# Clinical Policy: Gemcitabine Intravesical System (Inlexzo)

Reference Number: CP.PHAR.753
Effective Date: 12.01.25
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## 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 health plans affiliated with Centene Corporation® 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. Provider attestation that Adstiladrin® therapy has been considered and not recommended (provider must submit clinical rationale supporting use of Inlexzo over Adstiladrin);
8. 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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Non-Muscle Invasive Bladder Cancer** (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Inlexzo for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the

relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

**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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**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 for all relevant lines of business 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 |
|---|---|
| J9183 | Gemcitabine intravesical system, 225 mg |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 09.17.25 | 11.25 |
| HCPCS code added [J9183]; codes removed [J3590, C9399]. | 02.19.26 | |
| Per June SDC, added requirement for provider attestation that Adstiladrin therapy has been considered and not recommended with clinical rationale supporting Inlexzo over Adstiladrin. Added ICHRA line of business. | 06.09.26 | 08.26 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.