



MED RX POLICY

- POLICY:** Oncology (Intravesical) – Bladder Cancer Med Rx Policy
- Adstiladrin® (nadofaragene firadenovec-vncg intravesical suspension – Ferring)
 - Anktiva® (nogapendekin alfa inbakicept-pmln intravesical solution – ImmunityBio/Altor BioScience)
 - Inlexzo™ (gemcitabine intravesical system – Janssen/Johnson & Johnson)

REVIEW DATE: 02/04/2026; effective 07/01/2026

OVERVIEW

Adstiladrin, a non-replicating adenoviral vector-based gene therapy, is indicated for treatment of high-risk **Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)** with or without papillary tumors in adults.¹

Anktiva, an interleukin-15 receptor agonist, is indicated in combination with BCG for the treatment of **BCG-unresponsive NMIBC with CIS** with or without papillary tumors in adults.²

Inlexzo, a nucleoside metabolic inhibitor, is indicated for the treatment of **BCG- unresponsive, NMIBC with CIS** with or without papillary tumors in adults.³

POLICY STATEMENT

This Med Rx program has been developed to encourage the use of the Preferred Products. For all products (Preferred and Non-Preferred), the patient is required to meet the respective standard *Oncology (Intravesical) Utilization Management Medical Policy* criteria. The program also directs the patient to try at least one Preferred Product prior to the approval of a Non-Preferred Product. All approvals are provided for the duration noted in the respective standard *Oncology (Intravesical) –Utilization Management Medical Policy*.

Automation: None.

Documentation: Documentation is required for use of Preferred Products as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. All documentation must include patient-specific identifying information.

Preferred Products: Adstiladrin, Anktiva
Non-Preferred Product: Inlexzo

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Inlexzo	<p>1. <u>Non-Muscle Invasive Bladder Cancer.</u> Approve if the patient meets BOTH of the following (A and B):</p> <p>A) Patient meets the standard <i>Oncology (Intravesical) – Inlexzo Utilization Management Medical Policy</i> criteria; AND</p> <p>B) Patient meets ONE of the following (i or ii):</p> <p>i. Patient has tried at least ONE of the following: Adstiladrin or Anktiva [documentation required]; OR</p> <p>ii. Patient is currently receiving Inlexzo.</p>

REFERENCES

1. Adstiladrin® intravesical suspension [prescribing information]. Kastrup, Denmark: Ferring; October 2025.
2. Anktiva® intravesical solution [prescribing information]. Culver City, CA: ImmunityBio and Altor BioScience; April 2024.
3. Inlexzo™ intravesical system [prescribing information]. Horsham, PA: Janssen/Johnson & Johnson; September 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 07/01/2026.	02/04/2026