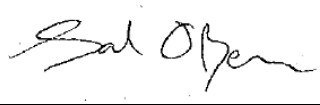
Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) For Healthcare Professionals In NHS Grampian

Co-ordinators:	**Consultation Group**:	**Approver:**
Lead Pharmacist, Grampian Medicines Information Centre	See relevant page in the document.	Medicines Guidelines and Polices Group

Signature:		**Signature:**
		

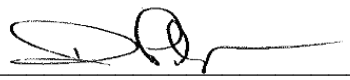
Identifier:	**Review Date:**	**Date Approved:**
NHSG/Guide/DMARDs /MGPG1235	March 2024	March 2022

Uncontrolled when printed

Version 2

Executive Sign-Off

This document has been endorsed by the Director of Pharmacy and Medicines Management

Signature: 

Title: Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) For Healthcare Professionals In NHS Grampian

Unique Identifier: NHSG/Guide/DMARDs/MGPG1235

Replaces: NHSG/Guide/DMARDs/MGPG1078

Across NHS Boards	Organisation Wide	Directorate	Clinical Service	Sub Department Area

Lead Author/Co-ordinator: Lead Pharmacist, Grampian Medicines Information centre

Subject (as per document registration categories): Guidelines

Key word(s): Monitoring, SCA, Shared Care Arrangements, DMARDS, Disease Modifying Anti-rheumatic drugs, Azathioprine, Methotrexate, Mycophenolate, Sulfasalazine, Leflunomide, Ciclosporin, Tacrolimus,

Process Document: Policy, Protocol, Procedure or Guideline Guidelines

Document application: NHS Grampian

Purpose/description: This guideline applies to DMARDs prescribed to patients under the care of rheumatology, dermatology, gastroenterology and ophthalmology. It outlines the monitoring requirements for DMARDs, independent of indication. For DMARDs not listed, please see separate shared care protocols.

Responsibilities for implementation:

Organisational: Chief Executive and Management Teams
Corporate: Senior Managers
Departmental: Heads of Service/Clinical Leads
Area: Line Managers
Hospital/Interface services: Assistant General Managers and Group Clinical Directors
Operational Management Unit: Unit Operational Managers

Policy statement:	It is the responsibility of all staff to ensure that they are working to the most up to date and relevant policies, protocols procedures.
Review:	This policy will be reviewed in three years or sooner if current treatment recommendations change.

Responsibilities for review of this document:	Lead Author/Co-ordinator
Responsibilities for ensuring registration of this document on the NHS Grampian SharePoint:	Lead Pharmacist, Grampian Medicines Information Centre
Physical location of the original of this document:	Pharmacy and Medicines Directorate, Westholme
Job/group title of those who have control over this document:	Lead Pharmacist, Grampian Medicines Information Centre
Responsibilities for disseminating document as per distribution list:	Lead Author/Co-ordinator:

Revision History:

Revision Date	Previous Revision Date	Summary of Changes (Descriptive summary of the changes made)	Changes Marked* (Identify page numbers and section heading)
Jan 2022		Rephrasing of introduction	P1
		Contents page created	P2
		General points section created	P3
		Reformatting of table	P4
		Reformatting of table	P5
		Removal of CRP from tables	P4, P5
		Instructions for monitoring after a dose increase added	P6
		Table for monitoring added	P6
March 2022		Added statement about weight loss and BP	P6
		Added statement regarding use in conjunction with SCAs	P1
		Added note regarding various tests	P3
		Consultation list added	

* Changes marked should detail the section(s) of the document that have been amended i.e. page number and section heading.

Guidelines for the monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) for healthcare professionals in NHS Grampian

This guideline applies to DMARDs prescribed to patients under the care of rheumatology, dermatology, gastroenterology and ophthalmology.

It outlines the monitoring requirements for DMARDs, independent of indication. For DMARDs not listed, please see separate shared care protocols.

This guideline should **not** be used for renal patients. The renal speciality will continue to manage their patients. GP practices are only required to undertake blood monitoring for renal patients in exceptional circumstances.

Any patients who require an alternative monitoring schedule to that indicated below will be highlighted on an individual patient basis.

Please note: the information below supersedes the monitoring arrangements outlined in the associated NHS Grampian Shared Care Arrangements (SCAs), but should be used in conjunction with the SCAs for other aspects relating to the prescribing of these medicines.

Contents

General Points

- Monitoring should not be less frequent than that stated below but may be more frequent, depending on individual patient factors.

- Standard Liver Function Test (LFT) monitoring locally includes albumin, alkaline phosphatase, alanine aminotransferase (ALT), gamma glutamyl transferase and total bilirubin. It does not include aspartate transaminase (AST). National guidance for many of the DMARDs listed below states that AST and/or ALT can be used. There may be times when the speciality requests AST to be added to the LFT request. This may be required to facilitate additional liver monitoring. When this addition is required, it should be requested by the speciality on an individual patient basis.

- C-Reactive Protein (CRP) is often used as a measure of disease progression or control. Specialities may request this test prior to reviewing a patient. It can be helpful in determining how the patient's condition is responding to treatment.

- Full Blood Count (FBC) includes haemoglobin, platelets, white cell count, neutrophils and lymphocytes.

- Urea and Electrolytes (U&Es) includes serum sodium, serum potassium, urea, creatinine and eGFR.

	Azathioprine, Methotrexate (single agent) or Mycophenolate	Sulfasalazine (single agent)	Leflunomide (single agent)
Standard Monitoring (✓)	**FBC U+Es LFTs**	**FBC U+Es LFTs**	**FBC U+Es LFTs Blood Pressure Weight**
Baseline	✓	✓	✓
Week 2	✓	✓	✓
Week 4	✓	✓	✓
Week 6	✓	✓	✓
MOVE TO MONTHLY MONITORING ONCE ON STABLE DOSE FOR 6 WEEKS			
Week 10	✓	✓	✓
Week 14	✓	✓	✓
Week 18	✓	✓	✓
MOVE TO QUARTERLY STANDARD MONITORING IF STABLE			
Week 30	✓	✓	✓
Week 42	✓	✓	✓
Week 54	✓	✓	✓
	CONTINUE QUARTERLY STANDARD MONITORING IF STABLE	**MONITORING NOT REQUIRED IF STABLE AFTER 54 WEEKS**	**CONTINUE QUARTERLY STANDARD MONITORING IF STABLE**

	Ciclosporin or Tacrolimus	Sulfasalazine AND Methotrexate (combined)	Leflunomide AND Methotrexate (combined)
Standard Monitoring (✓)	**FBC U+Es LFTs Blood glucose Blood pressure**	**FBC U+Es LFTs**	**FBC U+Es LFTs Blood Pressure Weight**
Baseline	✓	✓	✓
Week 2	✓	✓	✓
Week 4	✓	✓	✓
Week 6	✓	✓	✓
MOVE TO MONTHLY MONITORING ONCE ON STABLE DOSE FOR 6 WEEKS			
Week 10	✓	✓	✓
Week 14	✓	✓	✓
Week 18	✓	✓	✓
Week 22	✓	✓	✓
Week 26	✓	✓	✓
Week 30	✓	✓	✓
Week 34	✓	✓	✓
Week 38	✓	✓	✓
Week 42	✓	✓	✓
Week 46	✓	✓	✓
Week 50	✓	✓	✓
	MOVE TO, AND CONTINUE, QUARTERLY STANDARD MONITORING IF STABLE		

Monitoring of DMARDs after a dose increase
After a dose increase, increase monitoring to every 2 weeks until dose is stable for 6 weeks, then revert to previous schedule.

Management of blood test results and/or side effects
Whilst absolute blood monitoring values are important, trends are equally important, and any rapid fall or consistent downward trend in any parameter warrants extra vigilance and discussion with the specialist team.

Abnormal Monitoring Results/Symptoms	Action To Be Taken
Total white cell count <3.0 x 10^9/L	Withhold until discussed with consultant
Neutrophils <1.5 x 10^9/L	Withhold until discussed with consultant
Lymphocytes <0.5 x 10^9/L	Withhold until discussed with consultant
Platelets <140 x 10^9/L	Withhold until discussed with consultant
MCV >105fl	Investigate and if B12 or folate low start supplementation
>2-fold rise in ALT or Alk Phos (from upper limit of reference range)	Withhold until discussed with consultant
Unexplained fall in albumin less than 30g/L	Withhold until discussed with consultant
Rash, oral ulceration	Withhold until discussed with consultant
New or increasing dyspnoea or cough (methotrexate, leflunomide)	Organise chest x-ray Withhold until discussed with consultant
Abnormal bruising or sore throat	Withhold until FBC result available. Discuss with consultant
Creatinine increased by more than 30% over 12 months and/or calculated GFR is less than 60 mL/min	Withhold until discussed with consultant
Weight loss >10% (leflunomide)	Investigate and consider withholding until discussed with consultant
Elevated blood glucose and/or blood pressure	Assess and manage accordingly. If clinically relevant changes are seen, discuss with consultant.

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