DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Leflunomide for patients within adult services

(Note: May be used in combination with methotrexate with a different monitoring schedule outlined in section vii)

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 that the patient's condition is stable or predictable.
- When transfer agreed the patient will be given a supply sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant 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. **4.** Perform monitoring tests as specified in section vii. **5.** Be aware of the pregnancy contraindications affecting both men and women, as per the C/I and cautions section below. **6.** Adjust the dose as advised by the specialist. **7.** Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arises. e.g. signs of serious infection, liver or respiratory disease, unexplained bleeding or bruising, are exposed to chickenpox or shingles. **8.** Discuss with the specialist if the patient plans to become pregnant. **9.** Ensure the patient is offered an annual flu vaccination and a one off pneumococcal vaccination. Live vaccinations may be recommended on case by case basis following consultant/ specialist advice. – See section vi **10.** Report any adverse effects to the referring specialist and the MHRA yellow card scheme	**1.** Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol. 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 (Including pregnancy contraindications affecting both men and women) and provide the appropriate counselling. Provide an appropriate patient information leaflet. **3.** Perform baseline tests (as recommended in section vii) and provide results of baseline tests. **4.** Initiate, prescribe and monitor leflunomide for the first three months or until monitoring is stable **5.** Contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care protocol. **6.** Recommend dose of the drug and frequency of monitoring as per section 4vii. **7.** Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist. **8.** 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. **9.** Ensure that clear backup arrangements exist for GPs to obtain advice and support. **10.** Advise on the suitability for e.g. herpes zoster vaccination in accordance with national screening programme. **11.** Report any adverse effects to the MHRA yellow card scheme and GP.

Patient responsibilities

- Report to the specialist or GP if there is not a clear understanding of the treatment and share any concerns in relation to treatment with leflunomide.
- Take leflunomide as prescribed and avoid withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Inform specialist or GP of any other medication being taken including over-the-counter products.
- Report any adverse effects or warning symptoms to the specialist or GP whilst taking the leflunomide
  - 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, high temperature, skin rash, swollen glands, or any other signs or symptoms of infection
  - Signs/ symptoms of liver problems, e.g. 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
- Report any weight (>10%) loss to specialist or GP
- Women of childbearing potential should be told that a waiting period of 2 years after treatment discontinuation is required before they may become pregnant.
- Male patients should be aware of the possible male-mediated foetal toxicity. Reliable contraception during treatment with leflunomide should be guaranteed. Men should use effective contraception for 3 months after stopping leflunomide (BNF).
- Moderate alcohol intake to no more than 4 units per week.

- Not to drive or operate heavy machinery if leflunomide affects their ability to do so safely.
- 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 consultant/nurse via switchboard: 01246277271
Nurse advice line: 01246 513097
Available Monday-Thursday 9am-4 pm, Friday 9am-12pm

University Hospitals of Derby and Burton NHS Foundation Trust
Derby Hospital- Rheumatology helpline: 01332 787710

Queens Burton Hospital
01283 511511/566333
Dr R Laximinarayan ext 3167; Dr S Das
Dr D Ray ext 3211/3247
Clinical Rheumatology Nurse Specialist ext 4112
bhft.rheumatologynurses@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, UHDB, 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
Burton Hospitals 01283 511511 / 566333 ask for on-call pharmacist via switchboard
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: http://www.rheumatology.org.uk/
Leflunomide in rheumatoid arthritis: Leflunomide in rheumatoid arthritis (RA) | NRAS
and: https://www.versusarthritis.org/about-arthritis/treatments/drugs/leflunomide/
General Information: https://patient.info/medicine/leflunomide-tablets-for-arthritis-arava

4. CLINICAL INFORMATION

i. Prescribed Indications	**Licensed** Rheumatoid Arthritis (RA) Psoriatic Arthritis (PsA)
ii. Therapeutic summary	Leflunomide is an isoxazole derivative with immunomodulatory action on T and B proliferation and immunoglobulin synthesis. Suppression of chemotaxis of neutrophils and adhesion molecules with a reduction of synovial macrophages have also been demonstrated. Time to respond 2-3 months. It has an extremely long half-life and without a 'washout' will remain for at least 6 months. Therapeutic effect usually starts after 4 – 6 weeks and continued improvement is possible.
iii. Dose & Route of administration	**Rheumatoid arthritis**: 10-20mg once a day with monotherapy is used. Combination therapy with other DMARDs such as methotrexate, is used with caution and extra monitoring, the dose of the second DMARD (e.g. methotrexate) or the leflunomide can be reduced. **Psoriatic Arthritis**: 10mg - 20mg OD Absorption of Leflunomide is unaffected by food but tablets should be swallowed whole. 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.
iv. Duration of treatment	Depends on disease activity, benefit of treatment and side effects reported. 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 should be discussed with a specialist before initiating procedure.

v. Immunisation

- **Live vaccinations** JCVI Green book recommends that low dose corticosteroids (prednisolone <20mg daily) and oral traditional DMARD therapy at standard doses are not a contraindication in most patients, although clinician discretion is advised. Live vaccinations may be recommended on case by case basis following consultant/ specialist advice.
- Annual flu vaccination is recommended
- One off Pneumococcal vaccination recommended unless severely immunocompromised where a different schedule is needed. See JCVI for more information
- COVID-19 vaccination is safe and recommended.

vi. Adverse effects

See BNF / SPC for full list

The active metabolite of leflunomide has a long half-life, usually 1 to 4 weeks. Serious undesirable effects might occur (e.g. hepatotoxicity, haematotoxicity or allergic reactions, see below), even if the treatment with leflunomide has been stopped.

Common or very common
Abdominal pain; accelerated hair loss; appetite decreased; asthenia; diarrhoea; dizziness; gastrointestinal disorders; headache; leucopenia; nausea; oral disorders; paraesthesia; peripheral neuropathy; skin reactions; tendon disorders; vomiting; weight decreased

Uncommon
Anaemia; anxiety; electrolyte imbalance; hyperlipidaemia; taste altered; thrombocytopenia

Rare or very rare
Agranulocytosis; eosinophilia; hepatic disorders; infection; pancreatitis; pancytopenia; respiratory disorders; sepsis; severe cutaneous adverse reactions (SCARs); vasculitis

Frequency not known
Cutaneous lupus erythematosus; hypouricaemia; pulmonary hypertension; renal failure

Hepatotoxicity
Potentially life-threatening hepatotoxicity reported usually in the first 6 months. Discontinue treatment (and institute washout procedure—consult product literature) or reduce dose according to liver-function abnormality; if liver-function abnormality persists after dose reduction, discontinue treatment and institute washout procedure.

Adverse effects	Action for primary care
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers.	*Check FBC immediately and discuss with the specialist team. See haematological monitoring below*
Acute infection	During serious infections temporarily withhold leflunomide until the patient has recovered. Consider if additional investigations (e.g. FBC) and washout procedure required.
Nausea	Review for reversible causes. Discuss with specialist team if persistent or severe. Washout, under specialist advice, may be required if severe.
Diarrhoea	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.
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. Treat with corticosteroids as advised by specialist and do not restart leflunomide.
Generalised Rash or itch	Discuss with specialist, washout may be required if severe.
Liver Toxicity	It is highly recommended that LFT continue to be checked MONTHLY if used in combination with other hepatotoxic drugs
Hair loss (mild/moderate)	Consider dose reduction, if severe STOP and consider wash out- discuss with specialist

Headache	If severe and in absence of any secondary cause, consider dose reduction. If still persists the STOP the treatment and wash out after discussion with the specialist team

The washout procedure
This should be discussed with a specialist before initiating procedure.
This is given as colestyramine 8g taken three times daily or activated charcoal 50g four times daily, usually for 11 days.

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.

Concentration of active metabolite should be < 20 micrograms /l (measured on 2 occasions 14 days apart) in men & women before conception after a further, but shorter period. It is worth nothing that both agents will reduce absorption and therefore effectiveness of oral contraception.

vii. Monitoring Requirements

Consultant/specialist responsibilities
Best practice recommends the following precautions for specialists 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.

Pregnancy must be excluded before starting treatment

Consultant/specialist monitoring schedule
Baseline and 2 weekly until on a stable dose for at least 6 weeks

- FBC
- U&E including creatinine clearance (CrCl)
- ALT and/or AST and albumin
- Blood pressure
- Patient is asked to report any unexplained weight loss (>10%)

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

For rheumatic patients CRP/ESR may be done every 3 months. 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.

GP responsibility monitoring schedule
In patients following the 6 weeks of dose stability conduct monthly monitoring as above for three months followed by three monthly monitoring thereafter of:

- FBC
- U&E including creatinine clearance (CrCl)
- ALT and/or AST and albumin
- Blood pressure
- Patient asked to report any unexplained weight loss (>10%)

Leflunomide in combination with methotrexate (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 2 weekly until stable for 6 weeks. Dose and monitoring to be agreed with consultant.

- FBC
- U&E including creatinine clearance (CrCl)
- ALT and/or AST and albumin
- Blood pressure
- Patient is asked to report and unexplained weight loss (>10%)

Monitoring to then continue at 3 monthly intervals (revert back to previous monitoring frequency).

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

1. 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.
2. Parameters below are to be used as a guide for clinicians rather than absolute values, where monitoring should be based on individualized 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 x109/L Lymphocytes < 0.5x109/L Neutrophils <1.6 x 109/L Platelets <140 x 109/L Eosinophilia >0.5x109/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.
Blood Pressure	Treat hypertension in line with NICE guidance. If BP remains uncontrolled, withhold leflunomide and discuss with specialist team
ALT and/or AST >100 U/l, or any sudden increases (e.g. double of baseline), or Unexplained fall in albumin <30g/l or jaundice	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 for example >30% over 12 months and/or CrCl <60ml/mi	Contact Specialist **urgently** and consider interruption
Weight decrease (>10%)	Contact Specialist **urgently** and consider interruption if no cause identified.

viii. Contraindications and cautions

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 (requiring IV antibiotics or hospitalization) treatment should be discontinued.
- 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.

	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. • Use of concurrent haematotoxic or hepatotoxic DMARDs e.g. 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.
ix. Clinically relevant drug interactions ***For a full list of interactions please refer to the BNF***	• **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 generally 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, ceflaclor, 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.
x. Pregnancy, paternal exposure and breastfeeding	**Pregnancy:** **Leflunomide is contraindicated in pregnancy**. **Pregnancy should be excluded before commencement of Leflunomide.** Leflunomide must not be given to pregnant women or women of child bearing potential **unless** a highly reliable contraception is used. 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 FSRH statement on contraception for women using known teratogenic drugs for information on contraceptives considered highly effective. 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. The manufacturer also advises that the plasma levels of the active metabolite of leflunomide (teriflunomide) should be below 0.02mg/L at the end of the two-year period, confirmed by a second test after an interval of at least 14 days. If both tests show plasma levels of teriflunomide to be less than 0.02mg/L, then no teratogenic risk is expected. It is important to note that this test may only be available to patients who are taking the branded Arava® leflunomide tablets. If a waiting period of 2 years using effective contraception is considered unpractical, a washout procedure may be advisable. Following this, the recommendations regarding verification of teriflunomide levels remain. Two tests must be done no less than 14 days apart and conception is not advised until one and a half months after the first plasma concentration below 0.02mg/L. This test may only be available to patients who are taking the branded Arava® leflunomide tablets. If 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. 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. 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 be guaranteed. **Men should use effective contraception for 3 months after stopping leflunomide**. (BNF)
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 policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care
xii. Supply of ancillary equipment	N/A
Prepared by **In consultation with**	The Shared Care Guidelines Group, University Hospitals of Derby and Burton, Chesterfield Royal Hospital Dr Austin, Consultant Hepatologist Dr Bleiker, Consultant Dermatologist Dr Ferguson, Consultant Dermatologist Dr Goddard, Consultant Gastroenterologist and Hepatologist Dr O'Reilly, Consulant Rheumatologist Dr Raj, Consultant Rheumatologist Dr Badcock, Consultant Rheumatologist Dr Shum, Consultant Dermatologist The Derbyshire Medicines Management Shared Care and Guidelines Group
Reviewed by (2019)	Dr L Badcock, ACD Consultant Rheumatology Dr R Laxminaryan, Deputy ACD Rheumatology In conjunction with fellow consultant rheumatologist Dr. K Fairburn, Consultant rheumatologist CRH Angela Lawrence, Rheumatology Lead Clinical Nurse Specialist CRH
Reviewed (2023)	The Shared Care Guidelines Group, University Hospitals of Derby and Burton, Chesterfield Royal Hospital in line with NHSE/ RMOC Shared Care Protocols- leflunomide for patients in adult services, July 2022. https://www.england.nhs.uk/publication/shared-care-protocols/

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

Date Prepared: October 2011 **Reviewed:** September 2023 **Review Date**: August 2026

References

1. NHSE/ RMOC Shared Care Protocols- leflunomide for patients in adult services, July 2022. https://www.england.nhs.uk/publication/shared-care-protocols/
2. EMC Summary of Product Characteristics for Leflunomide accessed online 10/04/2017 , 1/8/2019
3. British National Formulary 70, September 2015 accessed online 1/8/2019; August 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, 1/8/2019, August 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