Chemotherapy Protocol

GASTROINTESTINAL (UPPER) CANCER

TRASTUZUMAB (21 day-Maintenance)

Regimen

- GI (upper) – Trastuzumab (21 day-Maintenance)

Indication

- Trastuzumab, in combination with capecitabine and cisplatin or cisplatin and fluorouracil, is recommended as an option for the treatment of people with human epidermal growth factor receptor 2 (HER2) positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior treatment for their metastatic disease and who have tumours expressing high levels of HER2

- WHO performance status 0, 1, 2

Toxicity

Drug	Adverse Effect
Trastuzumab	Cardio toxicity, acute respiratory distress syndrome, infusion related effects

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.

Liver Impairment

Drug	Dose (% of original dose)
Trastuzumab	No dose adjustment necessary

Kidney Impairment

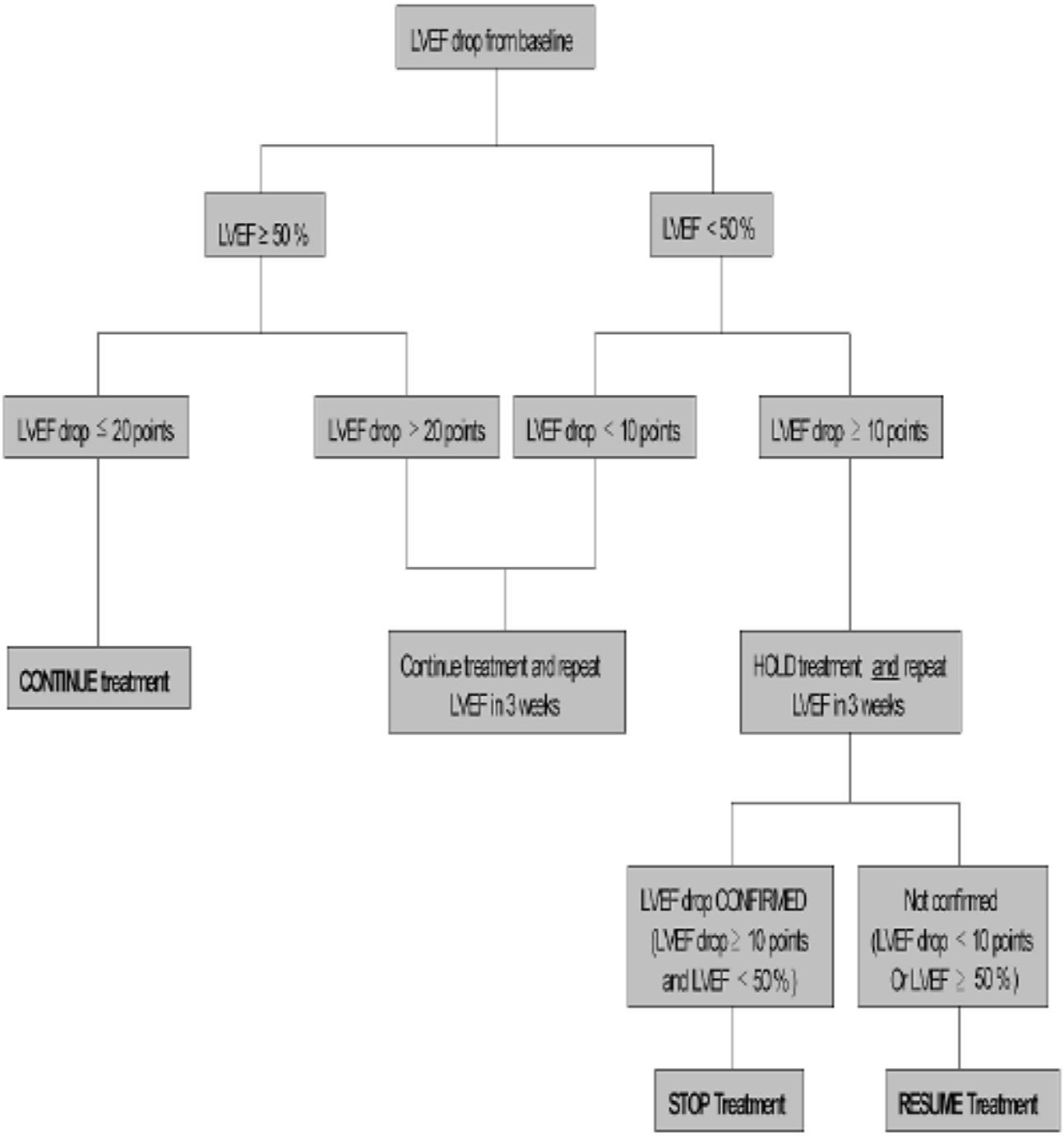
Drug	Dose (% of original dose)
Trastuzumab	No dose adjustment necessary

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 until disease progression or intolerance (6 cycles will be set in Aria)

Drug	Dose	Days	Route
Trastuzumab	6mg/kg	1	Intravenous Infusion in 250ml sodium chloride 0.9% over a minimum of 30 minutes

Dose Information

- Trastuzumab will be dose banded in accordance with national dose bands (21mg/ml)
- 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 re-loading 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

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

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

References
1. Bang YJ, Van Custem E, Fevereislova A et al. Trastuzumab in combination with chemotherapy versus chemotherapy alone for the treatment of HER2 positive advanced gastric or gastro-oesophageal junction cancer (TOGA): a phase 3, open label, randomised, controlled clinical trial. Lancet 2010; 376 (9742): 687-697.

2. National Institute for Health and Clinical Excellence (2010). NICE Technology Appraisal Guidance 208. Trastuzumab for the treatment of HER2-positive metastatic gastric cancer. DOH: London.

REGIMEN SUMMARY

Trastuzumab (21day-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

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.2	July 2024	Trastuzumab updated with national dose banding	Alexandra Pritchard Pharmacist	Nanda Basker Pharmacist
1.1	July 2014	Header changed Disclaimer added Tabulation used throughout Bolus removed from supportive therapies OPCS codes updated	Dr Debbie Wright Pharmacist	Donna Kimber Pharmacy Technician
1	Feb 2012	None	Dr Debbie Wright Pharmacist	Dr Tim Iveson Consultant Medical Oncologist