LITHIUM PRESCRIBING GUIDELINES

Lithium for the treatment and prophylaxis of mania, bipolar disorder and recurrent depression

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<tr>
<th>Document Author</th>
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<tbody>
<tr>
<td>Written by: Francis Johnson</td>
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<tr>
<td>Approval</td>
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<tr>
<td>DAC: December 2014</td>
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<td>Trust Executive Committee date:</td>
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<td>CCG Board date: January 2015</td>
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<td>Review Date: October 2019</td>
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<td>Effective Date: October 2015</td>
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Version Control History:

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August 2014
Lithium prescribing guidelines

These guidelines have been produced to support the seamless transfer of lithium prescribing and patient monitoring from secondary to primary care and provides an information resource to support clinicians providing care to the patient.

This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer’s current edition of the Summary of Product Characteristics (SPC or “data sheet”) for more details.
# Lithium Prescribing Guidelines

August 2014

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**Isle of Wight NHS Trust 01983 524081**

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<td>Lead Nurse</td>
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<td>Lead Pharmacist</td>
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<td>Medicines Information</td>
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August 2014
Lithium prescribing guidelines

1 INTRODUCTION

The ICD-10 (International Statistical Classification of Diseases and Related Healthcare Problems) diagnosis of bipolar affective disorder is characterised by repeated episodes in which the patient's mood and activity levels are significantly disturbed. The disturbance may consist of an elevation of mood with increased energy and activity (manic or hypomanic episode), or a lowering of mood with decreased energy and activity (depressive episode).¹

Without treatment, there is a deterioration in skill and functioning with increasing frequency and severity of episodes. The management of bipolar affective disorder aims to control the symptoms of an acute episode whilst lengthening the periods of remission and reducing the risk of further acute episodes occurring in the future.

Lithium is licensed for the management of acute manic or hypomanic episodes and the prophylaxis against bipolar affective disorders.² Lithium has been shown to reduce the severity and duration of episodes, increase the length of time between episodes and reduce the risk of suicide and premature mortality.³ Lithium may not be appropriate if compliance is poor and prescribing and monitoring must follow trust guidance due to a National Patient Safety Agency alert.⁴

The ICD-10 diagnosis of recurrent depressive episode is characterised by repeated episodes (each of at least 2 weeks minimum separated by several months) of a depressive disorder without any history of independent episodes of mood elevation and overactivity that fulfil the criteria for a manic episode (but not hypomanic). A diagnosis of depressive disorder can be confirmed when the patient has at least two of the key symptoms:

- Persistent depressed/low mood for most of the day, nearly every day
- Marked diminished interest and enjoyment in activities
- Reduced energy leading to fatigue.

As well as at least two of any of the other additional symptoms:

- Reduced concentration and attention
- Reduced self-esteem and self-confidence
- Ideas of guilt and unworthiness
- Bleak and pessimistic views of the future
- Psychomotor agitation or retardation
- Ideas or acts of self-harm or suicide
- Disturbed sleep
- Diminished appetite or significant (5% in a month) change in weight
The severity of the depressive episode is determined by the number and severity of symptoms, degree of functional impairment, duration and course of illness. NICE (National Institute for Health and Care Excellence) Clinical Guideline 90 for treatment of depression in adults recommends combining or augmenting an antidepressant with lithium as one of the options after inadequate response to initial treatment with an antidepressant.\textsuperscript{5}

The NICE guidelines for bipolar affective disorder recommend establishing a shared-care protocol with the patient’s GP (General Practitioner) for prescribing and monitoring lithium and checking for adverse effects.\textsuperscript{3} Patient’s GPs are more appropriately placed to monitor patients and ensure the necessary blood tests are carried out as per guidance.

**Drug Treatment**

Tablets and liquid for oral route:

- Lithium carbonate tablets (Priadel®) 200mg, 400mg
- Lithium citrate liquid (Priadel®) 520mg/5ml (5ml equivalent of 204mg lithium carbonate)

(Other brands of lithium carbonate tablets include Camcolit® 250mg&400mg and Liskonum® 450mg. Other brands of lithium citrate liquid include Li-Liquid® 509mg/5ml&1018mg/5ml)
Other treatments

Other 'mood stabilisers' used in bipolar affective disorder and recommended in NICE CG 38 include valproate/valproic acid, lamotrigine and carbamazepine. Antipsychotics that are licensed for use in bipolar affective disorder and recommended by NICE CG 38 are aripiprazole, olanzapine, quetiapine and risperidone.

Chapter 4.3 of the BNF (British National Formulary) contains all the licensed antidepressants used to treat depressive episodes in the United Kingdom. Benzodiazepines and hypnotics in chapter 4.1 are sometimes to treat associated symptoms of affective disorders (agitation and sleep disturbance).

Electroconvulsive therapy is considered for the treatment of severe manic or depressive episodes, after other treatments have improved ineffective or if the condition is life-threatening in people with:

- Severe depressive illness
- Prolonged or severe manic episode
- Catatonia

2 INDICATIONS

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.

3 PREPARATION

Lithium is available in tablet or liquid form as listed in section 1.

Note, when converting from tablet to liquid:

- Lithium carbonate tablet 200mg (Li⁺ 5.4mmol) is approximately equivalent to 520mg/5ml Lithium citrate liquid
## 4 SAFETY ISSUES

*Please see the current BNF and SPC*

### 4.1 Dose

For lithium carbonate (Priadel®):

**Adults over 18 years:** initially 400mg daily as a single dose at night.

**Elderly, over 65 years:** initially 200mg daily as a single dose at night.

Elderly or patients less than 50kg: initially 200–400 mg daily, increasing to 800-1800mg/day.

Not recommended for use in children

Dose adjusted to achieve a serum-lithium concentration of 0.4–1 mmol/litre 12 hours after a dose on days 5–7 of treatment, then every week until dosage has remained constant for 4 weeks and every 3 months thereafter; once daily administration in the evening is preferred to ensure consistent serum-lithium concentration. See section 4.7 for more detail.

### 4.2 Contra-indications

Lithium is contra-indicated in patients with:

- Low sodium levels (< 133 mmol/l)
- Addison’s disease
- Untreated hypothyroidism
- Personal or family history of Brugada syndrome
- Cardiac insufficiency or rhythm disorder
- Severe renal impairment (< 30 eGFR)
- Breast-feeding (women who are considering pregnancy should consider seeking specialist advice and stopping)
4.3 Cautions

The following cautions should be considered when prescribing lithium:

- Cardiac disease and QT-interval prolongation (caution with concomitant use of drugs that prolong the QT interval)
- Review dose as necessary in diarrhoea, vomiting, and intercurrent infection (especially if sweating profusely)
- May lower seizure threshold (caution with epilepsy, concurrent ECT (electroconvulsive therapy), concomitant use of drugs and any therapy that may lower seizure threshold)
- Psoriasis (risk of exacerbation)
- Elderly (reduce dose)
- Diuretic treatment (risk of toxicity)
- Myasthenia gravis
- Surgery
- Avoid abrupt withdrawal.

4.4 Common Side Effects

The most common adverse effects of lithium are:

- Fine tremor
- GI disturbances (e.g. nausea, diarrhea)
- Polyuria
- Metallic taste
- Polydipsia
- Weight gain

Other adverse effects to look out for include:

- Changes in thyroid function
- Oedema
- Exacerbations of skin disorders (e.g. psoriasis, acne)
- ECG (electrocardiogram) changes
4.5 Drug Interactions
Main drug interactions:

- Excretion of lithium reduced by: ACE (angiotensin-converting-enzyme) inhibitors, angiotensin-II receptor antagonists, diuretics and NSAIDs. Avoid co-prescribing these medicines and use alternatives where possible (e.g. different antihypertensive or analgesic, loop diuretics).
- Excretion of lithium increased by acetazolamide
- Avoid use with amiodarone due to risk of ventricular arrhythmias
- The risk of neurotoxicity is increased when lithium is given with antipsychotics, methyldopa, triptans, SSRIs (Selective Serotonin Reuptake Inhibitors), calcium channel blockers and carbamazepine without increased plasma concentration of lithium

4.6 Pre-treatment Assessment

- Measure height and weight, arrange tests for urea and electrolytes (including sodium and calcium), serum creatinine/renal function and thyroid function.
- Arrange an ECG for patients who have significant risk factors for or existing cardiovascular disease.
4.7 Routine Monitoring

Initial
- Plasma lithium level 5-7 days after starting and after every dose increase or formulation change, level to be taken 10-14 hours (ideally 12) after dose.

Ongoing (once in therapeutic range)
- Plasma lithium level every 3 months (more frequently if reduced renal function or prescribed interacting medicines).
- Thyroid and renal function tests and calcium levels every 6 months
- Measure weight every 6 months.

The results of all the above tests should be recorded in the patient record book (in the lithium pack).

Lithium level

Always check that the timing of the blood sample has been appropriate. The desired level depends on what indication lithium has been prescribed for and past clinical response:
- 0.4-1.0 mmol/L may be effective for recurrent depressive disorder
- 0.6-1.0 mmol/L in bipolar affective disorder, depressive episode
- 0.8-1.0 mmol/L in difficult to treat bipolar affective disorder, manic episode.

If the level is low (typically <0.4mmol/l)
  a. If the patient is well and the levels are consistently low but within the desired specified range for that patient, do not alter dose.
  b. If the patient is unwell and pattern of levels have been bordering on the lower end of the range:
     1. assess compliance
     2. increase the dose if appropriate
     3. recheck the level in 5 days
  c. If the low level is inconsistent with the trend:
     1. assess compliance
     2. consider other factors, e.g. drug interactions, excess intake of fluid, brand change.
     3. recheck level in 5 days

If the level is within therapeutic range (typically 0.4 – 1.0 mmol/l)
  a. If the patient is well and tolerating lithium, do not alter dose.
  b. If the patient is well but complaining of side-effects e.g. polyuria, polydipsia, reduce the dose and check:
     1. If change in diet e.g. dietary salt restriction.
     2. Initiation of interacting medicines by doctor or use of OTC products.
  c. If the patient is clinically unwell, liaise further with CPN / psychiatrist

If the level is high (typically >1.0 mmol/l) but with no signs of toxicity
  a. Contemplate withholding lithium for 2-3 days where appropriate and restarting at a lower dose. Consider whether there is an explanation for the high level e.g. dehydration, timing of level, interacting medicines or brand change. Correct where possible and recheck level.
  b. If the level is part of a pattern of levels which have bordered on being too high:
     1. Decrease the dose by 200-400mg
     2. Encourage fluids
     3. Recheck level in 5 days
  c. If there is no clear explanation for high level:
     1. Recheck level
     2. Investigate renal function
Lithium toxicity

- Patients are at particular risk to lithium toxicity when there are changes to sodium levels e.g. low sodium diets, dehydration, drug interactions and some physical illnesses (e.g. Addison’s disease).

- Toxic effects typically occur at levels >1.5 mmol/l and usually include:
  - Gastrointestinal effects (increasing anorexia, nausea and diarrhea)
  - CNS (central nervous system) effects (muscle weakness, drowsiness, ataxia, coarse tremor and muscle twitching)

- Above 2 mmol/l, increased disorientation and seizures usually occur, which can progress to coma and ultimately death.

- If a patient exhibits signs of lithium toxicity:
  1. Stop lithium immediately
  2. Check lithium levels and renal function
  3. Refer to hospital if clinical condition warrants
  4. Seek advice from psychiatrist for re-initiation of lithium

- In the presence of more severe symptoms, osmotic or forced alkaline diuresis should be used, above 3 mmol/l, peritoneal or haemodialysis is often used.
Lithium therapy will usually be initiated by a consultant psychiatrist. A GP may consider restarting lithium (preferably in consultation with a psychiatrist) for the same diagnosis if the patient has previously benefited but relapsed since discontinuation.

Responsibilities of the prescribing doctor and secondary care mental health team include:

- Provide a diagnostic service for individuals who are referred with a suspected diagnosis of bipolar disorder or recurrent depressive disorder
- The benefits, risks and side-effects of treatment with lithium should be discussed with the patient. This should include the need for compliance and long-term commitment to the therapy, and the risk of relapse if lithium is stopped abruptly.
- Issuing and ensuring patient understands the NPSA lithium pack (supplied by hospital pharmacy with initial prescription). Clinicians to update record book where appropriate
- Advise patient with regard to adequate fluid balance and sodium intake and interactions with medication that can be bought over the counter such as NSAIDs.
- Undertake baseline investigations before initiating lithium (see 4.6)
- Monitor for response during the initiation phase as well as monitoring for reports of adverse drug reactions from the patient, carer, GP or any individual of the MDT involved in that patients management.
- Titrate medication, once initiated, in close dialogue with the patient and carers according to serum lithium levels.
- To monitor the effects of medication on mental state until an effective dose has been reached. The consultant psychiatrist will liaise with the GP and share the patients care once a stable, optimum dose has been achieved.
- Make it explicit to the GP upon discharge how long they expect lithium to be continued (e.g. six months, three years, foreseeable future).
- Provide a comprehensive referral letter to the GP indicating when the patient should be referred back to the consultant. Conditions of assuming responsibility by the GP agreed and a shared care document sent.
### 6 RESPONSIBILITY OF COMMUNITY MENTAL HEALTH NURSE (if applicable)

- Where appropriate, take blood sample from patient.
- Monitor patient for efficacy, side effects and signs of toxicity.
- Provide lithium booklet if working in a secondary care mental health team.
7 RESPONSIBILITY OF GP

- To ensure continuation of lithium treatment, checking lithium dose and blood results prior to deciding if safe to continue to prescribe (including repeat prescriptions).
- Prescribe lithium by brand, ensure patient understands branded product is lithium.
- Use of phrases such as 'as directed' should be avoided when prescribing.
- Provide appropriate ongoing verbal and written information to patient regarding their lithium treatment.
- Ensure existing patients on lithium and patients being restarted on lithium are supplied the lithium pack and counselled on its use (if need another pack supplying can be obtained from community pharmacy).
- Advise the patient to bring their monitoring book with them, whenever requesting a further supply of lithium and to update their book when possible.
- Ensure monitoring as per 4.7 by issuing relevant blood test forms and checking the results, contacting the patient if any action is required.
- Ensure patients are aware of their blood testing requirements.
- Patients should be encouraged to know acceptable levels and their most recent results.
- If Lithium levels are above or below the range, see section 4.7 for guidance.
- Look for signs of toxicity and side-effects of lithium when patients are reviewed.
- Monitor for drug interactions and adverse drug reactions.
- Be aware that co-morbid conditions such as renal impairment may increase risk of lithium toxicity.
- Refer back to consultant if concerned about pregnancy, lithium related side effects, compliance or deterioration.
- Levels above the range should be discussed urgently with the specialist service contact and consideration given to referring patients to the emergency department or stopping the lithium for a period of time and restarting at a lower dose once the lithium level is within the normal range.
- Where appropriate, consider slowly withdrawing lithium in stable patients that have received lithium for the period of time advised by the psychiatrist on discharge.
- Review choice of lithium as treatment if patient is non-compliant with monitoring requirements. Refer back to psychiatrist to consider change in treatment.
8 RESPONSIBILITY OF PATIENT

- Adhere to monitoring requirements of lithium treatment (blood tests).
- Attendance at community mental health and GP appointments.
- Report any adverse effects to their GP and/or specialist.
- Ensure that they have a clear understanding of their treatment.
- Inform their GP in sufficient time to obtain repeat prescriptions.
- Patients should be encouraged to keep their monitoring book up to date and bring it to their community mental health/GP appointments and to their pharmacy when collecting medication.

9 FURTHER INFORMATION

References
2 Summary of Product Characteristics of Priadel, last updated on the eMC: 01/12/2011
http://www.medicines.org.uk/emc/medicine/25501/SPC/Priadel+200mg+prolonged+release+tablets./#INDICATIONS
Patient is seen by consultant psychiatrist who provides a diagnosis for the patient and recommends starting lithium.

Consultant psychiatrist will titrate the dose of lithium according to lithium serum levels and monitor efficacy and tolerance.

Once a stable, optimum dose of lithium has been achieved, the psychiatrist will liaise with the patient’s GP to ask them to take over the prescribing.

GP will supply patient with lithium, ensuring the recommended monitoring is being carried out (lithium level every 3 months, renal and thyroid function every 6 months, see section 4.7)

Psychiatrist may discharge the patient from their care with a recommendation of how long they expect the lithium to be continued and when the patient should be referred back.
Step 1. Identify who is responsible for the equality analysis.

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<td>Role:</td>
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Other people or agencies who will be involved in undertaking the equality analysis:

Step 2. Establishing relevance to equality

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<td>Gender Reassignment</td>
<td>Service Users</td>
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<tr>
<td>Race</td>
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<td>Sex and Sexual Orientation</td>
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<td>Religion or belief</td>
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<td>Disability</td>
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<td>Marriage and Civil Partnerships</td>
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<td>Human Rights</td>
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<td>Pregnancy and Maternity</td>
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Show how this document or service change meets the aims of the Equality Act 2010?

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<tr>
<td>Eliminates unlawful discrimination, harassment, victimization and any other conduct prohibited by the Act.</td>
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<tr>
<td>Advance equality of opportunity between people who share a protected characteristic and people who do not share it.</td>
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</tr>
<tr>
<td>Foster good relations between people who share a protected characteristic and people who do not share it.</td>
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Step 3. Scope your equality analysis

<table>
<thead>
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<tbody>
<tr>
<td>What is the purpose of this document or service change?</td>
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<tr>
<td>Who will benefit?</td>
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<tr>
<td>What are the expected outcomes?</td>
</tr>
<tr>
<td>Why do we need this document or do we need to change the service?</td>
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</table>

It is important that appropriate and relevant information is used about the different protected groups that will be affected by this document or service change. Information from your service users is in the majority of cases, the most valuable.
Equality Analysis and Action Plan

This template should be used when assessing services, functions, policies, procedures, practices, projects and

Information sources are likely to vary depending on the nature of the document or service change. Listed below are some suggested sources of information that could be helpful:

- Results from the most recent service user or staff surveys.
- Regional or national surveys
- Analysis of complaints or enquiries
- Recommendations from an audit or inspection
- Local census data
- Information from protected groups or agencies.
- Information from engagement events.

Step 4. Analyse your information.

As yourself two simple questions:
- What will happen, or not happen, if we do things this way?
- What would happen in relation to equality and good relations?

In identifying whether a proposed document or service changes discriminates unlawfully, consider the scope of discrimination set out in the Equality Act 2010, as well as direct and indirect discrimination, harassment, victimization and failure to make a reasonable adjustment.

Findings of your analysis

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<th>Description</th>
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<td>No major change</td>
<td>Your analysis demonstrates that the proposal is robust and the evidence shows no potential for discrimination.</td>
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<tr>
<td>Adjust your document or service change proposals</td>
<td>This involves taking steps to remove barriers or to better advance equality outcomes. This might include introducing measures to mitigate the potential effect.</td>
</tr>
<tr>
<td>Continue to implement the document or service change</td>
<td>Despite any adverse effect or missed opportunity to advance equality, provided you can satisfy yourself it does not unlawfully</td>
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Equality Analysis and Action Plan

This template should be used when assessing services, functions, policies, procedures, practices, projects and strategic documents that discriminate.

Stop and review Adverse effects that cannot be justified or mitigated against, you should consider stopping the proposal. You must stop and review if unlawful discrimination is identified.

5. Next steps.

5.1 Monitoring and Review.
Equality analysis is an ongoing process that does not end once the document has been published or the service change has been implemented.

This does not mean repeating the equality analysis, but using the experience gained through implementation to check the findings and to make any necessary adjustments.

Consider:

<table>
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<th>How will you measure the effectiveness of this change?</th>
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<tr>
<td>When will the document or service change be reviewed?</td>
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<tr>
<td>Who will be responsible for monitoring and review?</td>
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<tr>
<td>What information will you need for monitoring?</td>
</tr>
<tr>
<td>How will you engage with stakeholders, staff and service users?</td>
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5.2 Approval and publication
The Executive Board will be responsible for ensuring that all documents submitted for approval will have completed an equality analysis.

Under the specific duties of the Act, equality information published by the organisation should include evidence that equality analyses are being
Equality Analysis and Action Plan

This template should be used when assessing services, functions, policies, procedures, practices, projects and undertaken. These will be published on the organisations “Equality, Diversity and Inclusion” website.

Useful links:

Equality and Human Rights Commission