Clinical Policy: Gemcitabine Intravesical System (Inlexzo)

Reference Number: PA.CP.PHAR.753
Effective Date: 11/2025
Last Review Date: 10/2025

Description

Gemcitabine intravesical system (Inlexzo™) is a nucleoside metabolic inhibitor with antineoplastic activity.

FDA Approved Indication(s)

Inlexzo is indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Inlexzo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Muscle Invasive Bladder Cancer (must meet all)**:**

1. Diagnosis of NMIBC with CIS;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Member is refractory to BCG* treatment (*see Appendix D*);
   **Prior authorization may be required for BCG immunotherapy*
5. Member is not a candidate for cystectomy;
6. Member has previously undergone transurethral resection of bladder tumor (TURBT);
7. Request meets one of the following (a or b):
   a. Dose does not exceed 225 mg once every 3 weeks for 8 instillations, followed by once every 12 weeks for 6 instillations;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Non-Muscle Invasive Bladder Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy as evidenced by lack of disease recurrence or progression;
3. Member has not received ≥ 14 instillations;
4. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. If member has received < 8 instillations: New dose does not exceed 225 mg once every 3 weeks for up to 8 total instillations, followed by once every 12 weeks for 6 instillations;
   b. If member has received ≥ 8 instillations: New dose does not exceed 225 mg once every 12 weeks for up to 6 total instillations;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BCG: bacillus Calmette-Guerin
CIS: carcinoma in-situ
FDA: Food and Drug Administration
NMIBC: non-muscle invasive bladder cancer
TURBT: transurethral resection of bladder tumor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Bacillus Calmette-Guerin (TICE BCG®)	1 to 8 × 10^8 CFU (a vial) intravesical instillation once per week for 6 weeks	1 to 8 × 10^8 CFU/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): perforation of the bladder, hypersensitivity to gemcitabine or any component of the product
- Boxed warning(s): none reported

Appendix D: General Information

- Refractory or "BCG unresponsive" is defined as persistent or recurrent CIS alone or with recurrent Ta/T1 disease within 12 months of adequate BCG therapy, defined as at least one of the following:
  a. At least 5 or 6 doses of an initial induction course plus 2 of 3 doses of maintenance therapy;
  b. At least 5 or 6 doses of an initial induction course plus at least 2 of 6 doses of a second induction course.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BCG-unresponsive NMIBC	225 mg inserted into the bladder once every 3 weeks for 8 instillations, followed by once every 12 weeks for 6 instillations	See regimen

VI. Product Availability

Single-dose intravesical system: 225 mg

VII. References

1. Inlexzo Prescribing Information. Horsham, PA: Janssen Biotech Inc.; September 2025. Available at: www.inlexzo.com. Accessed September 17, 2025.
2. Daneshmand S, Van der Heijden MS, Jacob JM, et al. TAR-200 for Bacillus Calmette-Guérin-unresponsive high-risk non-muscle-invasive bladder cancer: Results from the phase IIb SunRISe-1 study. *J Clin Oncol.* 2025 Jul 30:JCO2501651. doi: 10.1200/JCO-25-01651.
3. National Comprehensive Cancer Network. Bladder Cancer Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed September 17, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy created	10/2025