

## Regimen Reference Order – ESOPH – pembrolizumab + XELOX

ARIA: ESOPH - [pembrolizumab + XELOX]

ESOPH - [pembro q21d (maintenance)]

ESOPH - [pembro q42d (maintenance)]

**Planned Course:** pembrolizumab + XELOX every 21 days for 6 cycles, followed by maintenance pembrolizumab:

pembrolizumab every 21 days up to 29 cycles or until disease progression or unacceptable toxicity (maximum 2 years of therapy total)

OR

pembrolizumab every 42 days up to 15 cycles or until disease progression or unacceptable toxicity (maximum 2 years of therapy total)

**Indication for Use:** Esophageal/Gastroesophageal Junction Tumor/Gastric Cancer; Metastatic

**Drug Alert:** Immune Checkpoint Inhibitor (pembrolizumab)

**CVAD:** At Provider's Discretion

**Proceed with treatment if:**

**Cycles 1 to 6**

- 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 equal to or greater than 30 mL/minute

**pembrolizumab 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		

<b>Treatment Regimen – ESOPH – pembrolizumab + XELOX</b>		
<b>Establish primary solution 500 mL of: D5W</b>		
<b>Drug</b>	<b>Dose</b>	<b>CCMB Administration Guideline</b>
<b>Cycles 1 to 6 – pembrolizumab + XELOX</b>		
pembrolizumab	2 mg/kg	IV in normal saline 50 mL over 30 minutes <i>Use 0.2 or 0.22 micron filter</i>
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy
oxaliplatin	130 mg/m <sup>2</sup>	IV in D5W 500 mL over 2 hours
capecitabine	1000 mg/m <sup>2</sup>	Orally twice daily on <b>Days 1 to 14</b> , followed by 7 days off Take with food. Swallow whole <b>(Self-administered at home)</b>
<b>pembrolizumab Maintenance starts three weeks after Cycle 6, Day 1</b>		
<b>pembrolizumab Maintenance (Cycles 1 to 29 OR Cycles 1 to 15)</b>		
pembrolizumab	2 mg/kg (every 21 days) <b>OR</b>	IV in normal saline 50 mL over 30 minutes <i>Use 0.2 or 0.22 micron filter</i>
	4 mg/kg (every 42 days)	
<b>Maximum pembrolizumab dose is 200 mg (every 21 days) or 400 mg (every 42 days)</b> All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding document for more information		
<b>capecitabine available dosage strengths: 150 mg and 500 mg tablets</b> <b>Classification: Cytotoxic, Hazardous</b>		

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 every 6 weeks 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 pembrolizumab 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
<b>pembrolizumab + XELOX (Cycles 1 to 6)</b>		
dexamethasone	8 mg	Orally once daily on Days 2 and 3
prochlorperazine	10 mg	Orally every 6 hours as needed for nausea and vomiting
<b>pembrolizumab Maintenance</b>		
None required		

## 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 6

- Instruct patient to continue taking anti-emetic(s) at home
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

## ADDITIONAL INFORMATION

- pembrolizumab is an Immune Checkpoint Inhibitor. Consult with oncologist for immune-mediated adverse reactions; corticosteroids are often indicated
- capecitabine can cause diarrhea, hand-foot syndrome and neuropathy
- oxaliplatin causes cold intolerance and laryngopharyngeal dysesthesia
  - no ice chips or cold drinks
- oxaliplatin may cause progressive, irreversible neuropathy
  - dose modification may be required
- **ARIA ordering:**

**Note:** Upon completion of 6 cycles of **ESOPH - [pembrolizumab + XELOX]**, patients should be started on maintenance treatment with **ESOPH - [pembro q21d (maintenance)]** or **ESOPH - [pembro q42d (maintenance)]**

  - **ESOPH - [pembro q21d (maintenance)]** or **ESOPH - [pembro q42d (maintenance)]** regimen starts 21 days after Cycle 6, Day 1 of **ESOPH - [pembrolizumab + XELOX]**