

Specialty Guideline 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 Indications¹

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

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

Reference number(s)
7229-A

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:

- 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

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.

References

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