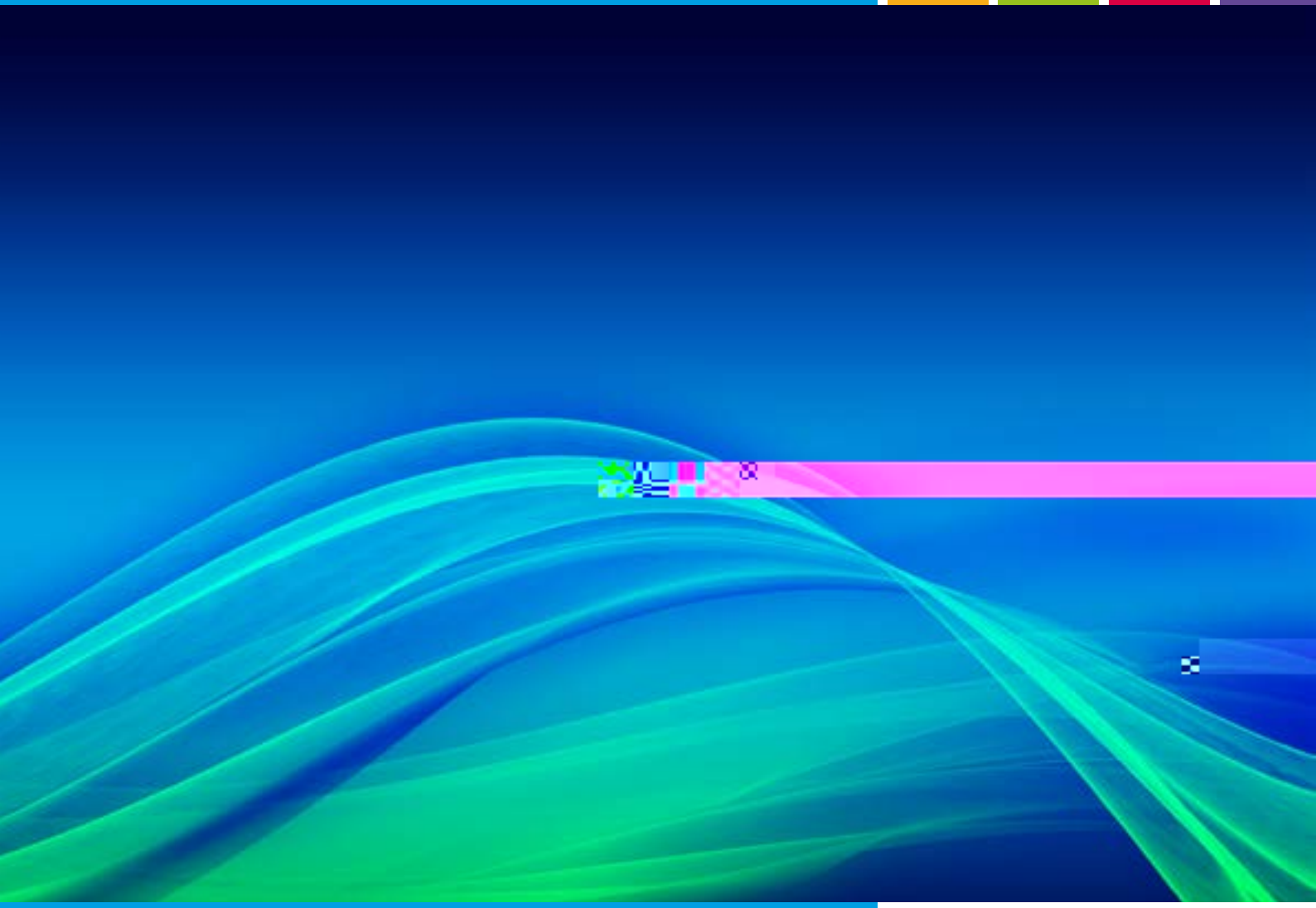
Royal College of Nursing

Biologic Disease Modifying Anti-Rheumatic Drugs (DMARDs) and Targeted-Synthetic DMARDs

CLINICAL PROFESSIONAL RESOURCE



Fifth edition

This updated publication has been reviewed by members of the RCN Rheumatology Nursing Forum. We would like to thank the following individuals for their assistance in revising and updating this valuable resource.

Editor

Sharon Petford, MSc, NMP, RCNRF Chair, Lead Clinical Nurse Specialist Rheumatology, The Dudley Group NHS Foundation Trust

Authors

Robert Clark, RN, Lead Nurse for Rheumatology and Scleroderma, Non-Medical Prescriber and Trainee Advanced Clinical Practitioner, Royal Free London NHS Foundation Trust

Alan Davidson, Clinical Nurse Specialist and Independent Prescriber, Modality LLP, Community Rheumatology Service, Birmingham

Julie Painter, NMP, Senior Clinical Nurse Specialist and New Cross Rheumatology Nurse Manager, The Royal Wolverhampton NHS Trust

Alison Kent, Rheumatology Nurse Manager, Salisbury NHS Foundation Trust

Leah Irungu, Lead Rheumatology Nurse Specialist, Lewisham and Greenwich NHS Trust, University Hospital Lewisham, London

Genevieve Zabate, RGN, NMP, Lead ANP Rheumatology, NHS Lothian

Kay Hughes, Rheumatology Clinical Nurse Specialist, New Cross, The Royal Wolverhampton NHS Trust

Alexandra Eden RN, BSc, NMP, Lead Nurse for Rheumatology, East and North Hertfordshire NHS Trust

Alison Duncan, RGN, DipHE, BSc, NMP and joint and soft tissue injector, Clinical Nurse Specialist

Prince Philip Hospital, Hywel Dda University Health Board, Wales

Lucy Craig, Paediatric Rheumatology Clinical Nurse Specialist, Great North Children's Hospital, Newcastle upon Tyne

Ruth Wyllie, Lead Nurse Children's Rheumatology, Great North Children's Hospital, Newcastle upon Tyne

This document has been designed in collaboration with our members to ensure it meets most accessibility standards. However, if this does not fit your requirements, please contact corporate.communications@rcn.org.uk

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External review team

Dr Sarah Ryan, Professor of Rheumatology Nursing, Midlands Partnership Foundation NHS Trust, Haywood Hospital, Stoke-on-Trent

Julie Begum, DipHE, BSc (Hons), MSc, ACP, NMP, Lead Nurse Rheumatology, Bedfordshire NHS Foundation Trust

Diane Finney, Consultant Rheumatology Nurse, Sussex MSK Partnership Central, Brighton

Elaine Wylie, Rheumatology Biologics Clinical Manager/Lead Rheumatology Nurse Specialist, Southern Health and Social Care Trust, Northern Ireland

Anne Quinn, Rheumatology Clinical Nurse Specialist, Belfast Health and Social Care Trust

Dr Karen MJ Douglas, Rheumatology Consultant, Dudley Group NHS Foundation Trust

Dr Zoe Cole, Consultant Rheumatologist, Salisbury District Hospital

Onajite Okoro, High-Cost Drugs and Homecare Pharmacist, Dudley Group NHS Foundation Trust

Clare Jones, Senior Rheumatology Specialist Pharmacist, Clinical Lead for Rheumatology Biologics Service, Wye Valley NHS Trust

Helen Smith, Rheumatology Nurse Specialist, University Hospitals Sussex NHS Foundation Trust

Patricia Cornell, Rheumatology Nurse Consultant, AbbVie and Honorary Senior Rheumatology Practitioner, University Hospitals Dorset NHS Foundation Trust

Clare Jacklin, Chief Executive Officer, National Rheumatoid Arthritis Society

Dr Polly Livermore, Rheumatology Matron/NIHR BRC Clinical Academic Lead, Great Ormond Street Hospital for Children NHS Foundation Trust, London

Liz Smith, Lead Nurse, Nottingham Children and Young People's Rheumatology Service, Nottingham Children's Hospital

Karen Hartley, Paediatric Rheumatology Pharmacist, Great North Children's Hospital, Newcastle upon Tyne

Dr Flora McErlane, Paediatric Rheumatology Consultant, Great North Children's Hospital, Newcastle upon Tyne

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The role of bDMARDs and tsDMARDs in the treatment of rheumatological conditions

Other long-term conditions treated with these advanced therapies which are not within the remit of this document include:

- systemic lupus erythematosus (SLE)
- skin conditions such as psoriasis
- inflammatory bowel conditions such as Crohn's disease (CD) and ulcerative colitis (UC)
- inflammatory eye condition, uveitis
- giant cell arteritis (GCA).

Part 2 of this document covers specific issues relating to the care of children and young people (CYP) with JIA, including transition of care to adult services.

There is a reference list and suggested further reading at the end of the publication on pages 53-60.

This document should not be regarded as definitive on all issues related to bDMARDs and tsDMARDs, but should be read alongside the following key texts:

- British Society for Rheumatology (BSR) resources and guidelines
- National Institute for Health and Care Excellence (NICE) technology appraisals and clinical guidelines
- Medicines and Healthcare products Regulatory Agency's (MHRA's) Yellow Card
- Scottish Intercollegiate Guidelines Network (SIGN) guidelines relevant to those working in Scotland
- Nursing and Midwifery Council (NMC) professional regulations or similar bodies for those practitioners where nursing is not their primary professional registration.

The Summary of Product Characteristics (SmPC) for all relevant drugs, including drugs prescribed alongside immunomodulatory anti-rheumatic drugs – found at the online Electronic Medicines Compendium (EMC) (Appendix 4)

- Local protocols, policies and guidelines.
- Local governance arrangements, including home care delivery services policies.

A full and comprehensive listing of these and additional advisory documents, alongside core documents produced by national regulatory bodies, can be found in Part 1, Appendix 1.

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NICE/SIGN technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS, and are based on a review of:

- clinical evidence – how well the medicine or treatment works
- health economic evidence – how well the medicine or treatment works, and if it represents value for money
- drug choice may depend on local funding agreements regarding cost effectiveness.

Practitioners are expected to take these issues into account when exercising their clinical judgement coupled with high-moderate disease activity. However, this guidance does not override the responsibility of individual practitioners to make a shared decision appropriate to the circumstances of the individual patient and/or guardian or carer.

Medicines management is defined by the MHRA as 'the clinical, cost effective and safe use of medicines to ensure patients get the maximum benefit for the medicines they need, while at the same time minimising protentional harm'.

Medicines management includes:

- the processes around the storage
- transportation and disposal of medicines
- administration of medicines
- prescribing of medicines
- supporting people to take their medicines correctly.

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1 Pre-treatment considerations 'virtual' biologics clinics (VBC)

NICE recommends the Manchester model of 'virtual' biologics clinics (NICE, 2016) to streamline the process of screening and managing referrals within a department.

- MDT approach considers the patient's co-morbidities, while choosing the most clinically effective and cost-effective treatment.
- There is a comprehensive screening document that all practitioners can complete (see Part 1, Appitel of 48.1 (g)7.4 (i)2.8 (n)5.3 (r)-0 0.259 0. (n)5Be.

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Stop-Think-Reflect

- Consider how to deliver patient education post-COVID-19.
- For RA patients the NRAS Self-Management Individualised Learning Environment has a module specifically explaining medications. See: nras.org.uk/smile
- What information and risk assessment should be considered?

2 Vaccinations

The following section is designed as a resource to support the practitioner in providing vaccination advice to the patient or carer – or a health professional providing vaccination (such as a practice nurse). It is not intended to support the process for provision of vaccination itself, as this is outside the remit of rheumatology services and this document.

Practitioners should identify the patient's immune/vaccination status in the screening process.

Unless contraindicated, it is recommended that all patients requiring treatment be up to date with all clinically indicated vaccinations.

- Influenza.
- Pneumococcal.
- COVID-19 vaccine (please refer to national guidelines.)
- Varicella zoster (VZ), noting the now available inacticate1.2 ci.5 (e ni)2.5 (o)el2s(t)17 (i)2.8 aad vaccin
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Patients should be advised to avoid exposure to potential risk factors for infection, given information on the signs and symptoms of infection to watch for, and advised to:

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4.4 Venous thromboembolism (VTE)

Despite the positive therapeutic impacts of JAK inhibitors, concerns have been raised regarding the risk of VTE, such as deep vein thrombosis (DVT) and pulmonary embolism (PE). There are several predisposing conditions and risk factors for VTE, including advanced age, obesity, diabetes mellitus, hypertension and hyperlipidemia. Smoking can also contribute to its development.

Greater VTE risk is noted in patients with chronic inflammatory conditions, particularly RA patients with uncontrolled disease activity and any comorbidity. Prior to the initiation of JAK inhibitors, clinicians should consider both the number and strength of VTE risk factors for each patient. In addition, clinicians should advise patients to seek prompt medical help if they develop clinical signs and symptoms that suggest VTE/PE (Mori et al., 2021).

4.5 Varicella/shingles

Please refer to The Green Book, chapter 34, for further information (UK Health Security Agency, 2013).

Definition of VZV contact

Contact is defined as being in the same room as someone with varicella for at least 15 minutes or having face-to-face contact eg, having a conversation. This particularly applies if the person has:

- chickenpox of any distribution (exposure to chickenpox is of greater clinical significance than shingles)

or

- shingles with facial nerve involvement (uncovered lesions eg, facial shingles)

or

- disseminated shingles (< 1 dermatome involved)

or

- if the person is also immunosuppressed.

Source: The Green Book, chapter 34 (UKHS, 2016)

5 Hepatitis B and C

BSR biologic guidelines (2018) recommend screening for Hepatitis B virus (HBV) and Hepatitis C virus (HCV) serology prior to commencing any b/tsDMARDs. Screening for HBV should include testing for Hepatitis B surface antigen (HBsAG) and Hepatitis B total core antibody (HBcAb) in all patients who will receive a b/tsDMARDs.

The reactivation of HBV and worsening HCV have been reported with virtually all the

biologic therapies. Close monitoring of signs and symptoms and of liver function tests should be undertaken for patients receivig b/tsDMARDs (always refer to the SmPC) (ACR, 2021).

For those who are HBsAg positive, advice should be sought from a physician with expertise in Hepatitis B. Ensure you are aware of your local specialist in this area.

For those who are negative for HBsAg, but are positive for HBcAb, then EDTA blood should be sent for HBV PCR. If the HBV PCR shows detection of HBV DNA, then advice should be sought from a physician with expertise in Hepatitis B (NICE, 2017; CG165).

In long-term treatment with bDMARDs, infection risks are posed from both new exposure and from reactivation of latent disease in the context of immunosuppression. Some recent studies suggest a need to repeat testing when switching biologic therapy or, for example, every 5 years (Eden et al., 2022).

6 bDMARDs and malignancy

There is no evidence of an increased risk of solid tumours or lymphoproliferative disease for people with inflammatory arthritis on bDMARDs. There is, however, evidence to suggest that there is an increased risk of some skin cancers as stated in the SmPC, such as melanoma with anti-TNF therapy.

In addition to this risk, patients with psoriasis that have undergone light treatment therapy Psoralen + ultraviolet light A/ultraviolet (PUVA/UVB) may be at further risk of skin malignancy (BSR, 2018). Consequently, ongoing vigilance is required which should include preventative skin care, skin surveillance and early reporting of new skin lesions (BSR, 2018).

Research also suggests that bDMARDs do not increase the risk of recurrent cancer

7 Considerations while on treatment

7.1 Tuberculosis (TB)

Patients started on b/tsDMARDs should be closely monitored for TB while on treatment and for at least 6 months after stopping treatment. Patients on biologics who develop symptoms suggestive of TB should receive full anti-TB treatment but may continue with their b/tsDMARDs, if clinically indicated, after risk/benefit analysis and discussion with a TB expert (BSR, 2018; BTS, 2016; ACR, 2021). As the reactivation of TB is a particular concern, patients must report any TB warning signs such as:

- persistent productive cough
- haemoptysis
- weight loss
- fever.

7.2 Uveitis

There have been several case reports of uveitis developing in patients with anti-TNF therapy, reported in the BSR registry data, even though some anti-TNFs have also been reported to successfully treat patients with resistant uveitis.

A meta-analysis comparing incidence of anterior uveitis in both anti-TNF monoclonal antibodies, IL-17A inhibitors and placebo by Roche et al. (2021) found that the incidence of anterior uveitis flares was lower with anti-TNF monoclonal antibodies infliximab, adalimumab, golimumab and certolizumab compared to placebo. There was also a significant difference for a decreased incidence of anterior uveitis with anti-TNF monoclonal antibodies compared to IL-17A inhibitors including secukinumab and ixekizumab.

The other comparison between biologics or between biologics and placebo were not significant. While the results showed that IL-17A inhibitors did not have the same protective effect against anterior uveitis flares as anti-TNF monoclonal antibodies, they are reassuring with regards to a possible deleterious effect of IL-17A inhibitors without significant difference between them and placebo.

7.3 Blood dyscrasias

This is a rare event in patients on a combination of DMARD and biologic therapies. However, practitioners should ensure that patients are encouraged to report signs suggestive of blood dyscrasias, for example, bruising, bleeding, mouth ulcers, shortness of breath and persistent fever, and ensure that vigilance is applied during routine monitoring.

Stop-Think-Reflect

- If a patient has delayed their blood test, what would be your next step?

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7.4 Progressive multifocal leukoencephalopathy (PML)

Practitioners should be vigilant for PML, which has been primarily associated with rituximab but has been reported with anti-TNF and some DMARDs, like leflunomide

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7.8 Surgery and common practice

Prior to surgery, please refer to the half-life of the drug and type of surgery before pausing treatment. There will be regional variation and close liaison with the individual's surgeon should be sought.

8 Safety monitoring

All medicines are subject to a black triangle status (▼) at the time of initial authorisation. JAKi are currently subject to black triangle status as well as some biosimilars.

8.1 Adverse drug reactions

Adverse drug reactions, or events, are an undesired effect of a medication or medical product. They may occur from an incidental or non-incidental drug overdose, abuse or medication errors because of incorrect prescribing or administration.

The more often that suspected adverse drug reactions are reported, the more information regarding medications or medical products will be available for those prescribing and administering. This will enable prescribers to make a balanced decision based on risk and benefit.

Please see Adverse Drug Reactions in Appendix 4 for information on the most frequently used rheumatology medications and a hyperlink to each of the SmPCs available on the Electronic Medicines Compendium (EMC) website: medicines.org.uk/emc

8.2 Responsibility for reporting possible adverse drug reactions or adverse events

Anyone can report possible undesired effects of a drug or medical products, including members of the public and patients. In the UK, we use the Yellow Card scheme.

Adverse drug reactions can be easily reported online via the website or app.

See: yellowcard.mhra.gov.uk

8.3 Travel advice

Patients should be counselled on the need to avoid live vaccines while on csDMARDs, bDMARDs, tsDMARDs and certain doses of corticosteroid, and the implication that may have for travelling. Travel letters can be provided by the home care companies. Advice regarding cool chain for travel and how long treatment can be left out of the fridge needs to be discussed with the patient. Up-to-date information can be found in the SmPCs.

For information regarding immunisation of patients with underlying conditions, refer to chapter 7 of The Green Book: gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7

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to maintain the patient on the lowest dose and dose tapering that maintains clinical remission. This avoids unnecessary dose-related adverse events while remaining cost effective and preserving excellent clinical outcomes (EULAR, 2019; ACR, 2021; NICE, 2014; Van Herwaarden et al., 2014).

9.1 Switching between therapies

Approximately one-third of patients do not respond to the first therapy (primary failure) and a significant percentage will also lose efficacy later during therapy (secondary failure). For both subgroups different treatment options are available, including switching to an alternative b/tsDMARD therapy or changing to an agent with a different mechanism of action. The case for switching to another agent can be supported based on their different half-lives, which might be translated into a different duration of TNF neutralisation and responses at an individual level (EULAR, 2012, 2019; ACR, 2021).

There is evidence that overlapping therapies, without considering half-life, further increases the risk of infection and adverse effects, and so care should be taken when switching between advanced therapies. It is common practice to rescreen (including for infection), when switching between therapies. Local guidelines should be followed.

Individual risks and benefits must be considered and discussed clearly with patients.

9.2 Administration of therapies: intravenous therapies

There will be regional variations for where treatments are administered (ie, secondary, primary, or home care settings). Robust standard operating procedures need to be in place.

Therapies do not require specialist handling precautions as they are not chemotherapy agents and disposal of equipment and unused medication should be in accordance with local requirements.

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This guidance is general only. For additional detail please refer to the SmPC, discuss with the manufacturer's medical information department or your pharmacist.

9.4 Overview of home care

Most people who self-administer b/tsDMARDs will often have their drugs delivered to them at home by a home care delivery service and will receive subsequent training. The service should be well-integrated into the care pathway, provide high quality assurance of safety and quality, and provide evidence of meeting patients' needs.

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The first edition of this document was published in 2009. Since then, there have been a number of changes including new publications, advisory documents and updated guidance from professional organisations and regulatory bodies It is vital that practitioners using this document also refer to these core documents, which are listed below:

- BSR (2018) British Society for Rheumatology (2018) The British Society for Rheumatology biologic DMARD safety guidelines in inflammatory arthritis. *Rheumatology*, 58(2), 220-226. https://doi.org/10.1093/rheumatology/key207
- BSR (2022a) Guidelines for the treatment of psoriatic arthritis with biologic and targeted synthetic DMARDs. rheumatology.org.uk
- BSR (2022b) Guidelines on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids. rheumatology.org.uk
- NICE guidelines: NG100; NG65; QS3 N1679( )TjEnrn-t N0ny agS n-.9 (.)-3.3 (u)-2.4 (k

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Patient information/ID label	First biologic ☐ / Switch ☐ Therapy commencing	
Name		
Hospital number		
NHS number		
DOB		
Comments		
Pre-treatment screening questions	**Yes**	**No**
Patient meets NICE criteria (or exceptional request approved)		
Patient has received written and verbal information on proposed treatment		
Patient has understood the side effects and benefits of this treatment		
Patient has been advised to use effective contraception		
Patient advised not to have live vaccines		
Patient advised to have seasonal flu vaccine		
Patient advised to have pneumovax vaccine and keep up to date		
Patient up to date with COVID-19 vaccine (DATE)		
Patient provided with alert card		
Patient is taking methotrexate/other DMARD *unless approved as monotherapy or patient is intolerant of methotrexate		
Tocilizumab only – potential interaction with statins/calcium channel blockers/theophylline/warfarin/phenytoin/cyclosporine/ benzodiazepines		
CXR in last 12 months is normal or with no new changes/unexpected findings		
T-Spot/IGRA/Quantiferon/Mantoux test is non-reactive		
Hepatitis B status +ve/-ve, Hepatitis C status +ve/-ve		
HIV status +ve/-ve		

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Varicella status VZIGG immune/not immune		
ANA status +ve/-ve		
FBC, U&E		
Immunoglobulins normal (Rituximab only)		
Baseline ESR/CRP =		
Baseline lipids		
Weight in kgs		
RA DAS 28 CRP/ESR =		
AxSpa BASDAI = VAS =		
PsA DAS 66/68 TJC ( ) SJC ( ) Patient Vas Physicians Vas		
Exclusion criteria	Yes	No
Active infection		
Severe heart failure (New York criteria)		
Malignancy		
Patient is pregnant or breastfeeding (excluding certolizumab pegol). Discuss other options including other TNF inhibitors that can be ah6.4 TEer[oliz d up y-6.1 (s o)6.5 (t)5.5 (h)-5.6 (e)-6.2 o(a)-2.3 (n b)-8.e(a)-2.3 (n o)-7 (r)-9.3 r8 (cy)-1d(a)-2.3 r-4.9 (e .8 (o)-68 (n))-0.6 (+u)-8 (p y-6.1 (s 4-2.3 .w 0 -1.75 Td[(		

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History or high risk of venous thromboembolism (Baricitinib, Tofacitinib, Filgotinib, Upadacitinib)		
Immunocompromised patients		
Patient advised treatment will be withdrawn in the following circumstances	Yes	No
Malignancy (excluding non-malignant skin cancer such as basal cell)		
Severe drug related toxicity/unexplained adverse event		
Pregnancy (except in certolizumab pegol and other TNF inhibitors up to third trimester)		
Severe infection (until resolved)		
Patient requires surgery (for a period before and after procedure)		
Patient does not respond to treatment		
Consent	Yes	No
I have read the written information about this medication		
I have had the opportunity to ask questions regarding the risks and benefits of this treatment		
I understand that I must attend planned appointments to be reviewed		
I understand that the treatment will be discontinued if my condition does not respond or if it is no longer deemed appropriate		
I agree to my details being provided to a nominated home care service who will provide initiation of treatment and the supply of medication		

Script and registration sent to pharmacy/day case	Date:
Signature:	Date:
Practitioner/VBC name:	
Signature:	Date:

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(NICE guidance at time of production)

	Rheumatoid arthritis	Psoriatic arthritis	Axial spondyloarthritis
Validated assessment tool	DAS28	66/68 tender and swollen joint count	BASDAI and spinal VAS
NICE criteria for access to biologic therapy	Intensive therapy with a combination of cDMARDs (one of which must be MTX unless contraindicated) Moderate disease activity score >3.2 Severe disease activity score >5.1	2 DMARDs (one of which must be MTX unless contraindicated) Tender joint count = 3 or more Swollen joint count = 3 or more Patient GDS _ / 5 Physician GDS _ / 5	Adequate trial of 2 NSAIDs (unless contraindicated) BASDAI >4.0 Spinal VAS >4
Specialist review required following initiation of treatment	12-16 weeks depending on which biologic therapy commenced (See SmPC for individual medication)	12-16 weeks depending on which biologic therapy commenced (See SmPC for individual medication)	12-16 weeks depending on which biologic therapy commenced (See SmPC for individual medication)
Ongoing clinic review	As clinically required due to severity of disease Minimum 6 monthly [4] Local variations may apply	As clinically required due to severity of disease Minimum 6 monthly [4] Local variations may apply	As clinically required due to severity of disease Minimum 6 monthly [4] Local variations may apply
Response criteria	Improvement of DAS28 of >1.2 in severe disease and >0.6 in moderate disease by 6 months	Improvement in at least 2 of the 4 PsARC criteria, (one of which has to be joint tenderness or swelling score) with no worsening in any of the four criteria (People whose disease has a Psoriasis Area and Severity Index (PASI) 75 response at 12 weeks but whose PsARC response does not justify continuation of treatment should be assessed by a dermatologist to determine whether continuing treatment is appropriate on the basis of skin response)	Reduction in BASDAI score to 50% of the pre-treatment value or by 2 or more units And a reduction in the spinal pain visual analogue scale (VAS) by 2cm or more

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Blood monitoring (For further specific guidance check your locally agreed protocols)	Biologic without cDMARD (or with cDMARD that needs no blood monitoring): 3-6 monthly Patient on Biologic + DMARD may need more frequent monitoring IV/SC tocilizumab: Monthly monitoring of neutrophil count and AST/ALT IV rituximab: Requires checking of immunoglobulins before each cycle JAKi: Repeat lipids 8-12 weeks (see SmPC for individual medication)	Biologic without cDMARD (or with cDMARD that needs no blood monitoring): 3-6 monthly Patient on Biologic + DMARD may need more frequent monitoring JAKi: Repeat lipids 8-12 weeks (see SmPC for individual medication)	Biologic without cDMARD (or with cDMARD that needs no blood monitoring): 3-6 monthly Patient on Biologic + DMARD may need more frequent monitoring
Registry	BSRBR-RA (Recruitment until 2026)	BSRBR-PsA (Recruitment until 2026)	BSRBR-AS (Study recruitment ended 2020)

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RCN Competency Framework for Rheumatology Nurses: rcn.org.uk/Professional-Development/publications/pub-009004

Self-reflection exercise: to illustrate understanding behind the changes presented in this update (fifth edition) in line with the NMC (2018).

For revalidation each nurse is required to record a minimum of five written reflections relevant to their experience over three years. This is prior to the renewal of their registration. These (r)-1.2 (e)-1.8 (e)-0.6 (y)22 (ea)1.9 (r)-5.1 (s)-18.9 (. T)-5.5 (h)1.5 -9he7 (a)12.731 s (s)-13

3.9 (5.2 (e)18.5 (v)17.7 (a)1.9 (n)9.5 (t t)16.5 (o t)9.9 (h)-1.5 (e)2.3 (i)2.8 (r e)26.4 (x)1 (p7 (s4(5h)T)-6)23.1 (f)e6 (i)v)1. -2.8 (

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1 Introduction

This document provides guidance for all nurses caring for children and young people (CYP) under the age of 18 with rheumatological conditions requiring DMARDs. These are used to treat the underlying rheumatological condition and reduce inflammation.

There are three main types of DMARDs used in paediatric rheumatology:

- conventional synthetic DMARDs (cDMARDs): for example, methotrexate
- biological DMARDs (bDMARDs): for example, adalimumab and infliximab
- targeted synthetic DMARDs (tsDMARDs): JAK inhibitors, such as baricitinib and tofacitinib.

The role of cDMARDs and bDMARDs is well established. Whereas the use of tsDMARDs continues to evolve in the treatment of paediatric rheumatology conditions, these drugs are effective, well tolerated and safe in the vast majority of patients. However, they can be associated with complications such as neutropenia, infections and, in the long term, may increase the risk of certain types of cancer, for example, skin cancers.

Clinical services for CYP with rheumatological conditions have expanded significantly since 2001. The British Society of Paediatric and Adolescent Rheumatology (BSPAR) originally supported practitioners caring for CYP. BSPAR merged with the British Society for Rheumatology (BSR) in 2016 and BSR is now the parent committee supporting safe practice across the life course in rheumatology.

A multidisciplinary approach is essential to the provision of high-quality care to CYP with rheumatological conditions and this is often co-ordinated by the paediatric rheumatology nurse specialist based in a tertiary centre. Ongoing treatment is commonly given at home by family/carers with the support of children's community nursing (CCN) teams or closer to home in local paediatric units. CYP need developmentally appropriate health care delivered by the appropriate qualified health care professionals.

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the vasculitides). Despite these overlaps, paediatric treatment pathways may be quite different to adult pathways with variations in presentation, assessment, management and treatment. An increasingly complex range of auto-inflammatory diseases are also being treated by rheumatology practitioners with bDMARDs and tsDMARDs.

JIA is the most common paediatric rheumatological diagnosis. It is an umbrella term for a collection of subtypes of arthritis. JIA is defined as arthritis in one or more joints lasting for 6 weeks and starting under 16 years of age (see Part 2, Appendix 1 for Classification of JIA).

A recent study by Costello, McDonagh et al., (2022) showed that over the last 15 years the incidence and prevalence of JIA in the UK has not changed and remains as approximately 6 per 100,000 population and a prevalence of around 1:1000. Diagnosis is based upon clinical findings of persistent arthritis including the medical history, physical examination of all joints and laboratory tests. There is no single test to diagnose JIA. Diagnosis follows process of exclusion of conditions such as infection and leukaemia.

Uveitis can develop in isolation or in association with different inflammatory and rheumatological conditions, in particular JIA. Uveitis is inflammation inside the eye. Many CYP have no obvious symptoms but if left untreated it can result in blindness. Some patients with JIA will go on to develop uveitis in the years following diagnosis so screening of CYP is imperative (see: engage.england.nhs.uk/consultation/specialised-services-consultation/user_uploads/uveitis-paediatrics-policy.pdf). Visual symptoms or impairment are often not recognised and therefore not reported by CYP, hence regular screening is imp

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In addition, CYP and families/carers should have a training plan that provides them with a clear understanding of the process and responsibilities required for either hospital or home administration (see Part 2, Appendix 2). The time it takes to complete the training, together with the number of practice sessions, will vary.

Patient information leaflets on treatment are available from a number of patient organisations, some of which are listed at end of this document. Many manufacturers also produce illustrated patient guides and online videos in addition to their SmPCs and

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If the family/carer needs extra support with the administration of injections, they should be referred to the local community children's nursing team. If the prescribed medication is by oral route, and swallowing tablets is difficult for the CYP, there is an interactive training package developed to teach pill swallow (Tse, Vasey et al., 2019) e-lfh.org.uk/programmes/kidzmed.

Nurses administering medications for rheumatological conditions, via an infusion in a clinical environment should have access to the specialist team for support and guidance. Although rare, there is the potential for serious and life-threatening reactions, so CYP should be cared for in a suitable paediatric environment with access to paediatric resuscitation.

The paediatric rheumatology specialist team should provide ongoing support and education for nursing teams managing CYP on complex medications.

8.5 Assessment of a young person

Practitioners should be aware of the need for developmentally appropriate health care and education as children become teenagers and young adults. Key areas for assessment include:

- home: who do they live with and who supports them?
- education: are they attending regularly and do they have career aspirations?
- hobbies/interests: what do they like to do in their own time?
- risk-taking behaviors: consider drug or substance misuse and any potential interaction with prescribed medication
- sexual health: including partners, contraception, avoidance of sexually transmitted infections, and contraindications with medication
- mental health: consider mood, interaction with professionals, self-harm, suicidal feelings, eating problems, gender orientation
- safeguarding concerns: any previous or current involvement with social care, exploitation, gangs, neglect, radicalisation.

This is not an exhaustive list and is best encompassed within an assessment tool specifically designed for interaction and engagement with young people, such as HEADSSS (Goldenring, Rosen, 2004) and this online resource: health.nsw.gov.au/kidsfamilies/youth/Pages/heeadsss-videos.aspx

Stop-Think-Reflect

- What tool are you going to use in your service to assess and interact with young people prior to starting treatment?
- Explore useful online websites to support young people and their families including Young Minds and the NSPCC.

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8.6 Pre-treatment checklist and baseline investigations

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Stop-Think-Reflect

- Paediatric sepsis is the leading cause of child death. What is your hospital's paediatric sepsis guidance?
- A useful screening and treatment tool for paediatric sepsis is available at the Royal College of Paediatric and Child Health: rcpch.ac.uk/resources/paediatric-sepsis-podcasts

11.1 Varicella and measles infection

Primary or secondary chickenpox and measles is a major concern for patients taking DMARDs. The treatment of a CYP who has been in contact, varies from area to area and local management should be followed.

Prior to starting DMARDs, it's important to take a history of previous exposure to chickenpox, measles and childhood vaccines. Measuring measles and varicella IgG titres in all CYP prior to starting treatment is now standard practice and some even offer the vaccinations to those who have negative titres. These vaccines are live, and this will delay starting treatment. The risks of delaying treatment also need to be considered and should

12 Monitoring

Blood monitoring is central to high quality care for CYP on systemic immunosuppression and, in fact, normal blood monitoring tests are a key prerequisite to provision of repeat prescriptions. The following monitoring regime is recommended for CYP who start treatment, but it may vary according to individual centres, guidance is recommended by Ledingham et al., (2017).

Abnormal blood tests

14 Surgery/dental extraction

For CYP who have planned surgery or dental extraction, it is usually recommended that treatment is either stopped or timings adjusted prior to any surgical procedure. Each individual case should be discussed with the specialist team before stopping or restarting treatment.

If emergency surgery is required, patients or their families/carers should be advised to:

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It is known that a poorly planned or ineffective transition is associated with increased morbidity and/or mortality (Nagra et al., 2015). There are already several published documents guiding adolescent or transitional care. The Quality Standard (NICE, 2016) covers transitional care and recommends that adolescents are identified early with developmentally appropriate health care offered from Year 9 and a more recent report is helpful as a guide – ncepod.org.uk/2023transition/The%20Inbetweeners_summary%20report.pdf

Developmentally appropriate health care provides the CYP with the knowledge, skills and confidence to manage their own condition as they move into adult services. This model encourages the CYP to build up relationships and to connect with professionals to make decisions about their health and wellbeing while living with a chronic condition. Developmentally appropriate health care is recognised as a more effective approach during transition with the focus being upon the individual young person rather than their age (Dovey-Pearce et al., 2020).

In health care, transition describes the process of preparing, planning and moving from children to adult services. The Ready, Steady, Go, Hello programme is a useful pathway to help CYP and families/carers to prepare for transfer: readysteadygo.net/rsg-hello-to-adult-services.html

Transfer to adult care is not always seamless, therefore having a dedicated transitional co-ordinator as part of the MDT is recommended (NICE, 2016). Their role is to link with adult teams and CYP to improve engagement and care prior to and post transfer. Successful transition needs to be planned with established pathways to the most appropriate adult rheumatology team.

Stop-Think-Reflect

Reflect on how you prepare CYP for transfer to adult services.

Are they in an appropriate environment? Do you use the Ready Steady Go Framework for Transfer?

readysteadygo.net/rsg-hello-to-adult-services.html

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Training checklist for home administration of subcutaneous medication by a CYP or family/carer

Patient name:	
Person taught:	
Assessor:	

Check list	Date completed/ proved competence	CYP's /family/carer's signature	Assessor's signature
CYP/family/carer understands: • verbal and written information given on medication prescribed • reason for giving medication • potential complications/side effects.			
CYP assessment tool used and if appropriate contraception/pregnancy discussed.			
CYP/family/carer understands a normal temperature and has a working thermometer for use at home.			
CYP/family/carer knows and understands where to seek adrd id idseuse0.6 (u)-4.2 n-2.9idse (dseu)-fd			

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Certificate of competence for the home administration of subcutaneous medication by patient or patient's carer

Patient name:	
Address:	
Telephone number/email:	

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This complements *A Competency Framework for Rheumatology Nurses* (RCN, 2020).

Name of practitioner:	
Name of supervisor:	

Element of competence to be achieved	Date of achievement	Practitioner signature	Supervisor signature
Discuss the rationale for the use of DMARDs in rheumatology conditions.			
Discuss potential issues related to treatment including: • suitability of treatment for individual CYP • benefits of treatment • possible side-effects or adverse events.			
Discuss the process for assessing the patient's suitability for DMARD treatment. For example, medical and social history, concomitant medications, allergies, level of disease activity.			
Demonstrate the ability to check the validity of the current prescription. This includes expiry date, dose, route by which the drug is to be administered and checking patient identification.			
Demonstrate the ability to teach a CYP/family/carer how to administer subcutaneous treatment.			

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Goldenring JM and Rosen DS (2004) Getting into adolescent heads: an essential update. *Contemporary Pediatrics*, 21(1), 64-92. Available at: https://stpn.uk/wp-content/uploads/2023/04/HEADSSS-by-Goldenring-2004.pdf (accessed 22 May 2024)

Health and Safety Executive (2002) *Control of Substances Hazardous to Health*

Royal College of Nursing (2022) *Immunisation Knowledge and Skills Competence Assessment Tool*. Available at:

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UK Health Security Agency (2013) *Immunisation against infectious disease*. Available at: www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book (accessed 22 May 2024)

UK Health Security Agency (2013). *Immunisation of Individuals with Underlying Medical conditions: the Green book, Chapter 7 [Updated: 10 January 2020]*. [online] Available at: https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7 (accessed 22 May 2024)

UK Health Security Agency (2013). *Immunisation against Infectious Disease [Updated: 27, November 2020]*. [online]. Available at: www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book (accessed 22 May 2024)

Valenzuela C, Waterer G and Raghu G (2021) Interstitial lung disease before and after COVID-19: a double threat? *The European Respiratory Journal*, 58(6). Available at: https://doi.org/10.1183/13993003.01956-2021 (accessed 25 April 2024)

Wenhui X, Shiyu X, Yanrong H, Xiaoying S, Dai G, LanLan J, Guangtao L and Zhuoli Z (2020) A meta-analysis of biologic therapies on risk of new or recurrent cancer in patients with rheumatoid arthritis and a prior malignancy. *Rheumatology* PMID: 31620795 DOI: Available at: https://academic.oup.com/rheumatology/article/59/5/930/5588752 (accessed 25 April 2024)

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Patient information leaflets

Information for patients on biologics is provided at the following sites.

Adults and children and young people

British Society for Paediatric and Adolescent Rheumatology: bspar.org.uk

British Society for Rheumatology: rheumatology.org.uk

British Thoracic Society: brit-thoracic.org.uk

Children's Chronic Arthritis Association: ccaa.org.uk

JIA@NRAS: jia.org.uk

Juvenile SLE group: liverpool.ac.uk/life-course-and-medical-sciences/research/groups/ukjsle

Lupus UK: lupusuk.org.uk

Medicines for Children: medicinesforchildren.org.uk

National Axial Spondyloarthropathy Society: nass.co.uk

National Rheumatoid Arthritis Society: nras.org.uk

Paediatric Rheumatology International Trials Organisation: pediatric-rheumatology.printo.it

Patient held records: teens.aboutkidshealth.ca/myhealth-passport

Psoriatic and Psoriatic Arthritis Alliance: papaa.org

Versus Arthritis: versusarthritis.org

Manufacturers' websites

AbbVie: abbvie.co.uk

Biogen: biogen.com

Blueteq Ltd: blueteq.com

Bristol Myers Squibb UK: b-ms.co.uk

Jansen Biotech: stelarainfo.com/about-janssen-biotech-inc#:~:text=About%20Janssen%20Biotech%2C%20Inc.&text=STELARA%C2%AE%20(ustekinumab)

Lilly UK: lilly.co.uk

Novartis UK: novartis.com/uk-en

Pfizer (formerly Wyeth): pfizer.co.uk

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Roche UK: roche.co.uk

Schering Plough (MSD): msd-uk.com

UCB UK: ucbpharma.co.uk

Other useful websites

National Electronic Library for Medicines: nlm.nih.gov

NHS Commissioning Board: england.nhs.uk/commissioning

NHS Quality Improvement for Scotland: healthcareimprovementscotland.org

Paediatric Rheumatology European Society (PRES): pres.org.uk

RCN Rheumatology Nursing Forum:

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Abbreviation	Term
ACP	Advanced clinical practitioner
ACR	American College of Rheumatology
ADA	Adverse drug reaction
ADA titre	Anti-drug antibody
ANP	Advanced nurse practitioner
anti-TNF	Anti-tumor necrosis factor
ARMA	The Arthritis and Musculoskeletal Alliance
AS	Axial Spondyloarthropathy (Ankylosing Spondylitis)
ASAS	Assessment of Spondylarthritis International Society
AWMSG	All Wales Medicines Strategy Group
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
BASFI	Bath Ankylosing Spondylitis Functional Index
BASMI	Bath Ankylosing Spondylitis Metrology Index
bDMARDs	Biological Disease Modifying Anti-Rheumatic Drugs
BMI	Body mass index
BRC	Biomedical Research Centre
BSc	Bachelor of Science
BSR	British Society for Rheumatology
BTS	British Thoracic Society
CD	Crohn's Disease
CD20	B-lymphocyte antigen
cDMARDs	Conventional Disease modifying antirheumatic drugs
COVID-19	Coronavirus disease (2019)
CPD	Continuing professional development
CRP	C-reactive protein
csDMARDs	Conventional synthetic disease modifying anti-rheumatic drugs
CXR	Chest X-ray
CYP	Children and young people
DAS-28	Disease activity score of 28 joints

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DipHE	Diploma of Higher Education
DMARDs	Disease modifying anti-rheumatic drugs
EDTA	Ethylenediaminetetraacetic acid
EMC	Electronic medicines compendium
ESR	Erythrocyte sedimentation rate
EULAR	European League Against Rheumatism
FBC	Full blood count
GCA	Giant cell arteritis
GP	General practitioner
HACAs	Human anti-chimeric antibodies
HBcAb	Hepatitis B core antibody
HBsAG	Hepatitis B surface antigen
HBV	Hepatitis B
HBV DNA	Deoxyribonucleic acid (viral load)
HCQ	Hydroxychloroquine
HCV	Hepatitis C
HEADSSS	Home, education/employment, eating, activities, drugs, sexuality, suicidal ideation and safety
HIV	Human Immunodeficiency Virus
IBD	Inflammatory Bowel Disease
IgG	Immunoglobulin G
IGRA	Interferon Gamma Release Assay
IL	Interleukins
ILD	Interstitial lung disease
JAK i	Janus kinase inhibitors
JIA	Juvenile idiopathic arthritis
Lef	Leflunomide
LFT	Liver function test
LLP	Limited liability partnership
MDT	Multidisciplinary team

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RCN quality assurance

Publication

This is an RCN practice guidance. Practice guidance are evidence-based consensus documents, used to guide decisions about appropriate care of an individual, family or population in a specific context.

Description

The role of bDMARDs and tsDMARDs in the treatment of rheumatological conditions continues to evolve and is an area that has significant implications for all practitioners

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