NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT

Shared care guidelines for Oral and Subcutaneous Methotrexate for various indications – full details shown on page 2

Monitoring level - AMBER Level 3 – Prescribe the drug and perform significant monitoring including measurements such as height, weight, blood pressure and ECG. Monthly monitoring is necessary

Generic and Proprietary/Brand Name

Methotrexate

Tablets: *Matrex*® - generics also available

Pre-filled pens: *Metoject*® 50mg/ml strength, and *Nordimet*® 25mg/ml strength;

Pre-filled syringes: *Zlatal*® 25mg/ml strength – generic pre-filled syringes also available

Regarding injection devices: the product that the patient has been initially trained on should not be changed without adequate retraining on an alternative device. It is recommended to confirm with the patient which product is being used to ensure continuity of care

Indications for shared care

- Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, connective tissue disease, Felty's Syndrome, psoriasis, Crohn's disease and sarcoidosis.

Specialist Prescribing and Monitoring Responsibilities – summary. Full details in main body of document	GP / Community Team - Primary Care Prescribing and Monitoring Responsibilities – summary. Full details in main body of document
• Identify patients who will benefit from Methotrexate. • Baseline FBC, liver function tests (ALT and albumin), and eGFR. • Assess risk of co-morbid pulmonary disease and baseline investigations as needed. • Ensure patient is tolerating Methotrexate and monitoring results are satisfactory for the initial period until a stable dose has been achieved for six weeks. • Ensure prior dissemination of sufficient information to patient's GP and other carers. • Inform GP that methotrexate has been commenced, with details of the dose and future plans for dose escalation. • Request monitoring be transferred to primary care once the dose has been stable for 6 weeks. Recommended frequency of monitoring should be specified in GP letter. • Provide education to GPs, nurses, patients and carers. • Agree any necessary dose changes. • Review at intervals and confirm arrangements with GP. • Provide patients with a patient held record book/ printout of results and access to back-up and support facilities	• Immunise patients who are not immune to varicella prior to commencing therapy • Prescribe methotrexate at the dose recommended by the hospital specialist, once the patient has been stabilised on treatment for at least 6 weeks and side effects have been excluded as far as possible by the hospital. • Check for possible drug interactions when newly prescribing or stopping concurrent medication. • Encourage patients to carry an up-to-date monitoring record booklet and information sheet as provided by the • Alternatively, a printed copy of blood results can be made available. • Report side effects and any other issues to the hospital specialist The decision to restart methotrexate after a severe infection, where the patient has had a break from therapy e.g. of more than one month, should be undertaken by the hospital specialist team.

Patient Information

- Take or administer methotrexate as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist. ·
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. If provided, they should bring their monitoring booklet to each appointment. Be aware that medicines may be stopped if they do not attend.

- Report adverse effects to their primary care prescriber.
- Report the use of any over the counter (OTC) medications to primary care and specialist and be aware they should discuss the use of methotrexate with their pharmacist before purchasing any OTC medicines.
- Moderate their alcohol intake to no more than 14 units per week.
- Not to drive or operate heavy machinery if methotrexate affects their ability to do so safely.
- All patients should use appropriate contraception. Those of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

Specialist Contact Details

See list at end of document

GENERAL PRINCIPLES FOR SHARED CARE PRESCRIBING

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- GPs are **invited** to participate. If GPs are not confident to undertake these roles, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
- **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable if they are unwilling to do so.**
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and when the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring.
- **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Background to Treatment

Methotrexate is an immunosuppressant which reduces the signs, symptoms and progression of inflammatory disease.

Cytotoxic agent:

Competitive inhibition of the enzyme dihydrofolate reductase thus preventing the reduction of dihydrofolate to tetrahydrofolate and ultimately DNA synthesis and cellular replication

Disease Modifying Agent:

Mechanism of action in inflammatory conditions is unknown but possibly due to suppressing the secretion of interleukin-1, interferon-alpha and TNF

Licensed use and agreed local off-label use

- Leukaemia and malignancies
- Rheumatoid arthritis in adults, JIA in children aged 3 years and over (not oral), psoriatic arthritis, psoriasis, mild to moderate Crohn's disease (50mg/ml strength pre-filled syringe only)
- See individual manufacturers' SPCs www.medicines.org.uk/emc/ for current information
- Uses approved under Shared Care Agreement (SCA):
- Rheumatoid and inflammatory arthritis – licensed s/c, unlicensed s/c when licensed product not available in correct dose, and oral
- Juvenile idiopathic arthritis (JIA) – unlicensed oral, licensed s/c (25mg/ml & 50mg/ml strengths)
- Connective Tissue Disease – unlicensed s/c and unlicensed oral
- Psoriasis – licensed oral and licensed s/c (25mg/ml and 50mg/ml strengths)
- Psoriatic arthritis - licensed s/c (25mg/ml pre-filled syringe & 50mg/ml pen); unlicensed oral
- Crohn's disease – licensed s/c (50mg/ml strength products) ; (unlicensed) oral
- Sarcoidosis – unlicensed oral and s/c
- Felty's Syndrome – unlicensed oral and s/c

Criteria for Patient Selection

Treatment of rheumatoid arthritis, JIA in children, connective tissue disease, psoriasis, sarcoidosis, and mild to moderate Crohn's disease in adults refractory or intolerant to thiopurines.

Form and strength of preparation

Tablets:

Methotrexate is available in 2.5mg and 10mg tablets. However **it is standard practice to use the 2.5mg strength tablets only**, to avoid confusion and minimise the risk of potential overdose.

Injection:

Methotrexate is available in **pre-filled syringes** (*Zlatal®* and methotrexate in 25mg/ml strength – available in various volumes to cover different dosage requirements)

and **pre-filled pens** (*Metoject*® in 50mg/ml strength and *Nordimet*® in 25mg/ml strength – available in various volumes to cover different dosage requirements)

The injection product that the patient has been initially trained on should not be changed without adequate retraining on an alternative device. It is recommended to confirm with the patient which product is being used to ensure continuity of care.

Side Effects and Management

Folic Acid 5mg should also be given to adults to reduce the likelihood of side effects (nausea, mouth ulcers, abdominal discomfort, diarrhoea and anorexia). Initially 5mg is given once a week on a different day to when Methotrexate is taken. The weekly dose can be increased to a maximum of 5mg daily for 6 days a week if the patient exhibits signs of toxicity or side effects to Methotrexate. Occasionally, it may be suggested that folic acid is taken 7 days per week but this would be only in consultation with the consultant as a last attempt to reduce side effects.

In children there is no definitive evidence of benefit of Folic Acid and, therefore, this is reserved for those with symptoms. Children who cannot swallow tablets may be prescribed Folic Acid 1mg daily (except on day of methotrexate) if side effects develop (liquid formulations, 2.5mg/5mL strengths are available).

General compliance advice to patients for dosing with oral Methotrexate:

Methotrexate take on **M**onday **F**olic Acid take on **F**riday

The main adverse effects include:

Common – Nausea, anorexia, oral ulceration, minor hair thinning, abdominal discomfort, diarrhoea, headaches

Less common - Rash, bone marrow suppression causing thrombocytopenia, neutropenia and rarely anaemia. Patients should be warned to report a sore throat and abnormal bleeding/bruising.

Rare but important

- Hepatotoxicity – Rarely Methotrexate may cause liver fibrosis/cirrhosis. Where alcohol is avoided this has proven rare. Avoid if pre-existing liver disease unless risks are outweighed by the benefit and following consultation with a hepatologist. Advise patient that excessive alcohol consumption is to be avoided.
- Pulmonary toxicity – Acute pneumonitis or chronic pulmonary fibrosis may occur. This is not dose related. It presents with a dry cough, dyspnoea and often fever.

Drug Interactions

- Trimethoprim or Co-trimoxazole (*Septrin*®)
  - ***there is an increased risk of haematological toxicity when methotrexate is given with trimethoprim or with co-trimoxazole***, which can theoretically can still occur up to a month following the last dose of methotrexate. Co-prescription during this time period must therefore be avoided.
- Anti-convulsants – *Caution*
- Aspirin and other salicylate containing drugs – *Caution*
- Live vaccines – *Avoid* live vaccines for at least 6 months after cessation of treatment – *see specific advice regarding* Shingles vaccine *and* Influenza vaccine *under* **Contraindications and precautions**.
- NSAIDs – No contra-indications with the doses of Methotrexate prescribed for the above conditions; includes over-the-counter ibuprofen
- Surgery – Patient to inform anaesthetist that they are on Methotrexate
- Dentist – Patient to inform dentist that they are on Methotrexate
- **See BNF and manufacturers' SPC for current advice**

Cautions and Contraindications

Methotrexate is teratogenic to ova and was previously thought to also affect sperm and thus any fertilised egg. Patients of either sex were therefore counselled about contraception during treatment and for 6 months after stopping Methotrexate.
This is still the case for women of child-bearing potential who are taking methotrexate.
However current British Society for Rheumatology (BSR) and the British Health Professionals in Rheumatology (BHPR) guidelines on Prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids advise that men do not need to stop taking methotrexate before trying for a baby.
Patients should talk to their rheumatologist about these matters.

Close contact with chickenpox or shingles:

Non-immune patients on methotrexate require aciclovir or ZIG.

Vaccination:

Influenza & Pneumoccocal: Annual vaccination against influenza should be routinely offered, as should the one-off pneumococcal vaccination (polysaccharide PPV-23, *Pneumovax*).

Shingles: Long term stable low dose corticosteroid therapy (defined as <20mg prednisolone per day for more than 14 days), either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate less than or taking 25mg/week), are not considered sufficiently immunosuppressive and these patients can receive the vaccine. Patients on higher doses should be discussed with the consultant (Refn: Green Book Chapter 28a v3_0).

Varicella (Chickenpox): Patients who are identified by the specialist service as not immune to varicella should be vaccinated by their GP practice prior to being started on methotrexate therapy i.e. at baseline and at one month, at request of specialist (likely to be fewer than 5 patients per annum in Norfolk; there is no provision for the administration of vaccines in secondary care). Further information can be found in the Green Book, Chapter 34

Initiation of therapy and ongoing dose regimen

Hospital-led initiation of therapy

Administration Information

Initiation:

Adults:

7.5mg to 20mg once weekly – orally; **SAME DAY EACH WEEK**.

Please see "**Other information about dosage and administration**" for further advice.

Crohn's disease in adults:

Normally 25mg s/c weekly for 16 weeks

Children:

10mg to 15mg per m^2 once weekly - commonly by s/c injection, occasionally given orally; **SAME DAY EACH WEEK**. There is no need for an incremental increase in children.

Maintenance:

10mg to 25mg once weekly – oral /subcutaneous(s/c)

s/c route is preferred in gastroenterology patients due to variable absorption using the oral route.

A reduction in the bioavailability of oral Methotrexate can occur with continued use. Patients may be transferred by the specialist to s/c injection thereby improving bioavailability whilst maintaining the dose without increasing the potential for toxicity.

The specialist will adjust the weekly dose in increments of 2.5mg to 5mg according to clinical response at 4 weekly intervals. In some instances doses of 15mg or higher may be used at initiation.

Increasing doses above 15mg should be done only after discussion with the hospital consultant concerned. Do not adjust the dose in children without discussion with the hospital consultant concerned.

In some instances; e.g. for treatment of active Crohn's disease, a higher starting dose is recommended, usually 25mg s/c weekly for the first 16 weeks. This may then be reduced by the specialist to a normal maintenance dose of 15-25mg weekly thereafter, if there has been a clinical response to therapy. For maintenance of stable remission the usual starting dose is 15mg s/c weekly.

A formal system for notification of changes to parenteral (subcutaneous) doses of Methotrexate will be used to inform both the patient and their GP. This will be conveyed to the GP via the patient and will allow sufficient time for changes in supply to be made.

A clinical response usually occurs at 4 to 12 weeks

Renal Function:

Renal function declines with age and elderly patients often have reduced renal function, and because of reduced muscle mass may have a normal creatinine. eGFR is therefore more relevant.

With an eGFR of 30-59 mL/min/1.73m^2, a dose reduction of 50% is recommended.

With an eGFR of < 30 mL/min/1.73m^2, methotrexate is contraindicated.

Clinical discretion is required in determining how frequent monitoring should be undertaken in patients with renal impairment and in whom methotrexate therapy is not contraindicated and on the recommendation of the consultant.

Cardiovascular disease and prior malignancy are not considered contraindications to DMARD therapy, although methotrexate-induced lymphoproliferative disorder is an indication for cessation of therapy.

Duration of therapy / How the treatment will be reviewed and if appropriate, stopped

Long term therapy

Initial monitoring / Baseline assessment and ongoing monitoring – by Specialist

By Hospital – Undertake pre-treatment FBC, ALT and albumin, and eGFR.

Lung disease

Routine CXRs are no longer undertaken but clinical assessment of co-existing pulmonary disease may result in pulmonary function tests to assess lung reserve and CXR/ CT lung assessment being undertaken. Pre-existing lung disease is not a contraindication to DMARD use but prescription is undertaken with caution.

Liver disease

In patients with deranged liver biochemistry, hepatotoxic DMARDs should be used with caution, with careful attention to trends in test results. In patients with impaired liver synthetic function (e.g. cirrhosis), DMARD therapy should be used with extreme caution. Patients with chronic viral hepatitis infection should be considered for anti-viral treatment prior to DMARD initiation.

Occult viral infections

Screening for occult viral infections such as HIV and hepatitis B and C should be offered and Varicella status recorded. Undertake pre-treatment monitoring of FBC, LFTs, U&Es, creatinine, and record varicella status. Dermatology may check Procollagen 3 peptide, but in other specialties the role of such serological markers is unclear as it can be false positive in inflammatory disease.

Specialist monitoring responsibilities

Check FBC, eGFR, ALT and albumin every 2 weeks until a stable dose has been achieved for 6 weeks.

Once on a stable dose, check FBC, eGFR, ALT and albumin every month for 3 months.

Where there is a low risk of toxicity, monitoring may be then be reduced to 3-monthly as a minimum.

Risk factors for toxicity include:
History of adverse drug events; medical comorbidities including renal and liver impairment (e.g. NAFLD) and malignancy; patients at the extremes of weight (BMI <18 or >30 kg/m^2), and old age (>80 years).

Clinical discretion dictates frequency of monitoring in these circumstances and the consultant must advise.

MTX patients who are on concomitant DMARDs, especially leflunomide, should have on-going monthly monitoring.

GP / Community Team or other Primary Care monitoring responsibilities

- Report any suspected adverse drug reactions to the hospital specialist.
- Monitor FBC, eGFR, ALT and albumin monthly, once specified and requested by the specialist, after the patient has been on a stable dose for at least 6 weeks. This could be reduced to 3-monthly for patients at low risk of toxicity, but usually after discussion with the relevant consultant, and usually not in children or those at high risk of toxicity.

  Risk factors for toxicity include: a history of adverse drug events; medical comorbidities including renal and liver impairment (e.g. NAFLD) and malignancy; patients at the extremes of weight (BMI <18 or >30 kg/m^2), and old age (>80 years).

  Clinical discretion dictates frequency of monitoring in these circumstances and the consultant must advise.

  Patients on concomitant DMARDs, especially leflunomide, should have monthly monitoring.

  NB Blood tests should be taken preferably between 5 and 7 days after the last dose.

  Look for t*rends* in the monitoring e.g. rapidly falling WCC

  If the patient's:

  - WBC <3.5 x 10^9/L
  - Neutrophils <1.6 x 10^9/L
  - Platelets <140 x 10^9/L
  - Unexplained eosinophilia >0.5x10^9/L
  - ALT > twice upper limit of normal or
  - Unexplained falling albumin <30g/L
  - MCV >105fl (µm^3)
  - Creatinine increase >30% over 12 months and/or eGFR <50mL/min/1.73m^2
  - Symptoms of pneumonitis

  STOP METHOTREXATE and *inform* the hospital specialist

  (NB don't stop MTX in children until discussion has taken place)

- Undertake an urgent FBC to check for leucopenia in patients developing significant infection.

For children:

Blood tests for those under 10 years will normally be done at the Norfolk & Norwich University Hospital either by phlebotomy staff or specialist nursing staff with topical anaesthetic cream and play specialists available. Arrangements for local phlebotomy may be made for family convenience and usually in older children.

Consultant / Specialist prescribing responsibilities

- Identify those patients who will benefit from treatment with Methotrexate.
- Baseline FBC, liver function tests (ALT and albumin), and eGFR.

- Assess risk of co-morbid pulmonary disease and baseline investigations as needed.
- Ensure patient is tolerating Methotrexate and monitoring results are satisfactory for the initial period until a stable dose has been achieved for six weeks.
- Ensure prior dissemination of sufficient information to patient's GP and other carers.
- Inform the GP that methotrexate has been commenced, with details of the dose and future plans for dose escalation.
- Ask for monitoring to be transferred to primary care once the dose has been stable for 6 weeks. The recommended frequency of monitoring should be specified in the GP letter.
- Provide education to GPs, nurses, patients and their carers.
- Provide patients with a patient information sheet and education to the patients and carers on Methotrexate.
- Agree any necessary dose changes.
- Review the efficacy of treatment at intervals and confirm these arrangements with the GP.
- Provide patients with a patient held record book/ printout of results.
- Provide access to back-up and support facilities.
- The decision to restart methotrexate after a severe infection, where the patient has had a break from therapy, and also the initial subsequent monitoring until the patient is stable, should be undertaken by the hospital specialist team.

GP prescribing responsibilities

- Immunise patients who are not immune to varicella prior to commencing methotrexate therapy i.e. at baseline and at one month, at request of specialist (likely less than 5 patients per annum in Norfolk, and as no provision for the administration of vaccines in secondary care).
- Prescribe methotrexate at the dose recommended by the hospital specialist, once the patient has been stabilised on treatment for at least 6 weeks and side effects have been excluded as far as possible by the hospital. Any decision to alter treatment should usually be taken by the hospital specialist, including nurse practitioner.
- Check for possible drug interactions when newly prescribing or stopping concurrent medication.
- Encourage patients to carry an up-to-date monitoring record booklet and information sheet as provided by the hospital (the NPSA booklet is no longer freely available). Alternatively, a printed copy of blood results can be made available.
- **Report side effects and any other issues to the hospital specialist:**
  - Stop Methotrexate if serious adverse drug effect/reaction and contact specialist team.
  - There is no indication to stop methotrexate at the time of routine surgery.
  - Methotrexate should be stopped in the event of a severe infection e.g. requiring hospitalisation.

The decision to restart methotrexate after a severe infection, where the patient has had a break from therapy e.g. of more than one month, should be undertaken by the hospital specialist team.

Pregnancy, Paternal Exposure and Breastfeeding

Pregnancy:

Methotrexate is contraindicated in pregnancy. It is cytotoxic, and is used for termination of pregnancy and to treat ectopic pregnancy. Pregnancy should be excluded prior to starting treatment.

Patients of child bearing potential should use effective contraception during treatment and for 3 months afterwards. If a patient becomes pregnant within 3 months of treatment with methotrexate, folic acid 5 mg daily should be continued throughout the pregnancy. Those who wish to become pregnant should speak to their prescriber to discuss the possibility of switching to an alternative medicine.

Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-METHOTREXATE-IN-PREGNANCY/

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Methotrexate/

Breastfeeding:

The manufacturers contraindicate use of methotrexate while breastfeeding. The UK Drugs in Lactation Advisory Service recommends caution, and advises that breastfeeding should be avoided until at least 24 hours after a weekly dose not exceeding 25 mg. Infant blood counts should be monitored. Limited evidence indicates that small amounts are found in breast milk after weekly administration.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/methotrexate/

Paternal exposure:

There are hypothetical risks of genetic abnormalities in sperm which could potentially affect offspring conceived during treatment. Limited clinical evidence does not indicate an increased risk of malformations or miscarriage following paternal exposure to low-dose methotrexate (less than 30 mg/week). Where a couple wishes to attempt conception and the male partner's condition is well-controlled with methotrexate, the UK Teratology Information Service recommends an assessment and discussion of the potential benefits and risks of continuing paternal treatment vs. discontinuation. This should be undertaken by the specialist, using a shared decision making approach. The risks to the fetus are theoretical rather than established.

Paternal methotrexate use at the time of conception is not an indication for additional fetal monitoring. However, other risk factors may be present in individual cases which may independently increase the risk of adverse pregnancy outcome. Clinicians are reminded of the importance of consideration of such factors when performing case-specific risk assessments.

Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/PATERNAL-USE-OF-METHOTREXATE/

Fertility:

Methotrexate affects spermatogenesis and oogenesis and may decrease fertility. In humans, methotrexate has been reported to cause oligospermia, menstrual dysfunction and amenorrhoea. These effects appear to be reversible after discontinuation of therapy in most cases.

Indications for referral back to Specialist

- Deterioration of renal function increases the risk of methotrexate toxicity. Please inform the hospital specialist of marked changes in renal function.
- If the patient develops a sore throat, abnormal bleeding or bruising, check FBC and stop methotrexate if abnormal. Please inform hospital specialist.

Further information and supporting documents

- British Society for Rheumatology (BSR) and the British Health Professionals in Rheumatology (BHPR) have published guidance on Prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids
- BSR and BHPR guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs (February 2017) - **Link**

Contact Details

Consultant and medical staff and nurse practitioners are available to give advice and can be contacted either through the main hospital switchboard or direct:

NNUH Department / Specialist	Contact Telephone Number
Hospital switchboard – ask for specialist or On-Call specialist (rheumatology/dermatology) out-of-hours	(01603) 286286
Rheumatology	
Rheumatology Practitioners	(01603) 287801
Dr Chulanie De Silva	Via (01603) 288623
Professor Karl Gaffney	Via (01603) 289670
Professor Alex MacGregor	Via (01603) 288677
Dr Tarnya Marshall	Via (01603) 288677
Dr Peter Merry	Via (01603) 287003
Dr Chetan Mukhtyar	Via (01603) 286766
Dermatology	
Dr Jennifer Garioch	Via (01603) 288210
Dr Clive Grattan	Via (01603) 288265
Dr Anila Kapadia	Via (01603) 286286 (switchboard)
Dr Nick Levell	Via (01603) 288225
Dr Abby MacBeth	Via (01603) 286286 (switchboard)
Dr George Millington	Via (01603) 288209
Dr Syed Shah	Via (01603) 288254
Dr Eunice Tan	Via (01603) 288208
Samantha Browne - Dermatology Sister	(01603) 288385
Gastroenterology	
Dr Ian Beales	Via (01603) 288366
Dr Simon Chan	Via (01603) 288534
Dr Helen Fellows	Via (01603) 288368
Dr Ian Fellows	Via (01603) 288356
Dr Andrew Hart	Via (01603) 288367
Dr Sathish Mogan	Via (01603) 288607
Dr Martin Phillip	Via (01603) 288117
Dr Alison Prior	Via (01603) 288358
Dr Simon Rushbrook	Via (01603) 288367
Dr Richard Tighe	Via (01603) 288230

Dr Mark Tremelling	Via (01603) 288612
Prof Alastair Watson	Via (01603) 288366
Respiratory	
Professor Andrew Wilson	(01603) 289802
Dr Ajay Kamath	(01603) 289642
Dr Chris Atkins	(01603) 289644
Sandra Olive (Nurse consultant, ILD)	(01603) 289654
Paediatrics (Rheumatology)	
Paediatric Rheumatology Nurse Specialist	Via (01603) 287911
Dr Kate Armon (Visiting Thurs + some Tues)	Via (01603) 287534
Dr Peter Bale (visiting twice a month)	Via (01603) 287534
Dr Aravind Shastri	Via (01603) 287534
Paediatrics (Gastroentrology)	
Dr Mary-Anne Morris	Via (01603) 289936
Dr Graham Briars	Via (01603) 287174
Pharmacy	
Medicines Information Helpline	(01603) 287139 or Bleep 500 via 01603 286286
JPUH Department / Specialist	**Contact Telephone Number**
Hospital switchboard	(01493) 452452
Rheumatology	
Dr Joegi Thomas Dr Damodar Makkuni Dr Tarnya Marshall (Thursday mornings only) **Specialist Nurse:** June Sunghuttee	Via (01493) 452216 Via (01493) 452216
Dermatology	
Consultants: Dr Ingrid Salvary **Dermatology Team:** Associate Specialist / Specialty Doctor / Specialist Registrar / GPwSI Dermatology / Dermatology Nurse Specialist	 Via (01493) 452313 **Via (01493) 453601 or (01493) 453602**
Gastroenterology	
Consultants: Dr Rawya Badreldin	 Via (01493) 452766

Dr Paul Banim Dr Aamir Saleem Dr Matthew Williams Dr Mostafa Sayed **Inflammatory Bowel Disease (IBD) Nurse:** Donna Howson Trevor Hughes	Via (01493) 453725 Via (01493) 452858 Via (01493) 453572 Via (01493) 453406 Via (01493) 453992 Via (01493) 453992
Paediatrics (Rheumatology)– Via Tel 01493 452452	
Dr Kate Armon (visiting from NNUH)	Via (01603) 287534
Dr Shiras Thayath	Via (01493) 453342
Specialist Nurse: Jo Ridgers	Via switchboard
QEH Department / Specialist:	**Contact Telephone Number**
Hospital switchboard	(01553) 613613
Rheumatology	
Dr John Pradeep, Consultant Rheumatologist	Via (01553) 613177
Dr I Riaz	Via 01553 613177
Rheumatology Nurse Specialists	(01553) 613393
Dermatology	
Dermatology Reception	(01553) 613470
Dr Gillian Dootson	Via (01553) 613705
Dr Tina Green	Via (01553) 613040
Dr Simina Stefanescu	Via (01553) 613677
Gastroenterology	
Dr Abhay Bagewadi	Via (01553) 613989
Dr Andrew Douds	Via (01553) 613989
Dr Rad Hariraj	Via (01553) 613004
Dr Shailesh Karanth	Via (01553) 613708
Dr Rajaratnam Mathialagan	Via (01553) 613708
Dr Alan Wiles	Via (01553) 613004
Paediatrics (Rheumatology)	
Consultant Paediatrician – Dr Glynis Rewitzky	Via (01553) 613678
Community Paediatric Nurses – Mandy Parker & Jennifer Glover	Via (01553) 613214

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Document history:

Version	Date	Author / Editor	Status	Comment
1.	May 2004	Norfolk & Norwich University Hospital: Professor David Scott, Consultant Rheumatologist and Mrs Marie McGee, Rheumatology Nurse Practitioner Dr Jennifer Garioch, Consultant Dermatologist Dr Richard Tighe, Consultant Gastroenterologist Dr Kate Armon and Dr Mary-Anne Morris, Consultant Paediatricians Mrs Carol Farrow, Head of Pharmacy Services / Fiona Marshall, TAG Support Pharmacist	Superseded	Approved by the TAG May 2004. Date for review - not specified
2.	Sept 2006	/ Fiona Marshall, TAG Lead Pharmacist	Superseded	National Patient Safety Agency support materials added to webpage
3.	Jan 2013	Dr Tarnya Marshall Consultant, Rheumatologist and Mrs Corrinne Ellis, Senior Rheumatology Practitioner, NNUH / Fiona Marshall, TAG Lead Pharmacist	Superseded	NNUH proposed changes are: Clinical indications extended to include juvenile arthritis, connective tissue disorders and Felty's syndrome http://rarediseases.info.nih.gov/GARD/Condition/8234/Feltys_syndrome.aspx/Print (See also page 10 of the BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy (2008): http://www.rheumatology.org.uk/includes/documents/cm_docs/2009/d/diseasemodifying_antirheumatic

				_drug_dmard_therapy.pdf) Earlier use in treatment pathway i.e. no longer restricted to unresponsive or relapsing/resistant cases. Reference to intramuscular use removed and replaced with subcutaneous only. Changes to initial dosages and titration. Period of handover to GPs reduced to one month. Advice not to stop treatment in children in response to abnormal blood tests until agreed with consultant. Frequency of GP monitoring FBC and LFTs revised to monthly (was up to 3-monthly). Changes supported by the TAG and the D&TCG – January 2013
4.0	Jan 2015	As above	Draft	Reformatted into current TAG SCA template. Sent to authors, and to Dr John Pradeep (QEH) for review in preparation of returning to the TAG for approval.
4.1	July 2015	As above	Superseded	TAG July 2015: No changes recommended by specialists. Responsibility for first month's monitoring of FBC and LFTs changed from GPs to specialists. QEH specialist contact details added.
4.2	Jan 2016	As above	Superseded	TAG January 2016: Revised version of Appendix 1 – *Safety Guidelines for Administration of SC Methotrexate in the Treatment of Inflammatory Arthritis, Psoriasis and Inflammatory Bowel*

				Disease in the Community via GP Surgery submitted by the NNUH and supported by the TAG. TAG SCA updated in line with recommendation for use of generic MTX injection options and licensed uses of available products.
4.3	Jan 2016	As above	Superseded	JPUH and QEH specialists' contact details also added.
4.4	July 2016	Dr Tarnya Marshall, Consultant Rheumatologist, NNUH Heather Hasthorpe. Lead Rheumatology Clinical Nurse Specialist, NNUH (Corrinne Ellis retired) Dr John Pradeep, Consultant Rheumatologist, QEH	Superseded	**Contraindications and precautions:** Updated in line with revised information for men which states that it is no longer necessary to stop taking methotrexate when trying for a baby. **Patient Information** updated with**:** ARC MTX booklet 2016 http://www.arthritisresearchuk.org/arthritisinformation/drugs/methotrexate/pregnancy.aspx **Additional information** updated with**:** British Society for Rheumatology (BSR) and the British Health Professionals in Rheumatology (BHPR) have published guidance on Prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids
5.0	May-July 2017	Dr Tarnya Marshall, Consultant Rheumatologist, NNUH Heather Hasthorpe. Lead Rheumatology Clinical Nurse Specialist, NNUH	Superseded	Reviewed and updated following publication of revised British Society for Rheumatology (BSR) and the British Health Professionals in Rheumatology (BHPR)

				guidance for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs Feb 2017 - ***Link*** Circulated by the authors across all stakeholder specialisms and to the JPUH and the QEH for consultation. Changes made to monitoring requirements and responsibilities, side-effects, available products, advice to GPs regarding thresholds and responsibilities regarding referral back to specialists. Advice regarding shingles vaccination updated in line with the Green Book. Revised version supported by the TAG – July 2017. Final version approved by the D&TCG August 2017.
5.1	Oct 2017	As above	Superseded	Names and contacts for two new QEH gastroenterologists added.
6.0	Feb 2018	As per 5.0	Draft	At the request of the NNUH, under **GP Prescribing responsibilities**: Bullet point added regarding the need to administer varicella vaccine to non-immune patients prior to initiation of MTX at request of specialist. For consideration by the TAG March 2018.

				The TAG supported the request in principle but decided to seek advice from PHE on this issue to clarify whether this could be provided on the NHS. The TAG supported other amendments to the document as listed under 6.1 below.
6.2	May 2018	As per 5.0	Draft	Provision of varicella vaccine for non-immune patients ahead of treatment to be reconsidered by TAG following general verbal support from PHE. Supported by the TAG and the D&TC – May 2018
6.3	Jan 2019	As per 5.0	Current	Appendix 1 – Safety Guidelines for Administration of SC Methotrexate in the Treatment of Inflammatory Arthritis, Psoriasis and Inflammatory Bowel Disease in the Community via GP Surgery – confirmed by Heather Hasthorpe as no longer required – removed from document. Hyperlink withdrawn
6.4	May 2020	Jennifer Carroll, TAG Lead Technician, AGEM CSU	Current	Updated contact details for Gastro Consultants and IBD Nurse Specialists at JPUH
7.0	Oct 2020	Jennifer Carroll, TAG Lead Technician, AGEM CSU	Draft for review following discussion at TAG meeting Oct 2020	Updated 'contraindications and precautions' and 'additional information' to reflect vaccination advice as per pubmed.gov randomised study – June 2018 – 'Impact of temporary methotrexate discontinuation for 2 weeks on immunogenicity of seasonal influenza

				vaccination in patients with rheumatoid arthritis: a randomised clinical trial'
7.1	Nov 2020	As 7.0	Final	Recommendations supported by authors
8.0	Oct 2021	Jennifer Carroll, TAG Lead Technician, AGEM CSU	Final	Removed information and reference to documents that were added at version 7.0 above. No longer advise patients to take a 2-week break from MTX following flu jab unless they are a member of a research trial
8.1	Nov 2021	Specialist clinicians at NNUH and Jen Carroll, TAG Lead Technician, AGEM CSU	Final	Amendments include respiratory medicine and sarcoidosis. SCA transferred by JC onto new template Agreed by TAG, D+TC and CCG Governing Body
8.2	July 2022	Jen Carroll, TAG Lead Technician	Draft	Amended title wording and 'Indications' section on page 2
9.0	Jan 2024	Jen Carroll, TAG Lead Technician	Draft	Information transferred to new template. Existing links checked and updated where necessary. 'Pregnancy, paternal exposure and breastfeeding' section updated as per RMOC shared care guidance. To go to TAG for final oversight before publishing
9.1	Mar 2024	Jen Carroll, TAG Lead Technician	Final	Ratified for publishing