

Indication	First-line treatment of multiple myeloma in patients who are unable to tolerate, or have contraindications to, thalidomide and who are unsuitable for stem cell transplantation. Or For the treatment of multiple myeloma in patients who have received only 1 prior therapy, which included bortezomib. Or For the treatment of multiple myeloma in patients who have received at least 2 prior therapies (NICE TA171), but who are NOT eligible for treatment with the ixazomib + lenalidomide regimen. A formal medical review as to whether treatment with lenalidomide in combination with dexamethasone continues or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.
Treatment Intent	Disease Modification
Frequency and number of cycles	Repeat every 28 days. Continue until progressive disease, unacceptable toxicity or patient's choice, whichever occurs first.
Monitoring Parameters pre-treatment	• 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. • U&Es and LFT's on day 1 of each cycle. • FBC on day 1, 8 and 15 for the first 2 cycles and then on day 1 only of each cycle thereafter. • Thyroid function at baseline and as clinically indicated throughout treatment. • Haematological toxicity: • First line treatment: ○ Treat when neutrophils $> 1.0 \times 10^9/L$ and platelets $> 50 \times 10^9/L$. ○ Neutropenia: if neutrophils fall below $0.5 \times 10^9/L$ interrupt treatment and resume at starting dose once resolved to $\geq 1 \times 10^9/L$ 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 $\geq 0.5 \times 10^9/L$. 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 1). • Thrombocytopenia: if platelets fall to $< 25 \times 10^9/L$ interrupt treatment and resume at one reduced dose level once resolved to $\geq 50 \times 10^9/L$. • Treatment following one prior therapy: ○ Treatment must not be started if the ANC $< 1.0 \times 10^9/L$, and/or platelet counts $< 75 \times 10^9/L$ or, dependent on bone marrow infiltration by plasma cells, platelet counts $< 30 \times 10^9/L$. ○ Neutropenia: if neutrophils fall below $0.5 \times 10^9/L$ interrupt treatment and resume at original dose once resolved to $\geq 0.5 \times 10^9/L$ if neutropenia is the only observed toxicity, if other dose dependant haematological toxicities are observed other than

Protocol No	HAEM-MYEL-009	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V3	Written by	M.Archer
Supersedes version	V2	Checked by	H.Paddock V2/V3 O.Okuwa V1 V2 / V3 updated as agreed by the Haem TSSG 19.05.25. full protocol review not performed.
Date	15.09.2025	Authorising consultant (usually NOG Chair)	J.Lindasy V1

	neutropenia resume at one reduced dose level when neutrophils have resolved to $\geq 0.5 \times 10^9/L$. For each subsequent episode of neutropenia ($< 0.5 \times 10^9/L$) decrease the dose of lenalidomide to the next dose level (see table 2). Do not dose $< 5mg$ od. ○ Thrombocytopenia: if platelets fall below $30 \times 10^9/L$ interrupt treatment and resume at one reduced dose level once resolved to $\geq 30 \times 10^9/L$. For each subsequent drop below $30 \times 10^9/L$ interrupt treatment and resume at next lower dose level once returned to $\geq 30 \times 10^9/L$ (see table 2). Do not dose $< 5mg$ daily. • Renal impairment: • Lenalidomide: No dose reduction required in mild impairment. If CrCl 30-49 ml/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. NB an alternative dosing schedule which may be considered, but is not within the licence, is: CrCl 30-50ml/min, give 25mg on alternate days; CrCl $< 30ml/min$, give 25mg twice a week. • Allopurinol: Ensure renal function is normal before prescribing Allopurinol (usual dose is 300 mg od). Reduce Allopurinol dose to 100mg od if CrCl is 10-20ml/min and 100mg on alternate days if CrCl is $< 10ml/min$. • Hepatic impairment: • Lenalidomide has not formally been studied in patients with impaired hepatic function and there are no specific dose recommendations. • Non-haematological toxicity: • For 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. • Steroid toxicity: • Dose modification of dexamethasone is to be made on a patient by patient basis at the prescribing clinicians' discretion, this can be a dose reduction or escalation to 40mg if appropriate. • 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. • Drug interactions: 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: 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.
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	- No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve). - 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). - Consider PCP prophylaxis/ antiviral/ antifungal therapy if lymphocyte count $<1.0 \times 10^9/L$ - Patients should be advised that lenalidomide can have an effect on their ability to drive and use machines. - For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet.
References	SPC accessed on line 28.09.2023; CDF list v1.137; KMCC proforma HAEM-MYEL-009v1

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

Table 1: Dose reduction for first line treatment:

	Lenalidomide ^a
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

Table 2: Dose reduction for treatment following one prior therapy:

Starting dose	25 mg
Dose level -1	15 mg
Dose level -2	10 mg
Dose level -3	5 mg

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Repeat every 28 days:

TTO	Drug	Dose	Route	Directions
Day 1	LENALIDOMIDE	25mg	PO	ON for 3 weeks. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole, preferably with water, either with or without food.
	DEXAMETHASONE	20mg	PO	Weekly (Days 1, 8, 15, 22) Take with or after food.
	Omeprazole	20mg	PO	OD
	Allopurinol	300mg	PO	OD for 4 weeks Cycle 1 only
	Metoclopramide	10mg	PO	up to TDS PRN (supply 28 tablets) Do not take for more than 5 days continuously
	Apixaban	2.5mg	PO	BD
	Consider prophylactic PCP			
	Consider levofloxacin prophylaxis for 12 weeks for all newly diagnosed myeloma patients			

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