Chemotherapy Protocol

LYMPHOMA

LENALIDOMIDE

There are multiple versions of this protocol in use. Please ensure you have the correct protocol for the relevant diagnosis.

This protocol may require funding

Regimen

- Lymphoma – Lenalidomide

Indication

- Relapsed or refractory Non Hodgkin's Lymphoma

Toxicity

Drug	Adverse Effect
Lenalidomide	Peripheral neuropathy, pneumonia, infections, venous thrombotic events, respiratory dysfunction, rashes, hypokalaemia, hypomagnesaemia, hypocalcaemia, teratogenic risk, GI disturbances, flu-like symptoms.

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

Monitoring

Drugs

- FBC, LFTs and U&Es prior to day one of treatment
- Calcium and magnesium levels at regular intervals throughout treatment
- Thyroid function tests at baseline and at regular intervals throughout treatment
- Perform a venous thromboembolism (VTE) risk assessment prior to starting treatment. Prescribe thromboprophylaxis for patients with additional risk factors.

Dose Modifications

The dose modifications listed are for haematological, liver and renal function and drug specific toxicities 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.

Haematological

Dose modifications for haematological toxicity in the table below are for general guidance only. Always refer to the responsible consultant as any dose reductions or delays will be dependent on clinical circumstances and treatment intent. Low counts can be a consequence of bone marrow infiltration as well as drug toxicity.

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

Neutrophils ($x10^9$/L)	**Dose Modifications**
1 or more	100%
Less than 1	1st Occurrence Delay until recovery has occurred. Restart at full dose. 2nd Occurrence Delay until recovery has occurred. Restart at a dose of 15mg 3rd Occurrence Delay until recovery has occurred. Restart at a dose of 10mg 3rd Occurrence Delay until recovery has occurred. Restart at a dose of 5mg
Platelets ($x10^9$/L)	**Dose Modifications**
50 or more	100%
Less than 50	1st Occurrence Delay until recovery has occurred. Restart at a dose of 15mg 2nd Occurrence Delay until recovery has occurred. Restart at a dose of 10mg 3rd Occurrence Delay until recovery has occurred. Restart at a dose of 5mg

Hepatic Impairment

Drug	**Bilirubin µmol/L**		**AST/ALT units/L**	**Dose (% of original dose)**
Lenalidomide				No dose adjustments needed

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Lenalidomide	Greater than 50	100%
	30-50	Start treatment with 10mg once a day
	Less than 30	Start treatment with 15mg on alternate days
	Less than 30 and requiring dialysis	5 mg once a day On dialysis days, the dose should be administered following dialysis.

Other

Dose reductions or interruptions in therapy are not necessary for those toxicities that are considered unlikely to be serious or life threatening. For example, alopecia, altered taste or nail changes.

In general for all other non-haematological NCI-CTC grade 3 and above toxicities delay treatment until the adverse effect has resolved to NCI-CTC grade 1 or below. Reduce the daily dose to 15mg. On subsequent occurrences delay until recovery the dose may then be reduced to 10mg and 5mg consecutively. If a dose of 5mg is not tolerated treatment should be stopped.

Allergic or hypersensitivity reactions that occur at NCI-CTC grade 2, withhold treatment until the symptoms have resolved to NCI-CTC grade 1 or below. Treatment may be cautiously restarted at a daily dose of 15mg. For NCI-CTC grade 3 or above reactions discontinue the lenalidomide.

Lenalidomide should be discontinued if a desquamating rash of NCI-CTC grade 3 or above or NCI-CTC grade 4 non-desquamating rash develops.

Where a venous thrombosis or embolism develops at NCI-CTC grade 3 or above, stop treatment and start anticoagulation. Lenalidomide may be reinstated at the clinician's discretion.

Regimen

28 day cycle for 12 cycles

Drug	Dose	Days	Administration
Lenalidomide	25mg	1-21 incl.	Oral

Dose Information

- Lenalidomide is available as 25mg, 15mg, 10mg and 5mg tablets

Administration Information

- Lenalidomide tablets should be swallowed whole, not chewed.

Additional Therapy

- Antiemetics
    - metoclopramide 10mg three times a day when required oral
- Allopurinol 300mg once a day cycle one only
- Thromboprophylaxis in patients with additional risk factors for VTE.

Additional Information

- Patient, prescriber and pharmacy must comply with the pregnancy prevention programme.
- The National Patient Safety Agency alert NPSA/2008/RRR001 must be followed when prescribing, dispensing or administering oral chemotherapy.
- It must be made clear to all staff, including those in the community, that this is a short course of oral chemotherapy that must not be continued.
- Patients should be assessed for suitability for oral chemotherapy prior to starting treatment.

Coding

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

References

1. Wiernik P, Lossos I, Tuscano J et al. Lenalidomide Monotherapy in Relapsed or Refractory Aggressive Non-Hodgkin's Lymphoma. JCO **(**2008); 26 (30): 4952-4957

2. Zaja F, Larson S, Vitolo U et al. Salvage treatment with lenalidomide and dexamethasone in relapsed/refractory mantle cell lymphoma: clinical results and effects on microenvironment and neo-angiogenic biomarkers. Haematologica (2012); 97(3): 416-422

3. Fehniger T, Larson S, Trinkaus K et al. A phase 2 multicenter study of lenalidomide in relapsed or refractory classical Hodgkin lymphoma. Blood (2011); 118 (19): 5119-5125

REGIMEN SUMMARY

Lenalidomide

Day One

Take Home Medicines

1. Lenalidomide 25mg once a day for 21 days oral
2. Metoclopramide 10mg three times a day when required oral*

*The metoclopramide will be supplied on cycle one only. Thereafter it can be added from supportive treatments if further supplies are required.

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	Jan 2015	Header changed Toxicities removed Metoclopramide dose changed to 10mg Disclaimer added	Donna Kimber Pharmacy Technician	Rebecca Wills Pharmacist
1	June 2012	None	Rebecca Wills Pharmacist Dr Deborah Wright Pharmacist	Dr Andrew Davies Consultant Medical Oncologist Dr Alison Milne Consultant Haematologist

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 Hospitals 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.