

DRUG POLICY

Inlexzo® (gemcitabine intravesical system)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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

Criteria for Initial Approval

Bladder Cancer

1. Authorization of up to 12 months 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:
 - A. The requested drug will be used as a single agent inserted intravesically.
 - B. 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

Bladder Cancer

1. 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.

Other

Inlexzo (gemcitabine intravesical system) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Inlexzo (gemcitabine) 225 mg single-use intravesical system	One system (225 mg) per 3 weeks for 6 months then one system per 12 weeks up to 18 months	Administer 225mg intravesically every 3 weeks for up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months (6 doses). Remove Inlexzo after each 3-week indwelling period.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9183 – Gemcitabine intravesical system, 225 mg
- J9999 - Not otherwise classified, antineoplastic drugs
- J3490 - Unclassified drugs
- J3590 - Unclassified biologics
- C9399 - Unclassified drug or biologic, hospital outpatient

REFERENCES

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

POLICY HISTORY

Policy #: 05.06.19

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Reviewed: August 2026

Revised:

Current Effective Date: February 27, 2026