

“Terrible Crisis” as Shortage of Bladder Cancer Therapy Persists

Since 2020, there has been a nationwide shortage of the bladder cancer therapy Bacillus Calmette Guérin (BCG). Here’s why.

February 28, 2023 By Laura Schmidt

The United States continues to face a shortage of the bladder cancer therapy [Bacillus Calmette-Guérin \(BCG\)](#), which has been a standard of care for many patients for more than 40 years.

Around 82,000 people will be diagnosed with bladder cancer and about 17,000 people will die of it this year in the United States, according to the [American Cancer Society](#). What’s more, bladder cancer has a 30% to 40% recurrence rate, which is relatively high.

More than 8,300 people with [bladder cancer](#) each year are not receiving full BCG treatments, according to a [recent report](#) by the End Drug Shortages Alliance. The therapy is older and relatively expensive and complicated to manufacture. BCG is a biologic drug, meaning it is isolated from a natural, living source (a bacterium, in this case). Plus, the market for BCG is small, none of which entices pharmaceutical companies to make the treatment.

“This is a terrible crisis. We should be doing everything we can to give every single one of these patients the best chance of survival,” Laura Bray, a board member of [End Drug Shortages](#), told [CNN](#). “It’s heartbreaking, and we must do better.”

These days, Merck is the only pharmaceutical company manufacturing BCG. Sanofi Pasteur stopped making the therapy in 2017.

A spokesperson for Merck told CNN that the company increased production of BCG by 200% between 2012 and 2019 and is building a facility to meet demand. However, the facility won’t be completed until late 2025 or late 2026, according to the spokesperson.

“Our company will continue to work to complete this project and meet patient needs in as timely a manner as possible,” the statement read. “Our commitment to [BCG] is at the core of Merck’s mission to save and improve lives. We continue to recognize the impact supply shortages can have on patients when they cannot receive the medicines they need.”

The Food and Drug Administration (FDA) released a statement assuring individuals that “whenever

a shortage occurs, FDA actively works with manufacturers and other U.S. federal agencies to try to address supply issues for the drug product in shortage.”

Last summer, the National Cancer Institute reported promising results of an alternative therapy to BCG. For more, see the NCI’s Cancer Health blog post “[For Common Form of Bladder Cancer, Chemo Combo Is Effective Alternative to BCG.](#)”

To learn more, click [#Bladder Cancer](#) or [Cancer Health Basics on Bladder Cancer](#). The Basics reads in part:

What is bladder cancer?

Bladder cancer develops when cells of the urinary bladder grow out of control. The most common type of bladder cancer is urothelial carcinoma (also known as transitional cell carcinoma), which starts in the lining of the urinary tract. Urothelial cancer can also originate in the lower part of the kidneys, the ureters (tubes that connect the kidneys to the bladder) or the urethra (tube that excretes urine from the bladder). Rare types of bladder cancer include squamous cell carcinoma, adenocarcinoma, small cell carcinoma and sarcoma. Noninvasive bladder cancer is limited to the inner layer of the bladder, while invasive cancer has spread to deeper layers of tissue.

What are the risk factors for bladder cancer?

Smoking is a leading risk factor for bladder cancer. Smokers are two to six times more likely to develop this malignancy than nonsmokers. Environmental exposures, such as exposure to industrial chemicals, diesel exhaust, petroleum products or arsenic in drinking water, have been linked with higher bladder cancer risk. Certain medical conditions are also associated with an increased risk, including a history of urinary tract infections, inflammation (cystitis), kidney or bladder stones, long-term catheter use, certain birth defects and schistosomiasis (a disease caused by a parasitic worm).

What are the symptoms of bladder cancer?

The bladder is a hollow muscular organ that stores urine collected from the kidneys before it is disposed of by urination.

Symptoms of bladder cancer in early stages may include:

- Blood in the urine (hematuria)
- Need to urinate frequently
- An intense feeling of needing to urinate (urinary urgency)
- Difficulty urinating or weak urine stream

- Pain or a burning sensation during urination.

Symptoms of bladder cancer in later stages may include:

- Inability to urinate
- Pain in the lower back or rectum
- A lump in the pelvis
- Swelling in the feet, legs, or genitals
- Loss of appetite
- Weight loss
- Fatigue.