Regimen Reference Order – GAST – cetuximab + irinotecan

ARIA: GAST - [cetuximab + irinotecan]

Planned Course: Every 14 days until disease progression or unacceptable toxicity
Indication for Use: Colorectal Cancer Metastatic

CVAD: At Provider's Discretion

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

- **Contact Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – GAST – cetuximab + irinotecan

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Cycles 1 and 2		
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	8 mg	IV in normal saline 50 mL over 15 minutes
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes
Wait 30 minutes after completion of IV pre-medication(s) before starting cetuximab		
cetuximab	500 mg/m^2	IV over 2 hours (administered undiluted) Doses greater than 1200 mg must be administered over 2.5 hours *Use 0.2 or 0.22 micron filter* **Alert:* *Pharmacy to ensure final volume on label* **Nursing Alert:* *IV tubing is primed with cetuximab* **Nursing Alert:* *irinotecan infusion starts after observation period is complete*
atropine	0.6 mg	IV Push over 2 – 3 minutes pre-irinotecan May be repeated once if diarrhea occurs during irinotecan infusion
irinotecan	180 mg/m^2	IV in D5W 500 mL over 90 minutes
Cycle 3 and onwards		
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy

cetirizine	10 mg	Orally 30 minutes prior to cetuximab
dexamethasone	8 mg	IV in normal saline 50 mL over 15 minutes
Wait 30 minutes after completion of IV pre-medication(s) before starting cetuximab		
cetuximab	500 mg/m^2	IV over 2 hours (administered undiluted) Doses greater than 1200 mg must be administered over 2.5 hours *Use 0.2 or 0.22 micron filter* **Alert:* *Pharmacy to ensure final volume on label* **Nursing Alert:* *IV tubing is primed with cetuximab*
atropine	0.6 mg	IV Push over 2 – 3 minutes pre-irinotecan May be repeated once if diarrhea occurs during irinotecan infusion
irinotecan	180 mg/m^2	IV in D5W 500 mL over 90 minutes
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 Doses

- Clinical assessment for cetuximab-related skin toxicity

Doses 1 and 2 (cetuximab)

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) at baseline, after 1-hour observation and as clinically indicated
- Observe patient for 1 hour after cetuximab infusion. Full vital signs prior to discharge

Dose 3 and Onwards (cetuximab)

- 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 reactions to cetuximab, no observation period is required. Patient can be discharged from treatment room if stable
- For patients who have had a previous reaction to cetuximab, observe patient for 1 hour after cetuximab infusion. Full vital signs after 1-hour observation

All Cycles

- CBC, serum creatinine, urea, liver enzymes, magnesium, calcium and albumin as per Physician Orders

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
loperamide	2 – 4 mg	Orally as directed below
Sunscreen	Broad-spectrum, Minimum SPF 15 (PABA free, zinc oxide or titanium dioxide preferred)	Apply liberally to exposed skin 30 minutes before going outdoors. Reapply every 2 hours and after swimming
Moisturizing lotion	Fragrance-free	Apply topically to face, hands, feet, neck, back and chest daily in the morning on rising and **as needed**
In the event of a cetuximab-induced skin rash:		
doxycycline	100 mg	Orally twice daily as directed by clinic
hydrocortisone cream	1%	Apply topically daily at bedtime to face, hands, feet, neck, back and chest as directed by clinic

DISCHARGE INSTRUCTIONS

- Warn patients of the possibility of a late onset reaction to cetuximab as reactions may occur several hours after infusion or with subsequent infusions
- 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) and to use recommended support medications at home
- If diarrhea occurs within 24 hours of irinotecan administration:
  - Return to cancer care clinic or go to the emergency department. A second dose of intravenous atropine may be required
- If cramping or diarrhea occurs more than 24 hours after irinotecan administration:
  - Take loperamide 4 mg (two 2 mg tablets) orally STAT; then
  - During the day: take 2 mg (one 2 mg tablet) orally every 2 hours
  - During the night: take 4 mg (two 2 mg tablets) orally at bedtime and then every 4 hours until morning
  - STOP loperamide once no bowel movement has occurred (e.g. diarrhea-free) for 12 hours
  - If diarrhea has not stopped despite taking **12 tablets (24 mg) of loperamide over a 24 hour period,** please contact your clinic for further instructions. If this occurs after clinic hours, please call the Medical Oncologist on-call and/or report to the nearest emergency room/urgent care centre. Please note that 24 mg per 24 hours is higher than the usual "over the counter" dose for loperamide.
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- Nurse to provide patient with 30 tablet supply of loperamide 2 mg, labelled by Pharmacy, to take home with Cycle 1
- cetuximab causes dermatological and nail changes
- cetuximab can cause interstitial lung disease, pneumonitis and exacerbation of pre-existing fibrotic lung disease
- cetuximab can cause hypomagnesemia
- Administration site restrictions are in place for cetuximab. Dose 1 of cetuximab should only be administered at CCMB MacCharles or Tache in Winnipeg