

Indication	For the 1st line treatment of metastatic breast cancer in patients whose tumours significantly overexpress HER2 at the 3+ level or greater, and are unsuitable for anthracycline.
Treatment Intent	Palliative
Frequency and number of cycles	Repeat every 21 days Docetaxel and trastuzumab SC every 3 weeks for a maximum of 6 cycles, then continue trastuzumab SC until progressive disease, unacceptable toxicity or patient choice.
Monitoring Parameters pre-treatment	<ul style="list-style-type: none"> • Virology screening: All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • The use of trastuzumab is restricted to patients whose tumours significantly overexpress HER2 at the 3+ level or greater. • Monitor FBC, U&E and LFT at each cycle from cycle 1 to 6, then from cycle 7 FBC, U&E and LFT every 3 months or as clinically indicated. • If neuts 1.0-1.4 and PLT ≥ 100 d/w consultant. If neuts ≥ 1.5 and PLT ≥ 100 continue with treatment. If neuts < 1.0 or PLT < 100 defer 1 week. • Renal and Hepatic Impairment: • Docetaxel is not recommended in severe hepatic impairment. A dose reduction of docetaxel may be made dependent on PS and liver function. • There are no recommendations for dose adjustments of trastuzumab in renal or hepatic impairment. • Cardiotoxicity: <ul style="list-style-type: none"> ○ Caution in patients with prior history of coronary heart disease, arrhythmias and angina pectoris. ○ Avoid anthracyclines for up to 7 months after stopping trastuzumab. If used, monitor cardiac function closely. • Cardiac Monitoring: <ul style="list-style-type: none"> ○ Cardiac function should be monitored at baseline (ECHO/MUGA and ECG) and then every 6 months (ECHO or MUGA) during treatment or as clinically indicated. ○ It is the prescribers' responsibility to check that the ECHO/MUGA result is satisfactory before continuing treatment. ○ At each nurse assessment patients should be assessed for signs of dyspnoea. • Trastuzumab SC injection administration and monitoring: <ul style="list-style-type: none"> ○ Inject into the subcutaneous tissue of the thigh, injection sites should alternate between left and right thigh. ○ New injections should be given at least 2.5 cm from the previous site. ○ Do not inject into areas where the skin is red, bruised, tender, or hard. ○ During treatment with trastuzumab solution for subcutaneous injection, do not administer other medicinal products for subcutaneous use at the same site. ○ Patients should be observed for 30 minutes after the first trastuzumab injection and for 15 minutes after subsequent injections. • Hypersensitivity: <ul style="list-style-type: none"> ○ Ensure dexamethasone pre-medication (8mg bd for 3 days starting the day before chemotherapy) is prescribed and given to the patient at new patient chat. ○ Docetaxel: Patients who have developed severe hypersensitivity reactions should not be re-challenged with docetaxel.

Protocol No	BRE-041	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V1	Written by	M.Archer
Supersedes version	New protocol	Checked by	C. Waters P. Chhabhaiya
Date	27.05.2025	Authorising consultant (usually NOG Chair)	J, Glendenning

	<ul style="list-style-type: none"> • Missed dose: If the patient misses a dose of trastuzumab, administer the dose as soon as possible. The interval between the consecutive dose should not be less than 3 weeks. • Dose Modification: • Dose reduction of docetaxel should be considered if grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&V and alopecia). Delay until resolution of toxicity to <= grade 1. • No dose reductions required for trastuzumab sc. • Common drug interactions (for comprehensive list refer to BNF/SPC): <ul style="list-style-type: none"> ○ Trastuzumab SC: No formal drug interaction studies have been performed. Caution with other cardiotoxic drugs. ○ Docetaxel: Concomitant use with medicines which induce, inhibit or are metabolised by cytochrome P450-3A (e.g. ciclosporin, ketoconazole and erythromycin) may affect levels of docetaxel, use with caution. Avoid concomitant use with strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin and ritonavir), if treatment cannot be avoided consider dose reduction of docetaxel and monitor patient closely for signs of toxicity. • Missed dose: If the patient misses a dose of trastuzumab, administer the dose as soon as possible. The interval between the consecutive dose should not be less than 3 weeks. • Driving: Patients should be advised their ability to drive or operate machinery may be impaired.
References	ARIA regimen BRE-041 SPC accessed online 08.01.2025

NB For funding information, refer to CDF and NICE Drugs Funding List

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Cycles 1 to 6:**Repeat every 21 days**

Day	Drug	Dose	Route	Infusion Duration	Administration
1	TRASTUZUMAB (Herceptin®)	600mg	SC	2 – 5 min	Alternate injection site between the right and left thigh at least 2.5cm away from previous injection site
	Patients should be observed for 30 minutes after the first trastuzumab injection and for 15 minutes after subsequent injections. Observation should be completed prior to any subsequent administration of chemotherapy.				
	Metoclopramide	20mg	IV		
	Ensure dexamethasone pre-med taken before administration of docetaxel				
	DOCETAXEL	75mg/m²	IV	60 min	In 250ml Sodium Chloride 0.9%
TTO	Drug	Dose	Route	Directions	
Day 1	Dexamethasone	8mg	PO	BD for 3 days starting day before next cycle of chemotherapy Not required on last cycle of docetaxel	
	Metoclopramide	10mg	PO	3 times a day for 3 days after docetaxel, then 10mg up to 3 times a day as required. (max. 30mg per day including 20mg pre-chemo dose) Do not take for more than 5 days continuously.	

Cycle 7 onwards:

Day	Drug	Dose	Route	Infusion Duration	Administration
1	TRASTUZUMAB (Herceptin®)	600mg	SC	2 – 5 min	Alternate injection site between the right and left thigh at least 2.5cm away from previous injection site
	Patients should be observed for 30 minutes after the first trastuzumab injection and for 15 minutes after subsequent injections.				

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