UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Intravesical) – Inlexzo Utilization Management Medical Policy
- Inlexzo™ (gemcitabine intravesical system – Janssen/Johnson and Johnson)

REVIEW DATE: 09/24/2025

OVERVIEW

Inlexzo, a nucleoside metabolic inhibitor-containing intravesical system, is indicated for the treatment of Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors in adults.[1]

Dosing Information

Inlexzo is administered intravesically using the co-packaged urinary catheter and stylet The recommended dose of Inlexzo is one system (225 mg of gemicitabine) instilled into the bladder once every 3 weeks for up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months (6 doses), or until persistent or recurrent disease, disease progression, or unacceptable toxicity. The Inlexzo system is removed after each 3-week indwelling period.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on bladder cancer (version 2.2025 – October 10, 2025) provide recommendations for high-risk NMIBC who are BCG-unresponsive or BCG intolerant.[2] The guidelines recommend cystectomy (preferred) or intravesical chemotherapy (e.g., gemcitabine [category 1; preferred] or mitomycin [category 1]). Inlexzo may be considered for patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors (category 2A). Adstiladrin® (nadofaragene firadenovec-vncg intravesical suspension) may be considered for patients with BCG-unresponsive high-risk NMIBC, including CIS with or without papillary tumors (category 2A), or high-grade Ta/T1 only tumors without CIS (category 2B). Keytruda® (pembrolizumab intravenous infusion) is also an option for similar patient groups in both categories who are ineligible for or decline cystectomy; Keytruda Qlex™ (pembrolizumab/berahyaluronidase-alfa-pmph subcutaneous injection) may be substituted for IV Keytruda. Anktiva® (nogapendekin alfa inbakicept-pmln) + BCG is recommended specifically for patients with CIS, with or without papillary tumors (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Inlexzo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Inlexzo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Inlexzo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inlexzo is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. Non-Muscle Invasive Bladder Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND
B) Patient has carcinoma in situ (CIS); AND
C) Patient has Bacillus Calmette-Guérin (BCG)-unresponsive disease; AND
D) The medication is prescribed by or in consultation with a urologist or oncologist.

Dosing. Approve the following dosing regimens (A and B):

A) Approve one Inlexzo system (225 mg of gemicitabine) instilled intravesically once every 3 weeks, for no more than 8 doses; AND
B) After 6 months of therapy, approve one Inlexzo system (225 mg of gemcitabine) instilled intravesically once every 12 weeks, for no more than 6 doses.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Inlexzo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Inlexzo™ intravesical system [prescribing information]. Horsham, PA: Janssen/Johnson and Johnson; September 2025.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – October 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 17, 2025

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	09/24/2025
Update	**10/17/2025:** The overview section was modified with National Comprehensive Cancer Network (NCCN) guideline updates.	N/A