

SHARED CARE PROTOCOL FOR THE PRESCRIBING AND MONITORING OF LITHIUM

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1. Introduction

This document describes the protocol for patients prescribed lithium to be managed safely in primary care, secondary care and across the interface. It sets out responsibilities for each party, to ensure that lithium is initiated, prescribed, dispensed and monitored appropriately and according to the National Patient Safety Alert (NPSA) and NICE guidelines.

Background

Lithium is used for the prophylaxis and treatment of mania and hypomania, bipolar affective disorder and refractory unipolar depression. The therapeutic range for lithium is narrow and all patients prescribed this medicine should be subject to routine monitoring. As patients frequently transfer between primary and secondary care there should be clear guidelines about how this monitoring should be carried out.

This protocol fulfils the recommendations from NHS England¹ and NICE² Clinical guideline CG185 to establish a shared care protocol with the patient's GP for the prescribing and monitoring of lithium. It also reflects the recommendations from the alert 'Safer lithium therapy' issued by the National Patient Safety Agency³ in December 2009 (NPSA/2009/PSA005).

2. Responsibilities

Secondary Care Prescriber Responsibilities

1. Assess the patient, determine and document a diagnosis, and decide and document a management strategy that includes the establishment of a care programme approach, and involves the community mental health teams.
2. Patients on CPA (Care Programme Approach) should remain with Secondary Care unless agreed by GP and stated on the CPA.
3. Ensure baseline physical examinations are carried out and documented, including U&Es, eGFR, BP and pulse, FBC, calcium, thyroid function tests, BMI and where necessary ECG if not already provided by GP (see appendix 1 of Chapter 3 EPUT Formulary and Prescribing guideline), especially where there is a history of cardiac disease or where a patient is also prescribed a tricyclic antidepressant, venlafaxine or an antipsychotic.
4. Discuss the anticipated benefits and side effects/ risks of lithium with patient, and document this.
5. Discuss contraceptive use with female patient of child-bearing age, and document their current method of contraception. Female patients of child-bearing potential should use effective contraceptive methods during treatment with lithium. Prescribe effective contraception if the patient is an inpatient, and document that this has been initiated, before prescribing lithium. If patient is an outpatient, direct the patient to their GP to obtain effective contraception.

Ensure that effective contraception has been initiated, before prescribing lithium for the outpatient.

6. Issue a Lithium Treatment Pack (containing lithium booklet, alert card and record book) at the same time as the first prescription, completing the patient details within the pack, and document this.
7. Discuss ongoing monitoring requirements with patient, and the importance of taking the Lithium Treatment Pack to all appointments and the pharmacy when prescriptions are dispensed, and document this.
8. Explain what a shared care arrangement means for the patient and why it might be an option in their case. The patient or their carers should have the opportunity to ask questions and explore other options if they don't feel confident that shared care will work for them. They should be fully involved in, and in agreement with, the decision to move to a shared care model for their ongoing care. The patient will not be used as a conduit for informing the GP that prescribing is to be transferred.
9. Obtain the patient's agreement to be involved in a shared care model. As part of the consent process, patients must be made fully aware of all monitoring requirements, in line with national guidance on consent. Document the patient's agreement.
10. Review risk of drug interactions between patient's current medicines and lithium (see Annex 1: Significant interactions).
11. Initiate lithium treatment, and document this.
12. Complete the lithium record book within the Lithium Treatment Pack, with details of lithium brand, formulation, dose, target levels (upper and lower), and test results (lithium level, e-GFR, TFTs, weight). Document these in patient's healthcare record too.
13. Ask GP to participate in a shared care agreement, using letter in Appendix 1, and document this. Seek agreement for prescribing, and seek agreement for who will undertake monitoring. Inform GP of any additional monitoring requirements if the patient is in a "Special Group" (see Table 2) (detailing what is to be monitored, frequency of monitoring, duration of this monitoring, and reason for this additional monitoring), so that they are fully aware of the implications of shared care for this patient.
14. Continue to prescribe lithium until the dose has been stable for at least four weeks, and document this.
15. If GP chooses not to participate in a shared care agreement, the CCG should be asked for assistance in facilitating suitable prescribing arrangements for the patient. Document the arrangement.
16. If GP agrees to participate in a shared care agreement, document this. When patient is stable send a completed Appendix 2 to GP, requesting that they start the shared care prescribing of lithium. The secondary care prescriber will supply 28 days of lithium to cover the transition period. The patient should then be informed to obtain further prescriptions from the GP.
17. When completing Appendix 2 include the following:
 - Full details of diagnosis, lithium brand, formulation, dose, target levels (upper and lower), recent test results (lithium level, e-GFR, TFTs, weight), and next due dates.

- Inform GP, if appropriate, of any additional monitoring requirements if the patient is in a “Special Group” (see Table 2) (detailing what is to be monitored, frequency of monitoring, duration of this monitoring, and reason for this additional monitoring).
 - Communicate what has been agreed as to which party will undertake routine monitoring, and any additional monitoring.
 - Include details of the circumstances under which the patient should be referred to the secondary care prescriber.
 - Request GP to observe for side-effects and signs of lithium toxicity.
18. If the patient is readmitted to hospital undertake any routine monitoring due according to the information provided by the GP and update the lithium record as necessary.
 19. Fully communicate in writing to GP all results of monitoring carried out and lithium levels (if not available electronically). This is especially important if the patient declines to carry a lithium treatment pack.
 20. Support the GP with advice on changing the dose if the lithium level is outside the therapeutic range, or they develop signs of lithium toxicity.
 21. Promptly review patient if necessary, at the request of the GP, when there are signs of lithium toxicity, renal impairment, unmanageable side effects or deterioration in mental state. Inform GP of any changes through formal correspondence within 2 weeks and supply necessary prescription for 28 days if dose changed. Information may need to be shared by secure email or telephone if doses have been changed so necessary adjustments can be made to GP records.
 22. Undertake an annual review of lithium treatment with the patient, and fully communicate in writing to GP the results of the review, including physical health monitoring carried out, lithium levels, and a prescribing plan for the next 12 months. At the review the patient’s Lithium Record Book will be updated with the latest monitoring results, including details of lithium brand, formulation, dose, target levels (upper and lower), and test results (as listed in Table 1 – “monitoring guidance”). These are also to be documented in the patient’s healthcare record.
 23. Telephone details and secure email addresses of both parties (secondary care prescriber and GP) should be exchanged and recorded. This will enable the practice to access timely advice, guidance and information if problems arise, and also enable secondary care clinicians to easily contact the GP if necessary. This should include out-of-hours contact numbers, e.g. how to access the on-call duty doctor. Patients and their carers should also be provided with contact details for support and help if required; both in and out of hours.

General Practitioner Responsibilities

If further information is required contact 0300 1230808 (EPUT contact centre).

1. Reply to the request for shared care within 2 weeks, with agreement or non-agreement.
2. If not in agreement, document in the primary care record that this patient is not in a shared care arrangement for lithium.

3. If in agreement the GP will confirm the agreement and acceptance of the shared care prescribing and monitoring arrangement. On receipt of a comprehensive referral letter from the secondary care prescriber (Appendix 2), take over the routine prescribing once the lithium dose has been stable for at least four weeks.
4. If agreed, also undertake the routine monitoring (and additional monitoring, if appropriate) as per schedule described in "Monitoring Guidance". Inform the secondary care prescriber of the results of this additional monitoring. Perform/request additional tests and investigations during maintenance therapy if abnormal results obtained, or as stated by the secondary care prescriber.
5. Ensure the brand, formulation, dose, frequency, timing of lithium prescribed is the same as that communicated by the secondary care prescriber.
6. Prescribe using specific instructions, for example, 'take one tablet (400mg) at night'. Avoid using prescribing instructions such as 'as directed'.
7. Prescriptions are recommended to be provided as acute prescription or with appropriate safeguarding.
8. Where repeat prescriptions are necessary, it is recommended that 28-day prescription is adopted unless not deemed appropriate.
9. Adjust the dose of lithium with support of the secondary care prescriber if the patient has lithium levels outside the therapeutic range, or develops signs of lithium toxicity (see "Precautions and warnings").
10. Update the patient's lithium record book with lithium levels/ monitoring results, and check these results before issuing prescriptions for lithium.
11. Update the lithium record book if lithium treatment is changed (whether brand, formulation, dose, frequency, or timing), and inform secondary care prescriber of the changes.
12. Inform the secondary care prescriber of any physical illness/ medicine that may affect the patient's treatment with lithium.
13. Stop lithium if signs of lithium toxicity become apparent and contact secondary care prescriber, or refer patient to A&E if appropriate (see "Signs of toxicity" below).
14. Observe the overall health and wellbeing of the patient, including side effects and signs of lithium toxicity, and provide appropriate ongoing verbal and written information to patient.
15. Seek the opinion of the secondary care prescriber in the following circumstances:
 - a. Lithium level is above 0.8mmol/L (unless the target range has been specified as 0.8 - 1 mmol/L by the secondary care prescriber), or if the lithium level falls below 0.4 mmol/L). Although the usual target level is 0.6 - 0.8 mmol/L, patients with lower levels (0.4 - 0.6 mmol/L) who have been clinically stable for a long time do not need to have their lithium dose increased.
 - b. Patient becomes mentally unwell (shows signs and symptoms of mania or depression) NOTE: Lithium patients can be referred urgently to the First response/ Access and Assessment teams /Community Mental Health Teams.
 - c. Non-compliance or suspected non-compliance with treatment.

- d. Patient is planning pregnancy or is pregnant. (Lithium therapy should not be used during pregnancy, especially during the first trimester, unless considered essential.)
 - e. Patient plans to breastfeed, or is breastfeeding. (Lithium should not be used during breast-feeding).
 - f. Patient develops renal impairment, or renal impairment worsens.
 - g. Introduction of a potentially interacting medicine.
 - h. Overdose/suspected overdose of lithium or any other psychotropic medication.
 - i. Patient has unmanageable side effects from lithium.
16. Refer back to secondary care prescriber for ongoing need and review of stable patients when lost to follow up.
17. Telephone details and (if appropriate) secure email addresses of both parties (secondary care prescriber and GP) should be exchanged and recorded. This will enable the practice to access timely advice, guidance and information if problems arise, and also enable secondary care clinicians to easily contact the GP if necessary. This should include out-of-hours contact numbers, e.g. how to access the on-call duty doctor. Patients and their carers should also be provided with contact details for support and help if required; both in and out of hours.

Patient/ Carer Responsibilities

- Ensure that they have a clear understanding of their treatment.
- Take/ administer lithium as prescribed.
- Attend all appointments for review of lithium.
- Report any adverse effects to their GP and/or secondary care prescriber.
- Report any changes in disease symptoms to GP and/or secondary care prescriber.
- Alert GP and/or secondary care prescriber of any changes of circumstance which could affect management of disease e.g. plans for pregnancy.
- Undertake any monitoring as requested by the GP and/or secondary care prescriber.
- Ensure that their monitoring booklet is kept up to date and taken to all appointments.
- Inform their GP in sufficient time to obtain repeat prescriptions.
- Present their Lithium Record Book to the GP when ordering repeat prescriptions.
- Keep monitoring booklet safe and bring to appointments with GP/ secondary care prescriber.
- Show monitoring booklet to pharmacist when collecting medication.

3. Prescribing information

Indications and licensing

- Management of acute mania or hypomanic episodes.

- Management of refractory depressive disorders where lithium is used for augmentation of antidepressants.
- Prophylaxis of bipolar affective disorder.

Administration

The usual starting dose is lithium carbonate 400mg at night (200mg in the elderly). Once daily dosing at night is preferred due to monitoring of lithium levels. The dose of lithium is adjusted to achieve a lithium concentration that is usually between 0.4 – 1.0 mmol/litre, but target levels are very patient specific and may fall outside this range.

Brand Prescribing

Lithium should be prescribed by brand name because of its narrow therapeutic range and difference in product bioavailability between brands. Brands are not interchangeable. Not all products are modified release (MR).

The brand Priadel® is recommended within EPUT and is available as 200mg and 400mg tablets⁴. Priadel tablets contain lithium carbonate and are scored tablets which can and should be halved when appropriate for the dose, e.g. 300mg, 500mg, 700mg, 900mg.

Liquid and tablet dose equivalence

Particular care is needed with Priadel 520mg lithium citrate / 5ml sugar free liquid. 520mg lithium citrate is equivalent to 204mg lithium carbonate. When switching from tablet to liquid, 5ml of 520mg/5ml lithium citrate liquid should be prescribed for every 200mg lithium carbonate tablet, see table below.

“Priadel” Lithium carbonate modified release tablet dose	“Priadel” lithium citrate 520mg/5ml equivalent dose
200mg	5ml
300mg	7.5ml
400mg	10ml
500mg	12.5ml
600mg	15ml
700mg	17.5ml
800mg	20ml
900mg	22.5ml
1000mg	25ml

Liquid doses are initially divided throughout the day, but once-daily (at night time) administration is preferred when lithium levels have stabilised. See BNF.

Using a single brand (Priadel) throughout EPUT will help to reduce medicine errors.

Reference should be made to the current BNF for any other brands and formulations of lithium that the patient is prescribed.

Lack of clarity over which liquid preparation is intended when prescribing can lead to the patient receiving a sub-therapeutic or toxic dose. Note that lithium liquid is also available as lithium citrate 509mg/5ml (equivalent to 200 mg lithium carbonate in

5ml), and as “double-strength” lithium citrate 1018mg/5ml (equivalent to 400 mg lithium carbonate in 5ml). For this reason the Priadel liquid (lithium citrate 520mg/5ml), shown in the table above is recommended.

Monitoring Standards

When starting lithium

Advise patients that poor adherence or rapid discontinuation may increase risk of relapse.

- Ensure that the patient is given appropriate information on taking lithium safely, including a Lithium Treatment Pack (patient information booklet, lithium alert card, and a record book for tracking serum-lithium concentration). See BNF for details of packs⁵.
- Establish a shared care arrangement with the patient’s GP for prescribing and monitoring adverse effects.

When stopping lithium

- Gradually reduce the dose over at least 4 weeks and preferably up to 3 months, even if the patient has started taking another anti-manic drug.
- During dose reduction and for 3 months after stopping lithium, monitor closely for early signs of mania or depression.

Monitoring Guidance

The safe and effective use of lithium requires regular general physical health monitoring^{2, 6, 7} (see Table 1) and lithium levels (see Table 2).

Table 1 - General Checks

Checks	Baseline (Pre-Treatment)	After Treatment Commenced
Weight / BMI	✓	Every 6 months
Urea & Electrolytes	✓	Every 6 months (more frequent in renal impairment – see below)
eGFR	✓	Every 6 months (more frequent in renal impairment – see below)
Calcium	✓	Every 6 months (more frequent if raised)
Thyroid Functions	✓	Every 6 months (more frequent if impairment)
FBC	✓	Annual
ECG	Recommended in patients who have risk factors for, or existing	Repeat only if appropriate (to be undertaken in secondary care).

Checks	Baseline (Pre-Treatment)	After Treatment Commenced
	cardiovascular disease.	
Pulse	✓	Annual
Blood pressure	✓	Annual
Fasting lipids	✓	Annual
Fasting blood glucose	✓	Annual

Table 2 - Lithium level checks

Blood samples for lithium levels should be taken 10 - 14 hours (ideally 12 hours) post dose. For patients on liquid preparations taking it twice daily, patients should be advised to delay the morning dose until after the blood sample has been taken.

Checks	Stabilising Treatment	Maintenance
Lithium levels	<p>Check levels 4 - 7 days after starting treatment then every 7 days until levels are stable for 4 weeks.</p> <p>Check levels 4 - 7 days after every dose change.</p> <p>If there is to be a change to the dose a current lithium level should be available that is no more than 2 weeks old.</p>	<p>GENERAL Once stable: Every 3 months</p> <p>SPECIAL GROUPS Every 3 months, or more frequently if necessary, particularly in the following groups:</p> <ol style="list-style-type: none"> 1.Older adults 2.Risk of impaired renal or thyroid function 3.Raised calcium levels 4.Poor symptom control 5.Poor adherence 6.Last plasma level 0.8 mmol /L or higher 7.Taking interacting drugs <p>PREGNANCY/ CHILDREN Seek specialist advice.</p>
Target Levels	As per patient need	

Lithium prescribing in Special Groups

If the patient falls into one of the Special Groups listed in Table 2 the secondary care prescriber will specify in their initial and subsequent referral letter the additional monitoring required for this patient, and will include:

- What is to be monitored, e.g. "lithium level", "e-GFR".
- The frequency of this additional monitoring, e.g. once a month;

- The duration of this additional monitoring, e.g. for 3 months from date X/X/XX;
- What Special Group the patient is in, or the reason for this additional monitoring, e.g. “Older patient”, “Poor adherence”.

Pregnancy

Seek specialist advice.

Do not offer lithium to women who are planning a pregnancy or pregnant, unless antipsychotic medication has not been effective.

If antipsychotic medication has not been effective and lithium is offered to a woman who is planning a pregnancy or is pregnant, ensure:

- The woman knows that there is a risk of foetal heart malformations when lithium is taken in the first trimester, but the size of the risk is uncertain
- The woman knows that lithium levels may be high in breast milk with a risk of toxicity for the baby
- Lithium levels are monitored more frequently throughout pregnancy and the postnatal period (see table 2 lithium level monitoring)
- If a woman taking lithium becomes pregnant, consider stopping the drug gradually over 4 weeks if she is well. Explain to her that:
 - Stopping medication may not remove the risk of foetal heart malformations
 - There is a risk of relapse, particularly in the postnatal period, if she has bipolar disorder.
- If a woman taking lithium becomes pregnant and is not well or is at high risk of relapse, consider:
 - Switching gradually to an antipsychotic or
 - Stopping lithium and restarting it in the second trimester (if the woman is not planning to breastfeed and her symptoms have responded better to lithium than to other drugs in the past) or
 - Continuing with lithium if she is at high risk of relapse and an antipsychotic is unlikely to be effective.
- If a woman continues taking lithium during pregnancy:
 - Check plasma lithium levels as above (Table 2)
 - Adjust the dose to keep plasma lithium levels in the woman's therapeutic range
 - Ensure the woman maintains an adequate fluid balance
 - Ensure the woman gives birth in hospital
 - Ensure monitoring by the obstetric team when labour starts, including checking plasma lithium levels and fluid balance because of the risk of dehydration and lithium toxicity
 - Stop lithium during labour and check plasma lithium levels 12 hours after her last dose. Restart lithium at least 24 hours after last dose and only

after reviewing the blood assay results (as dose may need to be readjusted).

Children

The use in children is not recommended.
Seek specialist advice.

Elderly

Elderly patients are particularly liable to lithium toxicity even at levels within the normal range and may exhibit adverse reactions at levels ordinarily tolerated by younger patients.

Caution is also advised since lithium excretion may be reduced in the elderly due to age related decrease in renal function (see also renal Impairment section).

Elderly patients or those below 50kg in weight often require lower lithium dosage to achieve therapeutic lithium levels, and lithium levels may need to be lower in the elderly population and particularly in the very old and frail elderly.

Reduced lithium clearance is expected in patients with hypertension, congestive heart failure or renal dysfunction.

The most clinically significant pharmacokinetic drug interactions associated with lithium involve drugs which are commonly used in the elderly. See section on significant interactions below.

Renal impairment

Since lithium is primarily excreted via the renal route significant accumulation of lithium may occur in patients with renal impairment. Therefore, if patients with mild or moderate renal impairment are being treated with lithium, lithium levels should be closely monitored, and the dose should be adjusted accordingly.

If very regular and close monitoring of lithium levels and plasma creatinine levels is not possible, lithium should not be prescribed in this population.

Lithium is contraindicated in patients with severe renal impairment.

Most common side effects include fine tremor, stomach upset, polyuria and polydipsia.

Other side effects include metallic taste in mouth, weight gain, ankle oedema, hypothyroidism and rashes.

Some skin conditions such as psoriasis and acne can be aggravated.

Signs of toxicity

Toxicity is likely with lithium levels above 1.5 mmol/L, however can occur within range, e.g.in the elderly.

Signs of lithium intoxication include:

Mild: Nausea, diarrhoea, blurred vision, polyuria, light headedness, fine resting tremor, muscular weakness and drowsiness.

Moderate: Increasing confusion, blackouts, fasciculation and increased deep tendon reflexes, myoclonic twitches and jerks, choreoathetoid movements, urinary or faecal incontinence, increasing restlessness followed by stupor. Hypernatraemia.

Severe: Coma, convulsions, cerebellar signs, cardiac dysrhythmias including sinoatrial block, sinus and junctional bradycardia and first degree heart block. Hypotension or rarely hypertension, circulatory collapse and renal failure.

Others:

Gastrointestinal disorders: increasing anorexia and vomiting.

Nervous system disorders: Encephalopathy, cerebellar syndrome with symptoms such as muscle weakness, lack of coordination, drowsiness or lethargy, giddiness, ataxia, nystagmus, coarse tremor. Tinnitus, dysarthria, twitching, myoclonus, extrapyramidal disorders.

If any of these signs are experienced by the patient, then lithium therapy should be stopped immediately and lithium levels checked urgently. Consider urgent medical referral and psychiatric advice, and refer back to the secondary care prescriber.

Further details about recognizing and managing lithium toxicity are provided in the BNF chapter: Home > Treatment summary > Poisoning, emergency treatment > Lithium poisoning⁶

Annex 1: LITHIUM (Priadel) drug fact sheet^{4,6,7}

Dosage and Administration

- The dose will depend on the preparation used and target lithium levels. Newly initiated patients will be prescribed and supplied the Priadel brand. Preparations vary widely in bioavailability.
- In patients with any degree of renal impairment lithium should either be avoided if possible or the dose should be reduced using levels to determine dose.

Precautions and Warnings

- If the lithium level is above 1.5 mmol/L serious side effects may develop which may be fatal. These include tremor, drowsiness and lethargy, ataxia, dysarthria, nystagmus, renal impairment and convulsions. If these occur the lithium should be stopped and not restarted until the level is within the normal range. A dosage adjustment may be necessary. If the lithium level is between 1.0 - 1.5 mmol/L the dose should be reduced. Check with the secondary care prescriber before making the reduction.
- Lithium should be avoided in pregnancy, but if a patient stabilised on lithium becomes pregnant the secondary care prescriber should be contacted.
- If a patient is or has recently suffered from diarrhoea or vomiting an additional lithium level should be taken to ensure that the level is maintained within the normal range.
- Beware of use in patients with psoriasis or epilepsy.
- Beware of interactions with other medicines.
- Regular renal, cardiac and thyroid function tests are necessary with lithium.
- Once a patient is stabilised on lithium, a level is required every 3 months.

Contra-indications

- 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.

Significant Interactions⁴

Lithium toxicity is made worse by sodium depletion.

Drug group	Magnitude of effect	Timescale of effect	Additional information
Ace inhibitors	Unpredictable. Up to 4-fold increases in lithium level.	Develops over several weeks.	7-fold increased risk of hospitalisation for lithium toxicity in the elderly. Angiotensin II inhibitors (sartans) may be associated with similar risk.
Thiazide	Unpredictable.	Usually	Loop diuretics, e.g.

diuretics	Up to 4-fold increases in lithium level.	apparent in first 10 days.	furosemide, are safer. Any effect will be apparent in the first month.
NSAIDs	Unpredictable. From 10% to 4-fold increases in lithium level.	Variable; from a few days to several months.	NSAIDs are widely used on a PRN basis. Can be bought over the counter. COX-2 inhibitors are likely to carry the same risk.
Oxytetracycline ⁸	Concomitant use of oxytetracycline may cause an increase in serum lithium levels. The lithium dosage should either be adjusted or concomitant treatment stopped, as appropriate.		

Side effects

Gastrointestinal disturbances, fine tremor, renal impairment, polyuria, polydipsia, weight gain and oedema are common. Signs of lithium toxicity include blurred vision, increasing gastrointestinal disturbances, vomiting, diarrhoea, muscle weakness, CNS disturbances, giddiness, coarse tremor. If any of these symptoms are present treatment should be stopped and immediate lithium levels taken. Lithium should not be restarted until levels return to within normal range.

Effects on ability to drive and operate machinery

Lithium may cause disturbances of the CNS. Since lithium may slow reaction time, and considering the side-effect profile of lithium, patients should be warned of the possible hazards when driving or operating machinery.

For full information consult the latest Summary of Product Characteristics and the BNF.

References

1. Responsibility for prescribing between Primary & Secondary/Tertiary Care. NHS England. January 2018. <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf>
2. NICE Clinical guideline [CG185]. Bipolar disorder: assessment and management. Published date: September 2014 Last updated: April 2018.
3. Close monitoring of patients prescribed Lithium. NPSA. December 2009.
4. Priadel (lithium carbonate 200mg) SPC, accessed 23/3/2018.
5. Lithium treatment packs. BNF on-line edition, accessed 20/6/2019.
6. BNF on-line edition, accessed 20/6/2019.
7. South London & Maudsley NHS Foundation Trust Prescribing Guidelines 13th edition (2018).
8. SPC Oxytetracycline tablets. Accessed 29/1/2020.

APPENDIX 1 - INITIAL LETTER

[Address]

[Date]

Dear Dr [Name]

Re: Lithium Shared Care Protocol
Patient: [Name, address, NHS No.]

I have seen this patient in clinic and believe that [he / she] is suitable for treatment with lithium.

I have initiated this patient on [Lithium carbonate/ Lithium citrate, Brand name, form, dose, frequency] and will be monitoring and prescribing for this patient at our clinics until such time that the patient is deemed stable, which is likely to be in the region of [No.] months.

*[*Delete as applicable]:*

- *This patient will require the routine monitoring as set out in the Lithium Shared Care Protocol

or

- *This patient will require the routine monitoring as set out in the Lithium Shared Care Protocol, PLUS the following ADDITIONAL monitoring (as they are in one of the Special Groups of patients requiring more intensive monitoring, e.g. older adult/ risk of impaired renal or thyroid function/ raised calcium level/ poor symptom control/ poor adherence/ last plasma level 0.8 mmol /L or higher/ taking interacting drugs).

name of parameter to be monitored:	
with this frequency:	
for this duration:	
for this reason:	

I would like to seek your agreement for you to take over the prescribing of this patient's treatment after this stabilisation period as per agreed Lithium Shared Care Protocol. A copy of this protocol can be found at <https://eput.nhs.uk/our-services/pharmacy/formulary-prescribing-guidelines-mental-health/>

Please would you also indicate who will be responsible for monitoring.

Please complete the form below and scan and email it from a secure nhs.net account to our secure nhs.net account below.

I thank you in anticipation.

Yours sincerely

[Name]
[Job title]

Scan and email to: [EPUT prescriber secure nhs.net email address]
nhs.net email to: [Clinical Commissioning Group secure nhs.net email address]

*[*Delete as applicable]:*

Agreement to undertake prescribing

*I agree to take over the prescribing responsibility for this patient as per Lithium Shared Care Protocol from such date as the patient is deemed stable.

Or

*I am not willing to undertake shared care for this patient because [reason].

Agreement to undertake monitoring

*[**Delete as applicable]:*

**I agree to the Secondary Care Prescriber monitoring the patient including responsibility for organising bloods and other tests (including the additional monitoring that has been highlighted as being required if the patient is in a Special Group, which is: parameter, frequency....., duration....., reason.....).

Or

**I agree to take over monitoring of the patient including responsibility for organising bloods and other tests as required (including the additional monitoring that has been highlighted as being required if the patient is in a Special Group, which is: parameter, frequency....., duration....., reason.....).

[Patient name]

[NHS No]

Yours sincerely,

[Dr]

[Date]

[Practice address]

APPENDIX 2 - SECOND LETTER TO START SHARED CARE

[Address], [Date]

Dear Dr [Name]

Re: Lithium Shared Care Protocol
Patient: [Name, address, NHS No.]

DIAGNOSIS:
 DATE LITHIUM STARTED:

Thank you for agreeing to shared care for the above named patient as per my initial letter dated [date].

I have been monitoring and prescribing for this patient for [no.] months and the patient is deemed stable as per agreed **Lithium Shared Care Protocol**.

I confirm that I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted, the need for monitoring, how monitoring will be arranged, and the roles of the consultant / nurse specialist, GP and the patient in shared care. I confirm the patient has understood and consented to this shared care arrangement at this time.

The patient is doing well and is currently prescribed:

BRAND OF LITHIUM:

LITHIUM CARBONATE TABLET - Dose in mg:	OR	LITHIUM CITRATE LIQUID - STRENGTH (AS CITRATE SALT): mg in 5ml
		Dose in ml:

Target lithium levels are between mmol/L andmmol/L

Recent lithium levels

Date	Lithium blood level (mmol/L)

Date next lithium level is due:	

Recent monitoring

Test	Date	Result	Date this is next due
e-GFR			
TFTs			
Weight			

Monitoring

*[*Delete as applicable]:*

- *This patient will require the routine monitoring as set out in the Lithium Shared Care Protocol

or

- *This patient will require the routine monitoring as set out in the Lithium Shared Care Protocol, PLUS the following ADDITIONAL monitoring (as they are in one of the Special Groups of patients requiring more intensive monitoring, e.g. older adult/ risk of impaired renal or thyroid function/ raised calcium level/ poor symptom control/ poor adherence/ last plasma level 0.8 mmol /L or higher/ taking interacting drugs).

name of parameter to be monitored:	
with this frequency:	
for this duration:	
for this reason:	

We have agreed the following:

*[**Delete as applicable]:*

****Secondary Care Prescriber to monitor the patient including responsibility for organising bloods and other tests (including the additional monitoring that has been highlighted as being required if the patient is in a Special Group).**

or

****GP to take over monitoring of the patient including responsibility for organising bloods and other tests as required (including the additional monitoring that has been highlighted as being required if the patient is in a Special Group).**

Referral back to secondary care

The patient should be referred to the secondary care prescriber (using a fast track) if the patient experiences any of the following:

- a. Lithium level is above 0.8mmol/L (unless the target range has been specified as 0.8 - 1 mmol/L by the secondary care prescriber), or if the lithium level falls below 0.4 mmol/L). Although the usual target level is 0.6 - 0.8 mmol/L, patients with lower levels (0.4 - 0.6 mmol/L) who have been clinically stable for a long time do not need to have their lithium dose increased.
- b. Patient becomes mentally unwell (shows signs and symptoms of mania or depression) NOTE: Lithium patients can be referred urgently to the First response/ Access and Assessment teams /Community Mental Health Teams.
- c. Non-compliance or suspected non-compliance with treatment.
- d. Patient is planning pregnancy or is pregnant. (Lithium therapy should not be used during pregnancy, especially during the first trimester, unless considered essential.)
- e. Patient plans to breastfeed, or is breastfeeding. (Lithium should not be used during breast-feeding).
- f. Patient develops renal impairment, or renal impairment worsens.
- g. Introduction of a potentially interacting medicine.
- h. Overdose/suspected overdose of lithium or any other psychotropic medication.
- i. Patient has unmanageable side effects from lithium.

Stop lithium if signs of lithium toxicity become apparent and contact secondary care prescriber, or refer patient to A&E.

Review

This patient will be reviewed by secondary care annually, with regards to their lithium treatment. The following will be communicated in writing to the GP: results of review, including physical health monitoring carried out, lithium levels, and a prescribing plan for the next 12 months. The patient's lithium record book will be updated at this review.

Lithium Treatment Pack

I confirm that the patient is in possession of a Lithium Treatment Pack (patient information booklet, lithium alert card, and a record book for tracking serum-lithium concentration). They have been explained the signs of lithium toxicity and the action they should take in the event of experiencing lithium side effects / lithium toxicity. They have been explained to present the lithium record book to the GP practice when making requests for repeat prescriptions.

Prescribing

If you are in agreement please would you start prescribing lithium for this patient within the parameters of the Lithium Shared Care Protocol. Please observe for side-effects of lithium, and signs of lithium toxicity. I have prescribed for this patient for a further 28 days. I will send a clinic letter so the GP practice will be in receipt of the clinic letter within ONE week of the prescription being issued.

Your agreement to shared care will be assumed unless I receive a formal letter from you declining shared care within 14 days of receiving this request. (In West Essex it should not be assumed that shared care has been agreed by the GP, and it should

be confirmed, not assumed). Please undertake prescribing and monitoring from *[insert date]* (NB: date must not be less than one month from the date of this letter).

If you are unwilling or unable to accept this shared care agreement, please reply within 14 days of receiving this request stating the reason why you are unable to provide this service.

Yours sincerely

[Name], [Job title], [Contact number], [Care coordinator & contact no.]
[Community team & contact no.]