Scottish Paediatric & Adolescent Rheumatology Network (SPARN)

Guidance for Infliximab 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.

This guidance has been prepared by NHS National Services Scotland (NSS) National Networks. Accountable to Scottish Government, NSS works at the heart of the health service providing national strategic services to the rest of NHS Scotland and other public sector organisations to help them deliver their services more efficiently and effectively. Working across professional and organisational boundaries, National Networks support the delivery of safe, effective healthcare that's designed around patients, carers and families.

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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) • 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 is needed for dosing, support, monitoring and use of drug levels, specific to Paediatric Rheumatology conditions.
Scope	For rheumatology specialists including hospital staff involved in managing Paediatric Rheumatology 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.

Introduction

Infliximab is an anti-inflammatory monoclonal antibody, derived from human and mouse cells. Infliximab inhibits the pro-inflammatory cytokine tumour necrosis factor alpha (TNF-alpha). It has been shown to be effective in the management of many paediatric rheumatological conditions including:

- Juvenile idiopathic arthritis (JIA): active arthritis (all JIA subtypes except systemic onset juvenile idiopathic arthritis), failure of methotrexate monotherapy, failure of other anti-tumour necrosis factor alpha (antiTNF) therapy, requirement to administer antiTNF therapy via intravenous (IV) route for patient concordance/tolerability
- JIA with active uveitis which has failed to respond to methotrexate monotherapy, where adalimumab has failed or adalimumab is not recommended due to route of administration
- Idiopathic uveitis which has failed to respond to methotrexate monotherapy, where adalimumab has failed or adalimumab is not recommended due to route of administration
- Juvenile dermatomyositis (JDM) after inadequate response to methotrexate and prednisolone
- Chronic nonbacterial osteomyelitis (CNO)
- Kawasaki disease

Contra-indications

- History of hypersensitivity to infliximab, other murine proteins or to any of the excipients
- Tuberculosis
- Severe infections e.g. sepsis, abscesses and opportunistic infections
- History of multiple sclerosis or other demyelinating disorders
- Moderate or severe heart failure
- Pregnancy*
- Live vaccinations

* *In addition, immunisation with live vaccines should be delayed until 6 months of age in children born to mothers who received immunosuppressive biological therapy during pregnancy. In practice, this means that children born to mothers who were on immunosuppressive biological therapy during pregnancy will not be eligible to receive rotavirus vaccine (and will need to defer BCG, if indicated, for 6 months). If there is any doubt as to whether an infant due to receive a live attenuated vaccine may be immunosuppressed due to the mother's therapy, including exposure through breast-feeding, specialist advice should be sought.*

Cautions

- History of malignancy
- Chronic hepatitis B infection

- Heart failure
- Predisposition to infection
- Family history of demyelinating disorders or multiple sclerosis
- Risk of delayed hypersensitivity reactions if drug free interval exceeds 12 weeks
- Severe needle phobia and potential vascular access problems

Pre-assessment considerations

- Full clinical history
- Height, weight, pubertal status
- Immunisation history – Consider delaying infusion until 4 weeks post administration of live vaccinations.
- Bloods including FBC, ESR, U&E, LFT, creatinine, CRP, ANA, dsDNA, varicella zoster serology
- Varicella Zoster serology
- Consider checking hepatitis B and C status, HIV status, MMR status
- Chest X-ray: To be performed and resulted prior to commencing infliximab if not performed in the last 3 months and if no relevant symptoms have developed in the interim
- Quantiferon gold or Ellispot (can use Mantoux as an alternative)
- 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

- **Induction**

Infliximab will be administered at a dose of 6mg/kg, rounded to the nearest 10mg (please note vials are 100mg), as an intravenous infusion over a 2 hour period using the following regimen:

1st Dose	–	Week 0
2nd Dose	–	Week 2
3rd Dose	–	Week 6

- **Maintenance**

Standard dosing is 6mg/kg as an intravenous infusion every 4-8 weeks, adjusted depending on response and trough drug levels. Dose and frequency will be adjusted in response to clinical response plus therapeutic drug monitoring. Doses of 10mg/kg may be used in severe disease, or if disease control has been lost. Doses up to 20mg/kg may be required in specific cases. This strategy would be initiated only following the advice of the consultant paediatric ophthalmologist or rheumatologist and usually following measurement of infliximab level and antibodies.

Monitoring Prior to Infusion

Ensure the following is complete before commencing the infusion:

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

Pre-medication

In those patients who have experienced previous mild/moderate infusion reactions or are non-compliant with co-medications the following premedication should be administered 30 minutes prior to infusion commencing.

Hydrocortisone (sodium succinate) intravenous bolus injection dosing:

- Children aged 1 - 5 years: 50mg
- Children aged 6 - 11 years: 100mg
- Children 12 – 17 years: 200mg

Chlorphenamine:

- Children aged 1-5 years: 1mg
- Children aged 6-11 years: 2mg
- Children aged 12-17 years: 4mg

Preparation

To prepare the infusion:

- Reconstitute each 100mg vial of infliximab with 10mL of water for injection directing the stream of water to the glass wall of the vial. Final concentration 10mg/ml.
- Gently swirl the solution by rotating the vial to dissolve the powder. Avoid prolonged or vigorous agitation. DO NOT SHAKE.
- Allow the reconstituted solution to stand for 5 minutes.
- Check that the reconstituted solution is colourless or light yellow. Do not use if opaque particles, discolouration or other foreign particles are visible.
- Calculate the required volume of reconstituted infliximab for the prescribed dose.
- **For Remicade®, Remsima®, Inflectra® and Flixabi®**, slowly add the reconstituted solution and gently mix the bag.
- **For Zessly®**, from a 250mL sodium chloride 0.9% infusion container, remove the equivalent dose volume from the container and discard. Withdraw the required dose and slowly add to the remaining infusion bag and mix gently.
- For doses above 1000mg contact pharmacy for advice.
- The infusion is now ready to be administered.

Administration:

- Prior to starting the infusion ensure emergency drugs are available in the ward area in case of any adverse reaction.

- All medications should be given in accordance with the hospitals Safe Use of Medicines Policy.
- Check all prescribed doses of infliximab are correct for the patient.
- Administer any prescribed premedication if required.
- Administer infliximab 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.
- Infusion length varies depending on local practice. Advice from EMC that at least the initial 3 infusions of infliximab be given over 2 hours, and if tolerated consideration may be given to administering subsequent infusions over 1 hour. If an infusion reaction occurs in association with a shortened infusion, a slower infusion rate may be considered for future infusions if treatment is to be continued. Shortened infusions at doses >6 mg/kg have not been studied.
- For doses less than 1000mg, infuse at 125ml/hr for infusions over 2 hours, or 250ml/hr for infusions over 1 hour. For doses above 1000mg contact pharmacy for advice.
- Flush with 30ml of Sodium Chloride 0.9% at the same rate as the infliximab infusion.

Monitoring

During the infusion

- Monitor pulse, temperature, respiratory rate and blood pressure every 30 minutes during the infusion.
- Acute infusion reactions may develop anytime during or after the infusion.
- If a patient develops a reaction follow the infusion related reaction treatment guidance in appendix A.

Post infusion

- Monitor pulse, temperature, respiratory rate and blood pressure every 30 minutes for 1 hour post a 2 hour infusion
- Monitor pulse, temperature, respiratory rate and blood pressure every 30 minutes for 30 minutes post a 1 hour infusion**
- If a patient develops a reaction follow the infusion related reaction treatment guidance in appendix A.
- 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.

***Manufacturers recommend that patients are observed for 1-2 hours following their infusion for the first 10 infusions. However there is evidence that monitoring time can*

be reduced to 30 minutes in the maintenance phase whilst maintaining patient safety.

Possible side effects

See BNFc or Summary of Product Characteristics for full list of side effects.

Common or very common

- Anaemia
- Constipation
- Dizziness
- Fatigue
- Gastrointestinal discomfort
- Hypertension/hypotension
- Increased risk of infection
- Infusion related reaction
- Skin reactions

Uncommon

- Anxiety
- Heart failure
- Seizure
- Thrombocytopenia

Rare or very rare

- Cyanosis
- Demyelinating disorders
- Pancytopenia

Frequency not known

- Bone fracture

Appendix 1 – 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 2 – 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.

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