Shared Care Protocol for the Management of Inflammatory Arthritis, Connective Tissue Disease & Systemic Vasculitis for Adult services (over 16)

Introduction

Shared Care Protocols are intended to provide clear guidance to General Practitioners (GPs) and hospital prescribers regarding the procedures to be adopted when clinical (and therefore prescribing and financial) responsibility for a patient's treatment with a shared care disease is transferred from secondary to primary care.

GPs, as independent contractors, have the right to decline to take clinical and prescribing responsibilities for a patient on their medical list that is being treated elsewhere. However, the reason for this action must be documented. In the view of the Doncaster and Bassetlaw Place Medicines Optimisation Committee (PMOC) Traffic Light System (TLS) classification on the Medicines and Product Directory (MPD), it would be the exception for a GP to refuse to take clinical and prescribing responsibilities for an individual drug, where shared care guidelines for that drug have become common practice and where shared care guidelines include adequate support, education, and information as approved by the Doncaster & Bassetlaw PMOC.

When the secondary care rheumatology service requests a GP to prescribe this medication in relation to these diseases, the GP should reply as soon as practicable. The doctor who prescribes the medication legally assumes the clinical responsibility for the drug and the consequence of its use.

While this document looks to medication used in the treatment of CT & IA diseases, not all medication will be covered by a shared care protocol for prescribing. There are 3 groups of medication under the traffic light system classification:

- Amber G - These drugs must be initiated and titrated to stable dosage by specialist (at least 1 month duration) before GPs take over prescribing responsibility. Shared care protocol is not required but there may be some guidance to accompany the medication entry on the MPD.
- Amber - The initiation and continued prescribing of this medication should only be undertaken under auspices of an agreed shared care protocol. In general, the hospital will initiate and titrate the medication until target dose (usually 3 months) before the GP is requested to take over prescribing responsibility.
- Red - The prescribing and monitoring of this medication is initiated and retained by specialist services unless as part of a specialist GP with a Special Interest service (GPwSI).

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This document will be reviewed in light of new or emerging evidence or by December 2029

Traffic Light System Classification			
Drug Class	**Amber-G**	**Amber**	**Red**
Conventional synthetic DMARDs		Sulfasalazine	
Antimalarials	Hydroxychloroquine		Mepacrine
Immunosuppressives		Azathioprine Leflunomide Methotrexate oral Methotrexate Injectable (Doncaster) Mycophenolate mofetil Mycophenolic acid	Ciclosporin Tacrolimus Cyclophosphamide Voclosporin Avacopan Methotrexate Injectable (Bassetlaw)
Biologics			All biologics
Targeted synthetic DMARDs			All targeted synthetic DMARDs

Monitoring of medication

The Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust (DBTHFT) is a multi-site trust covering 2 geographical areas: Doncaster and Bassetlaw. There are 2 forms of monitoring of medications used to treat IA, CTD and systemic vasculitis:

- Doncaster commissioned service - Computerised monitoring (with rheumatology oversight)

- Bassetlaw commissioned service - GP monitoring and prescribing.

For out of area GPs, the type of monitoring arrangement to be put in place will be agreed with the respective GP or commissioners (which would either be the computerised monitoring with rheumatology oversight or GP monitoring and prescribing).
There are 2 forms of monitoring schedule:

- Standard monitoring schedule – week 2, then monthly for 6 months and thereafter every 12 weeks.

- Extended monitoring schedule - 2 weekly until on stable dose for 6 weeks, then monthly for 3 months and thereafter every 12 weeks.

For any increase in dosing, additional monitoring is required at week 2 before reverting back to standard or extended monitoring

DBTHFT Medication monitoring protocol for Rheumatology Department

DRUG	MONITORING
Apremilast *Red*	• No monitoring required
Azathioprine *Amber*	• TPMT at baseline: • Standard monitoring schedule of FBC, LFT and U&E
Ciclosporin or Tacrolimus or Voclosporin *Red*	• ECG at baseline for tacrolimus to look for prolonged QTc • Extended monitoring schedule of (a) BP (b) FBC, U&E, LFT and HbA1C • Regular therapeutic drug monitoring for (a) Ciclosporin (target trough levels 100-200ng/ml) (b) Tacrolimus (target trough levels 4-10ng/ml)
Hydroxychloroquine *Amber-G*	• Annual retinal screening by Optical Coherence Tomography (OCT) after 5 years of therapy • Patients with increased risk of retinopathy would need annual retinal screening after 1 year of use. These patients are those who are taking high dose of hydroxychloroquine (>5mg/kg/day), taking concomitant Tamoxifen therapy or those with renal insufficiency. The selection and referral process will be determined by the specialist team. • The results of retinal screening will be communicated back to the prescribing specialist (rheumatologist/dermatologist), patient and GP as normal, possible or definite hydroxychloroquine retinopathy. • It is the specialist's responsibility to refer their patients to the retinal screening service and to make the decision of treatment continuation dependent on results of the screening.
Leflunomide *Amber*	• Standard monitoring schedule of (a) BP (b) FBC, U&E and LFT
Methotrexate *(Only 2.5mg is used for tablet form)* *Amber* *Sub-cut injection RED in Bassetlaw*	• Chest X-ray at baseline • Standard monitoring schedule of FBC, LFT and U&E
Methotrexate /Leflunomide combination *Amber*	• Extended monitoring schedule of (c) BP (d) FBC, U&E and LFT
Mycophenolate mofetil or Mycophenolic acid *Amber*	• Standard monitoring schedule of FBC, LFT and U&E
Sulfasalazine *Amber*	• Standard monitoring schedule of FBC, LFT and U&E for 12 months • No monitoring required after 12 months

Computerised Monitoring

DBTHFT Rheumatology Department uses a computerised monitoring system that can assess trends in a patient's blood test parameters and track when blood tests are not

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performed according to the monitoring protocol (such as when patients do not attend for blood tests). It will highlight when there is deviation outside the set parameters or when there has not been a blood test according to the monitoring protocol. There is oversight by the Rheumatology department on any deviation from the set parameters or monitoring protocol.

Patients are sent the regular blood forms through the post, each time the patient reaches the end of their group of forms. Patients are to contact the department on a dedicated phone line extension when they require more forms, which each patient is given.
The prescription of the Amber drugs will generally be with the GPs.
The Rheumatology department follows a monitoring protocol which is based on the BSR monitoring guidelines.

DNA protocol
If a patent fails to attend for blood tests, they are sent a reminder letter as soon as is practicable, requesting them to either attend for the blood test or contact Rheumatology helpline if there are problems. They are advised in the letter that it is dangerous to continue the medication unmonitored and if they fail to have the blood test performed, treatment might need to be stopped. If the patient fails to have a blood test performed following this, a letter recommending discontinuation of treatment with DMARD or immunosuppressives will be sent to the patient, their GP and whoever is prescribing the treatment (such as hospital pharmacy). Contact numbers are again provided on the letter.

Monitoring and Prescribing
It is the GP's responsibility to prescribe the medication, and responsibility for monitoring may lie with the GP, or GP and specialist, dependent on local place arrangements. The results of laboratory monitoring are available electronically for GPs in Doncaster and Bassetlaw areas. GPs are recommended to monitor the medication according to the BSR/BHPR guideline for disease modifying anti-rheumatic drug (DMARD) therapy which is available at: https://www.rheumatology.org.uk

Prescribing of DMARDS

Methotrexate Tablets
In line with NPSA/2006/13 Ref 0279 June 2006 “Improving compliance with oral methotrexate guidelines” the recommendation from the Doncaster and Bassetlaw PMOC is that only methotrexate 2.5mg tablets should be prescribed and dispensed.

All patients on methotrexate should have an agreed day of the week for dosing to minimise the risk of accidental overdosing.

Methotrexate Sub-cutaneous Injection (RED in Bassetlaw)
For patients who are initiated on sub-cutaneous methotrexate, the patient or carers who are administering the medication will be trained by the specialist team on administration of the subcutaneous injection.

The subcutaneous injection will be either pen device or pre-filled syringe and there are several brands of subcutaneous methotrexate injection. It is recommended that the same brand is prescribed as there are some differences in the device of different brands. Any

change in the brand prescribed should be agreed with the patient before it is implemented. Therefore, the prescription of subcutaneous methotrexate should state:
(a) brand of subcutaneous methotrexate
(b) type of device (pen or pre-filled syringe)

In addition, a cytotoxic “Purple lid” bin will need to be prescribed to patient for disposal of used subcutaneous methotrexate device by the prescriber

All patients on methotrexate should have an agreed day of the week for dosing to minimise the risk of accidental overdosing.

Pregnancy and Breastfeeding
When a patient is prescribed a DMARD or immunosuppressives there are significant issues regarding pregnancy and family planning posed by the potency and potential teratogenicity potential of these drugs. The decision about when and what medication should be stopped is a decision that needs to be taken based on advice from rheumatology specialist service. The decisions potentially affect both male and female patients depending on the medication being used.

DMARDs and immunosuppressives that are compatible with pregnancy are:

- Hydroxychloroquine
- Sulfasalazine
- Azathioprine
- Ciclosporin
- Tacrolimus

Overall, the principle is to keep inflammatory disease under control as uncontrolled inflammation is associated with adverse pregnancy outcomes.

Breastfeeding is generally not advised if a mother is on DMARDs or immunosuppressives. However, there is increasing evidence that certain medication such as Hydroxychloroquine and Sulfasalazine do not cause harm, even though very small amounts maybe in the breast milk. The biologic therapy Certolizumab (Cimzia), which is an anti-TNF therapy has a license to be used in breast feeding. All decisions about DMARDs and its interaction with breast feeding should be discussed with the specialist team and should form a discussion with the family as to the best way forward for baby and the mother’s rheumatic disease.

Infection and immunisations
During serious infection, conventional DMARDs, immunosuppressives, targeted synthetic DMARDs and biologics (which suppresses the immune system) should be temporarily discontinued until the patient has recovered from the infection. The exceptions are antimalarials and sulfasalazine (unless neutropenia present).

Chicken Pox
Immunosuppressed Varicella Zoster Virus (VZV) naïve patients have a significant risk of disseminated infection if exposed or contract the infection. Therefore, information is passed to all patients in secondary care on DMARD / steroid therapy as what to do if they are exposed or contract chicken pox.

Exposed to VZV and within incubation period

- Previous history of chicken pox
  - Only treat with antiviral if develop active infection

- No history of chicken pox
  - Urgent assessment of VZV antibodies
  - If antibody status negative: treatment with pooled immunoglobulin
  - If antibody status positive: only treat with antiviral if develop infection

Active VZV Infection

- Previous history of infection – treat with antiviral
- No history of chicken pox
  - Urgent assessment of antibodies
  - Detailed clinical assessment and anti-viral treatment dependent on clinical presentation

Immunisations

All patients on immunosuppressive medication (such as methotrexate, azathioprine, ciclosporin, leflunomide, mycophenolate and cyclophosphamide) should be offered non-live vaccination (such as influenza, covid, pneumococcal, varicella zoster vaccines) in line with Government recommendations unless contraindicated. See the section on immunosuppression in the document for specific DMARD advice and which ones are safe.

Live vaccine should be avoided in immunosuppressed patients. The immunosuppression threshold as recommended by JCVI whereby live vaccine may be administered are:

- Low dose methotrexate up to 25mg/week
- Azathioprine up to 3mg/kg/day

Following vaccination, methotrexate should be withheld for up to 2 weeks if disease is under control.

Shared Care Arrangements

Once a stable medication regime has been established (usually 3 months), monitoring and prescribing of amber category drugs can be transferred to primary care with agreement.

Responsibilities of Secondary Care

- Diagnosis and assessment
- Initiation and stabilisation of drug therapy, usually but not exceptionally, a period of 3 months.
- Patient/ family education -ensure patient is fully informed of potential benefits and side effects of treatment.
- Ensure the patient's guardian/carer is fully informed of the treatment.
- Provide a comprehensive treatment package in addition to medications including appropriate information/monitoring sheet(s)
- Ensure that shared care arrangements are in place before transfer of treatment:
- That the patient/carer is clear what is being monitored and by whom
- That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
- Any dose changes once the patient is established on treatment will be conveyed in writing to the GP for the GP to prescribe.

- Extra monitoring needed for dose changes will be organised by Rheumatology team and conveyed to patient.
- Monitor side effects of medication via routine out-patient visits or nurse telephone help line.
- Report adverse events to the MHRA (Yellow card scheme) https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/
- Monitor patient's response to treatment
- If a patient is being monitored via computerised monitoring system, patients will be sent blood forms and have the results actioned as described above (see section 2.1)

Responsibility of Primary Care

- Ensure that shared care arrangements are in place before transfer of treatment:
  - That the patient/carer is clear what is being monitored and by whom
  - That the patient knows what significant adverse effects/events to report urgently and to whom they should report (specialist or GP)
- When the specialist initiates treatment, reply to the request for shared care as soon as practicable
- Confirm that proposed therapy is not contra-indicated because of concurrent therapy for other conditions the patient may be suffering from (e.g. check drug-contraindications and drug-interactions). Contact specialist team, if possible
- interactions found and discuss with rheumatologist
- Confirm that specialist have provided the patient/carer with appropriate information sheet(s) for monitoring and/or to alert other clinical staff to the treatment they are receiving. If appropriate information has not been provided by the specialist, the GP must ensure the information is provided
- Ensure patient's guardian/carer is fully informed of the treatment
- Monitor treatment as stated in the shared care protocol
- Amend prescription as per requests from secondary care for dose changes in patients on established treatment
- Confirm with specialist which changes in these or other parameters should trigger urgent referral back to the specialist
- Seek specialist advice promptly as advised in the shared care protocol or if signs/symptoms of changes occur consistent with DMARD adverse event
- Report adverse events to the MHRA (Yellow card scheme) https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/
- If the medication has a black triangle status or is unlicensed, all events should be reported even if causal relationship is not known or if the adverse event is already known about
- Report adverse events to the consultant sharing the care of the patient
- Stop treatment on advice of specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue this therapy.

Responsibilities of patient or carer

- Discuss potential benefits and side effects of treatment with the specialist and GP. Identify whether they have a clear picture of these from the specialist and to raise any outstanding queries
- Check that where possible the specialists have provided a patient-held record or information sheet for monitoring and/or to alert other clinical staff to the treatment they are receiving

- Share any concerns they have in relation to treatment with the medicine
- Report any adverse effects to their specialist or GP whilst taking the medicine
- Report to the specialist or GP if they do not have a clear understanding of their treatment
- Participate in the monitoring of therapy and the assessment of outcomes, to assist health professionals to provide safe, appropriate treatment.

Procedure for adopting shared care

The specialist will send to the GP a diagnostic assessment report, a copy of the shared care protocol and a shared care referral specifying who is responsible for monitoring. The GP should sign the proforma with a record kept in the GP and specialist records. Full details will be given of the prescribing regime (brand, form, strength and dose of medication) and follow-up plan.

The patient will be asked to make arrangements with their GP for continued supply.

References

British Society for Rheumatology (BSR) guidelines which is available in 'Guidelines' section of BSR website at www.rheumatology.org.uk

Shared Care Development

- Version 2.0 written on April 2009 and reviewed by Doncaster and Bassetlaw Area Prescribing Committee in October 2009
- Version 3.2 updated by Dr Chee-Seng Yee Consultant Rheumatologist of Doncaster and Bassetlaw Hospitals NHS Foundation Trust on 20/05/2014
- Version 3.2 approved by Doncaster and Bassetlaw Area Prescribing Committee on 26th June 2014
- Version3.3 updated by Mrs Gill Bradley, Deputy Head of Medicines Management, Doncaster CCG (insertion of clarification on recommendation to use methotrexate 2.5mg tablets and to avoid the use of 10mg tablets)
- Version3.3 approved by Doncaster and Bassetlaw Area Prescribing Committee on 30th July 2015
- Version 4.0
- Updated by Dr Chee-Seng Yee Consultant Rheumatologist of
- Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust on 27/06/2017 Approved by Doncaster and Bassetlaw Area Prescribing Committee July 2017
- Version 5.0
- Updated by Dr Robert Stevens and Dr Chee-Seng Yee, Consultant Rheumatologists Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust August 2018 Approved by Doncaster and Bassetlaw Area Prescribing Committee August 2018
- Version 6.0
- Updated by Dr Robert Stevens Consultant Rheumatologist of Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust and V-Lin Cheong Deputy Head of Medicines Management of NHS Doncaster CCG February 2021 Approved by Doncaster and Bassetlaw Area Prescribing Committee March 2021

- Version 7.0
- Updated by Dr Chee-Seng Yee Consultant Rheumatologist of Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust Approved by Doncaster and Bassetlaw Place Medicines Optimisation Committee December 2024

- Version 8.0
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- Version 8.1
- Updated by Dr Chee-Seng Yee Consultant Rheumatologist of Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
- Version 8.2.
- Updated by PMOC with the updates Dr Chee-Seng Yee Consultant Rheumatologist of Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

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