

## Inlexzo™ (gemcitabine) (Intravesical)

-E-

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### I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for a total of 8 doses over 6 months (180 days).
- Renewal: Prior authorization validity may be renewed for up to 3 doses every 6 months (180 days) for a maximum of 6 doses over 18 months.

### II. Dosing Limits

#### Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 dose) every 3 weeks for 6 months (8 doses), followed by 1 billable unit (1 dose) every 12 weeks for 18 months (6 doses)

### III. Initial Approval Criteria <sup>1</sup>

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

#### Universal Criteria <sup>1</sup>

- Will not be used concurrently with other gemcitabine formulations; **AND**
- Member does not have a hypersensitivity to any gemcitabine formulations; **AND**
- Member will be evaluated for perforation of the bladder and mucosal compromise and, if present, will not receive therapy until bladder integrity has been restored; **AND**
- Therapy will be used for intravesical instillation only; **AND**
- Used as a single agent; **AND**
- Member is not a candidate for generically available gemcitabine instilled intravesically; **AND**

#### Bladder Cancer † ‡ <sup>1-4</sup>

- Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) (*with or without papillary tumors*); **AND**

- Member has high-risk disease that is unresponsive to Bacillus Calmette-Guerin (BCG)<sup>Δ</sup> (defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of completion of adequate BCG therapy<sup>\*\*</sup>); **AND**
  - Member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components) (Note: Member with residual CIS that is not amenable to complete resection is permitted); **AND**
  - Member does NOT have muscle invasive (T2-T4), locally advanced, metastatic, or extra-vesical (i.e., urethra, ureter, or renal pelvis) urothelial carcinoma; **AND**
  - Member is ineligible for or has elected not to undergo radical cystectomy
- \*\*Note:** Adequate BCG therapy is defined as administration of at least five of six doses of an initial induction course AND at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.
- ΔNote:** During times of BCG shortage, the member will still be required to try generic intravesical gemcitabine first prior to consideration of Inlexzo.

**Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.**

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (refer to Section I); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, etc.

#### V. Dosage/Administration <sup>1</sup>

| Indication | Dose |
|------------|------|
|------------|------|

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                           |
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| Bladder Cancer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p>Insert Inlexzo (225 mg of gemcitabine) 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 NMIBC, disease progression, or unacceptable toxicity. Remove Inlexzo after each 3-week indwelling period.</p> |
| <p>– Administer Inlexzo intravesically only. Do NOT administer by any other route. Inlexzo is co-packaged with a urinary catheter and stylet used to insert Inlexzo through the urinary catheter into the bladder. Administer using the co-packaged urinary catheter and stylet only.</p> <p>– Inlexzo should be inserted and removed by a trained healthcare provider. Healthcare providers should become thoroughly familiar with the insertion and removal instructions before attempting insertion or removal of Inlexzo.</p> <p>– Prophylactic antibiotics may be used at the discretion of the treating healthcare provider with each INLEXZO insertion and removal.</p> <p>– Inlexzo contains metal wire. The member can safely undergo an MRI exam only under very specific conditions. Complete the MRI Safety Information Card in the carton and give it to the member.</p> <p>– Instruct members to drink approximately 1500 mL of fluids per day during therapy with Inlexzo to ensure adequate urine production for drug release.</p> <p>– During indwelling period of approximately 3 weeks, advise members to avoid urine contact with skin, to void urine sitting on a toilet, to wash hands with soap and water and to wash their genital area with water after each urination, and to flush the toilet after use.</p> |                                                                                                                                                                                                                                                                                                                           |

## VI. Billing Code/Availability Information

### HCPCS Code(s):

- J9183 – Gemcitabine intravesical system, 225 mg; 1 billable unit = 1 dose (*Effective 04/01/2026*)
- J9999 – Not otherwise classified, antineoplastic drugs (*Discontinue use on 04/01/2026*)
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use Only*) (*Discontinue use on 04/01/2026*)

### NDC(s):

- Inlexzo 225 mg single-dose kit: 57894-0225-xx
  - One sterile single-dose of Inlexzo in two clear laminate sleeves and packaged in an inner pouch. The inner pouch and a desiccant are packaged in an outer foil pouch. The outside surfaces of the inner and outer pouches are not sterile.
  - One sterile urinary catheter and one sterile stylet packaged together in a pouch

## VII. References (STANDARD)

1. Inlexzo [package insert]. Horsham, PA; Janssen Biotech, Inc.; September 2025. Accessed May 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Gemcitabine intravesical system. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2026.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2026.
4. Daneshmand S, Van der Heijden MS, Jacob JM, et al. SunRISe-1 Study. TAR-200 for Bacillus Calmette-Guerin-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.

## VIII. References (ENHANCED)

- 1e. Di Lorenzo G, Perdonà S, Damiano R, et al. Gemcitabine versus bacille Calmette-Guérin after initial bacille Calmette-Guérin failure in non-muscle-invasive bladder cancer. Cancer. 2010;116(8):1893-1900. doi:https://doi.org/10.1002/cncr.24914
- 2e. Boorjian SA, Alemozaffar M, Konety BR, et al. Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial. The Lancet Oncology. 2021;22(1):107-117. doi:https://doi.org/10.1016/S1470-2045(20)30540-4
- 3e. Chamie K, Chang SS, Kramolowsky E, et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. NEJM Evidence. 2023;2(1). doi:https://doi.org/10.1056/evidoa2200167
- 4e. Chang SS, Chamie K, Kramolowsky E, et al. Prolonged Progression-Free Survival, Disease-Free Survival, and Cystectomy Avoidance With IL-15 Receptor Lymphocyte-Stimulating Agent NAI Plus Bacillus Calmette-Guérin in Bacillus Calmette-Guérin-Unresponsive Papillary-Only Nonmuscle-Invasive Bladder Cancer. J Urol. 2026 Jan;215(1):44-56.
- 5e. Prime Therapeutics Management. Zusduri Clinical Literature Review Analysis. Last updated May 2026. Accessed May 2026.

## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior

authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor                     | Conclusion            |
|----------------------------|-----------------------|
| Indication                 | Yes: Consider for PA  |
| Safety and efficacy        | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug               | Yes: Consider for PA  |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description                                 |
|--------|----------------------------------------------------|
| C67.0  | Malignant neoplasm of trigone of bladder           |
| C67.1  | Malignant neoplasm of dome of bladder              |
| C67.2  | Malignant neoplasm of lateral wall of bladder      |
| C67.3  | Malignant neoplasm of anterior wall of bladder     |
| C67.4  | Malignant neoplasm of posterior wall of bladder    |
| C67.5  | Malignant neoplasm of bladder neck                 |
| C67.6  | Malignant neoplasm of ureteric orifice             |
| C67.7  | Malignant neoplasm of urachus                      |
| C67.8  | Malignant neoplasm of overlapping sites of bladder |
| C67.9  | Malignant neoplasm of bladder, unspecified         |
| D09.0  | Carcinoma in situ of bladder                       |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                                   |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                                        |
| E (1)                                                         | CA, HI, NV, AS, GU, CNMI                                                                    | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)                                                     | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ                                                      | Noridian Healthcare Solutions, LLC                |
| 5                                                             | KS, NE, IA, MO                                                                              | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6                                                             | MN, WI, IL                                                                                  | National Government Services, Inc. (NGS)          |
| H (4 & 7)                                                     | LA, AR, MS, TX, OK, CO, NM                                                                  | Novitas Solutions, Inc.                           |
| 8                                                             | MI, IN                                                                                      | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)                                                         | FL, PR, VI                                                                                  | First Coast Service Options, Inc.                 |
| J (10)                                                        | TN, GA, AL                                                                                  | Palmetto GBA                                      |
| M (11)                                                        | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA                                      |
| L (12)                                                        | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)                                                   | NY, CT, MA, RI, VT, ME, NH                                                                  | National Government Services, Inc. (NGS)          |
| 15                                                            | KY, OH                                                                                      | CGS Administrators, LLC                           |