**Disease-modifying Anti-rheumatic Drug Monitoring Guidance Document**

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#  Introduction

## Guidance statement

This policy outlines the monitoring requirements for patients at this organisation who have been prescribed disease-modifying anti-rheumatic drugs (DMARDs) by a specialist in secondary care and are considered to be stable on the treatment. This policy must be read in conjunction with [NICE guidance](https://cks.nice.org.uk/topics/dmards/) and the [General Medical Council (GMC) Good practice in proposing, prescribing, providing and managing medicines and devices](https://www.gmc-uk.org/professional-standards/the-professional-standards/good-practice-in-prescribing-and-managing-medicines-and-devices).

## Status

In accordance with the [Equality Act 2010](https://www.legislation.gov.uk/ukpga/2010/15/contents), we have considered how provisions within this policy might impact on different groups and individuals. This document and any procedures contained within it are non-contractual, which means they may be modified or withdrawn at any time. They apply to all employees and contractors working for the organisation.

# Monitoring of DMARDs in general practice

## General principles

[NICE advise](https://cks.nice.org.uk/topics/dmards/management/general-principles-of-managing-dmards/%22%20%5Cl%20%22general-principles-of-managing-dmards)s that DMARDs should be initiated, and initial monitoring undertaken, by a specialist in secondary care. Once stabilised on the treatment, GPs at this organisation may be asked to prescribe and monitor the DMARD as part of a shared care protocol. For most conventional DMARDs, ongoing prescribing and monitoring can be undertaken at this organisation with review in secondary care when apt.

Patients on biologic DMARDs require clinical review in secondary care at least every six months to allow ongoing prescribing of their treatment. Monitoring blood tests are usually undertaken at these appointments; therefore, patients on biologic monotherapy will not usually require monitoring at this organisation.

However, if a patient is prescribed a conventional DMARD (such as methotrexate) in addition to a biologic DMARD, the prescribing and monitoring of the conventional DMARD may be undertaken at this organisation.

Clinicians must also monitor for the following:

* Adverse effects
* Major toxicity
* Drug interactions

Clinicians must be aware that patients taking DMARDs are more prone to infection, especially in the first six months of treatment. They should advise patients to avoid contact with people who have shingles or chickenpox. If they come into contact with such people, they must seek urgent medical advice.

Patients on DMARDs are to be offered an annual influenza vaccine and a pneumococcal vaccine, ideally before starting the DMARD. Live vaccines should be avoided in patients on DMARDs due to the increased risk of generalised infection. Clinicians at this organisation must seek specialist advice if a live vaccine is being considered.

This organisation will ensure that patients on DMARDs are provided with suitable patient information leaflets such as those from [Arthritis Care](http://www.arthritiscare.org.uk/Home), [Arthritis Research UK](http://www.arthritisresearchuk.org/) and the [National Rheumatoid Arthritis Society](http://www.rheumatoid.org.uk/).

## Additional considerations

[NICE explain](https://cks.nice.org.uk/topics/dmards/management/general-principles-of-managing-dmards/#general-principles-of-managing-dmards)s that for patients on any DMARD, treatment should be stopped and the patient referred urgently to rheumatology if the person develops any of the following:

* Skin/mucosal reaction, for example rash, pruritus, mouth or throat ulceration
* Sore throat
* Fever
* Unexplained bruising or bleeding
* Nausea, vomiting, diarrhoea or weight loss
* Diffuse alopecia
* Breathlessness, infection or cough
* Peripheral neuropathy

For patients on a biologic DMARD, treatment should be stopped and the patient referred urgently to rheumatology if they develop any of the following:

* Cough, haemoptysis or weight loss (symptoms of tuberculosis)
* Signs or symptoms of heart failure, or worsening heart failure
* Shortness of breath or dry cough (symptoms of interstitial lung disease)
* Skin rashes
* Severe abdominal pain or unexplained change in bowel habits accompanied by fever

Clinicians must always liaise with a specialist should they have any concerns about any side effects.

## Monitoring requirements

This organisation will adhere to the [NICE monitoring requirements](https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/):

**Azathioprine**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly for 3 months
* Thereafter, at least every 12 weeks
* Monitor more frequently in people at higher risk of toxicity
* If dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |  |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Ciclosporin**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly
* People who have been stable for 12 months can be considered for reduced monitoring frequency (every 3 months) on an individual basis
* Monitor more frequently in people at higher risk of toxicity
* If dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| Blood glucose |
| Blood pressure |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Cyclophosphamide**

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| **Monitoring** | **Frequency** |
| FBC | * 10 days after each pulse therapy
* Blood tests repeated immediately prior to the next pulse therapy
 |
| LFTs: ALT and/or AST and albumin |
| Urinalysis |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Hydroxychloroquine**

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| **Monitoring** | **Frequency** |
| Renal function | * Annually in people aged over 70 years old and in those with pre-existing renal impairment, hypertension and/or diabetes
 |
| Eye assessment (ideally including optical coherence tomography)  | * Annually for all people who have taken hydroxychloroquine for more than 5 years
* Annual monitoring may be commenced before 5 years of treatment if additional risk factors for retinal toxicity exist such as:
	+ Concomitant tamoxifen therapy, impaired renal function (estimated glomerular filtration rate less than 60 mL/minute/1.73 m2) or
	+ High-dose therapy (greater than 5 mg/kg/day of hydroxychloroquine)
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**Leflunomide**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly for 3 months\*
* Thereafter, at least every 12 weeks
* Monitor more frequently in people at higher risk of toxicity
* If the dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| Blood pressure |
| Weight |
| \*If leflunomide is combined with methotrexate, continue monthly monitoring until stable for 12 months then consider reduced frequency monitoring on an individual basis. |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Methotrexate**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly for 3 months\*
* Thereafter, at least every 12 weeks
* Monitor more frequently in people at higher risk of toxicity
* If the dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| \*If methotrexate is combined with leflunomide, continue monthly monitoring until stable for 12 months then consider reduced frequency monitoring on an individual basis. |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Mycophenolate**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly for 3 months
* Thereafter, at least every 12 weeks
* Monitor more frequently in people at higher risk of toxicity
* If the dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Penicillamine**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly
* Once stable for 12 months, consider reducing monitoring to 3-monthly
* If the dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| Urinalysis (blood and protein) |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Sulfasalazine**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly for 3 months
* Thereafter, at least every 12 weeks
* Monitor more frequently in people at higher risk of toxicity
* After 12 months, monitoring may be stopped
* If the dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Tacrolimus**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly
* People who have been stable for 12 months can be considered for reduced monitoring frequency (every 3 months) on an individual basis
* Monitor more frequently in people at higher risk of toxicity
* If the dose is increased, monitor every 2 weeks until dose is stable for 6 weeks then revert to previous schedule
 |
| Creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| Blood glucose |
| Blood monitoring |
| FBC: full blood count; GFR: glomerular filtration rate; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase  |

**Biologic DMARDs**

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| **Monitoring** | **Frequency** |
| FBC | * At 3-4 months
* Then every 6 months (and/or as clinically indicated)
 |
| Renal function: creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| Lipid profile | * Monitor 4-8 weeks after treatment started
* Hyperlipidaemia should be managed according to clinical guidelines
 |
| Signs of infection, such as chickenpox | * Before each injection/infusion
 |
| Hepatitis B (surface antigen and core antibody) | * If clinically indicated, for example in people with raised ALT and/or AST, or ongoing (annually) in people who are at increased risk of infection
 |
| Hepatitis C (IgG) | * If clinically indicated, for example in people with raised ALT and/or AST, or ongoing (annually) in people who are at increased risk of infection
 |
| HIV | * If clinically indicated, for example if there are symptoms of seroconversion, or ongoing (annually) in people who are at increased risk of infection
 |
| Autoantibodies | * If symptoms or signs suggest development of autoimmune phenomena, for example raised ALT and/or AST
 |
| Tuberculosis (interferon-gamma release assay and chest X-ray) | * If clinically indicated, for example in people with symptoms or signs of tuberculosis, new exposure to tuberculosis, or residence in high-incidence setting
 |
| Urinalysis | * If clinically indicated
 |
| Skin examination for non-melanoma skin cancer for patients at increased risk (history of psoriasis or PUVA therapy). | * As indicated by risk at baseline and in the context of immunosuppression
 |
| FBC: full blood count; U&E: urea and electrolytes; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase; ALT, alanine aminotransferase; AST, aspartate aminotransferase. |

**Targeted synthetic DMARDs (tofacitinib and baricitinib)**

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| **Monitoring** | **Frequency** |
| FBC | * Every 2 weeks until dose is stable for 6 weeks then monthly for 3 months
* Thereafter, at least every 12 weeks
* More frequent monitoring is appropriate in people at higher risk of toxicity
* If the dose is increased, monitor every 2 weeks until the dose is stable for 6 weeks then revert to previous schedule
 |
| Creatinine/calculated GFR |
| LFTs: ALT and/or AST and albumin |
| Lipid profile | * Monitor lipids after the treatment started (8 weeks after initiation of tofacitinib or 12 weeks after initiation of baricitinib) then monitor periodically
 |
| Tuberculosis | * If clinically indicated, for example in people with symptoms or signs of tuberculosis, new exposure to tuberculosis, or residence in high-incidence setting
 |
| FBC: full blood count; U&E: urea and electrolytes; LFTs: liver function tests; ALT: alanine aminotransferase; AST: aspartate transaminase; ALT, alanine aminotransferase; AST, aspartate aminotransferase. |