

[Insert Physician Letterhead]

[Insert Name of Medical Director]

[Insert Payer Name]

[Insert Address]

[Insert City, State ZIP]

RE: Member Name: [Insert Member Name]

Member Number: [Insert Member Number]

Group Number: [Insert Group Number]

REQUEST: Authorization for treatment with INLEXZO™ (gemcitabine intravesical system)

DIAGNOSIS: [Insert Diagnosis] [Insert ICD]

DOSE AND FREQUENCY: [Insert Dose & Frequency]

REQUEST TYPE: ☐ Standard ☐ EXPEDITED

Dear [Insert Name of Medical Director or name of individual responsible for prior authorization],

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with INLEXZO™, which 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. My request is supported by the following:

Summary of Patient's Diagnosis

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

Summary of Patient History

[Insert comorbidities if any/other medical conditions, previous therapies/procedures, response to those interventions, description of patient's recent symptoms/condition, summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with INLEXZO™. Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

Rationale for Treatment

[Insert summary statement for rationale for treatment such as: Considering the patient's medical history, condition, and the full Prescribing Information supporting use of INLEXZO™, I believe treatment with INLEXZO™ at this time is warranted, appropriate, and medically necessary, and should be a covered and reimbursed service. Please see the accompanying clinical information for this drug; supporting clinical guidelines; FDA approval letter; and full Prescribing Information for INLEXZO™ that provide additional clinical information to support my recommendation for INLEXZO™ for this patient.]

[Consider including this section if the patient has a history of treatment with other bladder cancer agents which have a dosing requirement of retaining the medication in the bladder for a period of time before urinating]. [Include specifics related to the patient's medical condition(s) and/or previous medication use.] [INLEXZO™ remains in the bladder for three weeks per treatment cycle for up to 14 cycles.] (Of the total gemcitabine dose, 77% was excreted by Day 7 and 99% was excreted by Day 21 in urine as gemcitabine and dFdU). With INLEXZO™, patients need to retain urine in the bladder prior to insertion but can resume normal urination after the procedure.]

[Given the urgent nature of this request], please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Please read full [Prescribing Information](#) for INLEXZO™.

Sincerely,

[Insert Physician Name and Participating Provider Number]

☐ If this request is denied, I am requesting an expedited Exception review by a professional in my specialty.

Enclosures [Include full Prescribing Information and the additional support noted above]