Milton Keynes Clinical Commissioning Group NHS | Central and North West London NHS Foundation Trust | Milton Keynes University Hospital NHS Foundation Trust

Working in Partnership

SHARED CARE PRESCRIBING GUIDELINE
Lithium Tablets and Oral Solution

NOTES to the GP

The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing lithium.

The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing agreement?
- Have you been provided with relevant clinical details including monitoring data?
- Have this document and the BNF provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

If, after reading the shared care agreement, you can answer YES to all these questions, then it is appropriate for you to accept prescribing responsibility.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with the appropriate Milton Keynes Mental Health specialist service, which will be willing to provide training and support.

GP agreement is voluntarily, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons and the cost of the medicine is NOT a barrier to sharing care. All prescribers will want to keep reasonably up-to- date with important developments in therapeutics. Practitioners have a duty to keep themselves informed of the medicines that are recommended for their patients.

Your CCG pharmacist will support you when making decisions about shared care

The patient's best interests are always paramount

Date prepared: September 2016	**Review date:** October 2018
Approved by: Milton Keynes Prescribing Advisory Group	**Date approved:** October 2016

Introduction and reason for shared care

To ensure continuation of care in the Community

LITHIUM Tablets and Oral Solution (Priadel®)

1. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient's condition is stable i.e. little or no immediate change in condition is expected.
- Patients will only be referred to the GP once the GP has agreed in each individual case and the mental health team will continue to provide prescriptions until successful transfer of responsibilities as outlined below.
- The patient will be commenced and stabilised on lithium treatment before referral to the GP for shared care. This will depend on the individual patient response and is not defined by a specific period of time.
- During the period of stabilisation, the prescribing and monitoring responsibility lies with the Consultant Psychiatrist.

2. AREAS OF RESPONSIBILITY

Consultant

1. Confirm a diagnosis and assess the need for and suitability of lithium treatment
2. Obtain consent and ensure provision of verbal and written information on lithium treatment to patient. Lithium treatment packs – A lithium treatment pack should be given to patients on initiation of treatment with lithium. The pack consists of a patient information booklet, lithium alert card, and a record book for tracking serum-lithium concentration. Packs may be purchased from 3M; Telephone number: 0845 610 1112; email: nhsforms@mmm.uk.com It should be explained that the record book will be used to record and track lithium dosing, blood results and other relevant tests.
3. Inform the patient of the signs of lithium toxicity and risks of teratogenicity in women of child bearing age.
4. Arrange for appropriate baseline testing as per guidance in this document.
5. Establish details of concurrently prescribed medication and consider the potential for interaction of these medicines with lithium; liaising with the GP to review or alter other medicines or increasing monitoring if necessary.
6. Initiate treatment, optimise dose and prescribe (by brand name), ensuring all required monitoring is conducted until the GP agrees to share care.
7. Request the GP to share care by completing the required shared care form at the end of this document.
8. To inform the patient of the outcome of the request for shared care.
9. Provide GP with dose, formulation and brand name of lithium.
10. Provide GP with the target serum levels for lithium and advice on action required when the serum level is outside this range.
11. Provide medication for the next 4 weeks, if shared care is agreed, and explain the transfer process (the need for an initial appointment with the GP to be made within 3 weeks in order to obtain the first prescription)
12. Advise GP on dose changes and concurrent therapy.
13. Advise GP on frequency of and maintenance monitoring requirements of lithium therapy.
14. Request for monitoring results and review these results at appointments with patients.
15. Monitor benefits of treatment, side effects and treatment adherence at appointments with patient (frequency indicated by clinical condition) and inform GP of progress or review of treatment where necessary.
16. To review the overall package with patient every 6 months or sooner if indicated.
17. To ensure backup advice is given in a timely manner (see appendix A) regarding the treatment plan in the event of abnormal laboratory test results or change in mental/physical condition.
18. To inform GP if appointments are not attended.
19. To update the patient held record book when any biochemical checks or dose changes are made.
20. To provide a clear plan for lithium treatment on discharge of patient from mental health services.

The consultant will retain overall responsibility for the patient however tasks may be undertaken by other members of the team.

GP

1. Receive request for shared care from Consultant, consider clinical details and own competency against agreement.
2. Reply to the senior trust prescriber requesting shared care (in writing) within 14 days by completing section B of this document.
3. Prescribe lithium **(by brand name)** following stabilisation.
4. Avoid prescribing medicines that interact with lithium wherever possible, if unavoidable inform the consultant team of any clinically important interactions identified and obtain advice on managing treatment (see BNF appendix 1 and SPC).
5. Monitor patients overall health and notify the Consultant of any changes in patients' physical state, adherence or other clinical concerns e.g. considering pregnancy.
6. Check patient for adverse effects and signs of toxicity, at each appointment, and inform the consultant team of any significant adverse effects; such effects include paraesthesia, ataxia, tremor and cognitive impairment, which can occur at therapeutic levels of lithium. Also check the patient for symptoms of hypercalcaemia, polyuria or polydipsia and manage as appropriate. The frequency of appointments is determined by patient's clinical condition.
7. Ensure blood tests are monitored as directed by consultant team and that results are within normal range before routinely authorising repeat prescriptions. If tests are overdue and patient shows no physical signs of toxicity, repeat prescription may be issued (consider shorter supply) and tests arranged. Do not increase dose of lithium without discussion with the consultant specialist. For monitoring requirements of lithium, refer to monitoring section.
8. To update the patient held record book (if available) when any biochemical checks or dose changes are made. Numerical values for test results must be documented.
9. Communicate any abnormal test results identified to Consultant team directly and promptly as guided by

Appendix A

10. To inform the consultant team if patient refuses to carry handheld record book. Test results will need to be directly communicated between GP and Consultant team, if joint electronic access to results is not available, in this case.
11. Discussion with consultant team if patient is becoming uncertain about continuing lithium or if there are compliance issues with medication or monitoring,
12. Withhold or stop treatment on advice of specialist.

Patient Role

1. To attend all appointments with GP and Mental Health Specialists
2. Report to the specialist or GP if he or she does not have a clear understanding of the treatment
3. Discuss experience of treatment with the specialist or GP
4. Report any adverse effects to the specialist or GP
5. Share any concerns in relation to treatment with lithium
6. Notify the specialist or GP of any medication changes (over the counter, alternative or prescribed) so prescriber can check for interactions.
7. Talk to specialist or GP as soon as possible if she is planning pregnancy or if she might be pregnant.
8. Carry handheld record book and ensure blood tests results are entered by the GP or mental health team.
9. Show handheld record book /lithium alert card when buying any new medicines or supplements over the counter, visiting the dentist or any other healthcare professional or if admitted to hospital.

3. COMMUNICATION AND SUPPORT

CNWL Mental Health services contacts:	**Out of hours contacts & procedures:**
(the referral letter will indicate named consultant and their contact details) **CNWL Milton Keynes Headquarters** **Milton Keynes Hospital** **Standing Way** **Eaglestone, Milton Keynes, Bucks** **MK6 5NG** **01908 243933**	Back-up advice and support from **On-Call Psychiatrist** accessed via MKUH switchboard 01908 660033 Back-up advice and support from CNWL **On-Call Pharmacist** via St Charles Hospital switchboard on 0208 206 7000

Specialist support/ resources available to GP including patient information:

- NICE CG185 – Bipolar disorder: assessment and management , Updated February 2016: https://www.nice.org.uk/guidance/cg185
- BAP Guidelines. Evidence-based guidelines for treating bipolar disorder: revised second edition - recommendations from the BAP. Goodwin GM, for the Consensus Group of BAP. J. Psychopharmacology 2009; 23 (4):346-388
- Current BNF https://www.medicinescomplete.com/mc/bnf/current/
- Manufacturer's Summary of Product Characteristics (SPC) https://www.medicine.org.uk/emc/
- CNWL Medicines Information Service (Tel: 020 8206 7271 or by email medinfo.cnwl@nhs.cnwl@nhs.net Mon-Fri) or your mental health pharmacist at your local mental health service
- CCG pharmacy team
- Patient's Lithium Therapy Pack
- Patient Safety Alert, National Patient Safety Agency NPSA 2009/PSA005: Safer Lithium Therapy http://www.nrls.npsa.nhs.uk/alerts/
- CNWL Choice and Medication Website: http://www.choiceandmedication.org/cnwl/class/7/
- CNWL Summary of Physical Health Monitoring with Mood Stabilisers and Antipsychotics: http://trustnet.cnwl.nhs.uk/Documents/Physical_Health_Monitoring_with_Mood_Stabilisers_AntipsychoticsBooklet.pdf#search=Summary%20of%20Physical%20Health%20Monitoring%20with%20Mood%20Stabilisers%20and%20Antipsychotics
- Standard Operating procedure: prescribing and monitoring of lithium therapy

4. CLINICAL INFORMATION

<table>
<tr><td>Indications:</td><td>1. In the management of acute manic or hypomanic episodes.
2. In the management of episodes of recurrent depressive disorders where treatment with other antidepressants has been unsuccessful.
3. In the prophylaxis against bipolar affective disorders.
4. Control of aggressive behaviour or intentional self- harm</td></tr>
<tr><td>Therapeutic Summary</td><td>The aim of treatment with lithium is to control symptoms and prevent relapse. Lithium should be initiated by or on the advice of a Psychiatrist. Lithium has a narrow therapeutic index.
Levels below 0.4mmol/L are sub therapeutic whilst those above 1.2mol/L are toxic in most patients.
Toxicity is serious and clinical consequences include seizures and irreversible renal damage. Even when lithium levels are within range the risk of long term side effects which include, hypothyroidism, hypercalcaemia, weight gain and renal impairment, remain. Changes in renal function, fluid balance and electrolyte levels can lead to lithium toxicity. Significant alterations in lithium levels can occur with commonly prescribed and over the counter medication such as NSAIDs. It is therefore important that patients' blood tests are monitored regularly in accordance with NICE guidance.
If lithium is to be discontinued, particularly in cases of high doses, the dose should be reduced gradually as abrupt withdrawal can cause relapse. Lithium should be stopped 24 hours before major surgery, but the normal dose can be continued for minor surgery if fluids and electrolytes are carefully monitored.</td></tr>
<tr><td>Dose and Administration</td><td>Dosage must be individualised depending on serum lithium levels and clinical response. The dosage necessary to maintain serum lithium levels within the therapeutic range varies from patient to patient. The minimum effective dose should be sought and maintained. The NICE guidance states that when initiating long-term treatment, clinicians should aim for levels of 0.6-0.8mmol/L normally and 0.8-1.0mmol/L in patients who have relapsed previously on lithium or have sub-syndromal symptoms.
Lithium should be prescribed by brand name as there are two different salts of lithium available (lithium carbonate and lithium citrate) and preparations vary widely in bioavailability. Dosing frequency depends on preparation prescribed. Liquid preparations should be prescribed twice daily. Other lithium preparations are usually prescribed as a single dose at night. Modified release tablets should not be crushed or chewed.</td></tr>
<tr><td>Duration of treatment</td><td>Full benefit may not occur for 6 to 12 months. In those with a positive response, treatment is likely to be long-term to prevent relapse.</td></tr>
<tr><td>Preparations available</td><td>Lithium Carbonate Tablet and Lithium Citrate Liquid (Priadel®)
Strength Available — Amount of Lithium (Li+)
200mg m/r (scored) — 5.4mmol/200mg
400mg m/r (scored) — 10.8mmol/400mg
520mg/5ml — 5.4mmol/5ml</td></tr>
<tr><td>Drug Interactions (refer also to BNF- Appendix 1 or SPC)</td><td>
<table>
<tr><th>Interaction</th><th>Effect</th></tr>
<tr><td>Diuretics (mainly thiazides),NSAIDs, ACE inhibitors, angiotensin II antagonists</td><td>Significant risk of toxicity as affects renal function and lithium excretion. May result in significantly increased lithium levels. Unless lithium levels monitored and dose adjusted, concomitant use should be avoided if possible</td></tr>
<tr><td>Metronidazole, tetracycline and drugs affecting electrolyte balance</td><td>Use with caution as may increase lithium levels</td></tr>
<tr><td>Theophylline, and marked consumption of caffeine or sodium containing preparations e.g. non-prescription antacids/urinary alkalinising agents</td><td>May cause a reduction in lithium levels and potential for relapse of symptoms</td></tr>
<tr><td>Steroids</td><td>May alter lithium excretion and should be avoided</td></tr>
<tr><td>Selective serotonin reuptake inhibitors</td><td>Although commonly prescribed together, consider serotonergic syndrome if increased agitation/ autonomic changes, rigidity occur and consider reducing/stopping SSRI dose</td></tr>
<tr><td colspan="2"></td></tr>
</table>
</td></tr>
</table>

Adverse Effects (Refer also to SPC and BNF Appendix 1)	**Adverse Effect**	**Frequency**	**Management**
	Fine tremor	Common	Check lithium level, may be a sign of toxicity. Consider other drug causes and a dose reduction in liaison with mental health team.
	GI disturbances	Common	Nausea/diarrhea usually transient following initiation. Give with food or change brand. If diarrhea or vomiting severe; check lithium level and U&Es- may be a sign of toxicity.
	Polyuria	Common	Usually transient following initiation. Consider dose reduction in liaison with mental health team. If persists, check creatinine and U&Es.
	Polydipsia	Common	Consider dose reduction in liaison with mental health team. Advise patient drinks fluid in moderation to avoid changes in fluid balance.
	Weight gain	Less common	Advise on exercise and diet.
	Oedema	Less common	Consider dose reduction in liaison with mental health team. Do not treat with diuretics.
	Hypothyroidism	Less common	Treat with levothyroxine. Monitor TFTs.
	Signs of toxicity: Blurred vision, muscle weakness, drowsiness, coarse tremor, dysarthria, ataxia, nausea & vomiting, confusion, convulsions, ECG changes (flat or inverted T waves, QT prolongation)	Rare	Stop Lithium immediately, measure serum lithium, creatinine, urea & electrolytes. Refer to hospital if clinical condition warrants
Contraindications	• Hypersensitivity to lithium or to any of the excipients. • Cardiac disease. • Cardiac insufficiency. • Severe renal impairment. • Untreated hypothyroidism. • Breast-feeding. • Patients with low body sodium levels, including for example dehydrated patients or those on low sodium diets. • Addison's disease. • Brugada syndrome or family history of Brugada syndrome.		

<table>
<tr><td>MONITORING REQUIREMENTS</td><td colspan="3">Baseline Tests should be completed by Consultant and should include eGFR, U&E, creatinine, LFT, thyroid function, fasting glucose and lipids (random if fasting not possible), FBC, Ca, ECG, BP &Pulse, Weight and BMI.
When to take Lithium Plasma levels:
Take the first sample 5-7 days after initiation and repeat every 5-7 days until the desired therapeutic level and dose is reached and patient is stable. Sample 12 hours post dose.
Lithium levels should be monitored 5-7 days after every change in dose, brand or formulation or after initiating or stopping other medicines which may affect lithium level (e.g. diuretics, NSAIDs, ACEI). Once the dose and level are stable the routine monitoring requirements are as follows:</td></tr>
<tr><td></td><td>Test</td><td>Frequency</td><td>Responsibility</td></tr>
<tr><td></td><td>Lithium Level</td><td>See above information
Every 3-6 months* (consultant to specify as appropriate based on risk factors)</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>Renal Function (eGFR)</td><td>Every 6 months*</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>Serum Creatinine</td><td>Every 6 months*</td><td>Prescribing doctor</td></tr>
<tr><td></td><td>Thyroid Function</td><td>Every 6 months</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>Fasting Glucose</td><td>Every 6 months</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>Fasting Lipids (random if fasting not possible)</td><td>Every 12 months for over 40s</td><td>Prescribing doctor</td></tr>
</table>

<table>
<tr><td></td><td>Test</td><td>Frequency</td><td>Responsibility</td></tr>
<tr><td></td><td>FBC</td><td>Repeat only if clinically indicated</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>Calcium</td><td>Every 6 months</td><td>Prescribing doctor</td></tr>
<tr><td></td><td>ECG</td><td>The need for further monitoring should be assessed on an individual basis.</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>BP and Pulse</td><td>Every 12 months</td><td>Prescribing Doctor</td></tr>
<tr><td></td><td>Weight and BMI</td><td>Every 6 months* Should be accompanied with an assessment of diet, nutritional status and levels of physical activity.</td><td>Prescribing doctor</td></tr>
<tr><td></td><td>Assessment of symptoms of neurotoxicity including paraesthesia, ataxia, tremor and cognitive impairment</td><td>Every appointment</td><td>GP and Mental Health Team</td></tr>
<tr><td></td><td colspan="3">*NICE recommends that lithium levels may be checked only 6-monthly in stable patients established on lithium for over a year (however this recommendation is outside the manufacturer's recommendations and would constitute off-label use).
3-monthly monitoring is still recommended for older people, people taking drugs that interact with lithium, people at risk of impaired renal or thyroid function, raised calcium levels or other complications, those with poor symptom control or poor adherence, and those whose last plasma lithium level was 0.8mmol/L.
More frequent monitoring is required if clinical indications arise or in 'high risk' patients (e.g. clinical deterioration, signs of toxicity present, an inter-current infection, abnormal blood test results, a change in sodium/fluid intake, or symptoms suggesting abnormal renal or thyroid function such as unexplained fatigue, if the patient is starting interacting medication such as ACE inhibitors, NSAIDs, antacids or diuretics). In these situations frequency will be on the advice of the mental health team and should be documented in the patients care plan and notes.</td></tr>
</table>

Appendix A: Normal ranges for blood tests and action required if the result falls outside normal range

Blood Test	Normal Range* (May differ according to lab)	Action if below normal range	Action if above normal range
Lithium level (12 hrs. post dose)	Once daily dosing: 0.4-1.0 mmol/l. Twice daily dosing: 0.5-0.8 mmol/l (lower end of range for elderly patients)	Contact consultant psychiatrist for advice on dose changes	**SAME DAY CONTACT** with patient and consultant psychiatrist. Assess for symptoms of toxicity. Reduce/omit dose as advised by consultant. Repeat plasma level after 7 days. Renal function will need to be assessed. Review use of over the counter medication and if any medicines recently initiated. Admission to hospital for supportive measures may be required in some cases.
eGFR	>90ml/min/1.73m^2 is considered normal	**Action if eGFR ≤90mllmin/1.73m^2 & ≥60mllmin/1.73m^2**	**Action if eGFR < 60 ml/min/1.73 m^2**
		Contact consultant psychiatrist for advice on dosing and frequency of lithium level monitoring.	**SAME DAY CONTACT** with patient and consultant psychiatrist. Increase frequency of eGFR monitoring and lithium monitoring. The decision whether to continue lithium depends on clinical efficacy, and degree of renal impairment; prescribers must consider seeking advice from a renal specialist and a clinician with expertise in the management of bipolar disorder on this. Lithium is contra-indicated in severe renal insufficiency (eGFR <30ml/min/1.73 m^2)
Serum Creatinine	40-120 micromol/L	**Action if below normal range**	**Action if above normal range**
		GP to assess relevance	**SAME DAY CONTACT** with consultant psychiatrist. Increase frequency of Serum Creatinine monitoring and lithium monitoring as agreed with consultant.
Thyroid Function	TSH- 0.3-5.5mU/L Free Thyroxine (fT4) 9-23 pmol/L	**Action if below normal range**	**Action if above normal range**
		GP to assess relevance and treat	If substantially raised make **SAME DAY CONTACT** with consultant psychiatrist and agree action.

LITHIUM Shared Care Guideline: Prescribing Agreement
(Note: Sections A and B MUST be forwarded to GP and returned by GP back to the Mental Health Consultant together)

Section A: To be completed by the Mental Health Team consultant initiating the treatment	
GP Practice Details: Name: …… Address: …… Tel no: …… Fax no: …… NHS.net e-mail: ……	**Patient Details:** Name: …… Address: …… DOB: ……/……/…… Hospital number: …… NHS number (10 digits): ……
Consultant name: …… **Clinic name:** …… **Contact details**: Address: ..... Tel no: …… Fax no: …… NHS.net e-mail: ……	
Diagnosis:	**Brand name, formulation & dose to be prescribed by GP:**
Next CNWL Mental Health appointment: ……/……/……..	

Dear Dr. ……..,
Your patient was seen on …../…../……and I have started …… (insert drug name and dose) for the above diagnosis. I am requesting your agreement to sharing the care of this patient from …../…../…….. in accordance with the (attached) Shared Care Prescribing Guideline (approval date: …./…./……..). Please take particular note of Section 2 where the areas of responsibilities for the consultant, GP and patient for this shared care arrangement are detailed.

The patient has been given information outlining potential aims and side effects of this treatment and a Lithium Therapy Pack supplied .The patient has given me consent to treatment possibly under a shared care prescribing agreement (with your agreement) and has agreed to comply with instructions and follow up requirements.
Please refer to the most up to date test results and monitor Lithium as per the requirements of this shared care agreement. We are grateful for your help in prescribing and monitoring lithium therapy for this patient.

Other relevant information:……
……

Consultant signature:…….. Date:…../…../……

CNWL will continue to supply lithium until the Care co-ordinator has arranged an appointment with the GP.

Section B: To be completed by the GP and returned to the consultant as detailed in Section A above

Please sign and return your agreement to shared care within 14 days of receiving this request
Tick which applies:
□ I accept sharing care as per shared care prescribing guideline and above instructions
□ I would like further information. Please contact me on:…….
□ I am not willing to undertake shared care for this patient for the following reason:
……

GP name: ……

GP signature: ……Date: …/…/…..

(Note: Sections A and B MUST be forwarded to GP and returned by GP back to the hospital together)