*Rheumatology Advances in Practice*, 2024, **8(3)**, rkae077
https://doi.org/10.1093/rap/rkae077
**Guideline**

British Society for Rheumatology
RHEUMATOLOGY ADVANCES IN PRACTICE
OXFORD

Guideline

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

**Louise Mercer[1,*], Abhishek Abhishek[2,3], Akhila Kavirayani[4], Alison Ahmed[5], Alan Davidson[6], Amy Foulkes[7], Claire Jones[8], Clare Nash[9], Emily Rose-Parfitt[10], Emmandeep Dhillon[11], Genevieve Zabate[12], Helen Twohig[13], Hope De Vere[14], Jennifer Scott[15], John Reynolds[16], Julia Holmes[17], Karen Hartley[18], Kishore Warrier[19], Kataryzna Nowak[20], Kate Parsons[21], Katie Bechman[22], Lisa Bray[23], Madura Adikari[24], Natasha Wood[25], Nicola Faithfull[26], Nicola Gullick[27], Pratyasha Saha[28], Rebecca Heaton[29], Samundeeswari Deepak[30], Samantha Hider[31,32], Sameena Khalid[33], Sanaa Suleiman Said[34], Sarah Ryan[35], Stuart Kyle[36], Subhra Raghuvanshi[37], Su-Yin Tan[38], Vinay Shivamurthy[39], James Galloway[40]; on behalf of the British Society for Rheumatology Guidelines Steering Group**

[1]Department of Rheumatology, Stepping Hill Hospital, Stockport NHS Foundation Trust, Stockport, UK
[2]Academic Rheumatology, City Hospital Nottingham, University of Nottingham, Nottingham, UK
[3]Nottingham NIHR BRC, Nottingham, UK
[4]Paediatric Rheumatology, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Foundation Trust, Oxford, UK
[5]Department of Rheumatology, Tameside and Glossop Integrated Care NHS Foundation Trust, Ashton-Under-Lyme, UK
[6]Community Rheumatology, Modality LLP, Birmingham, UK
[7]Department of Dermatopharmacology, Salford Royal NHS Foundation Trust, Salford, UK
[8]Medicines Management, Powys Teaching Health Board, Brecon, Powys, UK
[9]Pharmacy Department, Sheffield Children's NHS Foundation Trust, Sheffield, UK
[10]Department of Rheumatology, Southmead Hospital, North Bristol NHS Trust, Bristol, UK
[11]Department of Rheumatology, New Cross Hospital, Royal Wolverhampton NHS Trust, Wolverhampton, UK
[12]Rheumatic Diseases Unit, Western General Hospital NHS Lothian, Edinburgh, UK
[13]School of Medicine, Keele University, Keele, UK
[14]Department of Rheumatology, Gloucestershire Hospitals NHS Foundation Trust, UK
[15]Department of Hepatology and Gastroenterology, Stepping Hill Hospital, Stockport NHS Foundation Trust, Stockport, UK
[16]Institute of Inflammation and Ageing, University of Birmingham Research Labs, Queen Elizabeth Hospital, University of Birmingham, Birmingham, UK
[17]Expert by Experience, Versus Arthritis Fellowship Expert Committee Member
[18]Department of Pharmacy, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle, UK
[19]Paediatric and Adolescent Rheumatology, Nottingham Children's Hospital, Nottingham University Hospitals NHS Trust, Nottingham, UK
[20]Department of Rheumatology, Belfast Health and Social Care Trust, Belfast, UK
[21]Expert by Experience, UK
[22]Centre for Rheumatic Diseases, King's College London, London, UK
[23]Department of Paediatrics, St Richard's Hospital, Chichester, UK
[24]Department of Rheumatology, Rotherham General Hospital, Rotherham NHS Foundation Trust, Rotherham, UK
[25]Brannam Medical Centre, Barnstaple, UK
[26]Childhood Arthritis and Rheumatic Diseases Unit, Birmingham Children's Hospital, Birmingham, UK
[27]Department of Rheumatology, University Hospitals Coventry & Warwickshire, Coventry, UK
[28]Department of Rheumatology, Norfolk and Norwich University Hospital, Norfolk, UK
[29]Department of Rheumatology, Stockport NHS Foundation Trust, Stockport, UK
[30]Paediatric & Adolescent Rheumatology, Nottingham Children's Hospital, Nottingham University Hospitals NHS Trust, Nottingham, UK
[31]School of Medicine, Keele University, Keele, UK
[32]Department of Rheumatology, Haywood Hospital, Midlands Partnership Foundation Trust, Stoke-on-Trent, UK
[33]Rheumatology, Royal Hallamshire Hospital, Sheffield Teaching Hospitals, Sheffield, UK
[34]Department of Internal Medicine, State University of Zanzibar, Tunguu, Zanzibar, Tanzania
[35]Department of Rheumatology, Midlands Partnership University NHS Foundation Trust, Stoke-on-Trent, UK
[36]Department of Rheumatology, North Devon District Hospital, Royal Devon University, Devon, UK
[37]Department of Rheumatology, Wrexham Maelor Hospital, Betsi Cadawaladr University Hospital, Wrexham, UK
[38]Department of Rheumatology, NHS Tayside, Dundee, UK

**Received:** 27 February 2024. **Accepted:** 22 May 2024

[39]Department of Rheumatology, Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust, London, UK
[40]Centre for Rheumatic Diseases, King's College London, London, UK

*Correspondence to: Louise K. Mercer, Department of Rheumatology, Stepping Hill Hospital, Poplar Grove, Stockport SK2 7JE, UK.
E-mail: Louise.mercer@stockport.nhs.uk

## 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

Louise Mercer (co-chair, rheumatologist), James Galloway (co-chair, rheumatologist), Abhishek Abhishek (rheumatologist), Akhila Kavirayani (paediatric rheumatologist), Alison Ahmed (pharmacist), Alan Davidson (clinical nurse specialist), Amy Foulkes (dermatologist), Claire Jones (pharmacist), Clare Nash (paediatric pharmacist), Emily Rose-Parfitt (consultant pharmacist), Emmandeep Dhillon (specialist nurse), Genevieve Zabate (specialist nurse), Helen Twohig (general practitioner), Hope De Vere (trainee advanced clinical practitioner), Jennifer Scott (hepatologist), John Reynolds (rheumatologist), Julia Holmes (expert by experience), Karen Hartley (paediatric pharmacist), Kishore Warrier (paediatric rheumatologist), Kataryzna Nowak (rheumatology trainee), Kate Parsons (expert by experience), Katie Bechman (rheumatology trainee), Lisa Bray (paediatric rheumatologist), Madura Adikari (rheumatologist), Natasha Wood (general practitioner trainee), Nicola Faithfull (paediatric specialist nurse); Nicola Gullick (rheumatologist); Pratyasha Saha (rheumatology trainee), Rebecca Heaton (pharmacist), Samundeeswari Deepak (paediatric rheumatologist), Samantha Hider (rheumatologist), Sameena Khalid (rheumatologist), Sanaa Suleiman Said (internal medicine physician), Sarah Ryan (nurse consultant), Stuart Kyle (rheumatologist), Subhra Raghuvanshi (rheumatologist), Su-Yin Tan (rheumatologist), Vinay Shivamurthy (paediatric rheumatologist).

## Data availability

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

## Funding

This work was supported by the British Society for Rheumatology.

*Disclosure statement:* A.Abhishek has received institutional research grants from AstraZeneca and Oxford Immunotech and personal fees from UpToDate (royalty), Springer (royalty), Cadilla Pharmaceuticals (lecture fees), NGM Bio (consulting), Limbic (consulting) and Inflazome (consulting) unrelated to this work. A.Ahmed has received support to attend a conference from AbbVie, support to attend a course from Eli Lilly and presentation honorarium from AbbVie. K. B. has received institutional research grants from Pfizer, conference registration fees from UCB Pharma and honoraria from UCB, Vifor Pharma and Galapagos. S.D. has received lecture fees from Sobi. A.D. has received support to attend a conference from Nordic Pharma and advisory board fees from Galapagos. E.D. has received honoraria for educational meetings from Fresenius-Kabi. J.G. has received fees for advisory work from AbbVie, Galapagos, Janssen, Eli Lilly, Novartis, Pfizer and UCB. A.F. has received advisory/conference registration fees from Almirall, AbbVie, Eli Lilly, BMS, Leo Pharma, Janssen, Novartis, Pfizer and UCB and works on clinical trials with Janssen, Almirall and BMS in the field of psoriasis care. N.G. has received conference fees from Eli Lilly, Novartis and UCB; clinical trials funding (paid to employer) from AbbVie, AstraZeneca, Eli Lilly, Galapagos, Janssen, Novartis and UCB and honoraria from AbbVie, Eli Lilly, Janssen, Novartis and UCB. R.H. has received presentation honorarium from Nordic Pharma and AbbVie, focus group fees from Galapagos and funding to attend a conference from UCB. S.H. has received lecture fees from UCB. J.H. has received fees for public and patient involvement reviews from the Oliver Bird Fund (Nuffield Foundation) and for focus group attendance from the British Society for Immunology. C. J. has received focus group fees from Fresenius-Kabi and conference registration fees from UCB Pharma. S.K. has received conference fees from Novartis and honoraria from AbbVie and UCB. L.M. has received support to attend conferences from Nordic Pharma and UCB. K.P. works for a market research agency with pharmaceutical companies as clients, unrelated to this work. S.Raghuvanshi received support for conference fees from Eli Lilly. S.Ryan has received fees for editorial work from Janssen for an educational supplement on psoriatic arthritis published in Musculoskeletal Care. S.S.S. has received lecture fees from Novo Nordisk. V.S. received honoraria from Sobi and Fresenius-Kabi for advisory service and presentations. K.W. has received honoraria to speak at educational meetings organized by Sobi and Novartis. N.W. has received conference registration and advisory fees from Janssen. G.Z. has received advisory fees from Fresenius-Kabi, Nordic Pharma and Novartis. The remaining authors have declared no conflicts of interest.

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Rheumatology Advances in Practice, 2024, 8, 1–5
https://doi.org/10.1093/rap/rkae077
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