Chemotherapy Protocol

LUNG CANCER – NON-SMALL CELL (NSCLC)

GEFITINIB

Regimen

- NSCLC - Gefitinib

Indication

- Gefitinib is recommended as an option for the first-line treatment of people with locally advanced or metastatic non-small-cell lung cancer (NSCLC) if they test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation

- Palliative intent

Toxicity

Drug	Adverse Effect
Gefitinib	Diarrhoea, abdominal pain, dermatitis, acniform skin rash, interstitial lung disease, hepatotoxicity, eye disorders

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

Monitoring

Disease

- Current CT scan (ideally within 1 month) before starting gefitinib and repeat within 3 months of starting treatment, or earlier if necessary

- Chest x-ray should be performed before starting treatment and at every review appointment thereafter.

Regimen

- FBC, LFTs and U&Es before starting gefitinib and every 56 days thereafter.

Dose Modifications

Hepatic Impairment

Drug	Dose
Gefitinib	Patients with moderate to severe hepatic impairment (Child Pugh B or C) due to cirrhosis have increased plasma concentrations of gefitinib. These patients should be closely monitored for adverse events. Plasma concentrations are not increased in patients with elevated aspartate transaminase (AST), alkaline phosphatase or bilirubin due to liver metastases.

Renal Impairment

Drug	Dose
Gefitinib	Use with caution in those with a creatinine clearance equal to or less than 20ml/min.

Other

Gefitinib treatment should be interrupted for up to 14 days in the first instance where a toxicity, in particular diarrhoea, rash or eye problems, occurs at NCI-CTC grade three or above or grade one / two that fails to respond to initial symptomatic management. The gefitinib can be re-started at the original dose once the symptoms have resolved. If the symptoms recur consider stopping treatment.

Gefitinib treatment must be discontinued if interstitial lung disease occurs.

Regimen

Continuous (28 day cycle)

Drug	Dose	Days	Administration
Gefitinib	250mg once a day	Continuous	Oral

Additional Therapy

- Loperamide 4mg oral stat after the first loose stool and then 2-4mg when required for the relief of diarrhoea (maximum 16mg/24 hours)
- Metoclopramide 10mg oral three times a day when required for the relief of nausea and vomiting
- Skin support as per local guidelines

Additional Information

- Gefitinib interacts with a number of other medications including those that affect the pH of the stomach and the cytochrome 3Y4 liver enzymes. Always check for drug interactions.
- The National Patient Safety Alert on oral chemotherapy (NPSA/2008/RRR001) must be followed in relation to gefitinib.
- It must be made clear to patients that gefitinib should only be prescribed by the specialist cancer care team.
- An original pack of 30 tablets should be dispensed for every 28 day cycle. Patients may be prescribed up to three cycles at any one time.

Coding

These codes apply to cycle three only

- Procurement – X71.5
- Delivery – X73.1

References
1.National Institute of Clinical Excellence (2010). TA192. Gefitinib for the first line treatment of locally advanced or metastatic non-small cell lung cancer. London: DOH.
2. Maemondo M, Kobayashi K, Inoue A et al. Gefitinib or chemotherapy for non-small cell lung cancer with mutated EGFR. N Engl J Med 2010; 362 (25): 2380-2388.

REGIMEN SUMMARY

Gefitinib

1. Gefitinib 250mg once a day continuous oral

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.3	Feb 2014	Header and footer changed Toxicity removed and tabulated Renal and hepatic recommendations tabulated Regimen tabulated Metoclopramide dose changed Name added under summary Document control tabulated Hospitals and disclaimer added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician
1.2	Sept 2010	Antiemetic protocol choice removed from under adverse effects Summary page added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician
1.1	Aug 2010	Palliative intent added under indications	Dr Deborah Wright Pharmacist	Dr Andrew Bates Consultant Clinical 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 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.