Scottish Paediatric & Adolescent Rheumatology Network (SPARN)

Guidance for Rituximab use

NOTE
This guidance is not intended to be construed or to serve as a standard of care. Standards of care are determined based on all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guidance recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guidance or any local guidance derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

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Approved: February 2026
Review: February 2029
NSD610-013.18 V2

Contents

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Stakeholders involved	Consultant Paediatric Rheumatologists, Consultant Paediatricians, Rheumatology Nurse Specialists, Occupational Therapist, Lead Pharmacist, Highly Specialist Physiotherapist
Methodology used	• Literature search • Review of evidence • Review of available national and international guidance including UK Paediatric Rheumatology guidance (BSPAR) and SPRUN (renal network) guidance • Engagement with key stakeholders (see above) • Guidance drafted with review date • Submitted to Steering Group (see appendix 1) • For comment then approval
Rationale	This guidance was developed to replace the previous SPARN guidance for giving Rituximab[1] which was due for review and the previous UK(BSPAR) guidance for giving Rituximab. The previous guidance was frequently used to support staff around the SPARN network prescribing and administering Rituximab for Paediatric Rheumatology patients. Practice has changed over the years with reduced use of Cyclophosphamide[2] alongside Rituximab and the option for reduced doses of Rituximab for maintenance of well controlled disease in remission, particularly Anca Associated Vasculitis.
Scope	For rheumatology specialists including hospital staff managing children and young people with rheumatological conditions.
Approval process	The guidance was approved by the SPARN Steering Group on 20/02/2026. See appendix 1 for list of Steering Group members

[1] See Appendix 1 for more information
[2] See Appendix 2 for more information

Background

Rituximab is an anti-inflammatory monoclonal antibody, derived from human and mouse cells. Rituximab removes B cells, therefore reducing the amount of autoantibodies such as rheumatoid factor (RF), double stranded DNA (dsDNA) and anti-neutrophil cytoplasmic antibodies (MPO/PR3 ANCA) and thereby reduce disease activity. [1]

B cells reappear 4-12 months after therapy; however, memory B cells can remain suppressed for up to 2 years. It has been shown to be effective in the management of many paediatric rheumatological conditions including:

- Juvenile onset Systemic Lupus Erythematosus (JSLE) [2,3,4]
- Juvenile Idiopathic Inflammatory Myositis (JDM/JPM) [5]
- Rheumatoid factor positive juvenile idiopathic arthritis (JIA) [6]
- First line treatment for patients with ANCA positive vasculitis with severe major organ involvement e.g. renal or central nervous system (CNS) [7,8]
- Can be considered for non-ANCA associated systemic vasculitis refractory to first-line treatments
- IgG4 disease [9]
- Sjogren's syndrome [10]

Contra-indications [11]

- History of hypersensitivity to rituximab, other murine proteins or to any of the excipients
- Tuberculosis
- Severe infections e.g. sepsis, abscesses and opportunistic infections
- Moderate or severe heart failure
- Patients in a severely immunocompromised state
- Pregnancy

Cautions

- History of cardiovascular disease or renal impairment (dose adjustment may be required)
- History of malignancy
- Chronic hepatitis B infection
- Heart failure
- Severe needle phobia and potential vascular access problems

Pre-assessment considerations

- Full clinical history

- Height, weight, body surface area, pubertal status
- Immunisation history:
    - Specifically consider varicella, measles and Flu/COVID-19 vaccine status
    - Consider delaying infusion until 4 weeks post administration of any live vaccinations required as per green book guidance: Greenbook_chapter_6.pdf (publishing.service.gov.uk)
    - Avoid live vaccines while undergoing Rituximab treatment
    - Consider timing of non-live vaccinations in relation to Rituximab infusions – ideally these should be given 2-4 weeks before Rituximab to maximise response
    - Consider if needs altered vaccination schedule given immunosuppressed status
- Blood tests:
    - FBC, ESR, U&E, creatinine, LFT, CRP
    - Lymphocyte subsets (CD19/CD20)
    - Immunoglobulins
    - Assess TB risk factors and consider Quantiferon (note in urgent life-threatening situations you may not have time to wait for result before giving)
    - The following virology should be checked if not done previously and only repeated if thought to be clinically relevant: Varicella Zoster IgG; Hepatitis B core antibody & surface antigen; Hepatitis C antibody screen; HIV antigen/ antibody screen; EBV IgG and CMV IgG
    - Disease specific antibodies:
        - Antinuclear antibodies (ANA) and dsDNA in JSLE
        - RF and cyclic citrullinated peptide (CCP) in JIA
        - Myeloperoxidase (MPO) and proteinase 3 ANCA (PR3 ANCA) in ANCA positive vasculitis
        - Myositis specific antibodies in JDM
- Chest X-ray: To be performed and resulted prior to commencing if not performed in the last year or if relevant symptoms have developed in the interim.
- Pregnancy test for all females over 12 years of age who have reached menarche.
- Patient information to be given and discussed with the patient and carers

Dosage

Rituximab is administered as an intravenous (IV) infusion. Dose and frequency may vary according to underlying clinical condition and clinician's discretion.

INDUCTION:
Options include

- 750mg/m2 (maximum dose 1000mg) 2 weeks apart

- 375mg/m2 (maximum dose 500mg) 2 weeks apart

MAINTENANCE:
Rituximab can then be given as a single dose 4-6 monthly thereafter (usually calculated as either 750mg/m2, max dose 1g, or 375mg/m2, max 500mg).
This may be given on an 'ad-hoc' basis (guided by recurrence of symptoms or return of CD19/CD20 +ve B cells on lymphocyte subset testing), or as a fixed dosing regimen depending on the indication, and is at the clinician's discretion. [7,12]
In many cases the lower dose of 375mg/m2 (maximum dose 500mg) may be sufficient for maintenance. [13,14,15]

For moderately severe ANCA associated vasculitis without renal failure at presentation a standard dosing option is 375mg/m2 max dose 500mg, given at Day 0, Day 14 and 6 monthly thereafter for a minimum of 2 years. [16,17]

DURATION OF MAINTENANCE TREATMENT:
May differ according to clinical situation and clinician's discretion.
Is usually given for a period of 24-48 months.

Pre-medication (see table 1)

All patients will receive premedication with chlorphenamine and paracetamol, administered 60 minutes prior to infusion commencing. Methylprednisolone[3] IV infusion is administered immediately prior to the rituximab infusion.

Paracetamol and chlorphenamine oral dosing should be as per BNFC.

Methylprednisolone IV injection dosing:
Children aged 1 - 5 years 50mg
Children 6 years and over 100mg

Prescribing Rituximab

Rituximab is infused as follows (note mg/hr, not mls/hr)[1]:

Initial infusion rate 25mg/hr
Increase by 25mg/hr every 30 minutes as tolerated to maximum rate of 200mg/hr

If tolerated during first infusion, subsequent doses may be given slightly faster by starting at 50mg/hr, increasing every 30 minutes in increments of 50mg/hr as tolerated, to a maximum of 200mg/hr[1] .

[3] See Appendix 1 for more information

In NHS Lothian, a prescription proforma is available for rituximab prescribing. Where this is not available, a fluid infusion chart should be used.

Note that pre-made infusion bags are available, but a prescription request may need to be submitted to the hospital aseptic pharmacy in advance of the infusion in line with local policy. If not using a pre-made bag, the standard concentration is 2mg/ml.[18] In acute renal failure or fluid overload, higher concentrations may be used up to a maximum of 4mg/ml.

Please consult local Pharmacy Protocols for more information re infusion rates etc, as may vary.

Table 1: Prescription Schedule

Day	Time(hrs)	Drug	Dose
0	T=0	Chlorphenamine PO (IV if unable to take PO)	<6yrs = 1mg 6-12 yrs = 2mg 12-1yrs = 4mg
	T=0	Paracetamol PO (IV if unable to take PO)	15mg/kg (max 1g)
	T=0	Methylprednisolone IV	Children aged 1 - 5 years 50mg Children 6 years and over 100mg
	T=1 hour	Rituximab	750mg/m2 (max 1g) Or 375mg/m2 (max 500mg)
1	am	Prednisolone	30mg (or normal background daily dose if higher)
2	am	Prednisolone	20mg (or normal background daily dose if higher)
3	am	Prednisolone	10mg (or normal background daily dose if higher)

Prior to infusion

Ensure the following is complete before commencing the infusion (See Appendix 3 – Rituximab Checklist which may be helpful)

- Pregnancy test for all females over 12 years of age who have reached menarche.
- Ensure there is no underlying infection.
- Site an intravenous cannula in an appropriate vein.

- Take bloods for FBC, U&E's, LFTs, CRP, and ESR – do not wait for results before starting.
- Baseline temperature, pulse, respiratory rate, blood pressure. Record these immediately prior to commencing the infusion.

Administration

- Prior to starting the infusion, ensure emergency drugs are available in the ward area in case of any adverse reaction.
- Check all prescribed doses of rituximab are correct for the patient.
- Administer premedication.
- Administer the rituximab infusion using an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 1.2 micron or less).
- Visually inspect the infusion for particulate matter, discolouration or foreign particles.
- Infuse at the prescribed, 30-minute, stepwise rate.
- The required dose should be diluted with 0.9% NaCl or 5% Glucose to a concentration of between 1-4mg/ml.[18] This may be done by pharmacy aseptic services or arrive prepared at this concentration by the manufacturer. In this case the product will not need further manipulation on the ward.
- Flush with 30ml of Sodium Chloride 0.9% at the end of the rituximab infusion.

Monitoring during the infusion

- Monitor pulse, temperature, respiratory rate and blood pressure every 15 minutes during the patients first rituximab infusion. If well tolerated subsequent infusion monitoring can be every 30 minutes.
- Acute infusion reactions may develop at any time during or after the infusion.

Post infusion

- Monitor pulse, temperature, respiratory rate and blood pressure every 15 minutes for 1 hour the patient's first infusion.
- Monitor pulse, temperature, respiratory rate and blood pressure for 30 minutes after a patient's second infusion.
- Advise patients and carers to report any signs of infection or possible side effects. Delayed hypersensitivity-like reactions may appear 1-14 days after the infusion.
- Advise patients and carers to seek immediate medical advice if hypersensitivity symptoms occur. Delayed reactions are more likely to occur if a patient has had a previous course of infliximab.
- Patients should take oral prednisolone for 3 days after the infusion; Day 1 - 30mg OD (or normal background daily dose if higher), Day 2 - 20mg OD (or normal background daily dose if higher) and Day 3- 10mg OD (or normal daily dose if higher) and then continue with their normal maintenance prednisolone dose.

- Immunoglobulins and lymphocyte subsets (CD19/CD20) will be followed up at approximately 2-4 weeks post infusion and should be checked approximately 2-3 monthly until B cells normalise. Pragmatically this may mean checking these at the next clinic appointment, then again at 5-6 months after the last infusion.
- If / when Rituximab is discontinued, vaccine responses and VZV IgG status should be checked to consider need for re-vaccination.

Possible side effects

See BNFC or Summary of Product Characteristics for full list of side effects. [1,18]

Common or very common

- Anaemia
- Constipation
- Depression
- Fever
- Gastrointestinal discomfort
- Hypertension/hypotension
- Increased risk of infection
- Infusion related reaction
- Night sweats

Uncommon

- Haemolytic anaemia
- Progressive multifocal leukoencephalopathy

Rare or very rare

- Hepatitis reactivation

Appendix 1 – Off label drugs statement

Prescribing of medicines outwith their marketing authorisation
Recommendations within this pathway are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (MA) also known as product licence. This is known as 'off-label' use. Medicines may be prescribed 'off-label' in the following circumstances:

- for an indication not specified within the marketing authorisation
- for administration, via a different route
- for administration
- for a different dose for a different patient population.

An unlicensed medicine is a medicine which does not have MA for medicinal use in humans. Generally, 'off-label' prescribing of medicines becomes necessary if the clinical need cannot be met by licensed medicines within the marketing authorisation. Such use should be supported by appropriate evidence and experience.

"Prescribing medicines outside the conditions of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability".

The General Medical Council (GMC) recommends that when prescribing a medicine 'off-label', doctors should:

- be satisfied that there is no suitably licensed medicine that will meet the patient's need
- be satisfied that there is sufficient evidence or experience of using the medicine to show its safety and efficacy
- take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring the effects of the medicine, and any follow-up treatment, or ensure that arrangements are made for another suitable doctor to do so.

Make a clear, accurate and legible record of all medicines prescribed and when not following common practice, the reasons for prescribing an unlicensed medicine. Non-medical prescribers should ensure that they are familiar with the legislative framework and Royal Pharmaceutical Society's Competency Framework for all Prescribers.

Prior to any prescribing, the licensing status of a medication should be checked in the summary of product characteristics (www.medicines.org.uk). The prescriber must

be competent, operate within the professional code of ethics of their statutory bodies and the prescribing practices of their employers.

Appendix 2 – Steering Group membership

Name	Designation	Role	Area representing
Andrew Fell	Paediatric Rheumatology Nurse Specialist	Data Lead	NHS Greater Glasgow & Clyde
Angela Cruickshank	Paediatric Rheumatology Nurse Specialist	Former Nurse Lead	NHS Fife
Catriona Anderson	Consultant Paediatric Rheumatologist	Education Lead	NHS Lothian
Elaine Wallace	Senior Child Health Physiotherapist	Physio Lead	NHS Tayside
Emma Carson	Paediatric Rheumatology Nurse Specialist	Working with Families Lead	NHS GGC
Imogen Kelly	Rheumatology Nurse Specialist	Working with Families Lead	NHS Lothian
Jane Adam	Paediatric Rheumatology Nurse Specialist	Nurse Lead	NHS Grampian
Julie Duncan	Consultant Paediatrician	Clinical Guidance Lead	NHS Lothian
Karen Lapsley	Highly Specialist Physiotherapist	Physio Lead	NHS Forth Valley
Kirsten Healy	Consultant Paediatrician	Paediatrician with an interest	NHS Fife
Kirsty McLellan	Paediatric Rheumatology Consultant	Clinical Guidance Lead	NHS Greater Glasgow & Clyde
Klaire Connor	Young People and Families Manager Scotland	Third Sector Representative	Versus Arthritis
Lindsay Robertson	Consultant Rheumatologist	Transition Lead	NHS Grampian
Lois Freeland	SNAC Chair	Third Sector Representative	SNAC
Mairi Dunbar	Lead Pharmacist – Paediatrics	Pharmacy Lead	NHS Tayside
Mandy Fanning	Occupational Therapist	Occupational Therapy Lead	NHS GGC
Mary Brennan	Consultant Paediatric Rheumatologist	Chair	NHS Lothian

Neil Martin	Consultant Paediatric Rheumatologist	Lead Clinician	NHS Greater Glasgow & Clyde

Appendix 3 – Pre-Rituximab Checklist

Patient Details

Name:

Address:

DOB: Weight:

CHI: BSA:

Clinical Information

Indication:

JSLE JDM JIA ANCA+ VASCULITIS OTHER (Pls specify)

Pre-Infusion

Baseline Bloods:

Test	Date	Result
FBC		
ESR		
U&E		
LFT		
CRP		
Lymphocyte Subsets		
Immunoglobulins		
Disease specific Antibodies (e.g. RF/CCP, Myositis-specific Abs, ANA/DsDNA, PR3/MPO)		
Hepatitis B, anti-HBc & HBsAg, Hepatitis C antibody screen, HIV status		
Varicella Zoster IgG		
EBV/CMV IgG		

CXR (pre-dose or within last year)

YES / NO

Pregnancy test (all girls >12 years):

YES / NO/ NOT APPLICABLE

Vaccination History (Do not give live vaccines. If non-live vaccines required, ensure given at least 4 weeks before Rituximab. Consider need for re-immunisation of previous non-live vaccines following Rituximab if levels low)

Recent/Current Infection (If yes, give details)?

YES / NO

Risks/Benefits Discussed (hypersensitivity, malignancy, infection)

YES / NO

Patient Info leaflet given?

YES / NO

Infusion

Dose (/m2):

Rituximab Biosimilar used?

YES / NO (If Yes, which one?)

Date of Dose 1:

Date of Dose 2:

Date of other doses:

Pre-medication prescribed (Methylprednisolone, Paracetamol, Chlorphenamine)?:

YES / NO

Post-Infusion

Oral steroid given?

YES / NO

Monitoring Bloods

Test	Date	Result
Lymphocyte Subsets 2-4 weeks after dose*		
Lymphocyte Subsets (first clinic review)		
Lymphocyte Subsets		
Lymphocyte Subsets		
Lymphocyte Subsets		

*Consider booking this blood test at time of infusion

References

1. McErlane F, Pain C, McCann L. BSPAR Guidelines on Rituximab use in Paediatric Rheumatology.
2. Piantoni S, Korsten P. Rituximab-a B cell targeted therapy in systemic lupus erythematosus: where do we stand?. Rheumatology (Oxford). 2022;61(5):1752-1755. doi:10.1093/rheumatology/keac095
3. Mahmoud I, Jellouli M, Boukhris I, et al. Efficacy and Safety of Rituximab in the Management of Pediatric Systemic Lupus Erythematosus: A Systematic Review. J Pediatr. 2017;187:213-219.e2. doi:10.1016/j.jpeds.2017.05.002
4. Sawhney S, Agarwal M. Rituximab use in pediatric systemic lupus erythematosus: Indications, efficacy and safety in an Indian cohort. Lupus. 2021;30(11):1829-1836. doi:10.1177/09612033211034567
5. Oddis CV, Reed AM, Aggarwal R, et al. Rituximab in the treatment of refractory adult and juvenile dermatomyositis and adult polymyositis: a randomized, placebo-phase trial. Arthritis Rheum. 2013;65(2):314-324. doi:10.1002/art.37754
6. Kearsley-Fleet L, Sampath S, McCann LJ, et al. Use and effectiveness of rituximab in children and young people with juvenile idiopathic arthritis in a cohort study in the United Kingdom. Rheumatology (Oxford). 2019;58(2):331-335. doi:10.1093/rheumatology/key306
7. Biddle K, Jade J, Wilson-Morkeh H, et al. The 2025 British Society for Rheumatology management recommendations for ANCA-associated vasculitis. Rheumatology (Oxford). 2025;64(8):4470-4494. doi:10.1093/rheumatology/keaf240
8. Hellmich B, Sanchez-Alamo B, Schirmer JH, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. Ann Rheum Dis. 2024;83(1):30-47. Published 2024 Jan 2. doi:10.1136/ard-2022-223764
9. Orozco-Gálvez O, Fernández-Codina A, Lanzillotta M, et al. Development of an algorithm for IgG4-related disease management. Autoimmun Rev. 2023;22(3):103273. doi:10.1016/j.autrev.2023.103273
10. Ramos-Casals M, Brito-Zerón P, Bombardieri S, et al. EULAR recommendations for the management of Sjögren's syndrome with topical and systemic therapies. Ann Rheum Dis. 2020;79(1):3-18. doi:10.1136/annrheumdis-2019-216114
11. Joint Formulary Committee. British National Formulary (Online) London: BMJ Group and Pharmaceutical Press. Available at [http://www.medicinescomplete.com]. Accessed 10/12/19.

12. Garcia-Montoya L, Villota-Eraso C, Yusof MYM, Vital EM, Emery P. Lessons for rituximab therapy in patients with rheumatoid arthritis. *Lancet Rheumatol*. 2020;2(8):e497-e509. doi:10.1016/S2665-9913(20)30033-3
13. Emery P, Deodhar A, Rigby WF, et al. Efficacy and safety of different doses and retreatment of rituximab: a randomised, placebo-controlled trial in patients who are biological naive with active rheumatoid arthritis and an inadequate response to methotrexate (Study Evaluating Rituximab's Efficacy in MTX iNadequate rEsponders (SERENE)). *Ann Rheum Dis*. 2010;69(9):1629-1635. doi:10.1136/ard.2009.119933
14. Rubbert-Roth A, Tak PP, Zerbini C, et al. Efficacy and safety of various repeat treatment dosing regimens of rituximab in patients with active rheumatoid arthritis: results of a Phase III randomized study (MIRROR). *Rheumatology (Oxford)*. 2010;49(9):1683-1693. doi:10.1093/rheumatology/keq116
15. Verhoef LM, den Broeder N, Thurlings RM, et al. Ultra-low doses of rituximab for continued treatment of rheumatoid arthritis (REDO study): a randomised controlled non-inferiority trial. *Lancet Rheumatol*. 2019;1(3):e145-e153. doi:10.1016/S2665-9913(19)30066-9
16. Guillevin L, Pagnoux C, Karras A, et al. Rituximab versus azathioprine for maintenance in ANCA-associated vasculitis. N Engl J Med. 2014;371(19):1771-1780. doi:10.1056/NEJMoa1404231
17. Morishita KA, Wagner-Weiner L, Yen EY, et al. Consensus Treatment Plans for Severe Pediatric Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Care Res (Hoboken). 2022;74(9):1550-1558. doi:10.1002/acr.24590
18. Medusa IV Monographs (2019). Rituximab. Available at [https://medusa.wales.nhs.uk/]. Accessed 10/12/19.
19. Callaghan C, McRorie E. NHS Lothian Pharmacy Service/Rheumatic Diseases Unit Guidance for the use of rituximab. Version 6.

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