



June 2020

UPDATED NOTIFICATION OF SUPPLY ALLOCATION: *TICE*[®] BCG BCG LIVE (for intravesical use)

This is an update regarding the supply of *TICE*[®] BCG BCG LIVE (for intravesical use) (“TICE BCG”), from Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

As explained in our January 2019 notice, Merck has been experiencing a supply shortage for TICE BCG due to increasing global demand. Though Merck has increased production of TICE BCG in recent years, despite our best efforts, the demand for this medicine now outpaces our maximum supply.

Supply Update of TICE BCG:

Our commitment to TICE BCG, while other companies have stopped production, is at the core of Merck’s mission to save and improve lives. We recently confirmed a path forward to expand manufacturing, although any expansion could take years to fully realize. We will provide more information on the plans for expansion when available.

Supply Allocation of TICE BCG:

To address the imbalance between supply and demand of TICE BCG and to minimize disruption to patient care, Merck will continue to implement the product allocation plan described in our January 2019 notice. This allocation program was designed to help ensure proportional distribution of available supply and will continue for the foreseeable future.

As a reminder, Merck is allocating available supply of TICE BCG to wholesalers and distributors based on their historical purchasing patterns. Merck is directing wholesalers and distributors, in turn, to allocate and ship TICE BCG to their healthcare professional customers based on available supply and the historical purchasing patterns of their healthcare professional customers. The same allocation procedure applies to both 340B covered entities and non-340B covered entities. Questions about the quantity or timing of supply available for a healthcare professional practice should be directed to the practice’s wholesaler or distributor for more information.

Saline Update:

In the past, Merck has provided preservative-free saline with certain orders of TICE BCG. Merck is no longer able to provide saline with TICE BCG and will discontinue the distribution of saline beginning in July 2020. To order preservative-free saline (0.9% Sodium Chloride Injection USP), healthcare professional practices should contact their wholesaler or distributor. This change applies equally to both 340B covered entities and non-340B covered entities.

Merck’s Commitment:

The continuity of supply of our medicines and vaccines has been, and remains, one of our highest priorities. We regret any inconvenience these supply constraints may cause covered entities and their patients. Some customers have expressed concern that Merck will discontinue manufacturing of TICE BCG. We want to provide assurance that we are working diligently not only to produce TICE BCG to the full extent of our current manufacturing capacity, but also on plans to expand production of TICE BCG, in order to meet the increasing global demand. We understand the importance of the supply of our medicines for patients and clinicians, and we will continue to provide updates to help keep you informed.

Please contact the Merck National Service Center at 1-800-672-6372 with any questions regarding this updated notice.

Sincerely,

/S/

Tim Fratus
Executive Director, U.S. Commercial Supply Chain Strategy and Access
Merck Sharp & Dohme Corp.