BC Cancer Protocol Summary for Intravesical Therapy for Non-Muscle Invasive Bladder Cancer Using Gemcitabine and Docetaxel

Protocol Code

Tumour Group

Contact Physician

ELIGIBILITY:

- BCG-unresponsive high-risk non-muscle invasive bladder cancer (NMIBC)
- Patients with high risk NMIBC who are intolerant of or ineligible for intravesical BCG

EXCLUSIONS:

- Known hypersensitivity reaction to gemcitabine or docetaxel
- Presence of gross hematuria
- Presence of untreated urinary tract infection
- Suspected bladder perforation

TESTS:

No routine lab tests before each treatment

TREATMENT:

• Empty bladder completely at time of catheterization

INDUCTION:

• **Step 1:** Insert urinary catheter (14-16 Fr Foley) and instill gemcitabine:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	1000 mg	Diluted with normal saline up to 45 mL before instillation. Instillation into bladder via catheter. Clamp or plug foley (dwell time of 1 to 2 hours) *

*No need for patient to roll from side to side

- **Step 2:** Drain bladder until flow stops no need to irrigate
- Step 3: Instill docetaxel:

Drug	Dose	BC Cancer Administration Guideline
docetaxel	37.5 mg	Diluted with normal saline up to 45 mL before instillation
		Instillation into bladder via catheter. Clamp or plug foley (dwell time of 1 to 2 hours) *

*No need for patient to roll from side to side

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Activated: 1 August 2021 Revised: 1 Dec 2021 (Treatment and precautions information updated) Warning: The information contained in these documents are a statement of consensus of BC cancer professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expendent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is at your own risk and is subject to BC Cancer's terms of use available at <u>www.bccancer.bc.cat/ems-of-use.</u>

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Genitourinary

Dr. Peter Black

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• **Step 4:** After 1- 2 hours unclamp the catheter and allow the urine and drug to drain into the drainage bag, then remove catheter.

Duration: Weekly for 6 weeks (6 doses)

MAINTENANCE:

• **Step 1:** Insert urinary catheter (14-16 Fr Foley) and instill gemcitabine:

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Drug	Dose	BC Cancer Administration Guideline
docetaxel	37.5 mg	Diluted with normal saline up to 45 mL before instillation
		Instillation into bladder via catheter. Clamp or plug foley (dwell time of 1 to 2 hours) *

*No need for patient to roll from side to side

• **Step 4:** After 1 to 2 hours unclamp the catheter and allow the urine and drug to drain into the drainage bag, then remove catheter.

Duration: Once monthly for 10 months (10 doses), starting 6 weeks after last dose of induction.

PRECAUTIONS:

- 1. Patients should be advised to minimise oral fluids (especially those containing caffeine) for 4-6 hours before each treatment to minimise dilution of drug in the bladder. The treatment works best full strength in the bladder.
- 2. Solid foods does not affect treatment. Take diuretics after treatment.
- 3. After treatment increase fluid intake to flush out any remaining drugs from the bladder.
- 4. Wash hands thoroughly after passing urine. Wash the perineum (women) or head of penis (men) after voiding to decrease skin irritation. Additional information on handling of body fluids in the home can be found <u>Handling Cancer Drugs and Body Fluids in the Home</u>

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- 5. Patients may experience some bladder irritation, with more frequent or painful urination, urination at night and some blood or tissue in the urine.
- 6. Cystoscopy will be performed by the urologist every three months during treatment (after induction and every third maintenance dose). It is important not to delay cystoscopy appointments, since this leads to delays in booking and administration of intravesical therapy.

Call Dr. Peter Black or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Reference:

- Steinberg RL, Thomas LJ, Brooks N, et al. Multi-Institution Evaluation of Sequential Gemcitabine and Docetaxel as Rescue Therapy for Nonmuscle Invasive Bladder Cancer. *The Journal of Urology*. 2020;203(5):902-909.
- 2. Milbar N, Kates M, Chappidi MR, et al. Oncological Outcomes of Sequential Intravesical Gemcitabine and Docetaxel in Patients with Non-Muscle Invasive Bladder Cancer. *Bladder Cancer*. 2017;3(4):293-303.
- 3. Steinberg RL, Thomas LJ, O'Donnell MA, Nepple KG. Sequential Intravesical Gemcitabine and Docetaxel for the Salvage Treatment of Non-Muscle Invasive Bladder Cancer. *Bladder Cancer*. 2015;1(1):65-72.
- 4. Daniels MJ, Barry E, Milbar N, et al. An evaluation of monthly maintenance therapy among patients receiving intravesical combination gemcitabine/docetaxel for nonmuscle-invasive bladder cancer. *Urol Oncol.* 2020;38(2):40 e17-40 e24.