BCG Intravesical Induction and Maintenance Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Non-Muscle Invasive Bladder Cancer – very high risk, high risk and intermediate risk groups	C67, C68	00807a	N/A

* This is for post 2012 indications.

TREATMENT:

Induction BCG:

Bacillus Calmette-Guérin (BCG) is administered by instillation into the bladder intravesically once weekly for 6 weeks.

Maintenance BCG:

Bacillus Calmette-Guérin (BCG) is administered by instillation into the bladder intravesically at the intervals listed below.

High risk/ Very high risk: Bacillus Calmette-Guérin (BCG) is administered by instillation into the bladder weekly for 3 consecutive weeks at 3, 6, 12, 18, 24, 30, 36 months*.

Intermediate risk: Bacillus Calmette-Guérin (BCG) is administered by instillation into the bladder weekly for 3 consecutive weeks at 3, 6, 12 months*.

*(Above indicates the ideal duration of maintenance treatment but may vary based on patient factors, tolerance and BCG availability).

Day	Drug	Dose	Route	Diluent & Rate
1	Bacillus Calmette-Guérin (BCG)[a]	One vial	Intravesical	Diluted in NaCl 0.9% up to 50mL. Administer instillation into bladder via catheter (dwell time of 1-2 hours)
[a]Brand selection based on product availability and clinician's decision. BCG strain: The strain and supplier may change from time to time. A patient would ideally receive all induction and maintenance therapy with the same strain, but switching strains is recommended if necessary to ensure administration of full dose according to conventional dosing schedule.				

ELIGIBILITY:

- Indications as above
- Risk groups* defined as:

Intermediate Risk	Patients without carcinoma in situ (CIS) who are not included in either the low-, high-, or very high-risk groups
High Risk	• All T1 high grade (HG)/G3 without CIS, EXCEPT those included in the very high-risk group • All CIS patients, EXCEPT those included in the very high-risk group
	Stage, grade with additional clinical risk factors: • Ta low grade (LG)/G2 or T1G1, no CIS with all 3 risk factors • Ta HG/G3 or T1 LG, no CIS with at least 2 risk factors • T1G2 no CIS with at least 1 risk factor
Very High Risk	Stage, grade with additional clinical risk factors: • Ta HG/G3 and CIS with all 3 risk factors • T1G2 and CIS with at least 2 risk factors • T1 HG/G3 and CIS with at least 1 risk factor • T1 HG/G3 no CIS with all 3 risk factors

*EAU NMIBC Risk Calculator available here: https://nmibc.net/

EXCLUSIONS:

- TURBT or urethral trauma within 2 weeks
- Hypersensitivity to BCG or any of the excipients.
- Pregnancy and Breastfeeding

CAUTIONS:

- T-cell immunodeficiency (idiopathic CD4 lymphopenia, HIV with CD4 count 200-350, CLL
- B-cell /Antibody immunodeficiencies
- Severe G6PD deficiency
- Current or recent immunosuppressive treatment (steroids, mycophenolate, azathioprine, Sirolimus, methotrexate, Tacrolimus)
- History of systemic chemotherapy agents such as riTUXimab, cycloPHOSphamide.

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Urologist.

TESTS:

Pre treatment:

- Cystoscopy with biopsy or resection to confirm histologic diagnosis

Post treatment:

- Cystoscopy +/- biopsy (GA) and urine cytology 8 weeks after the last dose of BCG and at regular intervals thereafter

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant Urologist.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with the Consultant Urologist.

Renal and Hepatic Impairment:

- There are no known published dose modification recommendations available for renal and hepatic impairment. Given that this is a localised treatment and is expected to have limited or no systemic absorption there is unlikely to be a dose modification in this setting.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- There are no known published recommendations available for emetogenic potential. Given that this is a localised treatment and is expected to have limited or no systemic absorption it is unlikely that anti-emetic cover is required in this setting.

PRE-MEDICATIONS: None usually required.

OTHER SUPPORTIVE CARE:

Patient education.

- To assist dwell time and reduce dilution of the BCG the patient should not drink any fluids over a period of 4 hours before the instillation and until 2 hours after the instillation.

ADVERSE EFFECTS

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.
- Please refer to the 2025 European Association of Urology (EAU) NMIBC guidelines for further information.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

REFERENCES:

1. EAU Guidelines on Non-muscle invasive Bladder Cancer (TaT1 and CIS). Last updated March 2025. Available at: https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Non-muscle-invasive-Bladder-Cancer-2025.pdf
2. BCG-medac®, powder and solvent for intravesical suspension. Last updated December 2023. Accessed January 2025. Available at: https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA0623-004-001_30092024155729.pdf
3. BCG LIVE-TICE ® (for intravesical use). Last updated August 2022. Available at: https://www.merck.com/product/usa/pi_circulars/t/tice_bcg/ticebcg_pi.pdf

Version	Date	Amendment	Approved By
1	22/04/2025		Ms Catherine Dowling
2	06/10/2025	References updated, addition of link to EAU NMIBC risk calculator	Ms Catherine Dowling

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.