## DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC) and DHCFT MEDICINES MANAGEMENT COMMITTEE

## SHARED CARE AGREEMENT

### Lithium

# Appendix 1 – Assurance framework for the management of initiation, monitoring and shared care responsibilities with primary care

## 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.
- The patient will be given a supply of Lithium Carbonate or Citrate sufficient for 4 weeks maintenance therapy except where the patient's risk assessment indicates a smaller quantity would be more appropriate.

GP responsibilities Consultant/specialist responsibilities	
<ul> <li>Upon request, share relevant patient information to aid consultant in optimising patient care such as cardiac risk status, psoriasis, list of current medication, ensuring adequate contraceptive precautions in women.</li> <li>Ensure medical record updated to clearly indicate secondary care co-prescribing whilst consultant stabilises dose.</li> <li>Respond to shared care request and if agreed, prescribe lithium by brand name, noting any risk concerns, restrictions to supply quantity and target serum lithium level as advised by consultant.</li> <li>Undertake monitoring of serum lithium levels and other parameters (see 4 vi below) such as renal &amp; thyroid function and calcium levels.</li> <li>Monitor for signs/symptoms of change in cardiac function &amp; consult with psychiatrist to arrange ECG &amp; to consider other potential causes if new signs of dysfunction arise.</li> <li>Copy reports of any monitoring to consultant &amp; discuss how to manage any aberrant results.</li> <li>Take serum lithium levels 12 to 14 hours after the last dose. Ensure full documentation on the request form of time &amp; date of last dose and blood sampling time to assure validity of results.</li> <li>Have a system in place to ensure blood test results are reviewed before prescribing and that these and any changes to treatment are recorded in the patient's 'purple book' or can be uploaded to the 'App' by the patient.</li> <li>Report unacceptable adverse effects promptlyto consultant.</li> <li>Be aware of potential for drug interactions and monitor serum levels as appropriate (see 4 vii)</li> <li>Avoid abrupt discontinuation unless indicated by toxicity or severe side effects. If patient does not attend for routine screening please seek support from mental health team to facilitate.</li> </ul>	<ul> <li>Provide diagnosis.</li> <li>Perform baseline tests as indicated below, copy results to GP. Seek information from GP regarding any cardiac risk, psoriasis and list of current medication.</li> <li>Discuss treatment with patient including benefits, side-effects, blood tests, likely duration, increased relapse risk in bipolar disorder after rapid discontinuation or due to poor adherence.</li> <li>Provide patient with lithium information, alert card and record book, ensuring details are recorded. Advise on the availability of a smartphone 'App' if the patient prefers.</li> <li>Counsel women on necessary contraceptive precautions; liaise with GP/family planning. Advise women to discuss with consultant as soon as possible if becomes pregnant or planning pregnancy.</li> <li>Consider potential drug interactions. Ensure patient is asked about medication use including herbal and OTC at each review and check medicines using the Summary Care Record/MIG and SystmOne records.</li> <li>Risk-assess patient, seeking cardiology opinion if ECG abnormal (see 4 vi below). Risk-assess appropriate supply quantity (see referral criteria).</li> <li>Start lithium; arrange for serum levels. Inform and copy GP test &amp; weight results during dose stabilisation period.</li> <li>Ask GP if willing to share care. If agreed, transfer prescribing (by brand name) and monitoring of serum levels and other parameters (see 4 vi below) such as renal &amp; thyroid function, calcium levels and new clinical signs/symptoms of cardiac dysfunction.</li> <li>Indicate to GP the individual's target serum lithium level and any restrictions to supply quantity. Advise GP of any risk assessment judgements made e.g. cardiac, overdose or medication interaction risks.</li> <li>If care is not to be shared, undertake all monitoring, as indicated below, and prescribing and copy GP in reports</li> <li>Assees response in conjunction with adherence.</li> </ul>

## 2. AREAS OF RESPONSIBILITY

<ul> <li>Respond to any discontinuation plan advised by consultant.</li> <li>Discontinue shared care and refer back to Consultant and to Perinatal psychiatrist if informed of pregnancy by patient. Inform midwife and ensure the woman is received in consultant-led maternity care.</li> <li>Report any adverse effects to the referring specialist and the MHRA yellow card scheme.</li> </ul>	<ul> <li>Evaluate and advise on adverse events noted by GP or patient.</li> <li>Promptly communicate any changes to GP and update electronic patient records. Where there is a purple booklet or lithium app ensure these are also updated.</li> <li>Advise GP on when and how to discontinue treatment (see 4 iv below).</li> <li>Undertake individual review on a case by case basis according to clinical need</li> <li>Report any adverse effects to the MHRA yellow card</li> </ul>
	scheme
Patient	responsibilities
	sts at recommended intervals; Be aware that medicines may be
• Moderate their alcohol intake to no more than 14 u	units per week. Avoid recreational drugs.
Not to drive or operate heavy machinery if lithium	affects their ability to do so safely.
<ul> <li>Use an appropriate form of contraception as agree</li> </ul>	ed with their doctor/nurse/sexual health service

- Use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service.
  Seek medical attention if they develop diarrhoea or vomiting or become acutely ill for any reason. Be aware of possible side-effects, especially signs of high lithium level and report promptly to professional involved with their care
- Share any other concerns regarding lithium such as an incomplete understanding of their treatment, with professional involved with their care
- Maintain their fluid intake, particularly after sweating (e.g. after exercise, in hot climates or if they have a fever), if they are immobile for long periods or if they develop a chest infection or pneumonia.
- Women should talk to their doctor as soon as possible if they become pregnant or are planning a pregnancy
- Seek advice before self-medicating with over the counter preparations.
- Carry the lithium alert card. Keep the lithium record book (purple book in a safe place and show the alert card to healthcare professionals involved in their care. Take the record book with them to their GP, clinic appointments and to pharmacies when collecting lithium medication (or use the 'App' if patient prefers).

## 3. COMMUNICATION AND SUPPORT

i. Hospital contacts:	ii. Out of hours contacts and
Consultant psychiatrist caring for patient	procedures:
	Duty doctor via switchboard:
	South :01332 623700
	North: 01246 277271 (CRH) - bleep 291

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

Mental health team/consultant caring for patient (Individual CMHT contact details corresponded to patient and primary care by DHCFT)

#### www.medicines.org.uk

#### Patient information on this medicine can be found at the following links:

- NHS: <u>https://www.nhs.uk/medicines/lithium/</u>
- MIND: https://www.mind.org.uk/information-support/drugs-and-treatments/lithium-and-other-mood-stabilisers/lithium/

#### 4. CLINICAL INFORMATION (continued overleaf)

i.	Prescribed indications	Treatment and prophylaxis of mania, hypomania and bipolar disorder.
	Indications	Augmentation of antidepressants in treatment resistant depression. Control of aggressive behaviour and intentional self-harm.
ii.	Therapeutic	Mode of action not fully understood, competes with sodium at various sites in the body and
	summary	used in the indications described in (i) above.
	Dose & Route of administration	Lithium carbonate Starting dose typically 400 mg once daily, then adjusted according to patient response and 12- hour plasma levels. In some scenarios, such as acute mania, a higher starting dose may be preferable.
		Doses may initially be divided throughout the day but once-daily administration is preferred when plasma lithium concentration is stabilised in the target range (specified by specialist team).

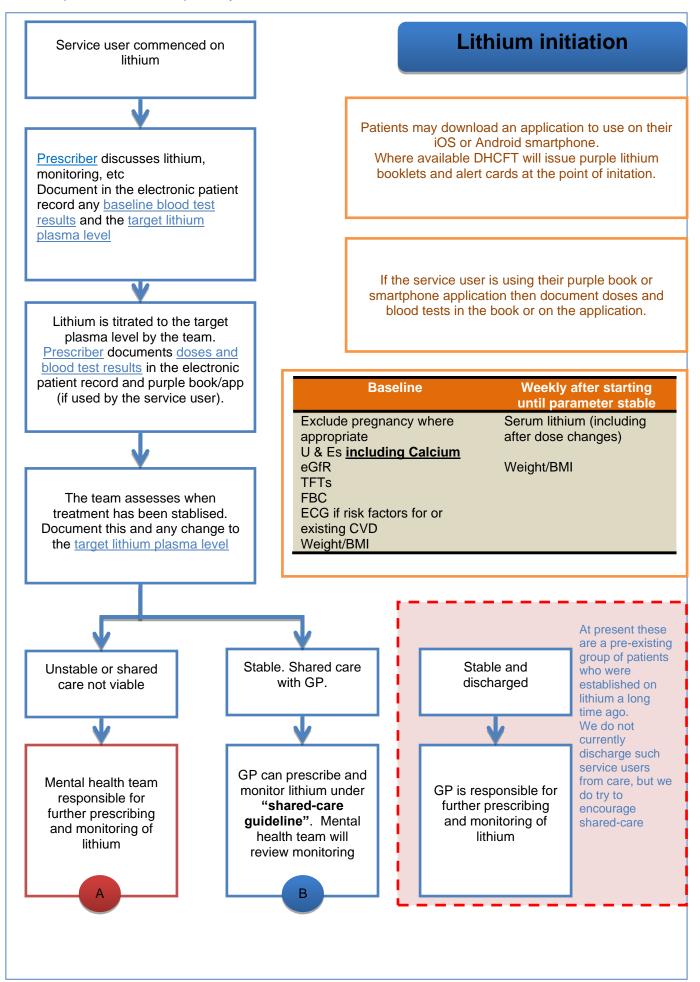
	Lithium carbonate tablets should be prescribed unless there is a sp swallowing difficulties.	pecific problem with	
	Lithium citrate Starting dose typically 509 mg or 520 mg twice daily (depending or evening, then adjusted according to patient response and 12-hour		
	Dosing is by slow upwards titration to achieve a target serum level usually between		
	0.4 – 0.8mmol/L. In bipolar disorder target level should be 0.6 – 0.8mmol/L but consider maintaining target level 0.8 – 1.0mmol/L for a trial of at least 6 months in those who have relapsed whilst taking lithium previously or who have subthreshold symptoms with functional impairment. Levels at the lower end of the therapeutic range 0.4 – 0.8mmol/L may be advisable in older adults or those at risk of renal impairment, heart disease or interacting concomitant medicine The specialist service will determine the target plasma range for each patient and advise the primary care prescriber accordingly.		
	Brands of lithium are <b>not</b> interchangeable due to considerable diffe bioavailability, inter-individual variability and narrow therapeutic inc <b>prescribed by brand name</b> .		
	Lithium is available as lithium carbonate (tablet formulations) and I formulations). The patient should be maintained on the same brailithium. If a switch in brand or formulation is considered, refer to the	nd and formulation of	
	Lithium tablets and liquids are not interchangeable. Liquid formula and doses are not equivalent to lithium carbonate; bioavailability is switch in formulation is considered, discuss with the specialist tear	s significantly different. If a	
	Extra care must be taken when prescribing lithium in liquid form, as some offer different strengths under the same brand names, and some brands are used for the liquid and tablet forms. Lack of clarity may lead to the patient receiving a sub-therapeutic or toxic dose.		
iv. Duration of treatment and discontinuation	Duration of treatment will be determined by the indication and the individual's previous history. According to the indication, assessment of response can take from 3 months or longer. Prophylaxis can sometimes be for many years. Unless adverse effects dictate otherwise, when discontinuing in bipolar disorder this should be done gradually over at least 4 weeks and preferably over 3 months. Monitor closely for early signs of mania or depression during dose reduction and for 3 months after stopping.		
v. Adverse effects	Serum lithium levels > 1.3mmol/L are generally associated with <u>acute toxicity</u> , signs & symptoms include: coarse tremor, nausea & vomiting, dysarthria, drowsiness, ataxia, blurred vision, muscle weakness, tinnitus, confusion, convulsions, ECG changes – STOP lithium immediately, urgently measure serum Lithium, U & Es and refer to hospital as necessary.		
	Other adverse effects include: weight gain (avoid sugary drinks), o disturbances e.g. nausea, diarrhoea, (but see acute toxicity above polyuria, exacerbation of psoriasis, acne.		
	Longer term - hypothyroidism (see monitoring vi), hypercalcaemia vi - serum calcium check), renal impairment & diabetes insipidus (s U&Es & avoid episodes of acute toxicity), bradycardia, arrhythmias	see vi - regular eGFR &	
vi. Monitoring	Consultant/ specialist responsibility	Weekly after starting	
requirements	until parameter stable		
	Exclude pregnancy where appropriate U & Es <u>including Calcium,</u> eGfR TFTs		
	FBC ECG if risk factors for or existing CVD Weight/BMI	Serum lithium (including after dose changes) Weight/BMI	
	<ul> <li>Additional baseline investigations (bipolar disorder):</li> <li>Cardiovascular status including pulse and blood pressure</li> <li>Metabolic status including fasting blood glucose, glycosylated haemoglobin (HbA1c) and blood lipid profile.</li> <li>Liver function tests (LFTs).</li> </ul>		
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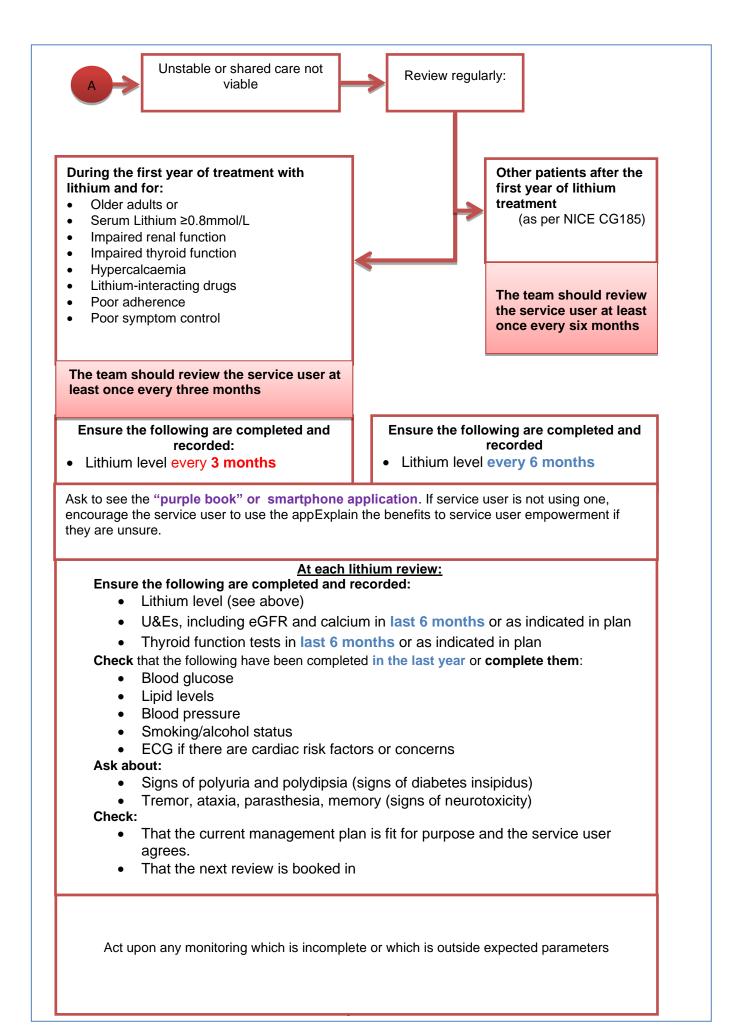
	Ongoing Monitoring- GP respo	onsibility (once taken pres	cribing)
	All patients to have lithium monitoring every 3 months for first year and then:		
	Every 3 months	Every 6 months (or more often if abnormal)	Annual
	<ul> <li>serum Lithium (12-16 hr level) in these patients During the first year of treatment with lithium and for:</li> <li>Older adults or</li> <li>Serum Lithium ≥0.8mmol/L</li> <li>Impaired renal function</li> <li>Impaired thyroid function</li> <li>Hypercalcaemia</li> <li>Lithium-interacting drugs</li> <li>Poor adherence</li> <li>Poor symptom control</li> </ul>	<ul> <li>Serum lithium (after the first year) for those with stable level and not in the 3 monthly category recommendations</li> <li>U &amp; Es <u>including</u> <u>Calcium, eGFR</u></li> <li>TFTs</li> <li>Weight/BMI</li> </ul>	<ul> <li>Physical health check i.e. blood glucose, BP, lipids smoking/alcohol</li> <li>ECG if cardiac risk factors continue or new concerns</li> <li>At each appointment</li> <li>Ask about polyuria or polydipsia symptoms (diabetes insipidus signs)</li> <li>Ask about tremor, ataxia, paraesthesia, memory (neurotoxic signs)</li> </ul>
	<ul> <li>Contraindications:</li> <li>Hypersensitivity to lithium or a</li> <li>Addison's disease</li> <li>Cardiac disease associated w</li> <li>Cardiac insufficiency</li> <li>Family or personal history of</li> <li>Patients with abnormal sodiu sodium diets</li> <li>Untreated hypothyroidism</li> <li>Severe renal impairment</li> </ul>	vith rhythm disorder Brugada syndrome m levels, including dehydra	
	<ul><li>Pregnancy (especially the first</li><li>Breastfeeding</li></ul>	st trimester), unless conside	ered essential
vii. Contraindications and cautions	<ul> <li>importance in hot weather, or enteritis or urinary infections,</li> <li>Review lithium dose if diarrho has an infection and/or profus</li> <li>Risk of seizures may be increative threshold, or in patients with</li> <li>Cardiac disease</li> <li>May exacerbate psoriasis</li> <li>Surgery: discontinue 24 hour once kidney function and fluid required prior to minor surger</li> </ul>	and fluid intake should be in during infectious diseases when dose reduction may bea and/or vomiting present se sweating. Adjustments in eased if co-administered with epilepsy. s prior to major surgery and d-electrolyte balance is normally by, providing fluids and elect	be required. t and in cases where the patient nay be required. th drugs that lower the seizure d re-commence post-operatively malised. Discontinuation is not trolytes are carefully monitored.
viii. Clinically	Check lithium levels after interact	ing meds are started (at 1	week) or stopped (within 4 weeks)
relevant drug interactions	Risk of lithium toxicity in sodium of diuretics, NSAIDs, ACE inhibitors Risk of potentially serious serotor SSRIs, triptan migraine products, stopping serotonergic agent. Risk of neurotoxicity due to concu phenytoin, haloperidol, phenothia Theophylline increases lithium ex increase lithium levels, whilst add	and Angiotensin II antagor <u>hergic syndrome</u> with concu- certain opioids e.g. tramac urrent diltiazem, verapamil, izines or SSRIs ccretion therefore stopping o	nists. urrent serotonergics including dol, which resolves rapidly on methyldopa, carbamazepine,
ix. Pregnancy, paternal exposure and breast feeding	All patients should be informed pregnancy and breastfeeding. <u>Pregnancy</u> : If a patient becomes pregnant wh immediately (but do not stop the	ilst on lithium, the specialis	s of taking this medicine during

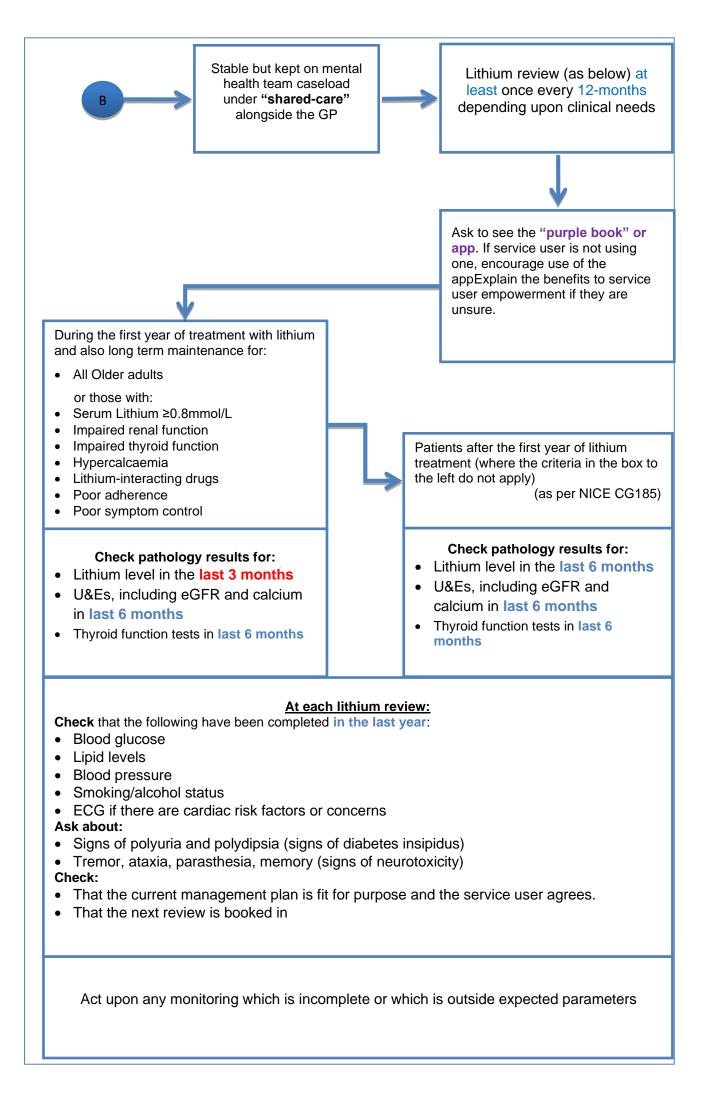
Lithium should not be used during pregnancy where possible, especially in the first trimester (risk of teratogenicity, including cardiac abnormalities). In certain cases where a severe risk to the patient could exist if treatment were stopped, lithium has been continued during pregnancy; under these circumstances prescribing is the responsibility of the specialist team.         Patients of child-bearing potential should be advised to use a reliable form of contraception. It is the responsibility of the specialist to provide advice on the need for contraception. It is the responsibility of providing this advice rests with both the GP and the specialist.         Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-LITHIUM-IN- PREGNANCY/         Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine pregnancy/Lithium/         Breastfeeding: Lithium is secreted in breast milk and there have been case reports of neonates showing signs of lithium toxicity. Breastfeeding should be avoided during treatment with lithium. Information for healthcare professionals: https://www.sps.nb.uk/medicines/lithium/         Paternal exposure: Animal studies have reported spermatogenesis abnormalities that may lead to impairment of fertility. It is unknown if this risk applies to humans.         xi. Supply of and reconstitution instructions       N/A         xii. 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 • NHSE/NHSCC guidance = learns which should not be routinely prescribed in primary care: guidance tor CCGS • NHSE/NHSCC		
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This does not replace the SPC, which should be read in conjunction with it		

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Date approved: June 2023 Review Date: May 2026 Appendix 1: Assurance framework for the management of initiation, monitoring and shared care responsibilities with primary care







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 <u>www.derbyshiremedicinesmanagement.nhs.uk/clinical\_guidelines/shared\_care\_guidelines</u>). 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 <b>{Insert</b> <i>medicine name</i> } from
The baseline test results are (if appl	licable):	
See overleaf for initiation criteria.		

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

	Specialist to complete
patient has been initiated on this therapy and has been on an optimised dose j	for the following
	period of time:
ne investigation and monitoring as set out in the shared care documents have	been completed Yes / No
and v	were satisfactory
condition being treated has a predictable course of progression and the patien	t can be suitably
maintained	by primary care Yes / No
The risks and benefits of treatment have been explaine	ed to the patient Yes / No
s of the specialist/specialist team/ Primary Care Prescriber / Patient and pharn	nacist have been
expla	ained and agreed Yes / No
nt has agreed to this shared care arrangement, understands the need for ongo	oing monitoring,
and has agreed to attend all necessa	ry appointments Yes / No
enclosed a copy of the shared care protocol which covers this treatment/the S	SCP can be found
here (insert elec	ctronic/ web link) Yes / No
I have included with the letter copies of the information the pati	ient has received Yes / No
I have provided the patient with sufficient medica	ation to last until
I have arranged a follow up with this patient in the foll	lowing timescale

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

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 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 <i>[insert reason]</i> . 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