

Durvalumab and Bacillus Calmette-Guérin (BCG)

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for certain types of bladder cancer.
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Durvalumab (dur-VAL-yoo-mab): Imfinzi (im-FIN-zee)	Boosts your immune system to help it attack cancer cells more effectively.	Infusion into a vein (intravenous (IV) infusion).
Bacillus Calmette-Guérin (buh-SIL-uhs kal-MET geyRAN): Tice BCG (TYSS BEE-SEE-JEE) • This treatment is often called “BCG”.	Uses a weakened bacterium to boost the immune system, helping the body fight off cancer cells.	Injection through a catheter directly into your bladder (intravesicular) that is left there for 2 hours. During this time your care team may change your position about every 15 minutes to help the treatment reach all surfaces of your bladder.

Treatment Administration and Schedule

- Durvalumab is typically repeated every 28 days. This length of time is called a “cycle.” Treatment is typically continued for up to 13 cycles.
- BCG treatment typically has 2 parts: induction and maintenance.

Durvalumab

Treatment Name	Cycle 1								Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	...	Day 28	Day 1
Durvalumab	✓								✓

Treatment Administration and Schedule (Continued)

BCG

Induction

- BCG is given once a week for 6 weeks.
- If needed, your care team may recommend a second 6-week induction course.

Treatment Name	Induction: Week 1 of Treatment							Week 2
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 1
BCG	✓							✓

Maintenance

- BCG is given once a week for 3 weeks at months 3, 6, 12, 18, and 24 (total of 15 maintenance doses).
- Your care team may also recommend an additional maintenance course. BCG is sometimes given once a week for 3 weeks at months 25, 31, and 37 (total of 9 additional maintenance doses).

Treatment Name	Maintenance: Month of Treatment								
	Day 1	...	Day 8	...	Day 15	...	Day 22	...	Day 28
BCG	✓		✓		✓				

Appointments

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
Supportive care used to treat or prevent side effects		

Common Side Effects

Side Effect	Important Information
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak or very tired, or may make you look pale. Recommendations: - Aim for 7 to 8 hours of sleep each night. - Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. - Balance activity and rest — stay as active as you can, but rest when needed. - Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: - Shortness of breath - Dizziness or fainting - Fast or irregular heartbeats - Sudden or severe headache
Liver Problems	Description: Treatment can cause your immune system to attack healthy cells in your liver. Your care team may check your liver with blood tests before and during treatment. Talk to your care team if you have: - Yellowing of your skin or the white part of your eyes (jaundice) - Severe nausea or vomiting - Pain on the right side of your stomach area (abdomen) - Dark, tea-colored urine - Bleeding or bruising more easily than normal
Kidney Problems	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment. Recommendations: - Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. - Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: - Decrease in your amount of urine - Blood in your urine - Swelling of your ankles - Loss of appetite

Bladder Problems and Urinary Tract Infections (UTI)	Description: Treatment can irritate the bladder lining and may also increase your chance of getting a UTI. This may cause burning with urination (dysuria), blood in the urine (hematuria), frequent urination, strong urges to urinate, cloudy or foul-smelling urine, lower stomach (abdominal) discomfort, or fever. Recommendations: • Drink plenty of fluids (unless your care team says otherwise) to help flush the bladder. • Avoid caffeine, alcohol, and spicy foods if they make symptoms worse. • Urinate gently and do not hold urine for long periods. • Your care team may recommend or prescribe medicine to help with bladder problems. • Wash your hands often and bathe regularly. • Keep any catheter site clean and dry. Follow all instructions provided by your care team. Talk to your care team if you have: • Blood in your urine or blood clots • Red-tinged urine lasting more than 24 hours after treatment • Severe or worsening pain when urinating • Inability to urinate or very little urine output • Fever of 100.4°F (38°C) or higher, chills, or signs of infection • Fainting, dizziness, or very heavy bleeding • Cloudy or foul-smelling urine • Frequent urination
High Blood Sugar (Hyperglycemia)	Description: Treatment may cause high blood sugar levels. Your care team may perform blood tests to check for these changes and treat you if needed. Recommendations: • Eat a well-balanced diet. • Limit sugary drinks and foods. • Eat smaller, more frequent meals. • Be physically active for at least 30 minutes most days. • Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently. Talk to your care team if you have: • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar

Muscle or Bone Pain	Description: Treatment can cause your immune system to attack your bones and muscles. This can make your muscles and bones hurt. Recommendations: • Keep a pain diary: note pain levels, locations, and activities that make it better or worse. • Try gentle exercise (walking, stretching, yoga) to maintain mobility and strength. Check with your care team before starting a new activity. • Use a warm compress for stiff muscles or a cold pack to reduce swelling and numb pain—use what helps the area. • Your care team may recommend or prescribe medicines, including over-the-counter pain relievers. Talk to your care team if you have: • Pain you cannot control with usual measures • Swelling, redness, or warmth in a joint • New weakness • Trouble walking or moving
High Potassium Levels in Your Blood (Hyperkalemia)	Description: Treatment may cause high levels of potassium in your blood. Your care team will perform blood tests to check for these changes and will treat you if needed. Talk to your care team if you have: • New or worsening muscle weakness or numbness • Fast, slow, irregular, or pounding heartbeats • Severe dizziness, fainting, or near-fainting • Shortness of breath or chest pain

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms	
Infections (Boxed Warning)	BCG placed in the bladder can rarely spread beyond the bladder and cause serious or life-threatening infections. The risk is higher if the bladder is actively bleeding, after recent bladder procedures, with other infections, or if you take immune-suppressing medicines. Your care team may perform a purified protein derivative (PPD) test before you start treatment to rule out tuberculosis (TB). - Fever, chills, or night sweats - Severe or increasing belly, pelvic, or flank pain - Heavy or worsening blood in the urine or large blood clots - Persistent cough, coughing up blood, or breathing trouble - New unexplained weight loss, fatigue, or swollen lymph nodes - Any sudden severe illness after treatment, even months later	
Intestinal Problems	Diarrhea (loose stools) or more frequent bowel movements than usual	- Stools that are black, tarry, sticky, or have blood or mucus - Severe stomach-area (abdominal) pain or tenderness
Kidney Problems	- Decrease in your amount of urine - Blood in your urine	- Swelling of your ankles - Loss of appetite
Lung Problems	- Cough - Shortness of breath	Chest pain or tightness
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 - Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
Skin Problems	- Rash - Itching	- Skin blistering or peeling - Painful sores or ulcers in the mouth or nose, throat, or genital area

Problems in Other Organs and Tissues	- Chest pain, irregular heartbeat, shortness of breath, swelling of ankles - Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs	- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight - Persistent or severe muscle pain or weakness, muscle cramps - Low red blood cells, bruising
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Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body**. However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
 - If you are able to become pregnant:
 - Your care team will verify your pregnancy status before treatment.
 - Use an effective method of birth control during treatment with durvalumab and BCG, and for 3 months after your last dose of durvalumab.
 - If you think you might be pregnant or if you become pregnant, tell your care team right away.
 - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment with durvalumab and BCG.
- Do not breastfeed** during treatment and for 3 months after your last dose of durvalumab. It is **not known** if BCG is present in **breast milk**. Talk with your care team if you are breastfeeding or plan to breastfeed.

Safety and Hygiene

- People who are immunosuppressed or immune-deficient should not prepare, administer, receive, or come into contact with BCG.
- Do not drink anything for 4 hours before your treatment.
- Go to the bathroom and empty your bladder just before you arrive for your treatment.
- When you first urinate after the treatment, you may feel a burning or stinging sensation. This is common.
- Sit down to urinate to avoid splashing.
- For the first 6 hours after treatment, disinfect your urine before flushing. Add an equal amount of household bleach to the toilet (for example, if the toilet bowl has one cup of water, add one cup of bleach), let it sit for 15 minutes, then flush. If your home has a septic tank system, contact your local septic tank service company for advice or questions before using bleach. Follow any local safety rules on bleach use and ventilation.
- If using an incontinence pad, disinfect the pad only after it becomes soiled or has been used: pour bleach onto the used pad, allow it to soak, place it in a sealable plastic bag, and dispose of it in the trash.
- Drink plenty of water after the treatment to help flush your bladder.
- Wash your hands with soap and water after you use the bathroom.

- **Tell your care team about all the medicines you take.**

- **Tell your care team about all your health problems.** This includes issues with your immune system, like Crohn's disease, ulcerative colitis, or lupus. Also, tell them if you have had an organ transplant, like a kidney or eye transplant. Let them know if you had a stem cell transplant from a donor, had radiation to your chest, or have a nerve problem like myasthenia gravis or Guillain-Barré syndrome.

- **This Patient Education Sheet may not describe all possible side effects.**

Notes

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ACCC
ASSOCIATION OF CANCER CARE CENTERS



HOPA
Hematology/Oncology
Pharmacy Association



NCODA
Network for Collaborative Oncology
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