Mass General Brigham
Health Plan

Intravesical Bladder Cancer Agents
Inlexzo (gemcitabine intravesical system)
Effective 02/17/2026

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
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.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

1. Diagnosis of Bacillus Calmette-Guerin (BCG)-unresponsive nonmuscle-invasive bladder cancer (NMIBC)
2. Disease is high-risk with carcinoma in situ (CIS)
3. Prescriber is an oncologist or urologist
4. Appropriate dosing

Continuation of Therapy
Resubmission by prescriber will infer positive response to therapy and can be recertified for maximum of 14 total doses.

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months (maximum of 14 total doses)

References

1. Inlexzo® [prescribing information]. Horsham (PA): Janssen Biotech, Inc.; 2025 Sep.
2. National Cancer Institute SEER Program. Cancer Stat Facts: Common Cancer Sites. https://seer.cancer.gov/statfacts/html/common.html. Accessed November 22, 2022.
3. FDA approves first gene therapy for the treatment of high-risk, non-muscle-invasive bladder cancer [press release on the Internet]. U.S. Food & Drug Administration. 2022 Dec 16 [cited 2022 Dec 19].

Available from: FDA Approves First Gene Therapy for the Treatment of High-Risk, Non-Muscle-Invasive Bladder Cancer (govdelivery.com).
4. Kassouf W, Black P. Treatment of primary non-muscle invasive urothelial bladder cancer. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2025 [cited 2025 Aug 26]. Available from: http://www.utdol.com/utd/index.do.
5. European Association of Urology (EAU) Guidelines for non-muscle-invasive bladder cancer (TAT1 and CIS), update 2021. Edn. presented at the EAU Annual Congress Amsterdam 2022. Available from: https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer. ISBN 978-94-92671-16-5.
6. Chang SS, Boorjian SA, Chou R et al: Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline. J Urol. 2016; 196: 1021 (amended 2020).
7. NCCN. Bladder Version 1.2025; 2025 Mar 25 [cited 2025 Aug 26]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.

Review History

1/2026 – Created for P&T. Criteria for new drug, managed under MB. Effective 2/17/26