

## The prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs

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## Guideline

# The prescription and monitoring of conventional synthetic disease-modifying anti-rheumatic drugs: British Society for Rheumatology guideline scope

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## Abstract

This guideline will provide up-to-date, evidence-based recommendations on the safe use of non-biologic DMARDs, also called conventional synthetic DMARDs (csDMARD), across the full spectrum of autoimmune rheumatic diseases. The guideline will update the guideline published in 2017 and will be expanded to include people of all ages. Updated information on the monitoring of DMARDs and vaccinations will be included. The guideline will be developed using the methods and processes described in the British Society for Rheumatology's 'Creating clinical guidelines: our protocol', updated 2023.

## Lay Summary

### What does this mean for patients?

A revised guideline, produced by the British Society for Rheumatology (BSR), will provide up-to-date information about the safe prescribing and monitoring of the effects of non-biologic (or conventional synthetic) disease-modifying anti-rheumatic drugs (DMARDs). This guideline will be used by healthcare professionals, people living with autoimmune rheumatic diseases and other interested parties, such as patient groups and charities. DMARDs are a group of drugs prescribed to people with autoimmune rheumatic diseases. The main aims of these drugs are to control symptoms and reduce or prevent long-term progression of the disease. Biologic drugs and Janus kinase inhibitors—sometimes referred to as biologic DMARDs and targeted synthetic DMARDs, respectively—are excluded from this guideline. This article outlines the scope of the revised guideline for DMARD safety, which will be updated to include new information and is being extended to include children and young people. Guideline revisions will be undertaken by a working group of adult and paediatric and adolescent rheumatologists, other healthcare professionals and people living with autoimmune rheumatic disease. The guideline will be developed using the methods and processes outlined in the BSR document 'Creating clinical guidelines: our protocol'.

**Keywords:** DMARD management guideline.

## Introduction

The guideline will update the 2017 BSR guideline, published in *Rheumatology* [1]. The updated guideline will remain restricted to the safety of non-biologic (non-bDMARDs)/conventional synthetic DMARDs (csDMARDs) and apremilast. Janus kinase (JAK) inhibitors, a form of targeted synthetic DMARD (tsDMARD), and bDMARDs are beyond the scope of these guidelines. JAK inhibitors will be included in the next revision of the BSR bDMARD safety guidelines. The guideline will be developed using the methods and processes outlined in 'Creating clinical guidelines: our protocol' [2].

## Why the updated guideline is needed

Since the 2017 guideline, there has been considerable development in the understanding and clinical practices involving non-bDMARDs for the treatment of autoimmune rheumatic diseases (AIRDs). Very recently, work studying blood monitoring for adults treated long-term with DMARDs including MTX, leflunomide, thiopurine and sulfasalazine has been published [3–6].

The severe acute respiratory syndrome coronavirus 2 (COVID-19) pandemic has led to an explosion of interest in the need for and timing of vaccination in people exposed to DMARDs. New vaccines against COVID-19 and shingles have been made available since the 2017 guidelines were published. The literature around the optimum timing of vaccination and impact, if any, on omitting DMARD doses will be reviewed.

The Regional Medicines Optimisation Committee South has developed recommendations for monitoring patients who are receiving long-term hydroxychloroquine or chloroquine for National Health Service England [7]; this follows publication of updated guidelines from the Royal College of Ophthalmologists in 2020 [8]. Both the recommended dose of hydroxychloroquine and monitoring schedule have

changed since the 2017 BSR DMARD guideline was published.

Since publication of the 2017 BSR DMARD guideline there have been further publications relating the impact of DMARDs (MTX) on interstitial lung disease [9]. Thus this update is needed to reflect these advancements and provide more contemporary, evidence-based recommendations.

The previous guideline was limited to adults. This updated guideline includes people of all ages. The updated guideline will include voclosporin, which has recently been approved for use in the UK.

## Who the guideline is for

This guideline is for health professionals in the UK directly involved in managing patients with AIRDs, including adult and paediatric rheumatologists, paediatricians, allied health professionals, general practitioners, pharmacists and specialist nurses; people of all ages receiving DMARDs for rheumatic diseases; and other interested parties such as patient organizations and charities.

## What the guideline will cover

### Target clinical population

The target clinical population is people of all ages (children, adolescents, adults) with inflammatory arthritis, connective tissue diseases, vasculitis, juvenile idiopathic arthritis and other AIRDs.

### Settings

Settings include primary, secondary and tertiary care, especially adult and paediatric rheumatology departments.

### Key areas that will be covered

Key areas that will be covered include updated recommendations on the use of licensed and available non-bDMARDs

(csDMARDs) including the addition of voclosporin; new evidence-based recommendations for pre-screening and monitoring liver toxicity with MTX, including considering a role for fibroscans; updated guidelines on the frequency of DMARD monitoring; updated recommendations concerning patient education, vaccinations and considerations for comorbid conditions and updated guidelines on hydroxychloroquine retinopathy screening following publication of Royal College of Ophthalmology 2020 guidelines.

### Areas that will not be covered

Areas that will not be covered include the use of bDMARDs and tsDMARDs, e.g. JAK inhibitors, although apremilast remains in this guideline; indications for DMARD therapy; prescribing in relation to pregnancy, as there are separate BSR guidelines for this and the use of topical drugs (e.g. topical tacrolimus).

### Methodology

- Systematic literature review: identification of new studies published since 2017 that offer insights into DMARD treatment, monitoring and safety.
- Expert committee review: a panel of clinical experts and academics will review the gathered evidence.
- Public and professional consultation: a draft will be available for consultation among health professionals and patient groups to ensure it meets clinical needs.
- Final revisions and publishing: incorporation of feedback and finalization of the guideline.

### Time frame

The guideline is expected to be published in 2025.

### Related guidance

Related guidance includes

- 2017 Rheumatology Guideline on DMARDs [2]
- EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update [10]
- 2020 Royal College of Ophthalmologists recommendations on monitoring for hydroxychloroquine and chloroquine retinopathy [8]
- 2022 American College of Rheumatology guideline for vaccinations in patients with rheumatic and musculoskeletal diseases [11]
- 2022 American College of Rheumatology/American Association of Hip and Knee Surgeons guideline for the perioperative management of antirheumatic medication in patients with rheumatic diseases undergoing elective total hip or total knee arthroplasty [12]
- CARRA Consensus Treatment Plans (standardized treatment plans for multiple diseases in paediatric rheumatology, including polyarticular and systemic JIA, lupus nephritis, juvenile dermatomyositis, juvenile scleroderma, ANCA-associated vasculitis) [13, 14]

- 2021 Royal College of Nursing guidelines on administering subcutaneous methotrexate for inflammatory arthritis [15]
- 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: recommendations for nonpharmacologic therapies, medication monitoring, immunizations, and imaging [16]
- 2021 update of EULAR/PRES recommendations for vaccination of paediatric patients with autoimmune inflammatory rheumatic diseases [17]
- British Society for Rheumatology paediatric and adolescence guidance notes for methotrexate [18]
- Immunisation against infectious diseases: the Green Book [19]
- UK Clinical Pharmacy Association handbook of perioperative medicines [20]
- British Association of Dermatologists guidance on csDMARDs (azathioprine, ciclosporin, hydroxychloroquine and methotrexate) [21]
- Guidance from Medicines and Healthcare products Regulatory Agency (MHRA) to prevent inadvertent daily instead of weekly dosing of methotrexate [22]
- British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding [23, 24]

### Key issues and draft questions

We identified the following draft PICO (patient, population or problem, intervention, comparison and outcome) statements to direct the literature review. Evidence from both clinical trials and real-world observational studies will be included, where available. We acknowledge that there is likely to be a paucity of evidence in some areas, especially for children and young people, and that it might not be possible to make recommendations in all areas.

#### PICO STATEMENT 1 Proposal

Population (P): People receiving DMARD treatment for AIRD requiring vaccination

Intervention (I): Delay starting or interrupting DMARD treatment

Comparison (C): Continuing DMARD treatment

Outcome (O): Effects on vaccination response and safety (including disease flare)

#### PICO STATEMENT 2 Proposal

Population (P): People commencing hydroxychloroquine for AIRD

Intervention (I): Screening for retinal disease

Comparison (C): No screening for retinal disease

Outcome (O): Detection and prevention of retinal toxicity

#### PICO STATEMENT 3 Proposal

Population (P): People being considered for DMARD therapy for AIRD

Intervention (I): Screening for lung disease (e.g. pulmonary function tests, chest imaging)

Comparison (C): No routine screening for lung disease

Outcome (O): Early detection of lung disease and prevention of complications associated with DMARD use

### PICO STATEMENT Proposal 4

Population (P): People with abnormal baseline liver profile blood tests being considered for MTX therapy for AIRD  
 Intervention (I): Baseline FibroScan screening  
 Comparison (C): No baseline FibroScan screening  
 Outcome (O): Identification of pre-existing liver disease or fibrosis, early detection of liver-related adverse effects and optimized management of people receiving MTX for AIRD

### PICO STATEMENT Proposal 5

Population (P): People with ALT abnormalities and AIRD  
 Intervention (I): Initiating DMARD therapy  
 Comparison (C): Withholding DMARD therapy  
 Outcome (O): Liver-related adverse events, disease progression, treatment efficacy and overall safety

### PICO STATEMENT Proposal 6

Population (P): People receiving MTX therapy for AIRD  
 Intervention (I): Monitoring biomarkers levels/non-alcoholic fatty liver disease (NAFLD) scores  
 Comparison (C): No monitoring of biomarkers levels/NAFLD scores  
 Outcome (O): Detection of liver fibrosis, prediction of liver-related adverse events, optimization of MTX dosing and overall safety of MTX therapy

### PICO STATEMENT Proposal 7

Population (P): People on DMARD therapy for AIRD  
 Intervention (I): Stopping DMARDs perioperatively  
 Comparison (C): Continuing DMARDs perioperatively  
 Outcome (O): Postoperative complications, wound healing, disease flare, medication-related adverse events and overall surgical outcomes

## Guideline working group

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## Data availability

No new data were generated or analysed in support of this research.

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