NHS Dorset

Shared Care Protocol - Leflunomide for patients within adult services

As well this protocol, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- 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 (see section 11) to enable the patient to reach an informed decision. If the drug is being initiated in patients of childbearing potential, there should be documented evidence that they have been informed of the risks, and they are aware of the requirement to use effective contraception during treatment. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Explain where drugs are used outside of their license.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8). Arrange tests and review the results for the first 12 weeks of monitoring
- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient. Explain the process and the potential timescales for this
- Once treatment is established and stabilised, request shared care from the primary care provider either using the documentation in Appendix 1 or by clinic letter detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication taking into account any delays in communication to general practice to enable transfer to primary care, including where there are unforeseen delays to transfer of care.

- Conduct the scheduled reviews and monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support
- Review treatment and provide advice if a patient becomes or wishes to become pregnant (See section 12)
- Provide advice to primary care on the management of adverse effects if required
- Patients should be regularly reviewed, and the risk benefit re-assessed as patients get significantly older and frail with increasing co-morbidities and polypharmacy. Dose optimisation and/or dose tapering should be considered if clinically appropriate aiming for the lowest effective dose
- Advise primary care if treatment should be discontinued

Primary care responsibilities

- Respond to the request from the specialist for shared care if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response. It is asked that this be undertaken within 14 days of the request being received, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into any account potential drug interactions in section 7.
- Assess for interactions with leflunomide when starting any new medicines section 7.
- Adjust the dose of leflunomide prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop leflunomide and discuss urgently with the specialist if the patient develops signs of serious infection, liver or respiratory disease, unexplained bleeding, or bruising, are exposed to chickenpox or shingles, or becomes pregnant.
- Discuss with the specialist if the patient plans to become pregnant. See section 12
- Stop treatment as advised by the specialist. If the decision to stop treatment is made in primary care e.g. due to increased frailty index, to let the specialist team know so they can arrange a review as needed

Patient and/or carer responsibilities

- Take leflunomide as prescribed and avoid withdrawal unless advised by the primary care prescriber or specialist.
- Maintain engagement with specialist and primary care; attending regularly for monitoring and review appointments as requested; keeping contact details up to date with both teams. Be aware that medicines may be stopped if they do not attend for blood monitoring or the review appointments.
- Advised to take part in all national screening programmes e.g. for breast, bowel, and cervical cancers.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of leflunomide with their pharmacist before purchasing any OTC medicines.
- Tell anyone who prescribes them a medicine that they are taking leflunomide
- Moderate their alcohol intake as advised by the specialist team- the Versus Arthritis leaflet suggests no more than 4 units per week. Leflunomide | Versus Arthritis
- Not to drive or operate heavy machinery if leflunomide affects their ability to do so safely.

Patients of childbearing potential should use effective contraception during and for up to 2 years after treatment and 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. See section 12

1. Background

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This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

Leflunomide is a conventional disease-modifying anti-rheumatic agent (DMARD). It exhibits anti-inflammatory and antiproliferative effects through the inhibition of pyrimidine synthesis via dihydroorotate dehydrogenase.

It may be used as monotherapy or in combination with other DMARDs including methotrexate and sulfasalazine. Please note the frequency of monitoring requirements are different if leflunomide is used in combination with methotrexate

The therapeutic effect usually begins after 4-6 weeks, and benefit may accrue for up to 6 months.

Leflunomide has a very long half-life of approximately 2 weeks, and in circumstances where rapid elimination is required a washout procedure may be given if advised by the specialist. This may be due to severe adverse effects, pregnancy, severe infection or if an alternative DMARD is indicated. Washout is typically given as colestyramine 8g taken three times daily or activated charcoal 50g four times daily, for up to 11 days. See section 6 for further information.

2. Indications

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Leflunomide is licensed for use in:

- Rheumatoid arthritis
- Psoriatic arthritis

It may also be used off label for other inflammatory conditions including:

- Rheumatology conditions (e.g. systemic lupus erythematosus, axial spondyloarthopathy)
- Interstitial lung disease
- Vasculitis

The specialist must specify the indication for each patient when initiating shared care and clearly state when use is off label.

3. Locally agreed off-label use

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Nil further identified- see above

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to leflunomide or any excipients
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
- Serious infection
- Liver impairment
- Moderate to severe renal impairment
- Severe hypoproteinaemia
- Severe immunodeficiency

- Pregnancy and breastfeeding, or patients who are not using effective contraception during treatment. People of child-bearing potential should use effective contraception for up to 2 years after stopping treatment. Avoid where possible in people of child-bearing potential. See section 12.

Cautions:

- Anaemia: avoid if significant and due to causes other than rheumatoid or psoriatic arthritis.
- Localised or systemic infection which may be more severe
- History of HIV, tuberculosis, hepatitis B or C
- Impaired bone-marrow function, leucopenia, or thrombocytopenia: avoid if significant and due to causes other than rheumatoid or psoriatic arthritis.
- Frail or elderly – use minimum effective dose.
- Use of concurrent haematotoxic or hepatotoxic DMARDs e.g. methotrexate- note the frequency of monitoring requirements are different if leflunomide is used in combination with methotrexate
- There is a theoretical risk of male-mediated foetal toxicity so effective contraception should be used throughout treatment. Those patients wishing to father a child should discuss with the specialist who may want to follow the washout procedure before advising he attempt conception (see section 6).

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised, and with satisfactory investigation results for at least 4 weeks
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

An initial dose of 10-20mg once daily is normally given. Due to the long half-life, doses of 10mg and 20mg may be given on alternate days.

Short loading regimens may be used however these may increase the risk of adverse effects and are considered optional.

The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

10-20mg once daily. Due to the long half-life, doses of 10mg and 20mg may be given on alternate days.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

None

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Leflunomide 10mg, 15mg and 20mg tablets. Note the 15mg tablets are significantly more expensive and not readily available. Doses of 10mg and 20mg may be given on alternate days to achieve the average 15mg daily dose.
Administration details:	Tablets should be swallowed whole with sufficient amounts of water. Administration with food does not affect absorption.
Other important information:	The active metabolite of leflunomide has a half-life of approximately 2 weeks and undergoes extensive enterohepatic recycling and may therefore persist for long periods of time even after administration has stopped. It is not sufficient to only stop the drug because adverse effects may still occur or worsen If serious adverse effects occur, the patient becomes pregnant, before starting treatment with an alternative DMARD, or for other reasons which require the rapid elimination of leflunomide, a washout procedure may be necessary. This is given as colestyramine 8g taken three times daily **or** activated charcoal 50g four times daily, usually for 11 days. This should be discussed with a specialist before initiating procedure. The washout procedure interrupts the enterohepatic recycling mechanism and reduces the half-life of leflunomide to around 1 - 2 days. If the patient cannot manage the full 11-day course, there is evidence that even a few days treatment is likely to be beneficial and that 48 hours of treatment may reduce the active metabolite of leflunomide by 49 - 65% if using colestyramine and by 48% for charcoal.

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF & SPC for comprehensive information and recommended management.

- **Anticoagulants:** The anticoagulant effect of vitamin K anticoagulants may be increased by leflunomide. Close INR monitoring and follow-up is recommended.
- **Live vaccines** (e.g. oral polio, oral typhoid, MMR, BCG) should be avoided. There is evidence that doses at or below 20mg leflunomide, as either monotherapy or in combination with 20mg prednisolone per day or less, can safely receive live shingles vaccinations. Clinician discretion is advised, see section 9
- **JAK kinase inhibitors**, e.g. baricitinib, filgotinib: due to the increased risk of immunosuppression**.**
- **Colestyramine and activated charcoal:** Co-administration leads to a rapid and significant decrease in plasma levels of leflunomide metabolites by interrupting enterohepatic recirculation
- **Repaglinide, paclitaxel, pioglitazone, cefaclor, benzylpenicillin, ciprofloxacin, indomethacin, ketoprofen, furosemide, cimetidine, zidovudine, venetoclax:** Leflunomide may increase the exposure to these products.
- **Rosuvastatin** levels may be increased by leflunomide. A maximum rosuvastatin dose of 10mg is recommended. Caution is recommended with **other statins** and dose reduction may be required.

8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- Height and weight
- Blood pressure
- Full blood count (FBC)
- Urea and electrolytes (U&Es) including creatinine and creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and albumin
- Screening for viral infections as per local policy, e.g. HIV, Hepatitis B and C, Varicella Zoster, Epstein Barr virus, Cytomegalovirus

- Screening for lung disease, including interstitial lung disease, should be undertaken at clinician discretion on a case-by-case basis.
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)
- Pregnancy should be excluded before starting treatment.

Initial monitoring:

To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months.

- FBC
- U&Es, including creatinine and CrCl
- ALT and albumin (LFTs)
- Rheumatology patients: CRP &/or ESR (for monitoring disease activity/outcomes rather than for safety- this may continue to be monitored by the rheumatology team but will not be part of the primary care safety monitoring parameters)

Following a dose change repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.

More frequent monitoring is appropriate in patients at higher risk of toxicity, e.g. concurrent use of more than one DMARD. This is particularly important for patients co-prescribed methotrexate and leflunomide. The combination is highly effective but potentially synergistically toxic to liver and bone marrow and increase monitoring frequency is recommended.

The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually unless the patient has been stabilised on treatment for a long time and considered suitable for patient initiated follow up (PIFU). Rapid access to the specialist team for advice and guidance should still be available if the patient is enrolled with PIFU.

When a patient is reviewed, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.

9. Ongoing safety monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and advice	Frequency
• FBC • U&Es including creatinine and CrCl • LFTs/ Albumin • BP & weight	Every 12 weeks if leflunomide prescribed alone. If leflunomide is prescribed in combination with methotrexate the frequency of monitoring should be monthly in the first year of treatment. Patients who have been stable for 12 months can reduce to 3 monthly monitoring. Where necessary seek advice on increased frequency of monitoring on a case-by-case basis. **The exact frequency of monitoring to be communicated by the specialist in all cases**.
• Shingles vaccination- immunocompromised patients aged 50 years and over are eligible for the shingles vaccine (Shingrix®) • The eligible age for Immunocompetent patients will change in a phased implementation over a 10-year period • For patients taking concurrent DMARDs and/or doses of prednisolone exceeding 20mg daily, a non-live vaccine should be used. Specialist input may be required. Refer to Green Book Chapter 6 (Contraindications and special considerations) and Green Book Chapter 28a (Shingles) for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended.	• Shingles vaccination: Single course. • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. Other vaccinations as per national schedule.

• COVID-19 vaccination is safe and recommended. • Repeat pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	
(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
Full blood count: • White blood cells <3.5x10^9/L • Lymphocytes less than 0.5x10^9/L • Neutrophils <1.6x10^9/L • Platelets <140x10^9/L • Eosinophilia >0.5x10^9/L	Withhold and discuss with specialist team.
Mean cell volume >105 fL	Consider interruption in treatment if there is a significant increase from baseline Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are normal discuss with specialist team urgently.
Blood Pressure	Treat hypertension in line with NICE guidance. If BP remains uncontrolled, withhold leflunomide and discuss with specialist team

Weight	If >10% weight loss with no cause identified, withhold leflunomide and discuss with specialist team.
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers.	Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above.
Acute systemic infection requiring antibiotics	Temporarily withhold leflunomide until the patient has recovered. Consider if additional investigations (e.g. FBC) and washout procedure required – discuss with specialist team. See section 6
Liver function tests: ALT>100 units/L, or any sudden increases (e.g. double of baseline), OR Unexplained fall in serum albumin <30g/L Jaundice	Withhold and discuss with specialist team. Consider washout procedure. See section 6 Assess for other causes of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.
Renal function: Creatinine increases of greater than 30% from baseline in the last 12 months, or CrCl reduces to <60ml/min	Use clinical judgement and repeat in 1 week. Rule out other causes. If still more than 30% from baseline withhold and discuss with specialist team.
Gastrointestinal disorders: Nausea Diarrhoea	Review for reversible causes of nausea. Discuss with specialist team if persistent or severe. Washout, under specialist advice, may be required if severe. See section 6 Diarrhoea is common and usually settles. If persistent or severe, withhold and discuss with specialist team.
Ulcerative stomatitis, haematemesis, black or bloody stools, or suspected pancreatitis.	Withhold and discuss with specialist team. Washout, under specialist advice, may be required if severe. See section 6

Symptoms of interstitial lung disease e.g. persistent cough, dyspnoea, fever	If leflunomide-induced lung disease is suspected, discuss with specialist team urgently. Consider washout procedure. See section 6 Treat with corticosteroids as advised by specialist and do not restart leflunomide.
Generalised rash	Discuss with specialist, washout may be required if severe. See section 6
Pregnancy	Stop leflunomide immediately and discuss with specialist team urgently. Washout should be considered. See section 12.

11. Advice to patients and carers

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The specialist will counsel the patient regarding the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Symptoms of chickenpox or contact with a person with chickenpox or shingles.
- Persistent cough, shortness of breath, or any other problems with breathing.
- Sore throat, mouth ulcers, high temperature, skin rash, swollen glands, or any other signs or symptoms of infection
- Signs or symptoms of liver problems, such as yellow skin or eyes (jaundice), itching all over, nausea or vomiting.
- Unexplained bleeding or bruising, black stools, or blood in the vomit or stools.
- Suspected or confirmed pregnancy.
- Any tingling, numbness or weakness in extremities that may indicate peripheral neuropathy

The patient should be advised:

- Moderate their alcohol intake as advised by the specialist team- the Versus Arthritis leaflet suggests no more than 4 units per week. Leflunomide | Versus Arthritis Taking alcohol and leflunomide together increases the risk of liver injury.
- Tell anyone who prescribes them a medicine that they are taking leflunomide. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- During a serious infection leflunomide should be temporarily discontinued until the patient has recovered from the infection.

- To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP as soon as possible if they become pregnant. All patients, both male and female, should inform their specialist well in advance if they are planning a pregnancy so that changes can be made to their treatment regime.

Patient information:

Leflunomide in rheumatoid arthritis: Leflunomide in rheumatoid arthritis (RA) | NRAS

and: Leflunomide Versus Arthritis patient information General Information: https://patient.info/medicine/leflunomide-tablets-for-arthritis-arava

12. Pregnancy, paternal exposure, and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

Leflunomide is contraindicated in pregnancy. Patients of child-bearing potential should use effective contraception during and for up to 2 years after treatment unless a washout procedure is followed (see below). See FSRH statement on contraception for women using known teratogenic drugs for information on contraceptives considered highly effective.

The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises Leflunomide may not be a human teratogen but there remains insufficient evidence to support use at the time of conception or during pregnancy. Women on Leflunomide considering pregnancy should stop and undergo a standard cholestyramine washout procedure, and switch to alternative medication compatible with pregnancy. If unintended conception occurs on Leflunomide the drug should be stopped immediately and a standard cholestyramine washout procedure given, with early referral to a foetal medicine department considered. The active metabolite of leflunomide is highly protein bound and because of extensive enterohepatic recycling its half-life is prolonged. The manufacturer currently recommends a two-year waiting period after discontinuation of the medicine before attempting to conceive.

If a waiting period of 2 years using effective contraception is considered unpractical or a woman becomes pregnant while taking leflunomide or within two years after discontinuation, the manufacturer recommends an immediate 11-day washout procedure with colestyramine or activated charcoal (see section 6).

To note: information within leflunomide datasheets with regards to plasma level testing of the active metabolite of leflunomide (teriflunomide) is only available from Sanofi (via Eurofins) if the patient is taking the Arava brand of leflunomide.

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

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

Breastfeeding:

Leflunomide and its metabolites pass into breast milk in animal studies. Manufacturer states that leflunomide is contraindicated for breastfeeding patients. The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises that Leflunomide is not recommended while breastfeeding

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

Paternal exposure:

Male patients should be aware of the possible male-mediated foetal toxicity. Effective contraception during treatment with leflunomide should also be guaranteed. The British Society for Rheumatology updated guideline on prescribing drugs in pregnancy and breastfeeding 2022 advises paternal exposure to Leflunomide is compatible with pregnancy.

13. Specialist contact information

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Please approach the patient's named secondary care clinician via the usual method of communication, currently email or letter; if more urgent:

- Advice and Guidance.
- Consultant Connect
- UHD switchboard – on-call rheumatologist during office hours
- Rheumatology advice line: It is not a direct connection (answerphone service) and is not for emergency calls. It requires patients/clinicians to leave a message via the answerphone service. The messages will be logged, triaged and answered in order of need.

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another the GP is responsible for letting the specialist team know if they are unhappy with continuing the shared care. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

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- British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs.
- British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids | Rheumatology | Oxford Academic 2022

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- Rozman B. Clinical pharmacokinetics of leflunomide – Clin Pharmacokinet 2002; 41 (6): 421-30 PubMed.

16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Via the usual methods

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened regarding this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period:	
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	

Treatment was started on, *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you agree, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) Not routinely used in the Dorset system; acceptance of shared care is implied by a nil return.

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which applies
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 patient's 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 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 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 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)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs

would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

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

Primary Care Prescriber signature: _____
Date: _____

Primary Care Prescriber address/practice stamp