Medical Drug Clinical Criteria

Subject:	Inlexzo (gemcitabine intravesical system)		
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Overview

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, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. 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:

- 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.

Clinical Criteria

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)

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

I. Individual is under 19 years of age;

OR

II. Individual is using as intravesical instillation; **AND**
III. 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.

Initial approval duration: 6 months
Continuation approval duration: 12 months

Requests for continuation of Inlexzo (gemcitabine intravesical system) may be approved if the following are met:

I. Individual is under 19 years of age;

OR

II. Individual is using as intravesical instillation; **AND**
III. 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**
IV. Individual has a complete response to initial therapy defined as a negative result for urine cystoscopy and urine cytology.

Requests for Inlexzo (gemcitabine intravesical system) may not be approved for the following:

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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Inlexzo (gemcitabine intravesical)]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Inlexzo (gemcitabine intravesical)]

ICD-10 Diagnosis	
C67.0-C67.9	Malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder

Document History

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Document History:

- 11/14/2025 – Select Review: New PA for Inlexzo. Administrative update for age. Coding Reviewed: Added HCPCS NOC C9399 and J999 for Inlexzo. Added ICD-10-CM C67.0-C67.9, D09.0.

References

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.