



September 2020

Dear Members:

Last year we shared a message regarding the global shortage of Merck's TICE BCG due to an increasing global demand for the product.

The American Urological Association (AUA), American Association of Clinical Urologists (AACU), Bladder Cancer Advocacy Network (BCAN), Society of Urologic Oncology (SUO), the Large Urology Group Practice Association (LUGPA) and the Urology Care Foundation (UCF) remain extremely concerned about this ongoing shortage and its effects on the care of bladder cancer patients. Efforts to engage the U.S. Food and Drug Administration to approve additional strains and supplies of BCG are continuing and all organizations noted above maintain communications with Merck for the most up-to-date information on this issue. In that regard, Merck has provided us with the following statement:

Our commitment to TICE BCG, while other companies have stopped production, is at the core of Merck's mission to save and improve lives. Our teams remain focused on maximizing the output and reliability of our current facility striving to provide additional supply of TICE BCG to patients. Additionally, we have been exploring additional ways in which to expand our current manufacturing capacity. Although any manufacturing expansion will take years to fully realize, we have recently confirmed that we have a path forward. More detailed information will be shared at the appropriate time.

We are also assessing our current allocation process to look for additional ways to optimize the distribution of available supply in the U.S., to the best of our ability.

The AUA recommends several management approaches to maintain high quality care for patients with Non-Muscle-Invasive Bladder Cancer (NMIBC). These recommendations may supersede the guideline statements found in the [Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Joint Guideline \(2020\)](#). As always, these recommendations are subject to physician judgment in individual cases:

1. BCG should not be used for patients with low-risk disease.
2. Intravesical chemotherapy should be used as the first-line option for patients with intermediate-risk NMIBC. Patients with recurrent/multifocal low-grade Ta lesions who require intravesical therapy should receive intravesical chemotherapy such as mitomycin, gemcitabine, epirubicin, or docetaxel instead of BCG.

3. If BCG would be administered as second-line therapy for patients with intermediate-risk NMIBC, an alternative intravesical chemotherapy should be used rather than BCG in the setting of this BCG shortage.
4. For patients with high-risk NMIBC, high-grade T1 and CIS patients receiving induction therapy, they should be prioritized for use of full-strength BCG. If not available, these patients and other high-risk patients may be given a reduced 1/2 to 1/3 dose, if feasible.
5. If supply exists for maintenance therapy for patients with NMIBC, limit BCG dose to one year.
6. In the event of BCG supply shortage, maintenance therapy should not be given and BCG naïve patients with high-risk disease should be prioritized for induction BCG.
7. If BCG is not available, alternatives to BCG such as gemcitabine, epirubicin, docetaxel, valrubicin, mitomycin, or sequential gemcitabine/docetaxel or gemcitabine/mitomycin may also be considered with an induction and possible maintenance regimen.
8. Patients with high-risk features (i.e., high-grade T1 with additional risk factors such as concomitant CIS, lymphovascular invasion, prostatic urethral involvement or variant histology) who are not willing to take any potential oncologic risks with alternative intravesical agents, should be offered initial radical cystectomy, if they are surgical candidates.

ADDITIONAL NOTES:

As always, it is important these decisions be made after an informed discussion with the individual patients regarding their treatment options in the context of the ongoing BCG shortage.

It is further recognized that there are billing, consent, oncological, and administration concerns around split-vial dosing of BCG. The AUA suggests confirmation with any insurance company prior to splitting vials and appropriately consenting the patients, administering the doses consistent with the package insert, and providing appropriate safeguards against exposure risks.

Sincerely,



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