



January 2019

NOTIFICATION OF SUPPLY ALLOCATION: TICE® BCG BCG LIVE (for intravesical use)

Merck Sharp & Dohme Corp. ("Merck"), a subsidiary of Merck & Co., Inc., markets TICE® BCG BCG LIVE (for intravesical use) ("TICE BCG"):

Product	Description	NDC NUMBER
TICE® BCG BCG LIVE (for intravesical use)	Single Use Vial	00052-0602-02

Due to increased demand, and as the only source in many countries, Merck is anticipating supply constraints for TICE BCG beginning in January 2019. To minimize disruption to patient care and address the current imbalance between supply and increasing demand, we will be proportionally allocating the medicine across countries where Merck is the sole or primary supplier, including the United States. Limitations on purchasing of TICE BCG in the United States will be proportional and non-discriminatory for all customers, including 340B covered entities.

Beginning January 1, 2019, Merck will cease to accept drop shipment orders for TICE BCG and will move to a direct purchaser allocation model. Merck will allow each direct customer (including each wholesaler and distributor) to purchase a specified percentage of its historical purchase volume of TICE BCG, based on average utilization between April and September 2018. The specified allocation percentage will be determined by Merck based on available supply and will apply equally to all direct customers. Merck will then direct wholesalers and distributors to allocate their inventory of TICE BCG based on the specified allocation percentage as applied to each customer's historical purchasing patterns. For the first month, Merck will allocate TICE BCG to direct purchasers in a one-month supply and then will move to weekly allocations going forward. Merck will work with wholesalers and distributors to address requests by customers that do not have a previous history of purchasing TICE BCG, as we expect these circumstances to be rare. The same allocation procedure will apply to both 340B-covered entities and non-340B covered entities. Merck will continue to make TICE BCG available to covered entities at a price no higher than the statutorily calculated ceiling price.

Our company takes any disruption in access to our medicines seriously, and the continuity of supply remains one of our highest priorities. Over the past several years, Merck increased production of TICE BCG by more than 100 percent to enable production at the full extent of our company's manufacturing capacity. However, even with the increased production, the increasing global demand has led to supply constraints and unanticipated issues in the manufacturing process for TICE BCG can further impact availability. We believe the allocation approach described herein will help make TICE BCG available among all customers in a manner that takes into account the needs of patients based on historical demand during this period of limited supply.

At this time, Merck predicts that this allocation program will remain in place at least for 2019. Merck will adjust the specific purchase limits on an ongoing basis based on available supply or notification of end-customer movement between wholesalers (in all cases imposing a percentage reduction in purchasing that applies equally to all customers). We regret any inconvenience these supply constraints may cause to patients or our customers and are working diligently to identify ways to improve production of TICE BCG to help meet the increasing global demand. We will continue to make our customers aware of the availability of TICE BCG and we will provide updates as information is available.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Tim Fratus". The signature is written in a cursive, slightly slanted style.

Tim Fratus

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

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