ with or without papillary tumors; **AND**
- Patient is unresponsive or ineligible for treatment with Bacillus Calmette-Guerin (BCG); **AND**
- Patient is not currently receiving systemic therapy for bladder cancer (Adstiladrin only); **AND**
- Patient has not received any prior treatment with adenovirus-based therapies (Adstiladrin only)

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet initial approval criteria; **AND**
- Absence of unacceptable toxicity from the drug

Length of Authorization:

Adstiladrin – one time approval

All others - 1 year

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.