



Frequently Asked Questions about Supply & Availability of BCG in the U.S.

What is BCG?

Bacille Calmette-Guérin (BCG) is an immunotherapy drug used to treat early-stage bladder cancer. BCG is placed in the bladder through a catheter and triggers the body's immune system to stop or slow the growth of cancer cells. BCG is approved by the U.S. Food and Drug Administration (FDA) to treat patients in the United States. BCG is also used to treat bladder cancer patients in many other countries around the world.

Why is there a shortage of BCG?

Merck & Co., Inc. is the sole maker and supplier of BCG to the United States. They are also the only source of BCG to many other countries around the world.

Although Merck has boosted its production of BCG by more than 100 percent and is producing the drug to the fullest extent of their manufacturing capacity, they are not able to sustain the increasing global demand of this product. This has led to supply constraints and a BCG shortage.

How long will this shortage last?

Due to the increasing demand for BCG treatment in many countries, including the United States, Merck anticipates this shortage to continue throughout 2019.

Why can't Merck make more BCG?

While Merck has many years of experience producing BCG, this medicine has a lengthy and complex manufacturing process. Merck continues to produce BCG at full capacity, but the demand for the drug is greater than what can be produced. Merck understands this is a challenge for patients and is working hard to improve production so they are able to get this medicine to patients as quickly as possible. On October 4, 2020, Merck announced plans to construct a new TICE BCG manufacturing facility in the United States. Merck expects to break ground in 2021 and anticipates the build to take up to six years to complete. Once fully operational, the company expects to triple its current manufacturing capacity, which is expected to support the anticipated demand for TICE BCG for the foreseeable future.

Can I get BCG somewhere else?

Merck is the sole maker and supplier of BCG to the United States. While the FDA is exploring opportunities to approve additional strains and supplies of BCG, Merck is still the only approved supplier at this time.

There are companies in Japan, Canada, and Europe working to develop their own strains of BCG. If the FDA ultimately approves them, they might be able to alleviate future shortages of the drug.

How is Merck determining how much BCG each country will receive during this shortage?

For the existing quantity of the medicine, and as more of it becomes available, Merck will be allocating the quantity of available supply across countries based on historical demand.

How is Merck determining how much BCG each physician office in the United States will receive during this shortage?

As the sole supplier of BCG to the United States, Merck is allocating the quantity of available supply across states based on historical demand.

To minimize disruption to patient care, in January, Merck announced an immediate change to their BCG distribution model, and began allocating BCG exclusively to wholesalers and distributors based on product supply and historical purchasing patterns of physicians and hospitals. Wholesalers and distributors in turn, began utilizing the same allocation model to fulfill physician and hospital orders directly.

Who can I call with more questions about the BCG shortage?

We understand this situation may be stressful to those who rely on this drug, and we are sorry. Please understand that we are working with suppliers in order to provide the best possible care for our patients. We encourage you to talk to your provider about alternative treatment options to BCG while this shortage continues.

For further information about BCG, please feel free to reach out to Merck's National Service Center at 1-800-444-2080.