Indication	For treating transfusion-dependent anaemia caused by low or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate. A formal medical review as to whether treatment with lenalidomide continues or not will be scheduled to occur at least by the end of the first 4 cycles of treatment.
Treatment Intent	Disease Modification
Frequency and number of cycles	Every 28 days. Lenalidomide is to be discontinued if no response after 4 cycles. If patients are responding after 4 cycles, lenalidomide will be continued until loss of response (progression of MDS or need for RBC transfusion) or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.
Monitoring parameters pre-treatment	• Monitor FBC at baseline and every 2 weeks for the first 2 cycles, then on day 1 of each cycle. U&Es and LFT's on day 1 of each cycle. • Virology status should be checked prior to treatment. • Thyroid function must be assessed at baseline then periodically throughout treatment. • Neuts must be >/=0.5 and PLT must be >/=25 before starting treatment. • If neuts <0.5 and/ or PLT <25 interrupt treatment. Resume when neuts > /=0.5 and PLT >/=50 or PLT 25-49 on at least 2 occasions for >/= 7 days. Resume at next lower dose level. • **<u>Dose reductions:</u>** **Please note the duration of treatment during each cycle changes when a dose reduction is made.** 1st dose reduction level to 5mg each day for 28 days (of a 28 day cycle), 2nd dose reduction level to 2.5mg each day for 28 days (of a 28 day cycle), 3rd dose reduction level to 2.5mg on alternate days for 28 days (of a 28 day cycle). • Discontinuation of lenalidomide: Patients without at least a minor erythroid response within 4 months of therapy initiation, demonstrated by at least a 50% reduction in transfusion requirements or, if not transfused, a 1g/dl rise in haemoglobin, should discontinue lenalidomide treatment. • For other grade 3 or 4 toxicities judged to be related to lenalidomide, stop treatment and restart at next lower dose level when toxicity has resolved to </= 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, grade 4 rash, exfoliative or bullous rash, or if Stevens-Johnson syndrome, toxic epidermal necrolysis or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is suspected, and should not be resumed following discontinuation from these reactions. • Lenalidomide monotherapy is associated with a small increased risk of venous thromboembolism. All patients should be risk assessed and prophylactic anticoagulation considered. **Where required, prophylactic anticoagulation should be added to the prescription.** • **Lenalidomide is structurally related to thalidomide, a known human teratogen. Ensure patient is informed of requirement for strict contraception precautions during treatment with Lenalidomide. Follow Lenalidomide Pregnancy Prevention Programme.**

	The Lenalidomide Prescription Authorisation Form must be completed at time of prescribing. • **<u>Renal impairment</u>: Please note the duration of treatment during each cycle may change when a dose reduction is made.** No dose adjustment necessary for mild renal impairment. If CrCl 30-49ml/min, give 5mg od for 21 days repeated every 28 days (1st dose reduction level: 2.5mg od for 28 days repeated every 28 days, 2nd dose reduction level: 2.5mg every other day for 28 days repeated every 28 days); CrCl <30ml/min, give 2.5mg od for 21 days repeated every 28 days (1st dose reduction level: 2.5mg every other day for 28 days repeated every 28 days, 2nd dose reduction level: 2.5mg twice a week for 28 days repeated every 28 days). If CrCl <30ml/min and patient requires dialysis, treat as per <30ml/min but on dialysis days, the dose should be administered following dialysis. • **<u>Hepatic impairment</u>:** Lenalidomide has not formally been studied in patients with impaired hepatic function and there are no specific dose recommendations. • **<u>Drug interactions</u>**: 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. • **<u>Missed dose:</u>** 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. • Lenalidomide can have an effect on patients' ability to drive and operate machinery; patients should be advised to avoid driving or operating machinery if affected.
Reference(s)	SPC accessed online 21/11/19 CDF list v1.154 KMCC protocol HAEM-MDS-008v1

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

<u>Repeated every 28 days</u>

TTO	Drug	Dose	Route	Directions
Day 1	**LENALIDOMIDE**	**10mg**	PO	OD for 3 weeks. Swallow whole with water with or without food.
	Metoclopramide	10mg	PO	3 times a day for 3 days, then 10mg up to 3 times a day as required. Do not take for more than 5 days continuously.