Reference number(s)
7230-A

Standard Medicare Part B Management Inlexzo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Inlexzo	gemcitabine intravesical system

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

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.

Documentation

The following documentation must be available, upon request, for all submissions:

Documentation of chart notes or medical record documentation of no response to BCG.

Coverage Criteria

Authorization of up to 12 months (up to a total of 14 doses) may be granted for the treatment of BCG-unresponsive, NMIBC with CIS, with or without papillary tumors when all of the following criteria are met:

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- The requested drug will be used as a single agent inserted intravesically.
- The requested drug will be given once every 3 weeks for up to 6 months, followed by once every 12 weeks for up to 18 months.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested drug.
- The requested drug is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No unacceptable toxicity while on the current regimen, AND
    - No evidence of disease progression while on the current regimen, AND
    - No evidence of persistent or recurrent NMIBC while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Inlexzo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Bladder Cancer

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Inlexzo [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2025.

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