Regimen Reference Order – GAST – nivolumab + FOLFOX-6

ARIA: GAST - [nivolumab + FOLFOX-6]

Planned Course: **Every 14 days until disease progression or unacceptable toxicity up to a maximum of 52 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 x 10^9/L AND Platelets equal to or greater than 100 x 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 – nivolumab + FOLFOX-6

Establish primary solution 500 mL of: D5W

Drug	Dose	CCMB Administration Guideline
nivolumab	3 mg/kg	IV in normal saline 100 mL over 30 minutes *Use 0.2 or 0.22 micron filter*
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy
oxaliplatin	85 mg/m^2	IV in D5W 500 mL over 2 hours
fluorouracil	2400 mg/m^2	IV in D5W continuously over 46 hours by ambulatory infusion device

Maximum nivolumab dose is 240 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 once monthly (every two cycles) 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_2 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
dexamethasone	8 mg	Orally once daily on Days 2 and 3
prochlorperazine	10 mg	Orally every 6 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 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
- Numerous dosing variations exist for FOLFOX and depend on the primary cancer diagnosis
- oxaliplatin causes cold intolerance and laryngopharyngeal dysesthesia
    - no ice chips or cold drinks
- oxaliplatin may cause progressive, irreversible neuropathy
    - dose modification may be required