Regimen Reference Order

GAST – nivolumab + CARBOplatin + fluorouracil

ARIA: GAST - [nivolumab + CARBO + 5FU]

- Planned Course:nivolumab + CARBOplatin + fluorouracil every 21 days until disease progression
or unacceptable toxicity up to a maximum of 35 cycles (2 years)
- Indication for Use: Gastric or Gastroesophageal Junction or Esophageal Adenocarcinoma; Locally Advanced/Metastatic

Drug Alert: Immune Checkpoint Inhibitor (nivolumab)

CVAD: Required (Ambulatory Pump)

Proceed with treatment if:

- ANC equal to or greater than 1.5×10^9 /L AND Platelets equal to or greater than 100×10^9 /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-treatn	nent Requirements
Drug	Dose	CCMB Administration Guideline
	Ν	ot Applicable

Treatment Regimen – GAST – nivolumab + CARBOplatin + fluorouracil

Establish primary solution 500 mL of: normal saline			
Drug	Dose	CCMB Administration Guideline	
nivolumab	4.5 mg/kg	IV in normal saline 100 mL over 30 minutes Use 0.2 or 0.22 micron filter	
aprepitant	125 mg	Orally 1 hour pre-chemotherapy	
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy	
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy	
CARBOplatin	AUC 5 mg/mL.min; maximum dose 750 mg (see table below)	IV in D5W 250 mL over 30 minutes	
fluorouracil	4000 mg/m ²	IV in D5W continuously over 96 hours by ambulatory infusion device	

Maximum nivolumab dose is 360 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

All Cycles

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- 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 nivolumab administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

Recommended Support Medications			
Drug	Dose	CCMB Administration Guideline	
aprepitant	80 mg	Orally once daily on Days 2 and 3	
dexamethasone	8 mg	Orally once daily on Days 2 and 3	
metoclopramide	10 – 20 mg	Orally every 4 hours as needed for nausea and vomiting	

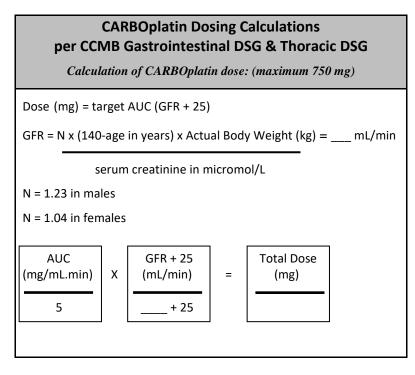
DISCHARGE INSTRUCTIONS

- 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 0 on call should be contacted
- Instruct patient to continue taking anti-emetic(s) at home
- Ensure patient has received a home chemotherapy spill kit and instructions for use
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- nivolumab is an Immune Checkpoint Inhibitor. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated
- CARBOplatin dose considerations:
 - CCMB Gastrointestinal DSG and Thoracic DSG use actual body weight to calculate GFR 0
 - CCMB Gastrointestinal DSG and Thoracic DSG use a maximum CARBOplatin dose of 750 mg for this 0 regimen
 - If calculated CARBOplatin dose differs more than 10% from prescribed CARBOplatin dose, contact the 0 prescriber





AUC= Area Under Curve

The estimated creatinine clearance is based on limited evidence. Sound clinical judgment and interpretation of the estimation are required, because the equation above may not be appropriate for some patient populations (for example, acute renal failure).

