LEFLUNOMIDE Drug Specific Monitoring Document

TARGET AUDIENCE	Board-wide
PATIENT GROUP	All patients aged 12 years and older taking Leflunomide

References

- British National Formulary (2024). *BNF | NICE*. [online] NICE. Available at: https://bnf.nice.org.uk/.
- Specialist Pharmacy Service (2021). *Medicines Monitoring*. [online] SPS - Specialist Pharmacy Service. Available at: https://www.sps.nhs.uk/home/tools/drug-monitoring/.
- Electronic Medicines Compendium (2019). *Home - electronic medicines compendium (emc)*. [online] Medicines.org.uk. Available at: https://www.medicines.org.uk/emc

Governance information for drug specific document

Lead Author(s):	Medicines Policy and Guidance Team
Endorsing Body:	Area Drug and Therapeutics Committee
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Medication Name	LEFLUNOMIDE
Actions by specialist clinician before initiation	• BP • FBC • LFTs • eGFR • Weight • Chest x-ray, if deemed clinically appropriate *For all drugs, specialist clinicians should consider whether vaccination/exclusion of other contraindications (including active infection), is required and arrange as appropriate. Specialist clinicians should also discuss the requirements around contraception, including washout before conception, with patients.*
DIS actions on starting treatment and following dose titration during initiation period	Every 2 weeks until on stable dose for 6 weeks, then monthly for 3 months • BP • FBC • LFTs • eGFR • Weight Any patients with concerning weight loss should be referred back to the specialist clinician.
Ongoing monitoring in Primary Care once stable	Every 12 weeks • BP • FBC • LFTs • eGFR Leflunomide is sometimes associated with weight loss. It is expected that this will be considered as part of the overall tolerability of treatment by specialist clinicians. If patients present to primary care with weight loss as a presenting complaint, it shouldn't be assumed this is due to leflunomide – other causes should be considered as with any other patient. For patients where leflunomide is also combined with methotrexate; continue monthly monitoring until stable for 12 months, then discuss reduced frequency with specialist clinician.

Action if monitoring is outside reference range	As per SPC, washout used when necessary for those with significant side effects, toxicity or those planning pregnancy. Adult accelerated elimination of leflunomide washout procedure – colestyramine by mouth 8g three times a day for 11 days. Seek specialist advice in these cases.
	
	Monitor Trends - be aware of trends in results and respond accordingly.
	Consider stopping treatment and contacting a specialist if any of the following develop:
	• Full blood count
	  ○ WCC less than 3.5 x 10^9/L
	  ○ Neutrophils less than 1.6 x 10^9/L
	  ○ Eosinophilia more than 0.5 x 10^9/L
	  ○ Platelets less than 140 x 10^9/L
	  ○ MCV greater than 105fL
	• Liver function
	  ○ Albumin less than 30g/L
	  ○ AST and/or ALT greater than 100units/L
	• Renal function
	  ○ Creatinine increase greater than 30% above baseline over 12 months
	  ○ eGFR less than 60ml/min/1.73m^2 (repeat in 1 week, if still more than 30% from baseline, withhold and discuss with specialist team)

Actions to take if restarting medication after treatment break	Actions may vary. Consult specialist team for any further guidance Patients should be referred by the specialist clinician to the drug initiation hub if re-titration or enhanced monitoring is required.

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CONSULTATION AND DISTRIBUTION RECORD	
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Distribution	Acute specialist consultants and pharmacists, Senior primary care pharmacists, all individuals involved with the Drug Initiation Service, LMC and GP sub-committee

CHANGE RECORD			
Date	**Lead Author**	**Change**	**Version**