

Regimen Reference Order

GAST – durvalumab + gemcitabine + CISplatin (biliary tract)

ARIA: GAST - [durvalumab + gem + CIS]

GAST - [durvalumab (maintenance)]

Planned Course: durvalumab + gemcitabine + CISplatin every 21 days for 8 cycles, followed by durvalumab every 28 days until disease progression or unacceptable toxicity

Indication for Use: Biliary Tract Cancer; Unresectable or Metastatic

Drug Alert: Immune Checkpoint Inhibitor (durvalumab)

CVAD: At Provider’s Discretion

Proceed with treatment if:

Day 1 of Cycles 1 to 8

- *ANC equal to or greater than $1.5 \times 10^9/L$ AND Platelets equal to or greater than $100 \times 10^9/L$*
- *AST/ALT equal to or less than 3 times the upper limit of normal*
- *Total bilirubin equal to or less than 1.5 times the upper limit of normal*
- *Creatinine clearance is greater than 45 mL/minute*

Day 8 of Cycles 1 to 8

- *ANC equal to or greater than $1.5 \times 10^9/L$ AND Platelets equal to or greater than $100 \times 10^9/L$*
- *Creatinine clearance is greater than 45 mL/minute*

durvalumab Maintenance

- *ANC equal to or greater than $1.5 \times 10^9/L$ AND Platelets equal to or greater than $50 \times 10^9/L$*
- *AST/ALT equal to or less than 3 times the upper limit of normal*
- *Total bilirubin equal to or less than 1.5 times the upper limit of normal*
- *Creatinine clearance is equal to or greater than 30 mL/minute*

❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements		
Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – GAST – durvalumab + gemcitabine + CISplatin

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
durvalumab + gemcitabine + CISplatin (Cycles 1 to 8)		
Day 1		
durvalumab	1500 mg	IV in normal saline 250 mL over 1 hour <i>Use 0.2 or 0.22 micron filter</i>
aprepitant	125 mg	Orally 1 hour pre-chemotherapy
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy
OLANzapine	2.5 mg	Orally 30 minutes pre-chemotherapy
gemcitabine	1000 mg/m ²	IV in normal saline 250 mL over 30 minutes
CISplatin	25 mg/m ²	IV in normal saline 250 mL over 1 hour
Day 8		
aprepitant	125 mg	Orally 1 hour pre-chemotherapy
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy
OLANzapine	2.5 mg	Orally 30 minutes pre-chemotherapy
gemcitabine	1000 mg/m ²	IV in normal saline 250 mL over 30 minutes
CISplatin	25 mg/m ²	IV in normal saline 250 mL over 1 hour
durvalumab Maintenance starts 3 weeks after Cycle 8, Day 1 of durvalumab + gemcitabine + CISplatin		
durvalumab Maintenance every 4 weeks		
durvalumab	1500 mg	IV in normal saline 250 mL over 1 hour <i>Use 0.2 or 0.22 micron filter</i>

In the event of an infusion-related hypersensitivity reaction, refer to the 'Hypersensitivity Reaction Standing Order'

REQUIRED MONITORING

All Cycles

Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin, glucose and TSH as per Physician Orders
- Medical oncologist or designate (i.e. family practitioner in oncology) must assess patient for immune-mediated adverse reactions prior to each cycle
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O₂ saturation) at baseline and as clinically indicated
- No observation period is required after durvalumab administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

Cycles 1 to 8 only

Day 8

- CBC and serum creatinine as per Physician Orders

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
Cycles 1 to 8 (durvalumab + gemcitabine + CISplatin)		
aprepitant	80 mg	Orally once daily on Days 2, 3, 9 and 10
dexamethasone	8 mg	Orally once daily on Days 2, 3 and 4 and 9, 10 and 11
OLANzapine	2.5 mg	Orally the evening of Days 1 and 8 then twice daily on Days 2, 3 and 4 and 9, 10 and 11. Also use OLANzapine 2.5 to 5 mg AS NEEDED for breakthrough nausea and vomiting (including Days 1 to 4 and 8 to 11) up to maximum of 10 mg per day. Contact clinic if nausea/vomiting is not adequately controlled

DISCHARGE INSTRUCTIONS

All Cycles

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- Confirm that patient has received the CCMB Immune Checkpoint Inhibitor Medical Alert wallet card
- Reinforce to patient the immune-mediated adverse reactions and importance of reporting immediately
 - For severe symptoms, the patient should be instructed to go to the nearest emergency room. Oncologist on call should be contacted

Cycles 1 to 8

- Instruct patient to continue taking anti-emetic(s) at home
- Maintain oral intake of 2000 mL (8 glasses) of fluid daily at home
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- durvalumab is an Immune Checkpoint Inhibitor. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated
- CISplatin is ototoxic and nephrotoxic
- CISplatin can cause hypomagnesemia
- **Note:** Upon completion of 8 cycles of **GAST - [durvalumab + gem + CIS]**, patients should be started on maintenance treatment with **GAST - [durvalumab (maintenance)]**
 - **GAST - [durvalumab (maintenance)]** should begin 21 days after Cycle 8, Day 1 of **GAST - [durvalumab + gem + CIS]**