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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 12/04/2025

Inlexzo™ (gemcitabine)

HCPCS: J9183

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved indication
 - b. FDA approved age
 - c. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Continue until persistent or recurrent non-muscle invasive bladder cancer (NMIBC), disease progression, or unacceptable toxicity up to a maximum 18 months of therapy

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Bladder cancer is one of the more common forms of cancer. Approximately 75% - 80% of newly diagnosed bladder cancers are classified as non-muscle invasive bladder cancer (NMIBC), a type of cancer that has grown through the lining of the bladder but hasn't yet invaded the muscle layer. This type of cancer is associated with high rates of recurrence, between 30 to 80%, and the risk of progression to invasive and metastatic disease.

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- Treatment and care of patients with high-risk NMIBC, including those with carcinoma in situ (CIS), often involves removing the tumor followed by Bacillus Calmette-Guérin (BCG) bladder instillation therapy to reduce the risk of recurrence. Few effective treatment options exist for patients who develop BCG-unresponsive disease. The failure to achieve a complete response, or the disappearance of all signs of cancer as seen on cystoscopy, biopsied tissue, and urine, is associated with an increased risk of death or a disease-worsening event.
- Inlexzo is a nucleoside metabolic inhibitor-containing intravesical system indicated for the treatment of adult patients with BCG-unresponsive, NMIBC with CIS with or without papillary tumors.
- The 2025 National Comprehensive Cancer Network Bladder Cancer Treatment Guidelines recommend TURBT for staging followed by a single dose of intravesicular mitomycin or gemcitabine as the first step in treatment. Following the tumor evaluation, if the tumor is considered high-grade, BCG is the preferred adjuvant therapy and intravesicular mitomycin or gemcitabine provide additional options to those who aren't candidates for BCG therapy. BCG is typically given weekly for 6 weeks at induction followed by maintenance of 3 weekly instillations at month 3, 6, 12, 18, 24, 30, and 36. Two 6-week BCG induction courses should be completed before the patient is considered non-responsive to the therapy. If patients have had recurrence or are considered non-responsive to BCG therapy, cystectomy, Keytruda®, Anktiva®, and Adstiladrin® are currently recommended as second-line therapies.
- Safety and efficacy were evaluated in cohort 2 of the SunRISe-1 trial, a phase IIb, single-arm, multicenter study of 83 patients with BCG-unresponsive, NMIBC with CIS, with or without papillary tumors (T1, or high-grade Ta) following transurethral resection. BCG-unresponsive NMIBC CIS was defined as persistent or recurrent CIS alone or with Ta/T1 disease within 12 months of adequate BCG therapy. Adequate BCG therapy was defined as a minimum administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course. Patients received Inlexzo into the bladder every 3 weeks for 6 months, followed by once every 12 weeks for up to 18 months, or until unacceptable toxicity, persistence or recurrence of CIS and/or high-grade papillary disease, or progression. The primary endpoints were complete response rate at any time defined as negative results for cystoscopy and duration of response. Results show 82% of study participants achieved a complete response (95% CI: 72, 90). This high response rate demonstrated strong durability with 51% of these patients maintained a complete response for at least one year.
- Inlexzo has not been compared to generic gemcitabine bladder instillation in a randomized controlled trial and there is no data to suggest Inlexzo is superior to generic gemcitabine bladder instillation.

References:

1. Inlexzo [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; September 2025.
2. Clinicaltrials.gov. A study of TAR-200 in combination with cetrelimab, TAR-200 alone, or cetrelimab alone in participants with non-muscle invasive bladder cancer (NMIBC) unresponsive to intravesical bacillus calmette-guérin who are ineligible for or elected not to undergo radical cystectomy (SunRISe-1). Available at: <https://clinicaltrials.gov/study/NCT04640623>. Accessed on September 11, 2025.
3. Daneshmand S, Van der Heijden MS, Jacob JM, et al. TAR-200 for bacillus calmette-guérin-unresponsive high-risk non-muscle-invasive bladder cancer: results from the phase IIb SunRISe-1 study. J Clin Oncol. 2025 Jul 30: JCO2501651. doi: 10.1200/JCO-25-01651.
4. American Cancer Society. Key statistics for bladder cancer. 2025 Jan 22. Available at: <https://www.cancer.org/cancer/bladder-cancer/about/key-statistics.html>. Accessed on September 11, 2025.
5. National Comprehensive Cancer Network. Bladder cancer (Version 1.2025). 2025 March 25. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed on September 11, 2025.

Policy History												
#	Date	Change Description										
1.1	Effective Date: 05/13/2026	UM medical management system update for BCBS, BCN, MAPPO, and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.0	Effective Date: 12/04/2025	New Policy <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.