Regimen Reference Order – GAST – ramucirumab + PACLitaxel

ARIA: GAST - [ramucirumab + PACLitaxel]

Planned Course: Every 28 days until disease progression or unacceptable toxicity
Indication for Use: Gastric/Gastroesophageal Junction Cancer; Locally Advanced or Metastatic

CVAD: At Provider's Discretion

Proceed with treatment if:

Day 1

- ***ANC equal to or greater than 1.5 x 10^9/L AND Platelets equal to or greater than 100 x 10^9/L***
- ***Total bilirubin equal to or less than 1.5 times upper limit of normal***
- ***AST and ALT equal to or less than 3 times upper limit of normal if no liver metastases***
- ***AST and ALT equal to or less than 5 times upper limit of normal if liver metastases***

Days 8 and 15

- ***ANC equal to or greater than 1 x 10^9/L AND Platelets equal to or greater than 75 x 10^9/L***
- ***Total bilirubin equal to or less than 1.5 times upper limit of normal***
- ***AST and ALT equal to or less than 3 times upper limit of normal if no liver metastases***
- ***AST and ALT equal to or less than 5 times upper limit of normal if liver metastases***
  - ❖ **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – GAST – ramucirumab + PACLitaxel

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Day 1		
acetaminophen	650 mg	**ONLY** *to be given if patient experienced a Grade 1 or 2 infusion-related reaction with any previous ramucirumab infusion* Orally 1 hour prior to ramucirumab
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes at least **30 minutes** prior to ramucirumab and at least **1 hour** prior to PACLitaxel **Nursing Alert: PACLitaxel starts **at least 1 hour after completion** of dexamethasone infusion*
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes **30 minutes** prior to ramucirumab and at least **1 hour** prior to PACLitaxel

Wait 30 minutes after completion of IV pre-medication(s) before starting ramucirumab

ramucirumab	8 mg/kg	IV in normal saline 250 mL over 1 hour *(Maximum rate 25 mg/minute)* *Use 0.2 or 0.22 micron filter* **Alert: Pharmacy to ensure final volume in bag = 250 mL* **Nursing Alert: PACLitaxel infusion starts after observation period is complete (if required)*
PACLitaxel	80 mg/m^2	IV in normal saline 250 mL over 1 hour, following the administration rates below: • Administer at 100 mL/hour for 15 minutes, then • Administer remaining volume over 45 minutes *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter* **Nursing Alert: Gently invert bag 8 to 10 times immediately prior to administration of PACLitaxel to evenly distribute the drug*
Day 8		
cetirizine	20 mg	Orally 1 hour prior to PACLitaxel
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes **1 hour** prior to PACLitaxel **Nursing Alert: PACLitaxel starts **1 hour after completion** of dexamethasone infusion*
Wait 1 hour after completion of IV pre-medication(s) before starting PACLitaxel		
PACLitaxel	80 mg/m^2	IV in normal saline 250 mL over 1 hour, following the administration rates below: • Administer at 100 mL/hour for 15 minutes, then • Administer remaining volume over 45 minutes *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter* **Nursing Alert: Gently invert bag 8 to 10 times immediately prior to administration of PACLitaxel to evenly distribute the drug*
Day 15		
acetaminophen	650 mg	**ONLY** *to be given if patient experienced a Grade 1 or 2 infusion-related reaction with any previous ramucirumab infusion* Orally 1 hour prior to ramucirumab
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes at least **30 minutes** prior to ramucirumab and at least **1 hour** prior to PACLitaxel **Nursing Alert: PACLitaxel starts **at least 1 hour after completion** of dexamethasone infusion*
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes **30 minutes** prior to ramucirumab and at least **1 hour** prior to PACLitaxel
Wait 30 minutes after completion of IV pre-medication(s) before starting ramucirumab		
ramucirumab	8 mg/kg	IV in normal saline 250 mL over 1 hour *(Maximum rate 25 mg/minute)* *Use 0.2 or 0.22 micron filter*

		**Alert: Pharmacy to ensure final volume in bag = 250 mL* **Nursing Alert: PACLitaxel infusion starts after observation period is complete (if required)*
PACLitaxel	80 mg/m^2	IV in normal saline 250 mL over 1 hour, following the administration rates below: • Administer at 100 mL/hour for 15 minutes, then • Administer remaining volume over 45 minutes *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter* **Nursing Alert: Gently invert bag 8 to 10 times immediately prior to administration of PACLitaxel to evenly distribute the drug*
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

Day 1

- CBC, serum creatinine, urea, AST, ALT, total bilirubin, urine protein and blood pressure as per Physician Orders
  - Urinalysis for protein: Where urinalysis is not possible, use dipstick. If lab urinalysis for protein is greater than or equal to 1 g/L or dipstick proteinuria shows 2+ or 3+, notify medical oncologist
- TSH as per Physician Orders

Day 8

- CBC, serum creatinine, urea, AST, ALT and total bilirubin as per Physician Orders

Day 15

- CBC, serum creatinine, urea, AST, ALT, total bilirubin, urine protein and blood pressure as per Physician Orders
  - Urinalysis for protein: Where urinalysis is not possible, use dipstick. If lab urinalysis for protein is greater than or equal to 1 g/L or dipstick proteinuria shows 2+ or 3+, notify medical oncologist

ramucirumab and PACLitaxel monitoring

Cycle 1

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) at baseline and as clinically indicated
- Observe patient for 1 hour after first and second ramucirumab infusions. Full vital signs after observation period is complete. PACLitaxel infusion begins after observation period is complete
- No observation period is required after PACLitaxel administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

Cycle 2 and Onwards

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) at baseline and as clinically indicated
- For patients with no prior infusion-related reaction to ramucirumab, no observation period is required
- For patients who have had a previous infusion-related reaction to ramucirumab, observe patient for 1 hour after ramucirumab infusion. Full vital signs after observation period is complete. PACLitaxel infusion begins after observation period is complete
- No observation period is required after PACLitaxel 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
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
- Instruct patient to continue taking anti-emetic(s) at home
- Inform patient of possibility of delayed infusion type reactions: chills, flushing, hypotension, bronchospasm, dyspnea and hypoxia
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- ramucirumab can cause increased risk of hypertension, post-operative bleeding, wound healing complications and thromboembolic events
- PACLitaxel may cause progressive, irreversible neuropathy