

# Regimen Reference Order – GAST – tremelimumab + durvalumab

ARIA: GAST – [treme + durvalumab]

**Planned Course:** tremelimumab + durvalumab for one cycle, followed by durvalumab every 28 days until progressive disease/unacceptable toxicity

**Indication for Use:** Hepatocellular Carcinoma; Locally Advanced; 1<sup>st</sup> Line

**Drug Alert:** Immune Checkpoint Inhibitor (tremelimumab and durvalumab)

**CVAD:** At Provider’s Discretion

***Proceed with treatment if:***

- *ANC equal to or greater than 1.5 x 10<sup>9</sup>/L AND Platelets equal to or greater than 50 x 10<sup>9</sup>/L*
- *AST/ALT less than 3 times the upper limit of normal*
- *Total bilirubin less than 1.5 times the upper limit of normal*
- *Creatinine clearance 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 – tremelimumab + durvalumab

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
<b>Cycle 1 – tremelimumab and durvalumab</b>		
tremelimumab	300 mg (single dose)	IV in 250 mL normal saline over 1 hour <i>Use 0.2 or 0.22 micron filter</i> <b>*Nursing Alert:</b> durvalumab infusion begins after observation period is complete <b>*Nursing Alert:</b> Start a new primary infusion line for durvalumab
durvalumab	20 mg/kg	IV in 250 mL normal saline over 1 hour <i>Use 0.2 or 0.22 micron filter</i>
<b>Cycle 2 and Onwards – durvalumab every 28 days</b>		
durvalumab	20 mg/kg	IV in 250 mL normal saline over 1 hour <i>Use 0.2 or 0.22 micron filter</i>

**Maximum durvalumab dose is 1500 mg**

All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding Document for more information

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

## REQUIRED MONITORING

### Cycle 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin, glucose and TSH as per Physician Orders
- Morning cortisol as per Physician Orders
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O<sub>2</sub> saturation) at baseline and as clinically indicated
- Observe patient for 1 hour after administration of tremelimumab. Full vital signs after observation period is complete. durvalumab infusion begins after observation period is complete
- No observation period required after durvalumab administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

### Cycles 2 and Onwards

- 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 O<sub>2</sub> saturation) at baseline and as clinically indicated
- No observation period is required after durvalumab. Patient can be discharged from treatment room if stable whether they had a reaction or not

### Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
None required		

## DISCHARGE INSTRUCTIONS

- Patient 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

## ADDITIONAL INFORMATION

- tremelimumab and durvalumab are Immune Checkpoint Inhibitors. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated
- This regimen can cause severe and fatal immune-mediated adverse reactions
- This regimen is also referred to as “**STRIDE**”: Single Tremelimumab Regular Interval Durvalumab rEgimen