

Indication	Daratumumab in combination with bortezomib, lenalidomide, and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable. This treatment is not funded for patients with primary amyloidosis. NB patients should have not received any systemic anti-cancer therapy for myeloma except for either an emergency use of a short course of corticosteroids before this treatment or the patient commenced induction therapy with the combination of daratumumab plus bortezomib, thalidomide and dexamethasone with the intention of proceeding to a stem cell transplant but despite responding to such treatment the patient is now ineligible for transplantation.
Treatment Intent	Disease modification
Frequency and number of cycles	Repeat every 28 days Cycle 1 and 2 every 28 days: weekly daratumumab (8 doses in total) with weekly bortezomib Cycle 3 to 6 every 28 days: 2 weekly daratumumab (8 doses in total) with weekly bortezomib Cycle 7 and 8 every 28 days: 4 weekly daratumumab (2 doses in total) with weekly bortezomib Cycle 9 onwards every 28 days: 4 weekly daratumumab Continue until progressive disease or unacceptable toxicity or patient choice, whichever occurs first.
Monitoring Parameters	• Lenalidomide Prescription Authorisation Form must be completed at time of prescribing • 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. • If positive hepatitis B viral serology is found, the patient should be monitored for hepatitis B virus reactivation. • Consider flu and pneumococcal vaccination pre-therapy. • Haematological monitoring and parameters: • Monitor LFT's and U&Es on day 1 of each cycle. • FBC on day 1, 8, 15 and 22 for the first 8 cycles, if FBCs stable monitoring can be reduced to fortnightly for cycles 3-8 at clinician's discretion, and then on day 1 only of each cycle thereafter. • Lenalidomide treatment must not be started if the Absolute Neutrophil Count (ANC) is $<1.0 \times 10^9/L$, and/or platelet counts are $<50 \times 10^9/L$. • Thyroid function at baseline and as clinically indicated throughout treatment. • BP baseline and if clinically indicated thereafter. • Lung function assessment required in patients with pre-existing respiratory disease (COPD, asthma) and heavy smokers. Clinician to decide if further imaging required in patients with additional co-morbidities. • Blood glucose every cycle. • ECG baseline and if clinically indicated thereafter. • Ensure patient is well hydrated (drinking ~3L/day) prior to treatment. • Limited data of daratumumab SC in patients $>120kg$, give at clinician's discretion. • Hepatic impairment: ○ Daratumumab: No dose adjustments necessary. ○ Bortezomib: Consider dose reduction in moderate/severe hepatic impairment (Bilirubin $>1.5ULN$), reduce Bortezomib to 0.7 mg/m² in the first treatment cycle. Consider dose escalation to 1.0 mg/m² or further dose reduction to 0.5 mg/m² in subsequent cycles based on patient tolerability. ○ Lenalidomide: Lenalidomide has not formally been studied in patients with impaired hepatic function and there are no specific dose recommendations. • Renal impairment: ○ Daratumumab: No dose adjustments necessary.

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	○ Bortezomib: CrCl < 20ml/min discuss with consultant. If to be given on the same day as dialysis, administer dose after dialysis. ○ Lenalidomide: No dose reduction required in mild impairment. If CrCl 30-49ml/min, give 10mg OD, after 2 cycles if the patient is tolerating this dose but not responding to treatment the dose may be escalated to 15mg OD. If CrCl <30ml/min give 15mg on alternate days. If CrCl <30ml/min requiring dialysis give 5mg OD, on dialysis days the dose should be given following dialysis. ● Daratumumab injection related reactions (IRRs): ○ Daratumumab can cause severe injection reactions which may result in admission to hospital. Pre-meds must be given 1-3 hours before the injection. ○ Patients should be pre-medicated with chlorphenamine, dexamethasone and paracetamol as well as monitored (vital signs before and after the injection) and counselled regarding IRRs, especially during and following the first and second injections. If an anaphylactic reaction or life-threatening (Grade 4) reactions occur, appropriate emergency care should be initiated immediately. Daratumumab therapy should be discontinued immediately and permanently. Patients should be observed for 6 hours post the 1st injection, 2 hours after 2nd dose and then 15 minutes observation after subsequent doses. ○ The use of post-infusion medications (e.g. inhaled corticosteroids, short and long acting bronchodilators) should be considered for patients with a history of chronic obstructive pulmonary disease to manage respiratory complications should they occur. ● Administration of sub cut daratumumab: ○ Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections. ○ Daratumumab solution for subcutaneous injection should never be injected into areas where the skin is red, bruised, tender, and hard or areas where there are scars. ○ Pause or slow down delivery rate if the patient experiences pain. In the event pain is not alleviated by slowing down the injection, a second injection site may be chosen on the opposite side of the abdomen to deliver the remainder of the dose. ○ During treatment with daratumumab solution for subcutaneous injection, do not administer other medicinal products for subcutaneous use at the same site as daratumumab. ● Drug specific cautions and dose adjustments: ● Daratumumab: ○ No dose reductions of daratumumab are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of haematological toxicity. ● Bortezomib: ○ Use with caution in patients with pre-existing heart disease or with high risk factors. ○ Patients should be advised to report any new or worsening respiratory symptoms. ○ At least 72 hours must elapse between consecutive Bortezomib doses. ○ Dose modification bortezomib: If Hb < 65g/l transfuse patient and restart treatment when Hb >65g/l. ○ Bortezomib should be withheld for any grade 3 non-haematological (see table 1 below for guidance on managing neuropathic toxicities) or Grade 4 haematological toxicities (neutrophils < 0.5 x 10⁹/L or platelets < 25 x 10⁹/L); once toxicity has settled reinstate at 75%, (i.e. 1.3mg/m² → 1.0mg/m² → 0.7mg/m²). ○ For Neuropathic Pain and or Peripheral Sensory or Motor Neuropathy dose reductions see table 1. ● Lenalidomide: ○ Haematological toxicity: Treat when neutrophils >= 1.0 x 10⁹/L and platelets >= 50 x 10⁹/L. If neutrophils fall below 0.5 x 10⁹/L interrupt treatment and resume at starting dose once resolved to >=1 x 10⁹/L if neutropenia is the only observed toxicity, if other dose dependant haematological toxicities are observed other than neutropenia resume at one reduced dose level when neutrophils have resolved to >=0.5 x 10⁹/L.
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	○ For each subsequent episode of neutropenia ($<0.5 \times 10^9/L$) interrupt treatment and decrease the dose of lenalidomide to the next dose level when neutrophils have returned to $\geq 0.5 \times 10^9/L$ (see table 2). ○ If platelets fall to $<25 \times 10^9/L$ interrupt treatment for the remainder of the cycle and resume at one reduced dose level once resolved to $\geq 50 \times 10^9/L$. ○ Non-Haematological toxicity: For other Grade 3 or 4 toxicities judged to be related to lenalidomide, treatment should be stopped and only restarted at next lower dose level when toxicity has resolved to $\leq$ Grade 2 depending on the physician's discretion. ○ Lenalidomide interruption or discontinuation should be considered for Grade 2 or 3 skin rash. Lenalidomide must be discontinued for angioedema, anaphylactic reaction, Grade 4 rash, exfoliative or bullous rash, or if Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is suspected, and should not be resumed following discontinuation from these reactions. ○ Ensure patient is informed of requirement for strict contraception precautions during treatment with Lenalidomide. Follow Lenalidomide risk management programme. ○ Treatment with lenalidomide has been associated with an increased risk of venous thromboembolism. All patients should be risk assessed and prophylactic anticoagulation prescribed if appropriate. ● Dexamethasone: Dose modification of dexamethasone is to be made on a patient by patient basis at the prescribing clinicians' discretion. Dose reduction may be considered in patients who are >75 years, patients who have a BMI <18.5, patients with poorly controlled diabetes mellitus or who have had prior intolerance/adverse event (AE) to steroid therapy. ● Interference with tests (refer to company risk materials): Daratumumab binds to CD38 on red blood cells and results in a positive Indirect Antiglobulin Test (Coombs test) which may persist for up to 6 months after the last infusion. Send a blood sample for group/ direct antiglobulin/phenotype testing prior to treatment. Daratumumab may be detected on SPE and IFE assays resulting in false positive results for patients with IgG kappa myeloma protein impacting initial assessment of complete responses. ● Common drug interactions (for comprehensive list refer to BNF/SPC): ○ Daratumumab: No interaction studies have been performed. ○ Bortezomib: The concomitant use of bortezomib with strong CYP3A4 inducers (e.g., rifampicin, carbamazepine, phenytoin, phenobarbital and St. John's Wort) is not recommended, as efficacy may be reduced. CYP3A4 inhibitors (e.g. ketoconazole, ritonavir) should be used with caution and patients monitored for toxicity. ○ Lenalidomide: Lenalidomide may increase digoxin concentration, monitor digoxin levels during treatment. Increased risk of rhabdomyolysis when administered with statins. Combined hormonal contraceptives are predicted to increase the risk of venous thromboembolism when given with Lenalidomide. Manufacturer advises avoid. ● Missed dose: ○ Daratumumab: If a planned dose is missed, the dose should be administered as soon as possible and the dosing schedule should be adjusted accordingly, maintaining the treatment interval. ○ Bortezomib: if a planned dose is missed, the dosing schedule should be adjusted to ensure there is at least 72 hours between doses. ○ Lenalidomide: If less than 12 hours after the usual administration time the patient should take the dose and continue as normal the following day. If more than 12 hours after the usual administration time the dose should be omitted and continue with the schedule the following day. ● Pregnancy and contraception: ○ Daratumumab and bortezomib: To avoid exposure to the foetus, women of reproductive potential should use effective contraception during treatment and for 8 months after cessation of daratumumab and bortezomib treatment. Male patients should use effective contraceptive measures during treatment and be advised not to father a child while receiving bortezomib and for 5 months following completion of treatment.
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	○ Lenalidomide: Ensure patient is informed of requirement for strict contraception precautions during treatment with Lenalidomide. Follow Lenalidomide risk management programme. Pregnancy test – if patient is of child-bearing age (every 4 weeks). ● Driving and machinery: ○ Patients should be advised that lenalidomide can have an effect on their ability to drive and use machines. ○ Bortezomib can affect the ability to drive and use machines. If patients experience fatigue/dizziness or blurred vision they should not drive. ● For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet.
References	https://www.medicines.org.uk/emc SPC accessed online 10.07.2026 CDF list V1.405 accessed online 08.07.2026 Kings protocol

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

Table 1: Dose modification of bortezomib for neuropathic toxicities

Severity of Peripheral Neuropathy Signs and Symptoms*	Modification of Dose and Regimen
Grade 1 (asymptomatic; loss of deep tendon reflexes or paraesthesia) without pain or loss of function	No Action
Grade 1 with pain or Grade 2 (moderate symptoms; limiting instrumental Activities of Daily Living (ADL)**)	Reduce bortezomib to 1 mg/m ²
Grade 2 with pain or Grade 3 (severe symptoms; limiting self-care ADL ***)	Withhold bortezomib therapy until toxicity resolves. When toxicity resolves, reinstitute with a reduced dose of bortezomib at 0.7 mg/m ² once per week
Grade 4 (life-threatening consequences; urgent intervention indicated)	Discontinue bortezomib
*Grading based on NCI Common Terminology Criteria for Adverse Events (CTCAE) v4.0 **Instrumental ADL: refers to preparing meals, shopping for groceries or clothes, using telephone, managing money etc; ***Self care ADL: refers to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.	

Table 2: Dose reduction for lenalidomide:

	Lenalidomide
Starting dose	25 mg
Dose level -1	20 mg
Dose level -2	15 mg
Dose level -3	10 mg
Dose level -4	5 mg
Dose level -5	2.5 mg

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Cycle 1 and 2: repeat every 28 days

Day	Drug	Dose	Route	Infusion Duration	Administration
1	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	Montelukast Cycle 1 only	10mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
8	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen. The solution should be injected, at a 45-90° angle. Injection sites should be rotated for successive injections.
	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
15	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
22	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.

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TTOs Cycle 1 and cycle 2

TTO	Drug	Dose	Route	Directions
Day 1	DEXAMETHASONE	20mg	PO	OM on days 2, 9, 16 and 23
	LENALIDOMIDE	25mg	PO	ON on days 1 to 21 followed by a 7 day break. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole, preferably with water, either with or without food.
	Aciclovir	400mg	PO	BD continuously (plus 3 more months after completion of last treatment dose)
	Co-trimoxazole	480mg	PO	TWICE daily on Mondays, Wednesdays and Fridays (plus 3 more months after completion of last treatment dose)
	Allopurinol	300mg	PO	OD and review after 4 weeks. Prescribe continuing supply if required from cycle 2 onwards.
	Omeprazole	20mg	PO	OD
	Metoclopramide	10mg	PO	Take 10mg TDS for 3 days after bortezomib then up to TDS when required. Do not take for more than 5 days continuously. On Cycle 1 only, then prescribe as required
	Loperamide	2mg	PO	Take two capsules (4mg) after first loose stool, then one capsule (2mg) after each loose stool when required. (Maximum 16mg per day). Dispense on Cycle 1 only, and then prescribe as required.
	Apixaban	2.5mg	PO	BD
Consider the use of prophylactic anti-fungals				
Consider levofloxacin prophylaxis for 12 weeks for all newly diagnosed myeloma patients				
Pre Med TTO packs to be dispensed				

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Cycle 3 to 6: repeat every 28 days

Day	Drug	Dose	Route	Infusion Duration	Administration
1	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
8	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
15	Dexamethasone	20mg	PO	stat	
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
22	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.

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TTOs Cycle 3 to 6

TTO	Drug	Dose	Route	Directions
Day 1	DEXAMETHASONE	20mg	PO	OM on days 2, 8, 9, 16, 22 and 23. (Where appropriate dose must be taken prior to bortezomib injection i.e. on days where bortezomib alone is administered)
	LENALIDOMIDE	25mg	PO	ON on days 1 to 21 followed by a 7 day break. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole, preferably with water, either with or without food.
	Aciclovir	400mg	PO	BD continuously (plus 3 more months after completion of last treatment dose)
	Co-trimoxazole	480mg	PO	TWICE daily on Mondays, Wednesdays and Fridays (plus 3 more months after completion of last treatment dose)
	Omeprazole	20mg	PO	OD
	Metoclopramide	10mg	PO	Take 10mg TDS for 3 days after bortezomib then up to TDS when required Do not take for more than 5 days continuously. On Cycle 1 only, then prescribe as required
	Loperamide	2mg	PO	Take two capsules (4mg) after first loose stool, then one capsule (2mg) after each loose stool when required. (Maximum 16mg per day). Dispense on Cycle 1 only, and then prescribe as required.
	Apixaban	2.5mg	PO	BD
	Consider the use of prophylactic anti-fungals			
	Pre Med TTO packs to be dispensed.			

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Cycle 7 to 8 repeat every 28 days

Day	Drug	Dose	Route	Infusion Duration	Administration
1	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections
	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
8	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
15	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.
22	BORTEZOMIB	1.3mg/m²	SC	bolus	Inject into the subcutaneous tissue of the thighs or abdomen, at a 45-90° angle. Injection sites should be rotated for successive injections.

TTOs cycle 7 to 8

TTO	Drug	Dose	Route	Directions
Day 1	DEXAMETHASONE	20mg	PO	OM on days 2, 8, 9, 15, 16, 22 and 23. (Where appropriate dose must be taken prior to bortezomib injection i.e. on days where bortezomib alone is administered)
	LENALIDOMIDE	25mg	PO	ON on days 1 to 21 followed by a 7 day break. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole, preferably with water, either with or without food.
	Aciclovir	400mg	PO	BD continuously (plus 3 more months after completion of last treatment dose)
	Co-trimoxazole	480mg	PO	TWICE daily on Mondays, Wednesdays and Fridays (plus 3 more months after completion of last treatment dose)
	Omeprazole	20mg	PO	OD
	Metoclopramide	10mg	PO	Take 10mg TDS for 3 days after bortezomib then up to TDS when required Do not take for more than 5 days continuously. On Cycle 1 only, then prescribe as required
	Loperamide	2mg	PO	Take two capsules (4mg) after first loose stool, then one capsule (2mg) after each loose stool when required. (Maximum 16mg per day). Dispense on Cycle 1 only, and then prescribe as required.
	Apixaban	2.5mg	PO	BD
	Consider the use of prophylactic anti-fungals			
Pre Med TTO packs to be dispensed.				

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Cycle 9 onwards repeat every 28 days

Day	Drug	Dose	Route	Infusion Duration	Administration
1	Dexamethasone	20mg	PO	stat	To be administered 1-3 hours prior to daratumumab. (dispensed as TTO pack)
	Paracetamol	1gm	PO	stat	
	Chlorphenamine	4mg	PO	stat	
	DARATUMUMAB	1800mg	SC	3-5min	Inject 15 mL into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes. Do not inject at other sites of the body as no data are available. Injection sites should be rotated for successive injections

TTOs cycle 9 onwards

TTO	Drug	Dose	Route	Directions
Day 1	DEXAMETHASONE	20mg	PO	OM on days 8, 15 and 22.
	LENALIDOMIDE	25mg	PO	ON on days 1 to 21 followed by a 7 day break. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole, preferably with water, either with or without food.
	Aciclovir	400mg	PO	BD continuously (plus 3 more months after completion of last treatment dose)
	Co-trimoxazole	480mg	PO	TWICE daily on Mondays, Wednesdays and Fridays (plus 3 more months after completion of last treatment dose)
	Omeprazole	20mg	PO	OD
	Metoclopramide	10mg	PO	Take 10mg up to TDS when required. Do not take for more than 5 days continuously. On Cycle 9 only, then prescribe as required
	Loperamide	2mg	PO	Take two capsules (4mg) after first loose stool, then one capsule (2mg) after each loose stool when required. (Maximum 16mg per day). Dispense on Cycle 9 only, and then prescribe as required.
	Apixaban	2.5mg	PO	BD
	Consider the use of prophylactic anti-fungals			
	Pre Med TTO packs to be dispensed.			

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