Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Gemcitabine intravesical system (Inlexzo™)	**MP-RX-FP-185-26**	☒ **MMM MA** ☒ **MMM MultiHealth**	**5/6/2026**	**5/6/2026**
			Last Review Date: **5/6/2026**	**Frequently Revision:** **Annual**

Service Category:

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other: Part B Drugs

Service Description:

This document addresses the use of Inlexzo. Inlexzo is a nucleoside metabolic inhibitor-containing intravesical system, FDA indicated for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)- unresponsive, nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Background Information:

Inlexzo is supplied as a single-use intravesical system containing 225 mg of gemcitabine, co-packaged with a urinary catheter and stylet for insertion. It is inserted via a catheter in the outpatient setting and remains in the bladder for 3 weeks per cycle.

It joins other FDA-approved options for BCG-unresponsive NMIBC such as Keytruda (pembrolizumab), Adstiladrin (nadofaragene firadenovec), and Anktiva (nogapendekin alfa inbakicept-pmln), though it differs in mechanism (chemotherapy vs. immunotherapy or gene therapy) and is locally acting.

At this time the National Comprehensive Cancer Network® (NCCN) does not provides additional recommendations for the use of Inlexzo.

Definitions and Measures

- Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.
- Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.
- Cytotoxic: Treatment that is destructive to cells, preventing their reproduction or growth.
- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
    - 0 = Fully active, able to carry on all pre-disease performance without restriction
    - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
    - 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
    - 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
    - 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
    - 5 = Dead
- Line of Therapy:

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- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second line therapy) are not effective or there is disease progression.

- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Approved Indications

A. 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.

Other Uses

A. None.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Inlexzo™ (gemcitabine intravesical system)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Initial requests for Inlexzo (gemcitabine intravesical system) may be approved if the following criteria are met:

i. Individual is using as intravesical instillation; **AND**
ii. Individual has a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Inlexzo (gemcitabine intravesical system) therapy medically necessary in members requesting reauthorization for an indication listed in Section A Above (Criteria for Initial Approval) when there is no evidence of persistent/recurrent NMIBC, disease progression, or unacceptable toxicity while on the current regimen, and the FDA-labeled duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
   A. A current urology/oncology note documenting clinical benefit and tolerance to therapy, with no evidence of persistent/recurrent NMIBC or progression; **AND**
   B. Current cystoscopy and urine cytology results demonstrating no evidence of persistent/recurrent disease; include biopsy/TURBT pathology, as applicable, when suspicious findings are present or additional objective confirmation is needed; **AND**
   C. INLEXZO is administered intravesically only; **AND**
   D. Individual has a diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors; **AND**
   E. Individual has a complete response to initial therapy defined as a negative result for urine cystoscopy and urine cytology.

C. Authorization Duration

i. Initial Approval Duration: 6 months

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ii. Reauthorization Approval Duration: 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

Requests for Inlexzo (gemcitabine intravesical system) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

i. Individual has muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e. urethra, ureter, or renal pelvis) urothelial carcinoma; **OR**
ii. Individual has a perforated bladder; **OR**
iii. When the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Dosage Forms & Strengths	Recommended Dosing/Limits
INLEXZO™ (gemcitabine intravesical system) 225 mg single-dose intravesical system	• Insert INLEXZO (225 mg of gemcitabine) into the bladder once every 3 weeks up to 6 months (8 doses), followed by once every 12 weeks (6 doses).
Exceptions	
• Remove INLEXZO after each 3-week indwelling period	

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C67.0-C67.9	Malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder

HCPCS Codes:

Codes	Description
C9399	Unclassified drugs or biologicals [when specified as Inlexzo (gemcitabine intravesical)]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Inlexzo (gemcitabine intravesical)]
J9183	gemcitabine intravesical system, 225 mg (effective April 1, 2026)

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Reference Information:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 14, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Janssen Biotech, Inc. (2025, September). INLEXZO (gemcitabine intravesical system) prescribing information. Johnson & Johnson. Retrieved March 9, 2026, from https://www.jnjlabels.com/package-insert/product-monograph/prescribing-information/INLEXZO-pi.pdf
5. INLEXZO. (n.d.). INLEXZO patient website. Retrieved March 9, 2026, from https://www.inlexzo.com/
6. Johnson & Johnson Medical Connect. (n.d.). Clinical practice guidelines. Retrieved March 9, 2026, from https://www.jnjmedicalconnect.com/products/inlexzo/medical-content/clinical-practice-guidelines
7. Johnson & Johnson Medical Connect. (n.d.). INLEXZO - Use in BCG-unresponsive high-risk NMIBC with papillary tumors only. Retrieved March 9, 2026, from https://www.jnjmedicalconnect.com/products/inlexzo/medical-content/inlexzo-use-in-bcg-unresponsive-high-risk-nmibc-with-papillary-tumors-only

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	5/1/2026	5/6/2026