Chemotherapy Protocol

LUNG CANCER – NON-SMALL CELL (NSCLC)

PEMETREXED

(Maintenance)

Regimen

- NSCLC – Pemetrexed (Maintenance)

Indication

- Pemetrexed is recommended as an option for the maintenance treatment of people with locally advanced or metastatic non-small-cell lung cancer other than predominantly squamous cell histology if disease has not progressed immediately following platinum-based chemotherapy in combination with gemcitabine, paclitaxel or docetaxel. People who have received pemetrexed in combination with cisplatin as first-line chemotherapy cannot receive pemetrexed maintenance treatment.
- WHO Performance status 0, 1
- Palliative intent

Toxicity

Drug	Adverse Effect
Pemetrexed	Diarrhoea, skin reactions, neuropathy

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

Monitoring

Disease

- A baseline chest x-ray should be performed before starting treatment and up to date (ideally within 1 month) cross section imaging should also be performed

Regimen

- FBC, LFTs and U&Es before each cycle
- A chest x-ray should be performed before each cycle

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.

Haematology

Prior to prescribing 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 haemoglobin of less than 8g/dL

For subsequent cycles if the neutrophils are less than $1.5x10^9$/L then in the first instance delay treatment for 7 days. If counts recover at this point continue at the initial dose. If counts still fall within this range then continue with treatment using 80% of the original dose. If the myelosuppression recurs despite this dose reduction stop treatment.

If the platelets are less than $100x10^9$/L then in the first instance delay treatment for 7 days. If the counts recover at this point continue at the initial dose. If the counts still fall within this range continue using 80% of the original dose. If the platelet level falls below $50x10^9$/L reduce the dose to 50% of the original dose. If the platelet count remains below $50x10^9$/L despite dose reductions consider stopping therapy.

Hepatic Impairment

Drug	Dose
Pemetrexed	The total bilirubin should be less than or equal to 1.5-times upper limit of normal. Alkaline phosphatase (AP), aspartate aminotransferase (AST or SGOT), and alanine aminotransferase (ALT or SGPT) should be less than or equal to 3-times upper limit of normal. Alkaline phosphatase, AST, and ALT should be less than or equal to 5-times upper limit of normal is acceptable if liver has tumour involvement.

Renal Impairment

Drug	Dose
Pemetrexed	Do not administer if the CrCl is less than 45ml/min

Regimen

21 day cycle until disease progression or unacceptable toxicity occurs (6 cycles will be set in Aria)

Drug	Dose	Days	Administration
Pemetrexed	500mg/m^2	1	Intravenous infusion in 100ml sodium chloride 0.9% over 10 minutes

Dose Information

- Pemetrexed will be dose banded as per the CSCCN agreed bands

Administration Information

Extravasation

- Pemetrexed - inflammitant

Additional Therapy

- Folic acid 5mg once daily starting 1 – 2 weeks prior to and continuing for three weeks after the last dose of pemetrexed.

- Hydroxocobalamin intramuscular injection 1mg every three months starting 1 – 2 weeks prior to pemetrexed.

- Antiemetics

  15-30 minutes prior to chemotherapy;

  - metoclopramide 10mg oral or intravenous

  Ensure the patient has taken dexamethasone oral starting the day before pemetrexed. On the occasions where individuals attend for treatment and have forgotten to take the dexamethasone pre-medication administer dexamethasone 20mg intravenous 15-30 minutes before chemotherapy.

  As take home medication;

  - dexamethasone 4mg twice a day oral for 3 days starting the day before chemotherapy is due.
  - metoclopramide 10mg three times a day when 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

- Prophylactic antibiotics can be considered if required

Additional Information

- Consideration should be given to draining pleural or peritoneal effusions prior to pemetrexed administration

Coding

- Procurement – X71.4

- Delivery – X72.3

References
1.National Institute of Clinical Excellence (2010). TA190 Lung Cancer (non-small cell) - pemetrexed (maintenance). London: DOH.
2.Ciuleanu T, Bradowicz T, Ziehnski C et al. Maintenance pemetrexed plus best supportive care for non-small cell lung cancer: a randomised double blind phase three study. Lancet 2009; 374 (9699): 1432-1440.

REGIMEN SUMMARY

Pemetrexed (Maintenance)

Day Minus One

1. Dexamethasone 4mg twice a day oral*

Day One

2. Dexamethasone 4mg twice a day oral*

3. Metoclopramide 10mg oral or intravenous

4. Pemetrexed 500mg/m^2 intravenous infusion in 100ml sodium chloride 0.9% over 10 minutes

Take Home Medicines

5. Dexamethasone 4mg twice a day oral for 3 days starting the day before the pemetrexed infusion*

6. Metoclopramide 10mg three times a day when required oral

7. Folic acid 5mg once daily oral (continuous)

Hydroxocobalamin will not be included as part of the Aria regime and must be prescribed separately on the cycle for which it is due.

* In Aria Planner the dexamethasone 4mg twice daily will appear on day 1 of treatment. This is the supply for the next cycle. The patient should have been given the supply for cycle one in the pre-assessment or consent clinic. The administration instructions reflect this. Dexamethasone is included in cycle six as the regimen should be continued until disease progression

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	February 2014	CSCCN removed from header Toxicities removed Tables used throughout < and > removed and replaced with words Hepatic and renal impairment updated and tabulated Metoclopramide dose changed to 10mg Antiemetic routes written in full and stat removed. Bolus removed from injection OPCS updated Summary re-numbered Hospitals and disclaimer added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician

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 NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS 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.