Chemotherapy Protocol

COLORECTAL CANCER

PANITUMUMAB (21 day)

This regimen may require funding and is an unlicensed dose

Regimen

- Colorectal Cancer – Panitumumab (21 day)

Indication

- Metastatic colorectal cancer that is positive for the wild type KRAS genotype and that has progressed after failure of oxaliplatin and irinotecan based therapy or who are intolerant to these agents.

- WHO performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Panitumumab	Infusion related reactions, interstitial lung disease, skin reactions, electrolyte abnormalities, fatigue, abdominal pain, constipation

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

Monitoring

Drugs

- Prior to starting therapy confirm a positive wild type KRAS status

- FBC, LFT's and U&E's prior to day one of cycle one and every 6 – 9 weeks thereafter

Dose Modifications

The dose modifications listed are for haematological, liver and renal function only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.

Please discuss all dose reductions / delays with the relevant consultant before prescribing, if appropriate. The approach may be different depending on the clinical circumstances. The following is a general guide only.

Haematological

Prior to prescribing on day one of cycle one the following criteria must be met;

Criteria	Eligible Level
Neutrophil	equal to or more than $1.5x10^9$/L
Platelets	equal to or more than $100x10^9$/L

Consider blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL

For haematological toxicity, if the neutrophil count is less than 1.5×10^9/L or the platelet count less than 100×10^9/L, delay treatment until these levels are achieved. The decision to continue treatment should be made at the consultant's discretion.

Hepatic / Renal Impairment

Drug	Hepatic	Renal
Panitumumab	No information available	No information available

Other

Allergic or hypersensitivity reactions have occurred during the administration of panitumumab. For a NCI-CTC grade 1 reaction reduce the infusion rate by 50%. For a NCI-CTC grade 2 reaction, stop the infusion and administer supportive therapies as indicated. Once the reaction has resolved to NCI-CTC grade 1 or below resume the infusion at 50% of the previous rate. For a NCI-CTC grade 3 or 4 toxicity stop the infusion immediately and disconnect the tubing from the patient. Administer appropriate supportive therapies. Once recovered, patients should not receive panitumumab again.

Once the rate has been reduced it should not be increased on subsequent infusions.

If a second reaction occurs on the slower infusion rate the infusion should be stopped and no further treatment given.

An acniform skin rash occurs in over 90% of those receiving panitumumab. The onset is normally within three weeks of starting therapy and often resolves after week twelve. For a NCI-CTC grade 1-2 reaction use symptomatic treatments such as topical or oral antibiotics and continue with the panitumumab. For a NCI-CTC grade 3 toxicity delay treatment until the toxicity resolves to NCI-CTC grade 2 or below. Re-instate therapy using 50% of the original dose. If the reaction does not recur escalate the dose in 25% increments as tolerated until the recommended dose is reached. If the reactions do not resolve to less than NCI-CTC grade 2 after withholding up to two doses or if the skin toxicity recurs or becomes intolerable at 50% of the original dose discontinue treatment.

UV radiation may worsen skin reactions. Sun safety practices should be followed during and for up to two months after the end of treatment.

Stop treatment if there is a confirmed pneumonitis.

Regimen

21 day cycle until intolerance or disease progression (6 cycles will be set)

Drug	Dose	Days	Route
Panitumumab	9mg/kg	1	Intravenous infusion in 100ml sodium chloride 0.9% over 60 minutes

Dose Information

- Panitumumab will be dose banded according to the CSCCN agreed bands

Administration Information

Extravasation

- Panitumumab - neutral

Other

- Panitumumab must be administered using a 0.22 micron in-line filter
- Doses of 1000mg and above must be administered over 90 minutes in 150ml sodium chloride 0.9%

Additional Therapy

- Antiemetics

  As take home medication

  - metoclopramide 10mg three times a day when required oral (supply on day one of cycle one only and then as required)

- Gastric protection with a proton pump inhibitor or a H_2 antagonist may be considered in patients considered at high risk of GI ulceration or bleed

Coding

- Procurement – X71.5
- Delivery – X72.3

References
1. Van Cutsem E, Peeters M, Siena S et al. Open label phase III trial of panitumumab plus best supportive care compared with best supportive care alone in patients with chemotherapy refractory metastatic colorectal cancer. J Clin Oncol 2007; 25: 1658-1664.

REGIMEN SUMMARY

Panitumumab (21 day)

Day One

1. Panitumumab 9mg/kg intravenous infusion in 100ml sodium chloride 0.9% over 60 minutes*

2. Metoclopramide 10mg three times a day when required for the relief of nausea oral**

*Please refer to the administration instructions

*The metoclopramide will only appear on day one cycle one. If further supplies are required they should be added from the support directory of Aria as necessary.

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	May 2014	Header changed Metoclopramide dose changed to 10mg throughout Set in Aria removed from number of cycles Disclaimer added	Dr Debbie Wright Pharmacist	Donna Kimber Pharmacy Technician
1	Feb 2012	None	Dr Debbie Wright Pharmacist	Dr Tim Iveson Consultant Medical Oncologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust
NHS Isle of Wight
Portsmouth Hospitals NHS Trust
Salisbury Hospital NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.