

<b>Indication</b>	<p><b>Breast:</b> As adjuvant treatment for triple negative breast cancer, where there has been a poor response to non-carboplatin containing neoadjuvant chemotherapy. or 2nd or subsequent line metastatic disease.</p> <p><b>Colorectal cancer</b> As adjuvant treatment in high risk stage II or stage III colorectal cancer. Or An option for metastatic colorectal cancer.</p>
<b>Treatment Intent</b>	<p>Adjuvant</p> <p>Palliative</p>
<b>Frequency and number of cycles</b>	<p>Repeat every 21 days.</p> <p>Adjuvant: for 8 cycles.</p> <p>Palliative: Continue until disease progression or unmanageable toxicity or patient choice. When using with palliative intent review every 12 weeks to assess if treatment should continue.</p>
<b>Monitoring Parameters pre-treatment</b>	<ul style="list-style-type: none"> <li>• <b>Virology screening:</b> 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.</li> <li>• For <b>adjuvant</b> treatment consider using actual BSA.</li> <li>• <b>ECG</b> prior to cycle 1.</li> <li>• <b>DPD</b> testing must be undertaken in all patients before starting treatment; the result must be checked before treatment is started.</li> <li>• <b>Cardiotoxicity:</b> Caution in patients with prior history of coronary heart disease, arrhythmias and angina pectoris.</li> <li>• Patients should be informed to contact the oncology team immediately if any chest pain/ coronary artery symptoms are experienced. Capecitabine should be withheld and an emergency medical assessment should be performed. Inform consultant.</li> <li>• <b>Monitoring:</b> At each cycle monitor FBC, U&amp;Es &amp; LFTs.</li> <li>• <b>Haematological parameters:</b> <ul style="list-style-type: none"> <li>• If neuts <math>\geq 1.5</math> and PLT <math>\geq 100</math> proceed with chemo.</li> <li>• If neuts 1.0-1.4 and WBC <math>\geq 3.0</math> and PLT <math>\geq 100</math> proceed with chemo.</li> <li>• If neuts <math>&lt; 1.0</math> or neuts <math>&lt; 1.5</math> <b>and</b> WBC <math>&lt; 3</math> or PLT <math>&lt; 100</math> defer one week and inform treating consultant.</li> </ul> </li> <li>• <b>Renal:</b> Calculate CrCl using Cockcroft and Gault formula at baseline and before each cycle. <ul style="list-style-type: none"> <li>○ Before starting treatment, GFR should be <math>\geq 50</math>ml/min.</li> <li>○ <b>During treatment:</b> <ul style="list-style-type: none"> <li>○ If CrCl <math>&gt; 50</math>ml/min proceed at 100% dose.</li> <li>○ If CrCl 30-50ml/min proceed at 75% dose.</li> <li>○ If CrCl <math>&lt; 30</math>ml/min omit capecitabine.</li> </ul> </li> </ul> </li> <li>• <b>Hepatic Impairment:</b> <ul style="list-style-type: none"> <li>○ <b>Prior to treatment:</b> no recommended dose adjustment.</li> <li>○ <b>During treatment:</b> Interrupt treatment if treatment-related elevation of bilirubin <math>&gt; 3.0 \times</math> ULN or in hepatic aminotransferases (ALT or AST) <math>&gt; 2.5 \times</math> ULN.</li> <li>○ NB significantly impaired hepatic function might be a sign of disease progression and require cessation or change of treatment.</li> </ul> </li> </ul>

Protocol No	MULTI-033	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	BRE-002 V5 COL-003 V3	Checked by	C. Waters B. Willis
Date	24.10.2024	Authorising consultant (usually NOG Chair)	G. McCormick / M.Durve

	<ul style="list-style-type: none"> <li>○ Discuss deteriorating function with consultant.</li> <li>● <b>Management of adverse reactions and dose adjustments:</b> <ul style="list-style-type: none"> <li>○ <b>Interrupt treatment</b> in the event of <math>\geq</math> grade 2 non-haematological toxicity (with the exception of side effects such as alopecia, alteration in taste etc, considered to be not serious) until resolution to grade 0-1.</li> <li>○ Dose reduction should be considered if grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&amp;V and alopecia). Delay until resolution of toxicity to <math>\leq</math> grade 1.</li> </ul> </li> <li>● <b>Adverse reactions:</b> <ul style="list-style-type: none"> <li>○ Dose limiting toxicities include diarrhoea, abdominal pain, nausea, stomatitis and hand-foot syndrome (hand-foot skin reaction, palmar-plantar erythrodysesthesia) have been reported. Most adverse reactions are reversible and do not require permanent discontinuation of therapy, although doses may need to be withheld or reduced.</li> <li>○ <b>Skin reactions:</b> Capecitabine can induce severe skin reactions such as Stevens-Johnson syndrome and Toxic Epidermal Necrolysis. Patients should be informed of the possibility of such reactions and informed to seek urgent medical advice should any symptoms of a severe skin reaction occur. Treatment should be permanently discontinued in affected patients.</li> </ul> </li> <li>● <b>Common drug interactions (for comprehensive list refer to BNF/SPC):</b> <ul style="list-style-type: none"> <li>○ <b>Sorivudine or derivatives (e.g. brivudine)</b> must not be given concurrently, see SPC.</li> <li>○ <b>Coumarin-derivative anticoagulants:</b> Monitor PT and INR regularly in patients taking these medications.</li> <li>○ <b>Phenytoin:</b> Monitor phenytoin levels with concomitant use.</li> <li>○ <b>Folic acid or folic acid:</b> Caution potential for increased toxicity.</li> <li>○ <b>Allopurinol:</b> possible decreased efficacy, avoid concomitant use.</li> </ul> </li> <li>● <b>Driving:</b> Capecitabine may cause dizziness, fatigue and nausea. Patients should be aware this may affect their ability to drive or operate machinery.</li> <li>● For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet.</li> </ul>
<b>References</b>	KMCC SACT protocol V5

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

### **Repeat every 21 days**

Day	Drug	Dose	Route	Administration
1	<b>CAPECITABINE</b>	<b>2500mg/m<sup>2</sup>/day</b>  <b>In 2 divided doses</b>	PO	<b>for 14 days</b> (the 1st dose will be taken as the evening dose on day 1 and the last dose is taken the morning of day 15, followed by a 7-day rest period) Take within 30 minutes after food, and approximately every 12 hours. <b>Available as 500mg and 150mg tablet</b>
TTO	Drug	Dose	Route	Directions
Day 1	Metoclopramide	10mg	PO	10mg up to 3 times a day as required. Do not take for more than 5 days continuously.

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