Gemcitabine (Inlexzo™) intravesical system

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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 Indication
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.

Compendial Use
Non-muscle invasive bladder cancer without carcinoma in situ

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of chart notes or medical record documentation of no response to BCG.

COVERAGE CRITERIA

Bladder Cancer

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

- The member has NMIBC with CIS or Ta/T1 papillary tumors without CIS.
- The disease is high-risk.
- The disease is BCG-unresponsive.
- The requested medication will be used as a single agent inserted intravesically.
- The requested medication 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

Authorization of 12 months (up to a total of 14 doses) may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of persistent or recurrent NMIBC, disease progression, or unacceptable toxicity while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Inlexzo [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 7, 2026.

EFFECTIVE DATE 1/30/2027

ID_CHS_72292026_1126

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