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.
- Patients will only be referred to the GP once the GP has agreed in each individual case, subject to receiving the relevant clinical information.
- 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.

2. AREAS OF RESPONSIBILITY

GP responsibilities	Consultant responsibilities
• 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. • Ensure medical record updated to clearly indicate secondary care co-prescribing whilst consultant stabilises dose. • 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. • Undertake monitoring of serum lithium levels and other parameters (see 4 vi below) such as renal & thyroid function and calcium levels. • Monitor for signs/symptoms of change in cardiac function & consult with psychiatrist to arrange ECG & to consider other potential causes if new signs of dysfunction arise. • Copy reports of any monitoring to consultant & discuss how to manage any aberrant results. • Take serum lithium levels 12 to 16 hours after the last dose. Ensure full documentation on the request form of time & date of last dose and blood sampling time to assure validity of results. • 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. • Report unacceptable adverse effects promptlyto consultant. • Be aware of potential for drug interactions and monitor serum levels as appropriate (see 4 vii) • Avoid abrupt discontinuation unless indicated by toxicity or severe side effects. If patient does not attend for routine screening please seek support from neighbourhood team to facilitate.	• Provide diagnosis. • Perform baseline tests, copy results to GP. Seek information from GP regarding any cardiac risk, psoriasis and list of current medication. • 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. • 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. • 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. • Consider potential drug interactions. • Risk-assess patient, seeking cardiology opinion if ECG abnormal (see 4 vi below). Risk-assess appropriate supply quantity (see referral criteria). • Start lithium; arrange for serum level and weight monitoring; titrate and stabilise dose. Inform and copy GP test & weight results during dose stabilisation period. • 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 & thyroid function, calcium levels and new clinical signs/symptoms of cardiac dysfunction. • 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. • If care is not to be shared, undertake all monitoring and prescribing and copy GP in reports • Assess response in conjunction with adherence. • Evaluate and advise on adverse events noted by GP or patient.

• Respond to any discontinuation plan advised by consultant. • 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. • Report any adverse effects to the referring specialist and the MHRA yellow card scheme.	• Promptly communicate any changes to GP and document these in the patient's hand held record (purple book) • Advise GP on when and how to discontinue treatment (see 4 iv below). • Undertake individual review on a case by case basis according to clinical need • Report any adverse effects to the MHRA yellow card scheme

- Patients will only be referred to the GP once the GP has agreed in each individual case, subject to receiving the relevant clinical information.
- 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.

Patient responsibilities

- Attend appointments and have recommended tests at recommended intervals
- 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 procedures:**
Consultant psychiatrist caring for patient or Hospital Pharmacy Dept, Kingsway 01332 623700 ext 33268	Duty doctor via switchboard: South :01332 623700 North: 01246 277271 (CRH) - bleep 291
iii. Specialist support/resources available to GP including patient information: Hospital Pharmacy Dept, Kingsway Telephone: 01332 623700 ext 33268	

4. CLINICAL INFORMATION (continued overleaf)

Prescribed indications	Treatment and prophylaxis of mania, hypomania and bipolar disorder. Augmentation of antidepressants in treatment resistant depression. Control of aggressive behaviour and intentional self-harm.
i. Therapeutic summary	Mode of action not fully understood, competes with sodium at various sites in the body and used in the indications described in (i) above.

ii. Dose & Route of administration

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

Brands of lithium are **not** interchangeable due to considerable differences in product bioavailability, inter-individual variability and narrow therapeutic index and should be prescribed by brand name.

iii. 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.

iv. 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.

<u>Other adverse effects</u> include: weight gain (avoid sugary drinks), oedema, mild GI disturbances e.g. nausea, diarrhoea, (but see acute toxicity above), fine tremor, polydipsia, polyuria, exacerbation of psoriasis, acne.

<u>Longer term</u> - hypothyroidism (see monitoring vi), hypercalcaemia & hyperparathyroidism (see vi - serum calcium check), renal impairment & diabetes insipidus (see vi - regular eGFR & U&Es & avoid episodes of acute toxicity), bradycardia, arrhythmias (see vi – ECG if risk)

v. Monitoring requirements

Baseline	Weekly after starting 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

All patients to have lithium monitoring for 3 months for first year and then:		
Every 3 months serum Lithium (12-16 hr level) in these patients	Or Every 6 months (or more often if abnormal)	Annual
During the first year of treatment with lithium and for: • Older adults or • Serum Lithium ≥0.8mmol/L • Impaired renal function • Impaired thyroid function • Hypercalcaemia • Lithium-interacting drugs • Poor adherence • Poor symptom control	• Serum lithium (after the first year) for those with stable level and not in the 3 monthly category recommendations • U & Es **<u>including Calcium, eGFR</u>** • TFTs • Weight/BMI	• Physical health check i.e. blood glucose, BP, lipids smoking/alcohol • ECG if cardiac risk factors continue or new concerns At each appointment • Ask about polyuria or polydipsia symptoms (diabetes insipidus signs) • Ask about tremor, ataxia, paraesthesia, memory (neurotoxic signs)

vi. Clinically relevant drug interactions	Check lithium levels after interacting meds are started (at 1 week) or stopped (within 4 weeks) Risk of lithium toxicity in sodium depletion or reduced renal clearance so avoid concurrent diuretics, NSAIDs, ACE inhibitors and Angiotensin II antagonists. Risk of potentially serious serotonergic syndrome with concurrent serotonergics including SSRIs, triptan migraine products, certain opioids e.g. tramadol, which resolves rapidly on stopping serotonergic agent. Risk of neurotoxicity due to concurrent diltiazem, verapamil, methyldopa, carbamazepine, phenytoin, haloperidol, phenothiazines or SSRIs Theophylline increases lithium excretion therefore stopping concurrent theophylline can increase lithium levels, whilst adding it can lower lithium.
vii. Supply of ancillary equipment	Replacement / new Patient-held lithium treatment alert/reminder cards are available from Primary Care Support England (PCSE) through the following link http://pcse.england.nhs.uk/ using your practice log in details.
viii. Supply, storage and reconstitution instructions	N/A
ix. Prepared by	Reviewed and updated by Beverley Thompson, Deputy Chief Pharmacist, Derbyshire Healthcare Foundation Trust

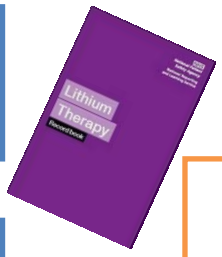
This does not replace the SPC, which should be read in conjunction with it.

Date approved: November 2015
Review Date: July 2019
Next Review Date: June 2022

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

Lithium initiation

Service user commenced on lithium



Supplies of purple books are available from Julia Deacon in the Pharmacy department at Kingsway Hospital. (ext 33263). Alternatively, patients may download an application to use on their iOS or Android smartphone

Prescriber discusses lithium, monitoring, etc and issues a purple book and explains its use. Document on PARIS/purple book along with baseline blood test results and the target lithium plasma level

Paris Live

If the service user is using their purple book or smartphone application then document doses and blood tests in the book or on the application. If not using the book, ask them if they want to. Provide another book if requested.

Lithium is titrated to the target plasma level by the team. Prescriber documents doses and blood test results in PARIS/purple book (if used by the service user).

Baseline	Weekly after starting until parameter stable
Exclude pregnancy where appropriate U & Es **including Calcium** eGfR TFTs FBC ECG if risk factors for or existing CVD Weight/BMI	Serum lithium (including after dose changes) Weight/BMI

The team assesses when treatment has been stablised. Document this and any change to the target lithium plasma level

Unstable or shared care not viable

Neighbourhood responsible for further prescribing and monitoring of lithium

A

Stable. Shared care with GP.

GP can prescribe and monitor lithium under **"shared-care guideline"**. Neighbourhood will review monitoring

B

Stable and discharged

GP is responsible for further prescribing and monitoring of lithium

At present these are a pre-existing group of patients who were established on lithium a long time ago. We do not currently discharge such service users from care, but we do try to encourage shared-care

A

Unstable or shared care not viable

Review regularly:

During the first year of treatment with lithium and for:

- Older adults or
- Serum Lithium ≥0.8mmol/L
- Impaired renal function
- Impaired thyroid function
- Hypercalcaemia
- Lithium-interacting drugs
- Poor adherence
- Poor symptom control

The team should review the service user at least once every three months

Other patients after the first year of lithium treatment
(as per NICE CG185)

The team should review the service user at least once every six months

Ensure the following are completed and recorded:

- Lithium level every **3 months**

Ensure the following are completed and recorded

- Lithium level **every 6 months**

Ask to see the **"purple book" or smartphone application**. If service user is not using one, offer a replacement if the service user wants one. Explain the benefits to service user empowerment if they are unsure.

At each lithium review:

Ensure the following are completed and recorded:

- Lithium level (see above)
- U&Es, including eGFR and calcium in **last 6 months** or as indicated in plan
- Thyroid function tests in **last 6 months** or as indicated in plan

Check that the following have been completed **in the last year** or **complete them**:

- Blood glucose
- Lipid levels
- Blood pressure
- Smoking/alcohol status
- ECG if there are cardiac risk factors or concerns

Ask about:

- Signs of polyuria and polydipsia (signs of diabetes insipidus)
- Tremor, ataxia, parasthesia, memory (signs of neurotoxicity)

Check:

- That the current management plan is fit for purpose and the service user agrees.
- That the next review is booked in

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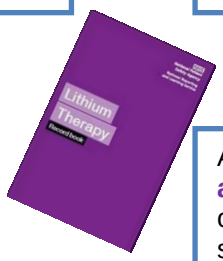
Act upon any monitoring which is incomplete or which is outside expected parameters

B

Stable but kept on neighbourhood caseload under **"shared-care"** alongside the GP

Lithium review (as below) at least once every 12-months depending upon clinical needs



Ask to see the **"purple book" or app**. If service user is not using one, offer a replacement book if the service user wants one. Explain the benefits to service user empowerment if they are unsure.

During the first year of treatment with lithium and also long term maintenance for:

- All Older adults

or those with:

- Serum Lithium ≥0.8mmol/L
- Impaired renal function
- Impaired thyroid function
- Hypercalcaemia
- Lithium-interacting drugs
- Poor adherence
- Poor symptom control

Check iCE/ICM for:

- Lithium level in the **last 3 months**
- U&Es, including eGFR and calcium in **last 6 months**
- Thyroid function tests in **last 6 months**

Patients after the first year of lithium treatment (where the criteria in the box to the left do not apply)

(as per NICE CG185)

Check iCE/ICM for:

- Lithium level in the **last 6 months**
- U&Es, including eGFR and calcium in **last 6 months**
- Thyroid function tests in **last 6 months**

At each lithium review:

Check that the following have been completed **in the last year**:

- Blood glucose
- Lipid levels
- Blood pressure
- Smoking/alcohol status
- ECG if there are cardiac risk factors or concerns

Ask about:

- Signs of polyuria and polydipsia (signs of diabetes insipidus)
- Tremor, ataxia, parasthesia, memory (signs of neurotoxicity)

Check:

- That the current management plan is fit for purpose and the service user agrees.
- That the next review is booked in

Paris Live

Act upon any monitoring which is incomplete or which is outside expected parameters

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_ADDRESS_3»
«GP_ADDRESS_4»
«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_ADDRESS_3» «CURRENT_ADDRESS_4» «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)

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:

1. The specialist/consultant requesting shared care
2. **AN <u>ANONYMISED</u> COPY OF THIS FORM ONLY** to the Medicines Management and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).