Chemotherapy Protocol

BREAST CANCER

TRASTUZUMAB (21 day- Maintenance)

Regimen

- Breast Cancer – Trastuzumab (21 day-Maintenance)

Indication

- Adjuvant treatment of breast cancer over expressing HER2
- Treatment of metastatic breast cancer over expressing HER2
- WHO Performance status 0, 1, 2

Toxicity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trastuzumab</td>
<td>Cardio toxicity, acute respiratory distress syndrome, infusion related effects.</td>
</tr>
</tbody>
</table>

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

Monitoring

Regimen

- HER2 status before initiating therapy
- Cardiac function must be assessed prior to starting trastuzumab. Thereafter in the adjuvant setting it should be assessed every 12 weeks unless there is clinical evidence of cardiac failure. In the metastatic setting cardiac function should be assessed every 12 weeks for 24 weeks then every 24 weeks thereafter, again, unless there is clinical evidence suggestive of cardiac failure
- Blood pressure prior to each trastuzumab administration
- FBC, U&Es and LFTs every 12 weeks in conjunction with cardiac monitoring

Dose Modifications

No dose modifications for haematological toxicity are necessary for trastuzumab. If treatment with trastuzumab is not tolerated it 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.

**Kidney Impairment**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Recommendation</th>
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</thead>
<tbody>
<tr>
<td>Trastuzumab</td>
<td>No dose adjustment necessary</td>
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**Liver Impairment**

<table>
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<th>Recommendation</th>
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**Cardiac**

The LVEF should be forty or above before starting cycle one of trastuzumab.

**Subsequent Echocardiograms**

The flow chart below describes the process to be followed if there is an **asymptomatic** decline in LVEF during trastuzumab treatment.
In general patients who develop **symptomatic** cardiac dysfunction should have trastuzumab discontinued, be commenced on ACE inhibitor therapy and be referred to a cardiologist. Further treatment should be discussed with the relevant oncology consultant.
Regimen

21 day cycle for 18 cycles in the adjuvant setting or until disease progression or intolerance in the metastatic setting (17 cycles will be set in Aria as the first cycle should be the loading dose)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Days</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trastuzumab</td>
<td>6mg/kg</td>
<td>1</td>
<td>Intravenous infusion in 250ml sodium chloride 0.9% over minimum 30 minutes</td>
</tr>
</tbody>
</table>

Dose Information

- Trastuzumab will be dose rounded to the nearest 50mg (up if halfway)
- If the patient misses a dose of trastuzumab by fourteen days or less, then the usual maintenance dose of 6mg/kg should be given as soon as possible. Do not wait until the next planned cycle. Subsequent maintenance doses should be given according to the previous schedule
- If the patient misses a dose of trastuzumab by more than fourteen days, a reloading dose of 8mg/kg should be given over 90 minutes. Subsequent maintenance doses should then be given every 21 days from that point

Administration Information

- Trastuzumab is associated with hypersensitivity reactions. Patients should be observed for six hours following the start of the first infusion of trastuzumab and for two hours following the start of subsequent infusions. If the patient has tolerated the first two infusions with no infusion related effects consideration can be given to reducing this observation period further
- This regimen should only be used where the patient has had recent exposure to trastuzumab as the first infusion is over 30 minutes. If this is not the case the first infusion should be administered over 90 minutes.

Extravasation

- Trastuzumab - neutral

Additional Therapy

For treatment of trastuzumab infusion reactions ‘once only when required’ doses of the following should be prescribed;

- chlorphenamine 10mg intravenous
- hydrocortisone 100mg intravenous
- paracetamol 1000mg oral
Coding

Maintenance doses

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

References
1. NICE Technology appraisal guidance No. 34
REGIMEN SUMMARY

Trastuzumab (21 day-Maintenance)

Day One

1. Trastuzumab 6mg/kg intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

2. Chlorphenamine 10mg intravenous when required for infusion related reactions

3. Hydrocortisone 100mg intravenous when required for infusion related reactions

4. Paracetamol 1000mg oral when required for infusion related reactions
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.