Reference number(s)
5711-A

SPECIALTY GUIDELINE MANAGEMENT

ADSTILADRIN (nadofaragene firadenovec-vncg)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Adstiladrin is indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

B. Compendial Use
Non-muscle invasive bladder cancer

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Bladder Cancer
Authorization of 12 months may be granted for treatment of bladder cancer when all of the following criteria are met:
1. The member has non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)
2. The disease is high-risk
3. The disease is Bacillus Calmette-Guerin (BCG)-unresponsive

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease recurrence while on the current regimen.

IV. REFERENCES

1. Adstiladrin [package insert]. Kastrup, Denmark: Ferring Pharmaceuticals; May 2024.
2. The NCCN Drugs & Biologics Compendium™ © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed June 3, 2024.