BC Cancer Protocol Summary for Adjuvant Treatment of Resected Muscle-Invasive Bladder Cancer using Durvalumab

Protocol Code	*GUBAJDUR*
Tumour Group	*Genitourinary*
Contact Physician	*GU Systemic Therapy*

ELIGIBILITY:

Patients must have:

- Resected muscle-invasive bladder cancer (MIBC), clinical stage T2N0-1M0 to T4aN0-1M0,
- Completed neoadjuvant treatment with GUBNADURPG,
- Adjuvant treatment initiation within 6 months of surgery, without evidence of disease progression

Patients should have:

- Good performance status,
- Adequate hepatic and renal function,
- Access to a treatment centre with expertise to manage immune-mediated adverse reactions of durvalumab

Notes:

- Patient who underwent bladder-sparing trimodal therapy are eligible
- Patients are eligible for subsequent immunotherapy treatments provided progression occurred at least 6 months after completion of GUBAJDUR

EXCLUSIONS:

Patients must not have:

- Any small-cell histologic features
- Pure non-urothelial carcinoma

CAUTIONS:

- Active or previous autoimmune disease
- Patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg predniSONE/day or equivalent)

TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, morning serum cortisol, appropriate imaging (at least a baseline chest x-ray if no baseline chest CT)
- Before each treatment: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH
- If clinically indicated: chest x-ray, morning serum cortisol, lipase, serum or urine HCG (required for woman of childbearing potential if pregnancy suspected), free T3 and free T4, serum ACTH levels, testosterone, estradiol, FSH, LH, random glucose, ECG, C-reactive protein (CRP), creatine kinase (CK), troponin
- Weekly telephone nursing assessment for signs and symptoms of side effects while on treatment (optional).

PREMEDICATIONS:

- Antiemetics are not usually required
- Antiemetic protocol for low emetogenicity (see SCNAUSEA)
- If prior infusion reactions to durvalumab: diphenhydrAMINE 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV 30 minutes prior to treatment

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
durvalumab	20 mg/kg* (maximum 1500 mg)	IV in 100 mL NS over 60 minutes Using a 0.2 micron in-line filter

* Select dose per Dose Banding Table (appendix).

- Repeat every 4 weeks for 8 cycles (i.e. a combined total of 12 cycles, including doses given as GUBNADURPG), unless disease progression or unacceptable toxicity

DOSE MODIFICATIONS:

No specific dose modifications. Toxicity managed by treatment delay and other measures (see SCIMMUNE for management of immune-mediated adverse reactions to checkpoint inhibitor immunotherapy).

PRECAUTIONS:

1. **Serious immune-mediated reactions**: can be severe to fatal and usually occur during the treatment course, but may develop months after discontinuation of therapy. They may include enterocolitis, intestinal perforation or hemorrhage, hepatitis, dermatitis, neuropathy, endocrinopathy, pneumonitis, as well as toxicities in other organ systems. Early diagnosis and appropriate management are essential to minimize life-threatening complications (see SCIMMUNE for management of immune-mediated adverse reactions to checkpoint inhibitor immunotherapy).

2. **Infusion-related reactions:** isolated cases of severe infusion reactions have been reported. For mild or moderate infusion reactions, decrease the infusion rate to 50% or temporarily interrupt infusion until the reaction has resolved. Consider premedication for subsequent infusions. Permanently discontinue durvalumab for severe reactions.
3. **Infections:** severe infections such as sepsis, necrotizing fasciitis, and osteomyelitis have been reported. Treat suspected or confirmed infections as indicated. Withhold durvalumab for severe infections.

Contact the GU Systemic Therapy physician at your regional cancer centre or the GU Systemic Therapy Chair with any problems or questions regarding this treatment program.

REFERENCES:

1. Powles T, Catto JWF, Galsky MD, et al. Perioperative durvalumab with neoadjuvant chemotherapy in operable bladder cancer. N Engl J Med 2024;391:1773-86
2. Durvalumab (Imfinzi) CADTH Reimbursement Recommendation. Canadian Journal of Health Technologies Jan 2026; 6(1): 1-13.

Appendix. Dose Bands

DURVALUMAB DOSE BANDING TABLE (20 mg/kg capped at 1500 mg)

Ordered Dose (mg)		Rounded dose (mg)
From:	To:	
Less than 369		**Pharmacy prepares specific dose**
369	440.49	**400**
440.5	475.49	**450**
475.5	555.49	**500**
555.5	666.49	**600**
666.5	777.49	**700**
777.5	888.49	**800**
888.5	999.49	**900**
999.5	1099.49	**1000**
1099.5	1199.49	**1100**
1199.5	1299.49	**1200**
1299.5	1399.49	**1300**
1399.5	1499.49	**1400**
1499.5	1500	**1500**