CICLOSPORIN Drug Specific Monitoring Document

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

References

Please also refer to the relevant Summary of Product Characteristics and BNF section for the medicine included in this document.

- 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
- NHS Lothian Shared Care Agreements. Ciclosporin (Neoral) for solid organ transplant in adult patients. Available at https://formulary.nhs.scot/east/help-and-support/for-healthcare-professionals/shared-care-of-medicines/nhs-lothian-shared-care-agreements/ Version 4.0; Review date: December 2026
- BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs; 2017. Available at https://academic.oup.com/rheumatology/article/56/6/865/3053478?login=false#google_vignette

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	Oral CICLOSPORIN *please note requirement for brand name prescribing*

Actions by specialist clinician before initiation	• At least twice before starting treatment
	  ○ Blood pressure
	  ○ U&Es including CrCl or eGFR
	• LFTs
	• Blood lipids
	• Weight
	• FBC
	
	Dermatology also:
	• Urinalysis
	
	Rheumatology also:
	• Blood glucose
	
	For all drugs, specialist clinicians should consider whether vaccination/exclusion of other contraindications (including active infection), is required and arrange as appropriate.

DIS actions on starting treatment and following dose titration during initiation period	**Non-transplant patients:**
	Every 2 weeks for first month, then monthly for next 3 months, then every 3 months.
	  ○ Serum creatinine (for creatinine clearance) or Calculated glomerular filtration rate
	Every 2 weeks until on stable dose for 6 weeks, then monthly for 3 months
	  ○ Albumin
	  ○ ALT or AST
	  ○ Blood pressure
	  ○ Blood glucose
	  ○ FBC
	After 1 month
	  ○ Lipids
	Periodically
	  ○ Serum magnesium
	  ○ Serum potassium
	Weight – only if significant change
	
	Transplant patients:
	Monthly for the first 6 months, thereafter according to NHS Lothian transplant specialist clinic follow-up frequency
	• U&Es
	• eGFR
	• LFTs
	• Ciclosporin trough levels
	• Blood pressure
	• Weight

Ongoing monitoring in Primary Care once stable	**Non-transplant patients** Every 3 months for first year: • Serum creatinine (for creatinine clearance) or Calculated glomerular filtration rate • FBC • LFTs • Glucose • BP After 12 months of stable treatment, bloods can be reduced to annual on an individual patient basis on advice of specialist

	The above guidance is likely to only apply to Rheumatology patients as in dermatology this drug is usually only for short term use. **Transplant patients** Although blood level monitoring is routinely carried out by the specialist team during clinic visits, in exceptional circumstances the team may request that the GP arranges for routine blood tests to be taken locally for patient convenience. If the GP agrees to this, the specialist will give advice on the management of abnormal results.
Action if monitoring is outside reference range	**The specialist will give advice on the management of all abnormal results.** **All monitoring and dose adjustments will be performed by the acute specialist teams. No dose adjustment decisions are expected to be made by primary care teams. The detail below is for primary care information only.** • Monitor trends - Be aware of trends in results (e.g. gradual decreases in white blood cells or albumin, or increasing liver enzymes). A downward trend of FBC and neutrophil count or an upward trend in liver transaminases could be a sign of toxicity, even if the absolute levels are normal. • Respond to absolute levels - 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 ▪ Unexplained eosinophilia more than 0.5x 10^9/L ▪ Platelets less than 140 x 10^9/L ▪ Unexplained fall in serum albumin less than 30g/L ▪ MCV greater than 105f/L (check B12, folate, thyroid-stimulating hormone levels – if abnormal treat, if normal discuss with specialist team) ○ **Liver function** - AST and/or ALT greater than 100units/L ○ **Renal function** ▪ Creatinine increase greater than 30% above baseline over 12 months. Dermatology specify that if > 30% at any time; stop ciclosporin. ▪ Calculated GFR 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	All changes to medication will be managed by the specialist team

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CONSULTATION AND DISTRIBUTION RECORD	
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Consultation Process / Stakeholders:	LMC, GP Sub-committee, Eimear Gordon, Anthony Carson, Richard Shearer, Rebecca Malley, Rosemary Beaton, Alison Yule, GGC and Lothian transplant pharmacy leads, Drug Initiation Service pharmacists, Acute specialist pharmacists.
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		
Lead Author	**Change**	**Version No.**