



IMFINZI + Bacillus Calmette-Guérin (BCG) Treatment Roadmap

for high-risk non-muscle-invasive bladder cancer (NMIBC)

An overview of IMFINZI + BCG, an FDA-approved treatment for adults with high-risk NMIBC who have not previously received treatment with BCG.

Explore this booklet to understand what you may expect from your treatment plan and to find resources to support you along the way.



Year 1:

IMFINZI + BCG work together to treat high-risk NMIBC



Year 2:

BCG continues to treat high-risk NMIBC alone

Your doctor will determine how often and how long you will receive treatment.
You will stop if your side effects are too difficult to manage.

What is IMFINZI?

IMFINZI is a prescription medicine used in combination with Bacillus Calmette-Guérin (BCG) to treat **a type of bladder cancer called high-risk non-muscle invasive bladder cancer (NMIBC) that has not spread into the muscle layer of the bladder**, when you have not had prior treatment with BCG.

It is not known if IMFINZI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMFINZI[®] (durvalumab)?

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Please see additional Important Safety Information on pages 12-15 and click the following for Full Prescribing Information including Medication Guide for IMFINZI.



Understanding IMFINZI and BCG

IMFINZI + BCG is the first and only combination immunotherapy treatment for adults with high-risk non-muscle-invasive bladder cancer (NMIBC) who have not previously been treated with BCG.

IMFINZI and BCG work together to treat high-risk non-muscle-invasive bladder cancer. They are both immunotherapies, but they work in different ways.



IMFINZI is a type of immunotherapy that works as a **systemic treatment**. This means it travels throughout the body to help the immune system fight cancer cells. IMFINZI may affect healthy cells.



BCG is an **intravesical immunotherapy**, which means it targets the cancer cells found inside of the bladder. BCG may affect healthy cells.

IMFINZI is given in a different way than BCG. While BCG is given into the bladder using a catheter, IMFINZI infusions are typically given into a vein in your arm.



Treatment companion worksheet

This roadmap may help you better understand your treatment journey. Use the prompts below to guide discussions with your care team and check in with yourself.

(Check all that apply.)

What’s most important to me?

- ☐ Understanding my full treatment plan
- ☐ Emotional support during treatment
- ☐ Knowing what side effects to expect

What do I need extra help with?

- ☐ Learning about NMIBC
- ☐ Talking to loved ones about my treatment
- ☐ Finding educational or support resources

How am I feeling about treatment so far?

- ☐ Feeling hopeful
- ☐ Having some worries
- ☐ Could use more support

What do I want my care team to know?



Sign up for the IMFINZI care package

Every bit of support helps. Discover additional tools and resources in the care package. Visit imfinzi.com/signup to sign up.

SELECT SAFETY INFORMATION (continued)
Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:
Lung problems: cough, shortness of breath, and chest pain
For additional Important Safety Information, [click here](#)



Getting started with IMFINZI + BCG

IMFINZI is given for



IMFINZI infusions

IMFINZI infusions are given in cycles. One cycle is typically equal to 4 weeks. When treating high-risk NMIBC, you will receive IMFINZI:

- Every 4 weeks for 13 cycles

BCG induction alongside IMFINZI

Induction refers to the first set of BCG treatments.

- While on IMFINZI, you will receive BCG once a week for 6 weeks

BCG maintenance alongside IMFINZI

Maintenance refers to the set of BCG treatments given to help continue treating high-risk NMIBC.

- While on IMFINZI, you will receive BCG once a week for 3 weeks, followed by 1 week off, during months 3, 6, and 12

BCG maintenance continues

- You will receive BCG alone once a week for 3 weeks, followed by 1 week off, during months 18 and 24

Your doctor will tell you how many treatments you need.



SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Intestinal problems: diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; and severe stomach-area (abdomen) pain or tenderness

For additional Important Safety Information, [click here](#).

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

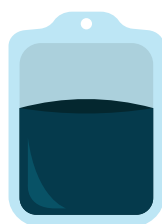


Your treatment plan overview

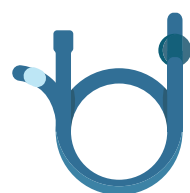
Here is what your treatment plan with IMFINZI + BCG may look like.

Your doctor will determine exactly how many treatments you may need based on how your body responds to treatment. Your healthcare provider may also need to delay or completely stop treatment with IMFINZI if you have severe side effects.

1 year of IMFINZI + BCG



IMFINZI, given **every 4 weeks** for **13 cycles**



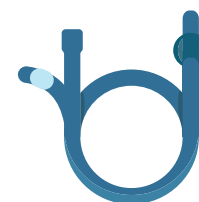
BCG induction while on IMFINZI
BCG, given **weekly** for **6 weeks**



BCG maintenance while on IMFINZI
BCG will continue being given, but at months 3, 6, and 12. This time you'll receive BCG **once a week** for **3 weeks**, followed by 1 week off



1 additional year of BCG alone



BCG maintenance continues
BCG will continue being given **every week** for **3 weeks**, followed by 1 week off, during months 18 and 24

As you learn more about your personal treatment plan, take notes to keep track of important dates and information.

IMFINZI infusions

First treatment date:

Where I'll receive IMFINZI:

How often I'll receive IMFINZI:

BCG treatments

First treatment date:

Where I'll receive BCG:

How often I'll receive BCG:

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Liver problems: yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), and bleeding or bruising more easily than normal

For additional Important Safety Information, [click here](#).





Preparing for treatment



Questions to ask your care team

Your treatment journey may feel overwhelming, and it's easy to forget some details. Use the questions below to keep track of important information to discuss with your care team.

How can I prepare for BCG treatment?

Where can I find support resources?

What are the side effects of IMFINZI + BCG that I should look out for?

What are the most important things I should know about treatment?

What can I do to feel more comfortable during treatment?

Who can I contact if I have questions between appointments?

SELECT SAFETY INFORMATION (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Hormone gland problems: headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

For additional Important Safety Information, [click here](#).





Staying inspired on treatment



During BCG treatment or IMFINZI infusion days, here are some ways to pass time and stay motivated:



Catch up on your favorite TV show



Listen to an online meditation



Read a book or do a puzzle



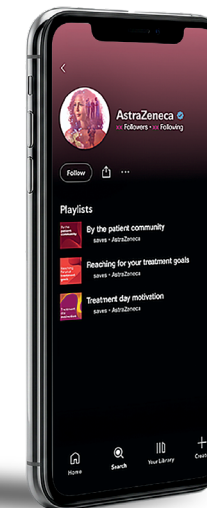
Write in a journal



Call a friend



Download a podcast



Listen to a Spotify playlist curated for patients

[Click here to listen](#)



Check out your IMFINZI wellness journal

Use the IMFINZI wellness journal to note important things you'd like to remember during treatment. Find it in your care package.



Important Safety Information

What is the most important information I should know about IMFINZI® (durvalumab)?

IMFINZI is a medicine that may treat certain cancers by working with your immune system. IMFINZI can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:



Lung problems: cough, shortness of breath, and chest pain



Intestinal problems: diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; and severe stomach-area (abdomen) pain or tenderness



Liver problems: yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), and bleeding or bruising more easily than normal



Hormone gland problems: headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness



Kidney problems: decrease in your amount of urine, blood in your urine, swelling of your ankles, and loss of appetite



Skin problems: rash; itching; skin blistering or peeling; painful sores or ulcers in mouth or nose, throat, or genital area; fever or flu-like symptoms; and swollen lymph nodes



Pancreas problems: pain in your upper stomach area (abdomen), severe nausea or vomiting, and loss of appetite



Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with IMFINZI. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include: Chest pain, irregular heartbeats, shortness of breath or swelling of ankles; confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems; tingling, numbness or weakness of the arms or legs; double vision, blurry vision, sensitivity to light, eye pain, changes in eye sight; persistent or severe muscle pain or weakness, muscle cramps, joint pain, joint stiffness or swelling; and low red blood cells and bruising



Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include: chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, and back or neck pain



Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ or tissue transplant that you have had



Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with IMFINZI. Your healthcare provider will monitor you for these complications

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with IMFINZI. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with IMFINZI if you have severe side effects



Important Safety Information (continued)

Before you receive IMFINZI, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ or tissue transplant, including corneal transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. IMFINZI can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with IMFINZI.
- You should use an effective method of birth control during your treatment and for 3 months after the last dose of IMFINZI. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with IMFINZI.
- are breastfeeding or plan to breastfeed. It is not known if IMFINZI passes into your breast milk. Do not breastfeed during treatment and for 3 months after the last dose of IMFINZI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of IMFINZI?

IMFINZI can cause serious side effects (see [pages 12-13](#)).

The most common side effects of IMFINZI when used with Bacillus Calmette-Guérin (BCG) in adults with high-risk NMIBC include increased liver function tests, urinary tract infection, increased level of potassium in blood, pain or discomfort with urination, decreased red blood cells (anemia), blood in urine, increased level of creatinine in the blood, muscle or bone pain, decreased lymphocyte counts, urinate more often, decreased level of sodium in the blood, feeling tired, rash, and fever.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of IMFINZI. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may [report side effects related to AstraZeneca products](#). If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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LEARN MORE ABOUT IMFINZI

Get started at IMFINZI.com/NMIBC

Or call AstraZeneca at 1-800-236-9933

Monday-Friday, 8 AM–6 PM ET, excluding holidays



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