Regimen Reference Order

ESOPH – nivolumab (Adjuvant) every 14 days followed by every 28 days

ARIA: ESOPH - [nivo (ADJ) q14d then q28d]

Planned Course: Every 28 days (Days 1 and 15) for 4 cycles, then every 28 days (Day 1) for 9 cycles for a total of 13 cycles (one year)

Indication for Use: Esophageal or Gastroesophageal Junction Cancer, Resected; Adjuvant

Drug Alert: Immune Checkpoint Inhibitor

CVAD: At Provider's Discretion

Proceed with treatment if:

Days 1 & 15 (Cycles 1 to 4) and Day 1 (Cycles 5 to 13)

- ***ANC equal to or greater than 1.5 x 10^9/L AND Platelets equal to or greater than 50 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
ESOPH – nivolumab (Adjuvant) every 14 days followed by every 28 days

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Cycles 1 to 4		
Days 1 and 15		
nivolumab	3 mg/kg	IV in normal saline 100 mL over 30 minutes *Use 0.2 or 0.22 micron filter*
Cycles 5 to 13		
Day 1		
nivolumab	6 mg/kg	IV in normal saline 100 mL over 30 minutes *Use 0.2 or 0.22 micron filter*

Maximum nivolumab dose is 240 mg (every 14 days – Cycles 1 to 4) OR 480 mg (every 28 days – Cycles 5 to 13)
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

Cycles 1 to 4
Days 1 and 15

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- TSH monthly (i.e. Day 1 only)
- Medical oncologist or designate (i.e. family practitioner in oncology) must assess patient for immune-mediated adverse reactions prior to each dose
- 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. Patient can be discharged from treatment room if stable whether they had a reaction or not

Cycles 5 to 13
Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- TSH monthly
- Medical oncologist or designate (i.e. family practitioner in oncology) must assess patient for immune-mediated adverse reactions prior to each dose
- 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. 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

- 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

ADDITIONAL INFORMATION

- nivolumab is an Immune Checkpoint Inhibitor. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated