

Gemcitabine Implant (INLEXZO)

Criteria for Use

May 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If any of the following are selected, the patient will NOT meet criteria for Gemcitabine Intravesical System.

- Evidence of muscle-invasive or metastatic bladder cancer
- Perforation of the bladder or risk for perforation
- Not a candidate for frequent bladder manipulation
- Anatomic features preventing safe insertion
- Known pregnancy
- Lactating/ Breastfeeding

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- BCG-Unresponsive, non-muscle invasive bladder cancer
- Formulary agents for BCG-unresponsive disease are contraindicated or not medically advisable
- Not a candidate for radical cystectomy or patient prefers bladder preservation

Additional Inclusion Criteria

All the following criteria must be selected to meet criteria.

- Care is provided by a VA/VA Community Care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria

Select if applicable.

- For females who can become pregnant and males with partners who can become pregnant: Counseling on treatment risks vs benefits and use of effective contraception during and for 6 months after last treatment for women and 3 months for men

Other Justification

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