Specialised Medicines Service Guideline ~ Priadel (Lithium) for patients in adult services

This guideline highlights significant prescribing issues. Not all prescribing information and potential adverse effects are listed. Please refer to the BNF and individual product SPCs for full prescribing data. The National Patient Safety Agency (NPSA) has also produced guidance on Safer Lithium Therapy.

Specialist: Please complete letter at the end of this document and send together with the shared care guideline to the GP.

GP: Please indicate whether you wish to share patient's care by completing letter at the end of this document and return to specialist.

GPs are invited to participate. If a GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

The doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

Introduction and aims of treatment

This guideline refers to the use of Priadel modified release (M/R) tablets and syrup, used in line with their licensed indications for the treatment of adult patients with acute episodes of mania or hypomania, recurrent depressive episodes (where treatment with other antidepressants has been unsuccessful), and prophylaxis of recurrent bipolar disorder.

Lithium is the most effective long-term treatment for bipolar disorder. The precise mechanism of action of lithium as a mood stabilizing agent is not known, although many cellular actions of lithium have been characterized.

Lithium is not metabolised and is almost entirely renally excreted; renal function should therefore be assessed before, and at regular intervals during treatment. All patients should be encouraged to maintain a good intake of fluids and to avoid sudden changes in dietary salt intake.

Lithium should be prescribed by **brand** name and **formulation** because of its narrow therapeutic range, toxicity in overdose, and differences in product bioavailability. Only Priadel preparations are supported by the Devon joint formularies. Priadel MR 200mg and Priadel MR 400mg tablets both contain lithium carbonate; Priadel 520mg/5ml SF liquid contains lithium citrate**.**

Lithium brands/formulations are not bioequivalent and should not be interchanged; any change of product should be regarded as initiation of new treatment.

Specialist responsibilities

Lithium should be initiated in secondary care or by a suitably experienced GP with a specialist interest in psychiatry. The initiating clinician should:

- Undertake baseline checks (see below)
- Discuss with the patient (and/or carer) the benefits, side effects, frequency of dosing and monitoring requirements of lithium treatment
- Advise people taking lithium to:
  - seek medical attention if they develop diarrhoea or vomiting or become acutely ill for any reason
  - ensure they maintain their fluid intake, particularly after sweating, if they are immobile for long periods or if they develop a chest infection or pneumonia
  - talk to their doctor as soon as possible if they become pregnant or are planning a pregnancy. Individuals of child-bearing potential should be advised to use an effective form of contraception.
- Advise the patient (and/or carer) of the symptoms of toxicity (see below) and to seek urgent medical attention should any of these occur

- Advise the patient (and/or carer) that poor adherence or rapid discontinuation may increase the risk of relapse
- Provide the patient with an NPSA Lithium Therapy Information Pack, which includes all relevant information as well as a lithium therapy record book (Purple book).
- Initiate and stabilise therapy (in exceptional circumstances, GPs may initiate lithium treatment under specialist advice). Patients will have been stabilised on a suitable dose for at least one month before being referred to their GP for sharing of care
- Monitor serum lithium levels (see below) during initiation and stabilisation until ongoing monitoring is undertaken by GP
- Send a letter to the GP, requesting the sharing of care for a particular patient. This letter should contain the following information:
  - Diagnosis
  - Results of blood tests and any other appropriate investigations
  - Dose and name of treatment (including **brand** name and **formulation**)
  - A target serum lithium level/range
  - Advice on dose alterations where appropriate
- Evaluate adverse effects/monitoring results reported by the GP
- Provide additional information and advice to the GP when required, and when requested
- Patients who have responded effectively to treatment and remain stable may return to primary care for ongoing management; in these cases coordinate transfer of responsibilities to ensure safe handover of care. This should include clear guidance on the likely duration of treatment.
- Decide when withdrawal of therapy is appropriate, (including in the case of no response), and provide individualised advice to the GP on dose reduction/discontinuation schedule.

General practitioner responsibilities

- Ensure a timely reply is sent to specialist in response to request for sharing of care.

If GP has agreed to share care:

- Carry out appropriate ongoing monitoring (see below)
- Prescribe treatment (Lithium should be prescribed by **brand** name and **formulation**)
- Be alert to the possibility of interactions when initiating new medicines or recommending over the counter (OTC) treatments e.g. NSAIDs.
- Monitor the patient for signs of toxicity, side effects of treatment, and signs of deterioration in mental state.
- Act on any abnormal results or observations
- Reduce the dose or discontinue treatment in cases of serious diarrhoea or vomiting, concurrent infection, excessive sweating, severe dieting. Use clinical judgement and seek advice from initiating specialist as required.
- Discuss with the specialist if the patient requires a medicine which is likely to affect lithium levels
- The ongoing responsibility to provide advice on the need for contraception rests with both the specialist and the GP.
- If the patient becomes pregnant, discuss the situation urgently with the specialist or perinatal service
- Seek specialist advice when necessary
- On the advice of the specialist, discontinue treatment (gradually – see below), if/when appropriate.
- Patients who have responded effectively to treatment and remain stable may be discharged to primary care for ongoing management (specialists will provide clear guidance on the likely duration of treatment). Continue to monitor discharged patients as described below (GPs may still claim the appropriate SMS fee for these patients).
- Refer discharged patients back to specialist services when discontinuation is considered (either in line with specialist advice provided on discharge, or at patient request, if earlier)

Patient responsibilities

- Tell the GP or specialist if they have any concerns or do not understand any aspect of treatment
- Attend specialist, GP and blood test appointments
- Refer to the NPSA Lithium Therapy Information Pack (purple book); keep their purple book up to date and show it to healthcare professionals when required e.g. prescribers, pharmacists
- Seek medical attention if they develop diarrhoea or vomiting, become acutely ill for any reason
- Maintain their fluid intake, particularly after sweating, if they are immobile for long periods, if they develop a chest infection or pneumonia
- Large changes in dietary sodium should be avoided – changing dietary regime may inadvertently alter sodium intake.
- **Report any of the following signs or symptoms to their GP without delay:**
  - Diarrhoea, vomiting, loss of appetite, muscle weakness or twitching, clumsiness or poor coordination, dizziness, confusion, tinnitus, blurred vision, coarse tremor, writhing movements, change in speech, lethargy and/or drowsiness, incontinence, restlessness, confusion, seizures/fits (possible lithium toxicity)
  - Fatigue, cold intolerance, weight gain, constipation and depression (possible signs of hypothyroidism)
  - Persistent headache and visual disturbance (possible signs of benign intracranial hypertension)
  - Extreme thirst or urinating a lot more than usual (possible signs of diabetes insipidus)
- Individuals of child-bearing potential should use effective contraception while taking lithium. Individuals should take a pregnancy test if they think there is a possibility they could be pregnant, and inform the GP or specialist immediately if they become pregnant or wish to become pregnant.
- Tell their community pharmacist that they are taking lithium when buying any over-the-counter medicine (e.g. NSAIDs such as ibuprofen and aspirin)
- Excessive alcohol consumption should be avoided as it can lead to dehydration, increasing plasma lithium levels and so risk of toxicity.
- Do not drive or operate heavy machinery if lithium affects ability to do so safely. It is illegal to drive with prescription medicines in your body if it impairs your driving, see Drugs and driving: the law.
  - People who drive must inform the DVLA if they have bipolar disorder.
  - If individuals have depression affecting the ability to drive safely this must be reported to the DVLA.
  - DVLA guidance is available here
- Store their medicines safely and securely.

Monitoring

Important: blood samples for serum lithium monitoring should be taken ideally 12 hours post dose

Baseline assessment & ongoing monitoring to be completed by the specialist service provider:

- At baseline:
  - Renal function – urea and electrolytes, estimated glomerular filtration rate (eGFR)
  - Calcium
  - Thyroid function
  - Cardiac function (ECG recommended in those with risk factors or existing problems)
  - Full blood count
  - Weight or BMI
  - Exclude pregnancy; individuals should be advised to use an effective form of contraception.
  - Ensure there are no drug interactions of clinical significance with current medication, recreational drugs, or over the counter (OTC) drugs.
- Serum lithium levels should be checked between 4 to 7 days following initiation and the dose adjusted accordingly.
- Serum lithium monitoring should be performed weekly after initiation and after each dose change until stabilisation is achieved i.e. the desired serum level and clinical effect are maintained

Monitoring during treatment to be completed by the GP:

<table>
<tr><th>Test</th><th>Frequency</th></tr>
<tr><td>Serum lithium concentration

Blood samples should be taken ideally 12 hours post dose.

If the dose is taken once daily in the evening – the blood sample should be taken the following morning.

In the event of a twice daily dosing regimen, the morning dose should be omitted until after the blood sample has been taken.</td><td>Every three months for the first year, then every 6 months (continue every three months in individuals aged ≥65 years; taking drugs that interact with lithium; at risk of impaired renal or thyroid function, raised calcium levels or other complications; poor symptom control; poor adherence; last serum lithium level ≥ 0.8mmol/L)

Serum levels should also be repeated one week after every dose change and then every week until stabilisation is achieved.

Consider additional monitoring whenever there is a change in the patient’s physical health e.g. acute illness, dehydration. Discuss with specialist as required.</td></tr>
<tr><td>Weight or BMI</td><td rowspan="4">Every six months
(more frequently if there is evidence of impaired renal or thyroid function, raised calcium levels, or an increase in mood symptoms)</td></tr>
<tr><td>Renal function – urea and electrolytes, eGFR</td></tr>
<tr><td>Thyroid function</td></tr>
<tr><td>Calcium</td></tr>
<tr><td>ECG</td><td>Annually in those with high risk of, or existing, cardiovascular disease (less frequent monitoring may be determined by GP on an individual patient basis depending on clinical picture).

Recheck after each dose increase if pre-existing cardiac abnormalities determined.</td></tr>
<tr><td>Signs of toxicity or adverse effects</td><td>Be alert to the possibility of toxicity or adverse effects at every contact</td></tr>
</table>

Action to be taken if serum lithium levels fall outside the optimum range: (see also Lithium Toxicity, below)

When interpreting lithium results consider patient compliance with treatment, possible interactions, timing of sample vs previous dose. If raised lithium levels are detected check patient hydration, physical and mental health status and features of toxicity. If toxicity present act according to advice below depending on severity.

Target serum lithium levels depend on dose frequency, specialists must always advise the GP of the individual's target lithium level.

Lithium Level	Action
<0.4mmol/L	Repeat lithium blood level as soon as possible and seek advice from initiating specialist on the need to adjust dose within 5 working days. Check compliance with treatment.
0.4mmol/L – 0.8mmol/L	**Target lithium levels usually sit within this range.** Seek advice from initiating specialist if results are outside the agreed range even if they remain within "normal" therapeutic limits.
0.8mmol/L – 1mmol/L	Unless this is a stated target level (normally reserved for acute manic presentation), seek specialist advice. Check serum lithium level, creatinine, urea and electrolytes.
>1mmol/L – ≤1.5 mmol/L	Contact patient the same day. Check on timing of dose prior to blood test and instruct to stop lithium. Seek advice from initiating specialist the same day regarding reducing dose or stopping treatment depending on clinical symptoms. Check serum lithium level, creatinine, urea and electrolytes.
>1.5mmol/L **or** mild features of lithium toxicity	Contact patient immediately. Stop lithium immediately, check serum lithium level, creatinine, urea and electrolytes. Seek urgent advice from initiating specialist. Monitor for symptoms of toxicity – See below (symptoms may be delayed up to 24 hours)
≥2mmol/L **or** moderate/severe features of lithium toxicity	Contact patient immediately. Stop lithium immediately and seek urgent medical care. A serum-lithium concentration in excess of 2 mmol/L requires urgent treatment as described in the BNF under Emergency Treatment of Poisoning. Inform initiating specialist.

Action to be taken if abnormal monitoring results recorded:

If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.

Monitoring Parameter	Result prompting further action	Action to be taken by GP
Weight or BMI	Outside healthy range or significant weight loss	Exclude other possible causes. Contact initiating specialist for advice. Lithium levels are influenced by body weight so lithium levels may need to be checked more frequently – initiating specialist to advise GP as required. Provide appropriate support to increase physical activity levels, improve eating behaviour and quality of diet. Remind patient of the importance of maintaining adequate fluid intake and avoiding sudden changes in diet. Consider measuring waist circumference for individualised monitoring.
Renal function	Urea or electrolytes out of range	Contact initiating specialist for advice. Check that the most recent 12-hour plasma lithium level is in the desired range and act accordingly if not (see guidance above). Determine whether there are symptoms and signs related to the electrolyte disturbance or lithium toxicity and act accordingly. Consider arranging an ECG in those at risk for QT prolongation.
	eGFR <45ml/min or consecutive results indicating a decline in renal function.	The decision whether to continue lithium depends on clinical efficacy and degree of renal impairment; seek advice from the initiating specialist and/or a renal specialist. A cardiovascular risk profile may guide specialist advice and should be provided if available. Use clinical judgement to determine the urgency of consultation. Dose adjustments may be advised. If renal function is significantly compromised, lithium may no longer be an appropriate treatment.
Thyroid* function	Subclinical or overt hypothyroidism	Contact initiating specialist for advice. Anticipate the need for additional monitoring, investigations and potentially initiating levothyroxine.
	Hyperthyroidism	Contact initiating specialist and/or endocrinology for advice.
Calcium	Hypercalcaemia	Check that the most recent 12-hour plasma lithium level is in the desired range and act accordingly if not (see guidance above). Determine whether there are symptoms and signs related to the electrolyte disturbance or lithium toxicity and act accordingly. Consider arranging an ECG in those at risk for QT prolongation. Contact initiating specialist. Changes in calcium levels may reflect parathyroid dysfunction and input from endocrinology services may be indicated.
ECG	Cardiac abnormalities or irregularities	Manage patient in accordance with local guidelines. Refer for prompt cardiology review if indicated. Contact initiating specialist for advice regarding ongoing treatment.

** Devon Formulary Guidance on the presentation and management of thyroid disorders can be found here: North and east Devon; South and west Devon*

Lithium toxicity

Refer to individual product SPCs for Priadel

Be alert to the signs of toxicity at every consultation.

Lithium toxicity can occur without apparent increase in serum level, it is important to "treat the patient, not the level". Symptoms of neurotoxicity that can occur at therapeutic levels include paraesthesia, ataxia, tremor and cognitive impairment.

Symptoms 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.

Refer to individual product SPCs for additional symptoms (gastrointestinal, CNS and cardiovascular etc.) of lithium toxicity.

At blood levels above 2-3 mmol/L, there may be a large output of dilute urine and renal insufficiency, with increasing confusion, convulsions, coma and death.

In the event of overdose/toxicity, discontinue lithium, monitor serum levels closely and seek urgent specialist advice. Supportive treatment should be initiated, including correction of fluid and electrolyte balance if necessary. Patients should be observed for a minimum of 24 hours, including ECG monitoring in symptomatic patients.

Refer also to the BNF guidance on Emergency Treatment of Poisoning.

Supporting Information

Please refer to individual product SPCs for full prescribing data; these can be accessed at www.medicines.org.uk.

Dosage and administration

Refer to the current BNF and Priadel SPCs. Patient specific guidance will be provided to the GP by the specialist.

Preparations vary widely in bioavailability and should be prescribed by brand name and formulation; changing the preparation requires the same precautions as initiation of treatment. **If a formulation switch is considered, discuss with the specialist team.**

Priadel tablets are usually given once daily; Priadel liquid is usually given twice daily.

Preparation	Usual dose
Priadel tablets	ADULT over 18 years, initially 0.4–1.2 g daily as a single dose or in 2 divided doses; ELDERLY or patients less than 50 kg, initially 200–400 mg daily.
Priadel liquid	ADULT over 18 years, initially 1.04–3.12 g daily in 2 divided doses; ELDERLY or patients less than 50 kg, 520 mg twice daily

Discontinuation of lithium

Lithium must never be stopped suddenly, unless the individual is suffering from signs of toxicity (see above) or has a serum lithium level greater than 1.5mmol/L. In order to minimise the risk of relapse when discontinuing lithium, it is recommended that it is stopped gradually over a period not less than 4 weeks, and preferably over at least 3 months. Incremental reductions in serum lithium of >0.2mmol/L should be avoided.

During dose reduction and for 3 months after lithium treatment is stopped, patients should be monitored closely for early signs of mania and depression.

Discontinuation should always be discussed on an individual basis with the specialist, and if appropriate, may be performed by the GP.

Contraindications and precautions

Refer to individual product SPCs for Priadel.

Pregnancy and lactation

Refer to individual product SPCs for Priadel.

Lithium therapy should not be used during pregnancy, especially during the first trimester, unless considered essential. Please refer to NICE guidance on antenatal and postnatal mental health for further information.

Individuals of child-bearing potential should use effective contraceptive methods during treatment with lithium, and must talk to their doctor as soon as possible if they become pregnant or are planning a pregnancy.

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.

Adverse effects

Refer to individual product SPCs for Priadel and Lithium Toxicity section (above).

Drug interactions

This list is not exhaustive, for additional information, and further interactions, consult the BNF and individual product SPCs for Priadel.

The following drug interactions are classified in the online version of the BNF as **potentially serious;** concomitant administration of the drugs involved should be **avoided** (or only undertaken with caution and appropriate monitoring).

- **ACE inhibitors** reduce excretion of lithium (increased plasma concentration)
- **Acetazolamide** increases excretion of lithium
- **Amiodarone** (risk of ventricular arrhythmias)
- **Angiotensin-II receptor antagonists** reduce excretion of lithium (increased plasma concentration)
- **Arsenic trioxide** (increased risk of ventricular arrhythmias)
- **Dapoxetine** (possible increased risk of serotonergic effects; manufacturer of dapoxetine advises lithium should not be started until 1 week after stopping dapoxetine , avoid dapoxetine for 2 weeks after stopping lithium)
- **Diuretics:** Loop diuretics, potassium-sparing diuretics and aldosterone antagonists, thiazides and related diuretics reduce excretion of lithium (increased plasma concentration and risk of toxicity)
- **Ketorolac** reduces excretion of lithium (increased risk of toxicity)
- **Methyldopa** (neurotoxicity may occur without increased plasma concentration of lithium)
- **NSAIDs** reduce excretion of lithium (increased risk of toxicity). 'As required' use of NSAIDs should be avoided since it may cause fluctuations in lithium levels and makes monitoring levels challenging.
- **Risperidone** (increased risk of extrapyramidal side-effects and possibly neurotoxicity)
- **SSRI antidepressants** (increased risk of CNS effects, lithium toxicity reported).

Care should be taken on initiation, dose adjustment or discontinuation of any interacting medicines. The onset and degree of the interaction can vary and additional lithium monitoring is likely to be indicated, with doses adjusted accordingly. Discuss with specialist team where required.

Support

Contact details	
Devon Partnership NHS Trust	Trust HQ (Wonford House reception): 01392 208866 First Response Service: 0808 196 8708 (outside office hours)
Livewell Southwest	Pharmacy: 01752 434726 or 439006 Out of hours/weekends: contact the mental health junior doctors via switchboard on 01752 268011

Perinatal mental health teams	
Exeter Email: dpn-tr.PerinatalTeamExeter@nhs.net Telephone: 01392 674964	**North Devon** Email: dpn-tr.perinatalNorth@nhs.net Telephone: 01271 322772
Plymouth Email: livewell.perinatalmht@nhs.net Telephone: 01752 431607	**South Hams and West Devon** Email: dpt.perinatalteamwestdevon@nhs.net Telephone: 01822 813 070
Torbay Email: dpn-tr.PerinatalTeamTorbay@nhs.net Telephone: 01803 396590	

For further support and information in relation to individual shared care agreements please contact your practice pharmacist or alternatively please contact the Medicines Optimisation Team.

Email: D-ICB.medicinesoptimisation@nhs.net

Date ratified: February 2018; (partial update February 2024)

Shared Care Agreement Letter - Specialist Request to GP

To	**GP name**	
	Practice address	
Patient name		
Hospital number		
NHS number		
Date of birth		
Address		

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

I have discussed and agreed the following treatment with the patient:

Priadel (lithium) tablets or SF liquid ……..

Lithium preparations vary widely in bioavailability; they are not interchangeable and should be prescribed by brand name and formulation.

Priadel (lithium) has been initiated for the treatment of *(select applicable indication):*	
Acute episodes of mania	
Acute episodes of hypomania	
Recurrent depressive episodes (where treatment with other antidepressants has been unsuccessful)	
Prophylaxis of recurrent bipolar disorder	

The current dose and frequency is ……..

Treatment was started on …….

The patient has been on the optimised dose stated for the following period of time: ……

The target serum lithium level/range is ……

This patient is now suitable for prescribing to move to primary care. The patient fulfils criteria for shared care therefore I am writing to request your agreement to continue the care of this patient according to the Specialised Medicines Service (SMS) Guideline for Priadel (lithium).

In accordance with this guideline, patients will have been stabilised on a suitable dose for at least one month before care is shared with the GP.

I have provided the patient with sufficient medication to last until ……..

Please undertake prescribing and monitoring from ……. in line with the SMS Guideline.

The next monitoring is due on ……..

I have arranged a follow up with this patient in ……

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

	Specialist to complete (YES/NO)
Baseline investigation and monitoring as set out in the SMS Guideline have been completed and were satisfactory	
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	
The risks and benefits of treatment have been explained to the patient	
The roles of the Specialist / GP / Patient have been explained and agreed	
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	
I have enclosed a copy of the SMS Guideline which covers this treatment. The guideline can also be found here	
I have included with this letter copies of the information the patient has received	

The results of baseline tests, early monitoring and any additional supportive information are included below and/or attached:

GP please sign response letter and return promptly (where possible this should be within 14 days of the request being made).

Specialist signature		**Date**	
Specialist name, role, speciality			
Daytime telephone number			
Email address			
Alternative contact e.g. clinic or specialist nurse			
Out of hours contact details e.g. duty doctor			

Remember to keep a copy of this letter for the patient's records.

Shared Care Agreement Letter – GP Acceptance Letter to Specialist

To	Specialist name	
Patient name		
Hospital number		
NHS number		
Date of birth		
Address		

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment:

Medicine	**Formulation** (Tablets or SF liquid)	**Route**	**Dose and frequency**
Priadel (lithium)		Oral	

Priadel (lithium) has been initiated for the treatment of (select applicable indication):	
Acute episodes of mania	
Acute episodes of hypomania	
Recurrent depressive episodes (where treatment with other antidepressants has been unsuccessful)	
Prophylaxis of recurrent bipolar disorder	

I can confirm that **I am willing to take on this responsibility** from …… and will maintain the prescribing and monitoring responsibilities as set out in the Specialised Medicines Service (SMS) Guideline for Priadel (lithium).

GP signature		**Date**	
GP name			
Practice address			
Telephone number			
Email address			

Remember to keep a copy of this letter for the patient's records. If this letter is not returned sharing of the care for this patient will not commence.

Shared Care Agreement Letter – GP Refusal Letter to Specialist

To Specialist name	
Patient name	
Hospital number	
NHS number	
Date of birth	
Address	

GPs are invited to participate in shared care agreements, but if the GP is not confident to undertake these roles then they are under no obligation to do so. If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Continuing the care assumes communication between the specialist, GP and patient; the intention should be explained to the patient and accepted by them.

The prescriber has the clinical and legal responsibility for the drug and the consequences of its use. Responsibility for drug monitoring and acting on results remains with the prescriber.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs."

In the interest of patient safety NHS Devon, in conjunction with local acute trusts have classified lithium as a "shared care" drug which requires a number of conditions to be met before transfer can be made to primary care.

Thank you for your request for me to accept prescribing responsibility for this patient. I regret to inform you that in this instance **I am unable to take on responsibility** due to the following:	**Tick applicable**
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 GP I do not feel clinically confident to manage this patient's condition. I have consulted with other GPs 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 below.**	

The condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement. As the condition requested to be treated is not included on the locally recognised list of indications for shared care for lithium I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this condition is identified locally as requiring shared care with lithium the responsibility for providing this patient with their medication remains with you.**	
A minimum duration of supply by the initiating specialist. 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.**	
Initiation and optimisation by the initiating specialist. **Patients will have been stabilised on a suitable dose for at least one month before being referred to their GP for sharing of care** 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.**	
Other (GP to complete if there are other reasons why shared care cannot be accepted):	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

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.

GP signature		**Date**	
GP name			
Practice address			
Telephone number			
Email address			

Remember to keep a copy of this letter for the patient's records.