Evolent Clinical Guideline 3189 for Inlexzo™ (gemcitabine intravesical system)

Guideline Number: Evolent_CG_3189	Applicable Codes	
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Original Date: October 2025	**Last Revised Date:** April 2026	**Implementation Date:** April 2026

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STATEMENT

Purpose

To define and describe the accepted indications for Inlexzo (gemcitabine intravesical system) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Bladder Cancer

- Inlexzo (gemcitabine intravesical system) may be used in adult members with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
    - BCG-unresponsive NMIBC after treatment with adequate BCG therapy is defined as a minimum of 5 of 6 full doses of an induction course (adequate induction) plus 2 of 3 doses of a maintenance course, or at least 2 of 6 doses of a second induction course.

CONTRAINDICATIONS/WARNINGS

- Contraindications
    - Hypersensitivity to gemcitabine or any component of the formulation
    - Perforation of the bladder

EXCLUSION CRITERIA

- Disease progression while taking Inlexzo (gemcitabine intravesical system).
- Concurrent use with other anticancer therapies.
- Members who are eligible for or have undergone radical cystectomy.
- Dosing exceeds single dose limit of Inlexzo (gemcitabine intravesical system) 225 mg.
- Treatment exceeds maximum duration limit of 14 total doses:
    - A dose given once every 3 weeks for up to 6 months (8 doses), followed by a dose given once every 12 weeks for up to 18 months (6 doses).
- Investigational use of Inlexzo (gemcitabine intravesical system) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9183 - Gemcitabine intravesical system, 225 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
April 2026	• Updated HCPC code • Updated references
October 2025	• New policy

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

1. Daneshmand S, et al; SunRISe-1 Study. 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 Nov 20;43(33):3578-3588. doi: 10.1200/JCO-25-01651.
2. Inlexzo prescribing information. Janssen Biotech, Inc. Horsham, PA 2025.
3. Clinical Pharmacology Elsevier Gold Standard 2026.
4. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2026.
5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2026.
6. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2026.
7. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
8. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf**.
9. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: **http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**.