



June 3, 2019

TO: Physicians Prescribing Treatment for Non-muscle Invasive Bladder Cancer (NMIBC)

RE: **UPDATE** - Approach for Consideration to Address Shortage/Outage of Bacillus Calmette-Guérin (BCG)

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As communicated previously, due to manufacturing capacity constraint, OncoTICE® supply in Canada has been in short supply and on an allocation program since Oct 2018. Bladder Cancer Canada has recently been informed that due to a manufacturing delay BCG will be temporarily unavailable in Canada beginning mid to late June until the end of July 2019.

Given this news, it is recommended that treatment facilities continue to closely monitor the BCG supply on hand. Conservation strategies to increase the pool of patients that can access BCG and provide alternatives if BCG is not available at all may be considered.

We are still awaiting final discussions between Health Canada and a second supplier with regards to accessing the BCG Russian strain for use in Canada. Bladder Cancer Canada is continuing to work closely with Health Canada and do everything possible to expedite the approval of a second BCG supplier in Canada and minimize the effect of the shortage on bladder cancer patients. While the shortage of BCG is ongoing, the Medical Advisory Board of Bladder Cancer Canada and the CUA Guidelines Committee have reviewed and support the following suggestions:

1. Intravesical chemotherapy should be used as first-line option for intermediate-risk NMIBC. All patients with multirecurrent/multifocal low-grade Ta lesions should receive mitomycin, gemcitabine or epirubicin instead of BCG.
2. If BCG is administered as second-line for intermediate-risk NMIBC, we suggest administering 1/3 dose of BCG (+/- interferon) instead of full dose BCG to triple the pool of patients that can get BCG. This requires treating multiple patients on the same day with the reduced dosage to avoid drug wastage. Maintenance BCG for intermediate-risk patients can be omitted.
3. For high-risk NMIBC, consider 1/3 dose BCG for both induction and maintenance BCG. Maintenance BCG can be shortened to one year (instead of 3 years) for 'low tier' high-risk tumors (TaHG tumors).
4. Other preferable alternatives to BCG include electromotive mitomycin (EMDA-MMC) or standard mitomycin (induction and maintenance up to one year). Other options such as gemcitabine, epirubicin or sequential gemcitabine/docetaxel may also be considered.
5. Consideration for upfront radical cystectomy as an option in patients with very high-risk disease (T1HG with additional risk factors such as concomitant CIS, lymphovascular invasion or micropapillary features) who are not willing to take any potential oncologic risks with alternative intravesical agents.

Sincerely,

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Chair, BCC Medical Advisory Board

Member, Canadian Urological Association Guidelines Committee