DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

METHOTREXATE for patients under adult services

(Oral/subcutaneous preparations for Chesterfield Royal Hospital & oral only preparations for University Hospitals of Derby and Burton)

1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring
- When transfer agreed the patient will be given a supply of methotrexate sufficient for at least 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

Methotrexate once-weekly for autoimmune diseases: new measures to reduce risk of fatal overdose due to inadvertent daily instead of weekly dosing (MHRA Sept 2020)

Advice for prescribers:

- before prescribing methotrexate, make sure that the patient is able to understand and comply with once-weekly dosing
- consider the patient's overall polypharmacy burden when deciding which formulation prescribe, especially for a patient with a high pill burden
- decide with the patient which day of the week they will take their methotrexate and note this day down in full on the prescription
- inform the patient and their caregivers of the potentially fatal risk of accidental overdose if methotrexate is taken more frequently than once a week; specifically, that it should not be taken daily
- advise patients of the need to promptly seek medical advice if they think they have taken too much

GP responsibilities	Consultant/ specialist responsibilities
1. If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1) 2. Ensure compatibility with other concomitant medication 3. Prescribe the dose and formulation recommended. (Reminder – prescribe SC injection by brand), specifying date of taking methotrexate on the prescription. Always prescribe oral methotrexate using multiples of the 2.5mg strength tablet, AVOID USING THE 10mg STRENGTH. 4. Prescribe ancillary equipment e.g. purple lidded cytotoxic waste bin and accept returns of full bins from patients (CRHFT only) 5. Continue to prescribe folic acid 5mg at least once weekly, avoiding the day of methotrexate, as recommended by the specialist 6. Perform monitoring tests as specified in section vii. 7. Adjust the dose as advised by the specialist. 8. Manage adverse effects as detailed in section vi. and discuss with specialist team when required. Report adverse effects to the referring specialist and the MHRA yellow card scheme. 9. Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arises. 10. Update the patient's methotrexate booklet, if used. 11. Ensure the patient is offered an annual flu vaccination and a one off pneumococcal vaccination. Live vaccinations can be used with caution in patients taking methotrexate up to a dose of 25mg, if not on any other immunosuppressant – See section v 12. Discuss with the specialist if the patient plans to	1. Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol and communicated to primary care. Assess for contraindications and cautions and interactions. 2. Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. 3. Ensure the patient and/or carer understands and can follow the once-weekly dose regimen. 4. Perform baseline tests (as recommended in section vii) and provide results of baseline tests 5. Prescribe methotrexate for the first three months or until medication monitoring is stable. Initiate folic acid 5mg at least once weekly, avoiding the day the methotrexate. 6. To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care protocol. 7. Recommend dose of the drug and frequency of monitoring. 8. Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist. 9. Ensure that clear backup arrangements exist for GPs to obtain advice and support. 10. Provide the patient with the NPSA hand held methotrexate booklet, if used. 11. Advise on the suitability for herpes zoster vaccination in accordance with national screening programme. Advise and respond to GP queries on live vaccination. 12. For parenteral methotrexate (CRHFT only): Notify the

become pregnant.	GP of arrangements for continued supply from the patient's chosen community pharmacy and waste management through GP practice. Ensure the patient is trained for the device and brand recommended. 13. Communicate any dose increase to the GP and transfer monitoring to GP when the patient's condition is stable or predictable following 6 weeks period of titration. 14. Report any adverse effects to the MHRA yellow card scheme and GP 15. Review treatment and reassume prescribing responsibility if a patient becomes or wishes to become pregnant.

Patient responsibilities

1. Report to the specialist or GP if there is not a clear understanding of the treatment. Share any concerns in relation to treatment with methotrexate.
2. Take or administer methotrexate as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
3. Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
4. Carry and present their methotrexate booklet (if used)/ patient card to their GP and community pharmacy at each prescribing and dispensing activity.
5. For parenteral methotrexate contact GP for ancillaries/ administrative issues**.**
6. Report any adverse effects or warning symptoms to the specialist or GP whilst taking the drug for example sore throat, bruising, mouth ulcers, breathlessness, dry persistent cough, vomiting and diarrhoea.
7. Inform specialist or GP of any other medication being taken including over-the-counter products.
8. Moderate their alcohol intake to no more than 14 units per week.
9. 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

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:

Chesterfield Royal Hospital NHS Foundation Trust
Contact the referring specialist via switchboard: 01246 277271
Rheumatology Nurse advice line: 01246 513097
Available Monday-Thursday 9am-4pm, Friday 9am- 12pm
IBD advice line 01246 512884 (answerphone) and GP mobile contact 07717700489
Dermatology 01246513106

University Hospitals of Derby and Burton NHS Foundation Trust
Derby Hospitals
Rheumatology - Rheumatology helpline: 01332 787710
Gastroenterology - IBD helpline: 01332 785504
Consultant/specialist nurse via switchboard: 01332 340131
Dermatology - specialist via switchboard: 01332 265500
Respiratory - Consultant via switchboard: 01332 340131
Neurology - Consultant via switchboard: 01332 340131/Neurology secretaries 01332 786478/783548 dhft.neurologysecretaries@nhs.net

Burton Hospitals
Switchboard: 01283 511511 / 566333
Rheumatology
Dr R Laximinarayan ext. 3167
Dr S Das / Dr Ray ext. 3211 / ext.3247
Clinical Rheumatology Nurse Specialist ext. 4112
Bhft.rheumatologynurses@nhs.net

Dermatology
Dr Beswick and Dr Cartwright secretary ext. 4061
Dr Elston and Dr Tudor secretary 5202

Gastroenterology
Dr Palejwala / Dr Dor secretary ext. 3004
Dr Watmough / Dr Guerra secretary ext. 3002
IBD Nurse Specialist ext. 5854 (voicemail service only) Bleep: 590
Dhft.ibdcns@nhs.net

ii. Out of hours contacts and procedures:

Chesterfield
Contact the CRH on-call Medic for the relevant speciality via switchboard: 01246 277271

Derby
Pharmacy, ask for on-call pharmacist via switchboard: 01332 340131
Messages can be left on the Derby Rheumatology nurse advice line: 01332 787710
The aim is to address these next working day

Burton
01283 511511 / 566333 ask for on-call pharmacist via switchboard

Burton Rheumatology
Messages can be left on the nurse advice line out of hours. 01283 511511 ext. 4112.

If the advice line is not staffed, messages may be left 24 hours a day. The team aim to respond at latest within two working days. The specialist nurses may also be bleeped via switchboard for urgent enquiries.

iii. Specialist support/resources available to GP including patient information:

Rheumatology

British Society of Rheumatology Specialist website: https://www.rheumatology.org.uk/practice-quality/guidelines
Versus Arthritis https://www.versusarthritis.org/about-arthritis/treatments/drugs/methotrexate/

Patient information leaflet:-
https://www.nhs.uk/medicines/methotrexate/

4. CLINICAL INFORMATION

i. Prescribed indications	**Licensed** rheumatoid arthritis (RA) psoriasis Crohn's disease (parental)	**off-label use** Psoriatic arthritis Crohn's disease (oral) Connective Tissue Disease (SLE, myositis, & vasculitis) Felty's syndrome Asthma Sarcoidosis
ii. Therapeutic summary	Methotrexate is a cytotoxic folic acid antagonist used to treat chronic inflammatory conditions and certain cancers. It inhibits the enzyme dihydrofolate reductase and inhibits synthesis of DNA, RNA and proteins. Methotrexate is licensed for the treatment of certain cancers, as well as some chronic inflammatory disorders. It is not licensed for all the conditions it is used to treat. However, its use for the indications below are well established and supported by clinical specialists.	
iii. Dose & Route of administration	Orally or subcutaneously (CRH hospital only- parenteral routes may be used where the patient fails to respond to or is intolerant of oral administration) **ALWAYS PRESCRIBE ORAL DOSE USING 2.5mg TABLETS** **Rheumatoid arthritis** - 7.5mg – 25mg once WEEKLY **Severe psoriasis** unresponsive to conventional therapy. Initially 2.5mg-10mg once WEEKLY. Then increased in steps of 2.5mg-5mg, adjusted according to response, dose to be adjusted at intervals of at least one week; usual dose 7.5-15mg once weekly. Maximum 30mg per week **Crohn's Disease -** maintenance of remission of severe Crohn's disease 10-25mg once WEEKLY **Psoriatic arthritis** 7.5mg – 25mg once WEEKLY For other indication see BNF or as per specialist advice Doses outside the recommended range may be considered with prior agreement with the specialist team and GP involved. Lower doses should be considered for frail elderly and patients with renal impairment. In patients with CrCl less than 60 mL/min consider reducing the dose by 50%. If CrCl is less than 30mL/min discontinuation may be indicated- follow specialist advice. Folic Acid 5mg at least once weekly, to be taken on a different day than their methotrexate dose, should be prescribed whilst patient remains on Methotrexate. Tablets should not be split or crushed for administration. If subcutaneous methotrexate is prescribed, secondary care must specify the brand and the patient should be maintained on that brand due to device familiarity.	
iv. Duration of treatment	Indefinite but may be withdrawn after a prolonged period of disease remission in selected cases. **Surgery-** Refer to trust guidelines. DMARD therapy should not routinely be stopped in the perioperative period, although individualised decisions should be made for high-risk procedures (BSR) on the advice of a consultant.	
v. Immunisation	• **Live vaccinations**- Individuals who are on or have recently received high doses of certain immunosuppressive or biological therapies should not be given live vaccines because of the risk of severe or fatal infections. JCVI Green book recommends that low dose corticosteroid (prednisolone <20mg daily) and oral DMARD therapy at standard doses (methotrexate <25mg per week in adults) are not considered sufficiently immunosuppressive and these patients can receive live vaccines, although clinician discretion is advised. • Annual flu vaccination is recommended. • One-off Pneumococcal vaccination recommended unless severely immunocompromised where a different schedule is needed. See JCVI for more information.	

- Patients aged 70-79 years old could be eligible for the shingles vaccine (herpes zoster). For patients on immunosuppressive therapy, a non-live vaccine may be indicated and specialist input may be required.
- Covid-19 vaccination is safe & recommended

vi. Adverse effects
See BNF/SPC for full list

Common or very common:
Anaemia; appetite decreased; diarrhoea; drowsiness; fatigue; gastrointestinal discomfort; headache; increased risk of infection; leucopenia; nausea; oral disorders; respiratory disorders; skin reactions; throat ulcer; thrombocytopenia; vomiting
In general, the incidence and severity of side effects are considered to be dose-related.

Adverse effects	Action for primary care
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, purpura, mouth ulcers.	Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring below.
Infection requiring antibiotics	Temporarily withhold methotrexate until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate.
Gastrointestinal disorders: Nausea	Review for reversible causes and treat as appropriate. Enquire which day of the week the patient takes their methotrexate, and which day(s) they take folic acid and confirm against the patient's records. Discuss with specialist team if persistent or severe.
Diarrhoea, ulcerative stomatitis, haematemesis, black or bloody stools, or suspected pancreatitis	Contact Specialist **urgently** and consider interruption
Symptoms of interstitial lung disease e.g. persistent cough, dyspnoea, fever	Contact Specialist **urgently** and consider interruption
Breathlessness	Contact Specialist **urgently** and consider interruption *and Consider emergency care if necessary*
Photosensitivity	Continue methotrexate. Reinforce appropriate self-care e.g. sun avoidance and purchasing of a broad spectrum sunscreen (at least SPF30).

MHRA August 2023 Methotrexate: advise patients to take precautions in the sun to avoid photosensitivity reactions. Advice for healthcare professionals:
- photosensitivity reactions (which include phototoxicity, where a drug is activated by exposure to UV light and causes damage to the skin that can look and feel like a sunburn or a rash) are known side effects of methotrexate treatment and can occur with both low-dose and high-dose treatment.
- reactions manifest as severe sunburn such as rashes with papules or blistering, with some patients reporting swelling; rarely, photosensitivity reactions have contributed to deaths from secondary infections.

vii. Monitoring Requirements

Before commencing immunosuppressant therapy
- Record patient's blood pressure, weight and height if clinically indicated.
- Screening for lung disease should be undertaken at clinician discretion on a case-by-case basis. The extent of screening should be influenced more by a patient's clinical features and risk factors for lung disease (e.g. underlying autoimmune disease or smoking history) rather than subsequent immunomodulating choice. Pre-existing lung disease should not be considered an absolute contraindication to any immunomodulating medication.
- Screen for viral hepatitis B&C and HIV as per local policy
- Investigate patient medical history including co-morbidities and previous immunomodulating medication use.

Consultant/specialist monitoring schedule
Baseline followed by 2 weekly monitoring until on a stable dose for at least 6 weeks
- FBC
- ALT and/or AST and albumin
- U&E including creatinine/ CrCl
- Serum Pro Collagen III measured **only** in Psoriasis *(not Psoriatic arthritis)*
- CRP &/or ESR in rheumatology patients

Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist.

GP responsibility monitoring schedule

In patients following the 6 weeks of dose stability conduct monthly monitoring for three months followed by three monthly monitoring thereafter of:

- FBC
- ALT and/or AST and albumin
- U&E including creatinine/CrCl

For rheumatic patients CRP/ESR may be done every 3 months (this is not done for dermatology patients). These tests are part of the assessment of the underlying rheumatic disease rather than a requirement for monitoring of immunomodulating therapy. The monitoring CRP/ESR may be coordinated between secondary and primary care on an individual basis.

Leflunomide in combination with MTX requires extended monthly monitoring for at least 12 months. Patients who have been stable for 12 months can be considered for reduced frequency of monitoring on an individual patient basis.

Dosage increase

For dose **increase**, monitor fortnightly until stable for 6 weeks. Monitoring to then revert to previous schedule. Dose and monitoring to be agreed with consultant.

- FBC
- ALT and/or and albumin
- U&E including Creatinine/CrCl

When restarting treatment after an abnormality has been detected repeat bloods in 2 weeks and then monthly for 3 months. Following this resume monitoring frequency to what it was prior to the abnormality.

Actions to be taken in Primary care

- In addition to responding to absolute values in laboratory tests, it is also relevant to observe trends in results (e.g gradual decreases in white blood cells (WBC) or albumin, or increasing liver enzymes)
  NB – a rapidly increasing or decreasing trend in any value should prompt caution irrespective of actual value.
- Parameters below are to be used as a guide for clinicians rather than absolute values, where monitoring should be based on individualised basis. It is important to consider alternative explanations other than the immunomodulation agents, especially in patients who have been stable for prolonged periods

WBC <3.5 x10^9 /L Lymphocytes < 0.5x10^9/L Neutrophils <1.6 x 10^9/L Platelets <140 x 10^9/L Eosinophilia >0.5x10^9/L	Discuss **urgently** with specialist team and consider interruption. Isolated low lymphocytes more likely to be due to disease or other factors- GP to consider non-drug related causes (contact specialist for advice if unsure). The specialist may advise on individual cases if the abnormality is thought to be due to other factors and in this instance may set differential parameters which can be communicated to the GP.
Mean cell volume >105 f/l	Check **serum B12, folate & TFT** Discuss urgently with specialist team and consider interruption.
ALT and/or AST > 3x upper limit of normal (ULN) or >100 units/ml (local consensus), or any sudden increases (e.g. double of baseline); or Unexplained fall in albumin (<30g/l)	Contact Specialist **urgently** and consider interruption. Assess for other causes of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.
Creatinine increase >30% over 12 months or CrCl <60ml/min	Contact Specialist **urgently** and consider interruption

viii. Contra-indications and cautions

Contraindications

- Hypersensitivity to methotrexate or any excipients.
- Significant hepatic impairment.
- Ascites or pleural effusion: drain prior to treatment to reduce the risk of methotrexate accumulation.
- Significant renal impairment – creatinine clearance (CrCl) less than 30 mL/min.

	• Severe infections (acute or chronic) or immunodeficiency syndromes. • Known active peptic ulceration. • Pregnancy and breast-feeding. • Vaccination with live vaccines during treatment with methotrexate at immunosuppressive doses. • Concomitant use of medicines with anti-folate properties, e.g. trimethoprim, co-trimoxazole **Cautions** • Renal impairment: dose reduction required • Alcohol dependence • Hepatic impairment, particularly if due to alcohol use • Pre-existing blood dyscrasias or disorders, including bone marrow hypoplasia, leucopenia, thrombocytopenia, or significant anemia. Confirm to primary care that any underlying dyscrasias have been considered, and whether any change to standard monitoring is required. • Respiratory disease. • Concomitant use with hepatotoxic or haematotoxic medicines • History of ulcers of the oral cavity, ulcerative stomatitis, gastrointestinal ulcers or ulcerative colitis. • History of chronic or recurrent infections (e.g. frequent infective COPD exacerbations, or recurrent urinary tract infection). • Frail or elderly- consider reduced dose. • Conditions which increase the risk of dehydration (e.g. vomiting) may increase the risk of toxicity. Consider interrupting treatment until symptoms cease.
ix. Clinically relevant drug interactions **For a full list of interactions please refer to the BNF**	• Co-administration of medicinal products which cause folate deficiency (e.g. **trimethoprim** and **co-trimoxazole**) can lead to increased methotrexate toxicity and is contraindicated. Particular caution should therefore also be exercised in the presence of existing folic acid deficiency. • **Leflunomide**: increased risk of bone marrow and liver toxicity; increased monitoring and vigilance required. • **Ciclosporin**: increased risk of nephrotoxicity and methotrexate toxicity. • **Azathioprine and mercaptopurine:** not advised due to increased risk of toxicity. • **Sulfasalazine**: may increase risk of bone marrow and liver toxicity. However, this combination is used in clinical practice without incident. Be aware of trends in monitoring parameters. • **Drugs with hepatotoxic, haematotoxic or nephrotoxic effects:** Increased frequency of monitoring may be recommended. • **Live vaccines** (e.g. oral polio, oral typhoid, MMR, BCG, Zostavax®) are advised in line with the national schedule for all patients, unless the patient is taking a dose of methotrexate or other immunosuppressive drug that exceeds those specified in the Green Book. Doses below this level are not considered sufficiently immunosuppressive and these patients can receive live vaccines. Clinician discretion is advised. Please refer to the Green Book Chapter 6 for current advice. • Avoid concomitant use of **cytotoxics, clozapine, and olanzapine:** increased risk of agranulocytosis. • **Retinoids**: increased risk of hepatotoxicity, and may increase plasma levels of methotrexate. • **Levetiracetam:** may increase plasma levels of methotrexate. • **Nitrous oxide and pyrimethamine**: increased antifolate effect of methotrexate. • **Lomitapide:** increased risk of hepatotoxicity. • **Probenecid:** excretion of methotrexate reduced. • **Phenytoin:** possible increased methotrexate toxicity, and decreased phenytoin effect. • **NSAIDs**, **COX-2 inhibitors, aspirin:** may reduce excretion of methotrexate, increasing risk of toxicity. These drugs are frequently used with methotrexate without incident, and aspirin at antiplatelet doses is unlikely to interact to a significant degree. Be aware of trends in monitoring parameters. • **Antibiotics** may alter methotrexate levels. Methotrexate should be interrupted during periods of acute infection. • **Theophylline and other methylxanthines:** may reduce methotrexate efficacy. Methotrexate may reduce theophylline clearance. • **Anticonvulsants:** may reduce methotrexate levels. • **Colestyramine**: may increase elimination of methotrexate. • **Alcohol:** consumption of alcohol increases the risk of hepatotoxicity. Patients should moderate their alcohol intake to no more than 14 units per week.

x. 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.
xi. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed **To be read in conjunction with the following documents** • RMOC Shared Care Guidance • NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care
xii. Supply of ancillary equipment	CRH- For patients receiving parenteral methotrexate therapy supplies of the drug, waste management products and collection of cytotoxic waste can be arranged through the GP practice (GP is responsible for prescribing suitable sized purple lidded cytotoxic waste bins e.g. 3 or 5L and accepting returns of full bins from patients). Waste bin can be prescribed or maybe cheaper to purchase from a community pharmacy if he patient pays prescription charges.
xiii. Supply, storage and reconstitution instructions	Injections can be stored at room temperature.
Prepared by	The Shared Care Guidelines Group DDICB Martin Shepherd, Head of Medicines Management, Chesterfield Royal Hospital Derbyshire Medicines Management Clinical Effectiveness Team

In consultation with	Derby Teaching Hospitals NHS Foundation Trust: Dr Bleiker, Dr Ferguson, Dr Shum -Consultant Dermatologist Dr Goddard, Consultant Gastroenterologist and Hepatologist Dr O'Reilly, Dr Raj, Consultant Rheumatologist Dr Austin, Consultant Hepatologist
Reviewed (2023)	In line with In line with NHSE/ RMOC Shared Care Protocols- Methotrexate for patients in adult services, July 2022. https://www.england.nhs.uk/publication/shared-care-protocols/ The Derbyshire Medicines Management Shared Care and Guidelines Group Dr. L Badcock, Consultant rheumatologist UHDB Dr. R Laxminarayan, Consultant rheumatologist UHDB Dr. K Fairburn, Consultant rheumatologist CRH Linda Longmore, Rheumatology Advanced Clinical Nurse Specialist CRH Dr. B Norton, Consultant dermatologist UHDB Dr Kid Wan Shum, Consultant Dermatologist UHDB Karen Kenny, Dermatology Clinical Nurse Specialist CRH Kath Phillis, Advanced Clinical Nurse Specialist IBD CRH

This does not replace the SPC, which should be read in conjunction with it

Date Prepared: October 2011 **Reviewed:** June 2023 **Review Date**: May 2026

References

1. NHSE/ RMOC Shared Care Protocols- Methotrexate for patients in adult services, July 2022. https://www.england.nhs.uk/publication/shared-care-protocols/
2. EMC Summary of Product Characteristics for Methotrexate accessed online 08/03/2017, 2/7/2019, March 2023
3. British National Formulary accessed online 2/7/2019, March 2023
4. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs, The British Society for Rheumatology, February 2017
5. The Green book, Immunisation against infection disease, September 2014, accessed online 08/03/2017, 2/7/2019, March 2023

Sample Transfer Letter

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_POSTCODE»

Your patient was seen on ***{Insert date}*** with a diagnosis of ***{Insert diagnosis}***. I have initiated the following medication ***{Insert drug name}*** and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

Dose Regimen	Date ***{Insert medicine name}*** started	Date for GP to start prescribing ***{Insert medicine name}*** from
The baseline test results are (if applicable): **See overleaf for initiation criteria.**		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}

GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care*)

* For completeness please record medication on GP clinical system as per guidance- 'Recording medicines prescribed and issued by other Healthcare Providers'

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	

6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to the specialist/consultant requesting shared care