3 Multiple Myeloma
3.10 Regimen name: Thalidomide (+/- pulsed dexamethasone)

Indications
Non-intensive treatment,
Relapsed or refractory myeloma,
Maintenance therapy

Pre-treatment Evaluation
- Document FBC (with film), plasma viscosity, U&E, creatinine, LFTs, calcium, glucose, serum free light chain measurements, serum protein electrophoresis and paraprotein quantitation, CRP, β₂-microglobulin and immunoglobulin levels.
- Urine for BJP (and formal evaluation of 24 hour urinary BJP excretion if light chain only myeloma).
- Bone marrow aspirate ± trephine (and cytogenetics if part of local protocol).
- Skeletal survey.
- Document height and weight and surface area.
- Consider ECG ± echocardiogram if clinical suspicion of cardiac dysfunction.
- Give adequate verbal and written information for patients and relatives concerning patient’s disease, treatment strategy and side effects.
- Obtain written consent from patient or guardian.

Drug Regimen (OPCS code: X70.5)

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuously</td>
<td>Thalidomide</td>
<td>100mg – 200mg daily for 2 weeks, increasing by 50mg every week up to 800mg daily if tolerated</td>
<td>PO</td>
<td>At night</td>
</tr>
</tbody>
</table>

See Concurrent Medication section for Dexamethasone dosing.

MAINTENANCE DOSING

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
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<th>Route</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuously</td>
<td>Thalidomide</td>
<td>50mg daily for 4 weeks, increasing to 100mg daily if tolerated</td>
<td>PO</td>
<td>At night</td>
</tr>
</tbody>
</table>

Considerations
- Incidence of thromboembolic events increases when thalidomide is given in combination with dexamethasone and/or chemotherapy.
- Incidence of VTS occurring with single agent thalidomide is <5%.
- For more information consult the UKMF/BCSH Guidelines [www.ukmf.org.uk/guidelines/thalidomide](http://www.ukmf.org.uk/guidelines/thalidomide).

Thalidomide is a known teratogenic agent.
The conditions of a Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

A female patient or a female partner of a male patient is considered to have childbearing potential unless she meets at least one of the following criteria:

1. Age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year*
2. Premature ovarian failure confirmed by a specialist gynaecologist
3. Previous bilateral salpingo-oophorectomy, or hysterectomy
4. XY genotype, Turner syndrome, uterine agenesis.

*Amenorrhoea following cancer therapy does not rule out childbearing potential.

For women of childbearing potential, thalidomide is contraindicated unless all of the conditions of a Pregnancy Prevention Programme (PPP) are met.

- Thalidomide must be discontinued and all supplies returned if the patient or a male patient’s partner becomes pregnant or pregnancy is suspected (positive pregnancy test). If using the Pharmion brand, this should then be reported to the Pharmion Risk Management Centre.

**Cycle Frequency**

Continuous

**Dose Modifications**

If a thromboembolic event eg. DVT or PE occurs the thalidomide should be stopped until good anticoagulant control is established using standard treatment guidelines.

The thalidomide may be restarted, as long as there are no other adverse events, at 50mg daily, increasing to maximum tolerated dose if anticoagulant control remains stable and there are no other adverse events.

Grade 3 – 4 toxicity of any of the major adverse effects (constipation, neuropathy, fatigue, sedation, rash, tremor and oedema) would necessitate:

- stopping the thalidomide until adverse event resolved,
- reintroduce at 50mg daily,
- escalate to maximum tolerated dose.

**Investigations prior to subsequent cycles**

- FBC, U&E, creatinine, LFTs, paraprotein level or urinary protein/BJP excretion, plasma viscosity.
- Reassess disease response after each cycle, and then 6 weekly during plateau phase.

**Treatment duration**

- Until disease progression
Concurrent Medication

- Allopurinol 300mg (or 100mg if creatinine clearance <20mls/min) od po during the first month.
- Dexamethasone (if used) 20-40mg daily for 4 days every 2-4 weeks. Reduced side-effects are seen with 20mg dose.
- H₂-antagonist or PPI is advised for patients receiving Dexamethasone.
- Consider oral systemic anti-bacterial, anti-viral and/or anti-fungal prophylaxis if patient is neutropenic - refer to local protocol.
- Bisphosphonates

Anti-emetics

- This regimen has mild emetic potential

Adverse Effects

See patient information

References


Patient Information

http://www.macmillan.org.uk/Cancerinformation/Cancertreatment/Treatmenttypes/Biologicaltherapies/Angiogenesisinhibitors/Thalidomide.aspx

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