Livewell Southwest

Lithium: Policy for the Safe Initiation, Prescribing, Monitoring and Dispensing of Lithium Preparations

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Notice to staff using a paper copy of this policy

The policies and procedures page of Intranet holds the most recent version of this guidance. Staff must ensure they are using the most recent guidance.

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Reader Information

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Author	Amy Rice, Advanced Clinical Pharmacist
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Target audience (who policy is applicable to)	All LSW staff involved in any aspect of lithium therapy
Circulation List	Electronic: Livewell Southwest (LSW) intranet and website (if applicable) Written: Upon request to the Policy Coordinator at **livewell.livewellpolicies@nhs.net** Please contact the author if you require this document in an alternative format.
Stakeholders	All LSW staff involved in any aspect of lithium therapy Derriford Combined Laboratories UHP Pharmacy Department Prescribers of lithium in primary care (under Devon CCG shared care agreement)
Consultation process	Expert group identified with representatives from inpatient and community mental health services for adults and for older people.
References/sources of information	See Appendix C
Equality analysis checklist completed	Yes
Is the Equality and Diversity Policy referenced	NA
Is the Equality Act 2010 referenced	NA

Associated documentation	One Devon Specialised Medicines Service Prescribing Guideline and Share Care agreement for Lithium (Priadel®) https://onedevon.org.uk/download/lithium-specialised-medicines-service-prescribing-guideline-devon/ Lithium Guidelines for the Safe Initiation, Prescribing, Monitoring and Dispensing of Lithium Preparations LSW Medicines Policy
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Document review history

Version no.	Type of change	Date	Originator of change (Name and job title)	Description of change
Refer to archived copies for information on previous versions				
3.0	Reviewed	November 2019	A Rice Advanced Clinical Pharmacist	Full review and transfer to current template. Added advice for elderly/frail patients. Increased prominence of Shared Care Guidelines. Removed LSW GP practice guidance.
4.0	Full Review	March 2023	Governance & Patient Safety Pharmacist	Updated and stripped to the 'must' dos. Guideline with additional information new document Asset 639 to be used in conjunction with each other

Lithium Policy for the Safe Initiation, Prescribing, Dispensing and Monitoring of Lithium Preparations

1 Introduction

1.1 Lithium therapy is supported by NICE guidance[1,2,3] as an effective treatment for acute episodes of mania or hypomania, prophylaxis against relapse in bipolar affective disorder and in the treatment of recurrent depressive disorders where treatment with other antidepressants has been unsuccessful.

1.2 Lithium is a 'high risk' medication with a narrow therapeutic range - if levels are too low there may be a lack of therapeutic effect, or, if too high symptoms of toxicity occur which can be serious or even fatal in extreme cases.

1.3 The NPSA alert NPSA/2009/PSA005 required all organisations (NHS and private) where lithium therapy is initiated, prescribed, dispensed and monitored to comply with five actions by the end of December 2010.[4] These are still applicable.

1.4 The NPSA alert includes five main actions for assurance:

- Patients prescribed lithium are monitored in accordance with NICE guidance.

- There are reliable systems to ensure blood test results are communicated between laboratories and prescribers.

- At the start of lithium therapy and throughout their treatment patients receive appropriate ongoing verbal and written information and a record book to track lithium blood levels and relevant clinical tests

- Prescribers and pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and / or dispense the prescribed lithium.

- Systems are in place to identify and deal with medicines that might adversely interact with lithium.

2 Purpose

2.1 The purpose of this policy is to provide assurance of robust and safe systems within LSW to manage the inherent risks to adult patients from the use of newly initiated or ongoing lithium therapy, based on the recommendations of the NPSA alert[4] and current NICE guidelines[1,2,3].

2.2 Where the word 'must', 'ensure' or similar is used this should be seen as mandatory.

2.3 This policy is also to be used in conjunction with the Lithium Specialised Medicines

Service prescribing guideline (Devon-wide) - One Devon - [5] which defines the responsibilities of primary and secondary care, and reference made to the supplementary information in the LSW Lithium Guidance and LSW Medicines Policy.

3 Definitions

Acronym	Definition
BNF	British National Formulary
GPSI	GP with Special Interest
NICE	National Institute for Health & Clinical Excellence
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning Service
LSW	Livewell Southwest
OTC	Over the Counter Medicines
ODSMSPG	One-Devon Specialist Medicines Service Prescribing Guideline
SPC	Summary of Product Characteristics
SWDF	South and West Devon Formulary and Referral
UHP	University Hospitals Plymouth NHS Trust

4 Duties & Responsibilities

4.1 The **Chief Executive** has overall statutory responsibility for the safe and secure handling of medicines and is ultimately responsible for the content of all policies, implementation and review.

4.2 The **Director of Safety and Quality** is responsible for ensuring an adequate response to all safety alerts including the requirement for relevant document production and review.

4.3 The **Medical Director** has overall professional responsibility for Medicines Management within LSW.

4.4 The **Clinical Director of Pharmacy** (also known as Chief Pharmacist) has overall organisational clinical governance and operational responsibility for Medicines Management & Medicines Optimisation within LSW. This includes the quality of medicines appropriate consultations and communications and the organisation of safe and secure systems for all stages of medicine handling from Pharmacy to the patient.

This responsibility includes implementation of all safety alerts, monitoring, and reporting on, the effectiveness of systems in place and investigation of any medication related incidents.

4.4 **Line managers** are responsible for, and must:

- ensure that staff involved in handling of lithium at any stage have access to this and any associated guidance.
- include this policy in the induction of new staff
- follow up prescribing/medication errors or incidents relating to the initiation, prescribing, dispensing or monitoring of lithium

4.5 **Consultant Psychiatrists** (or in CMHT the patient's lead psychiatrist) are responsible for and must:

- ensure that all the points listed under "Specialist" responsibilities in the Lithium Specialised Medicines Service prescribing guideline (Devon-wide) - One Devon are followed where care will be shared with GP.

- Complete the initiation checklist Appendix A

4.6 **Doctors/non-medical prescribers working on inpatient units (including community & rehab) or working under consultant psychiatrists** are responsible for:

- ensuring that prescribing but **not** initiating lithium unless working under the direction of a specialist and monitoring of lithium is done in accordance with the Lithium Specialised Medicines Service prescribing guideline (Devon-wide) - One Devon[5]
- ensuring the patient has a monitoring booklet that is up to date and information has been provided in accordance with the Initiation Checklist – Appendix A.

4.7 **Nurses on inpatient units** are responsible for reinforcing the initiation checklist Appendix A for new patients to lithium, and for both existing and new patients must:

- ensure they receive their lithium as prescribed
- check that their lithium monitoring booklet is available and up to date at the point of discharge
- enclose the monitoring booklet with the patient's TTAs on discharge.
- provide patients with appropriate verbal and written information on lithium
- ensure lithium blood tests are performed 12 hours post dose when required
- ensuring that patients are monitored for potential adverse effects and reported to the specialist/lead clinician

4.8 **LSW Pharmacists on inpatient units** are responsible for and must:

- ensure that the Lithium Specialised Medicines Service prescribing guideline (Devon-wide) - One Devon[5] is followed for newly initiated and existing patients
- reinforce the initiation checklist Appendix A for new patients to lithium
- clinically screening medication charts paying particular attention to checking:

- the indication
- the dose and time of dose is appropriate - normally given at night
- the brand of lithium previously taken by the patient is maintained or the dose is re-titrated where doses have been missed or an alternative brand has to be used – bring to the attention of/ discuss with the specialist as required
- the patient has a lithium monitoring booklet that is up to date
- blood tests and biochemical tests have been performed in accordance with the ODSMSPG[5] where care is shared/ Appendix B
- potential drug interactions (including OTC medications e.g. NSAIDS) / adverse reactions or toxic effects and bringing these to the attention of the prescriber with recommendations for corrective action.

4.9 **CMHT care coordinators** are responsible for patients on their caseload prescribed lithium and must:

- ensure they have adequate supplies of the preparation of lithium prescribed
- check they are taking lithium as prescribed
- ensure they have a lithium monitoring booklet that has been kept up to date
- ensure blood tests and biochemical tests have been performed in line the Lithium Specialised Medicines Service prescribing guideline (Devon-wide) - One Devon.[5] where care is shared with GP or as Appendix B
- ensure they report any suspected adverse effects / toxic effects or non-concordance with treatment to the patient's specialist and / or GP.

4.10 **Community / District Nurses** who come into contact with patients prescribed lithium must:

- ensure they have adequate supplies of the preparation of lithium prescribed
- check they are taking lithium as prescribed
- ensure they have a lithium monitoring booklet that has been kept up to date
- ensure blood tests and biochemical tests have been performed in line the Lithium Specialised Medicines Service prescribing guideline (Devon-wide) - One Devon.[5] where care is shared with GP or as Appendix B
- ensure they report any suspected adverse effects / toxic effects or non-concordance with treatment to the patient's specialist and / or GP.

4.11 **Pharmacists at UHP** dealing with inpatient or discharge prescriptions for lithium:

- Must check that a pharmacist clinical screen has been done at ward level before supplying lithium against in-patient / discharge prescriptions. If this is not the case proceed as for LSW pharmacists section 4.8
- Must not withhold lithium without checking. **If** lithium has been stopped on admission check that this is appropriate i.e. due to toxicity (see section 5.6) or other clinical reason. Confirm that the decision to stop has been agreed with the patient's specialist/consultant psychiatrist. A LSW pharmacist should be informed.

5 Initiation, Prescribing, Monitoring and Dispensing of Lithium

5.1 INITIATION[1,2,3,5,8,9,14]

5.1.1 Initiation of lithium is the **responsibility of the specialist**/lead psychiatrist, and must be carried out in accordance with the ODSMSPG**.** Refer to NICE CG185 (Bi-Polar), NG222 (Depression)

5.1.2 **BEFORE initiating** lithium therapy the specialist must consider:

- the appropriateness of therapy based on any existing conditions
- blood test results
- patients ability to understand and comply
- interactions with existing medication

Refer to Lithium Guidelines for supporting information.

5.1.3 The specialist must use the **Initiation Checklist** Appendix A to provide and reinforce information to patients at the start of therapy. Pharmacists and nurses must also complete the checklist to ensure appropriate information is received.

5.1.4 **AFTER initiation** serum **lithium levels** (under the specialist) (Also see section on monitoring and Appendix B)**:**

- Must be **checked between 4 to 7 days following initiation** and the dose adjusted accordingly
- Must be **checked 1 week after every dose change**
- Must be taken **weekly** until levels have shown stability for 4 week

BLOOD SAMPLES FOR LITHIUM MUST BE TAKEN 12 HOURS POST DOSE

5.1.5 If appropriate ongoing management can be shared with the patient's GP under a shared care agreement. The specialist psychiatrist must complete the Shared Care Agreement Letter in the ODSMSPG and send this to the GP.

5.1.6 The GP is under no obligation to accept ongoing management, if the GP does not take on shared care responsibility then the total clinical responsibility for the patient for the diagnosed condition must remain with the specialist

5.2 PRESCRIBING[3,5,6,8,9,11,12,13]

5.2.1 As lithium is available as more than one salt and **different brands/formulations of lithium are not bioequivalent they must not be interchanged**;

5.2.2 In order to minimise risk **lithium must always be prescribed by brand.** Devon Joint Formulary **only** supports the use of the brand **Priadel®.**

5.2.3 Where a change of product/brand is unavoidable this must be regarded as initiation of new treatment and treated as such.

Refer to Lithium Guidelines for additional information

5.2.4 Prior to prescribing **any** prescription for lithium, prescribers must check the scheduling, and any results, of blood tests to reassure themselves that, given the test results, no patient harm will result.

5.2.5 If a new drug (or change in dosage) is to be prescribed for a patient on lithium, the potential for drug interaction with any existing medication for physical or mental health conditions must be checked. Refer to the ODSMSPG, Lithium Guideline and/or the latest version of the BNF and SPC. Advice on management should be sought from either the specialist/ consultant psychiatrist, Pharmacy Services (4)34723 or Medicines Information, UHP Pharmacy via UHP switch x50.

5.2.6 If an interacting drug is to be used then this should be clearly communicated to all involved (patient, psychiatrist, GP, pharmacist and nurse as appropriate), this should also include any additional monitoring requirements and who to contact should the patient develop symptoms of toxicity or worsening mental state.

5.3 MONITORING [1,2,3,5]

5.3.1 Lithium must be monitored according to NG 105 (Bipolar), NG 222 (depression), CKS Bipolar, ODSMSPG – a summary of which is included in Appendix B

5.3.2 Initial monitoring of lithium must remain the responsibility of the specialist psychiatrist until stabilised for a minimum of 4 weeks or until care is shared with the GP under ODSMSPG. Where the GP declines shared care then the responsibility must remain with the specialist see section 5.1.

5.3.3 A recent lithium blood level must be available **before** any change in dose or review of treatment is planned.

5.3.4 All patients on lithium admitted to an inpatient unit must have their lithium levels checked on admission.

5.3.5 All patients must be monitored at every appointment/ inpatient admission for symptoms of neurotoxicity including paraesthesia, ataxia, tremor and cognitive impairment which can occur at therapeutic levels of lithium.

5.3.6 Where monitoring highlights levels outside the target serum level then specialist advice must be sought. Refer to ODSMSPG

5.3.7 Where patients are unwilling to accept and use a record system for personal monitoring, and it is not possible to otherwise perform this check, the patient must be referred back to the specialist /consultant psychiatrist for a review of lithium therapy.

5.4 COMMUNICATION [4,5]

5.4.1 The results of initial assessment tests and all monitoring to date must be

- included with the referral documentation from specialist to GP at the point of commencing a shared care agreement - ODSMSPG.

5.4.2 All test results must be:

- recorded in the patient monitoring booklet by the healthcare professional.
- included in discharge summaries and letters
- recorded on S1 / patient notes.

Results must **not** be transmitted verbally

5.5 DISPENSING AND ADMINISTRATION[1,2,3,5,6]

5.5.1 Prior to clinically screening, dispensing/supply of **any** prescription for lithium, pharmacists must check the scheduling and any results of blood tests to reassure themselves that, given the test results, no patient harm will result.

5.5.2 Ensure that **ALL** repeat lithium requests are brought to the attention of the prescriber so they can be assured that the necessary monitoring has taken place before signing the prescription.

5.5.3 Prescriptions must not be dispensed or supplied if **any** of the following apply (refer to ODSMSPG for actions to be taken at various lithium levels):

- If the current blood level is above the specified target range seek advice from the specialist/lead psychiatrist
- If the patient has symptoms of toxicity irrespective of target level – do not dispense/supply/administer and refer the patient immediately to their specialist/lead psychiatrist

Any discrepancies or problems must be brought to the attention of the duty doctor or specialist/ consultant psychiatrist.

5.5.4 Nurses must not administer lithium to any patient who is showing signs of toxicity and / or for whom the current blood level is above 1.5mmol/L (or above 1mmol/L in elderly patients). The duty doctor or specialist/consultant psychiatrist must be contacted immediately for advice.

5.6 TOXICITY [3,5,8,9]

5.6.1 For patients with symptoms of lithium toxicity (e.g. diarrhoea, vomiting, tremor, mental state changes, or falls) healthcare professionals must:

- **withhold** lithium
- take **urgent** serum lithium level and U&Es
- provide **supportive measures** such as correction of fluid and electrolyte balance if needed
- **monitor** patients for a **minimum of 24 hours**
- consider the need to refer for urgent medical care depending on the severity of symptoms and the certainty of toxicity

5.7 DISCONTINUATION OF LITHIUM THERAPY[5]

5.7.1 Lithium must never be stopped suddenly unless the individual is suffering from signs of toxicity or has a serum lithium level greater than 1.5mmol/L. Abrupt discontinuation of lithium increases the risk of relapse.

5.7.2 If lithium is to be discontinued, the dose should be reduced gradually over a period of at least 4 weeks (preferably over a period of up to 3 months). Refer to ODSMSPG.

6 Training implications

6.1 Training on the actions within this policy will be included in the following programme:

- Mental Health Junior Doctor induction training – Pharmacy sessions now include lithium prescribing & monitoring.

6.2 Clinical supervision of new or less experienced staff in these procedures by senior staff should occur as part of the routine clinical supervision in operation. The nurse in charge of each ward or unit is responsible for ensuring this occurs in respect of the specific circumstances of their ward or unit.

7 Monitoring compliance[4]

7.1 An audit tool has been developed that includes aspects of each of the five action points required by the NPSA alert.

7.2 Individual teams should plan an annual audit of compliance (and as otherwise requested) against these standards using the audit tool in the Lithium Guidance and provide audit results as requested by the Organisation or External Auditor.

8 Organisational Approval

All policies/protocols are required to be signed/electronically signed by the Lead Director. Proof of the electronic signature is stored in the policies database.

The Lead Director approves this document and any attached appendices. For operational policies this will be the Head of Service.

The Executive signature is subject to the understanding that the policy owner has followed the organisation process for policy Ratification.

Organisational Approval		
Board Approval	**Title**	Medical Director
	Organisation	Livewell Southwest
	Name	*Names and signature stored electronically*
	Signature	
	Date	
Supporting Consultant Psychiatrist	**Title**	Consultant Psychiatrist
	Organisation	Livewell Southwest
	Name	*Names and signature stored electronically*
	Signature	
	Date	
Supporting Pharmacist	**Title**	Governance & Patient Safety Pharmacist
	Organisation	Livewell Southwest
	Name	
	Signature	
	Date	
MGG Approval	**Title**	Chief Pharmacist
	Organisation	Livewell Southwest
	Name	*Names and signature stored electronically*
	Signature	
	Date	

Appendix A: Lithium Initiation Checklist

This checklist must be completed for all new individuals initiated on lithium.

- Ensure all the following information on the checklist is discussed with the individual and/ or carer (as appropriate).
- The checklist should initially be completed by the prescriber, but then reinforced by the prescriber, pharmacists and nursing staff to ensure the information is understood (or where the individual lacks capacity - ensure that adequate support systems are in place to ensure concordance).
- Written information should be provided as well as a verbal explanation.
- Nursing staff should reinforce information at the time of discharge if the individual has been an inpatient.

Patient Name:
Carers Name (if discussed where applicable):
Initiating Specialist:

Information given by:	**Dr / NMP**	**Pharmacist**	**Nurse**
	Initial and date		
Purple pack provided (including Record Book and Alert Card) and fully completed			
Why lithium been prescribed & benefits of therapy			
Dose to be taken			
Length of treatment & who will stop medication			
Importance of taking medication regularly and not stopping suddenly – risk of relapse			
What to do if a dose is missed?			
What are the common side effects			
What are the signs of lithium toxicity			
Importance of adequate fluid intake and maintaining a consistent salt intake, particularly if sweating, immobile, chest infection/pneumonia (dehydration can affect lithium levels)			
Seek medical advice if diarrhoea and vomiting or acutely unwell			
What blood tests are necessary and how often are they due			
Importance of not missing the blood test and contacting the GP			
Importance bringing purple book to GP, psychiatric appointments and to pharmacy			
Importance of telling other health professionals about being on lithium			
Checking with pharmacist before purchasing OTC products – avoiding ibuprofen			
Who to contact in an emergency			
Risks in pregnancy (where relevant) – advising specialist/GP if pregnant or planning to become pregnant			

A copy of this form should be scanned to the patient record on S1 after discharge

Appendix B: Lithium Monitoring

Lithium Monitoring Guideline[CKS, NG185, NG222,14]										
	Comment (if evidence of impairments tests should be carried out more frequently)	**Baseline** (specialist)	**4-7 days post initiation**	**Pre dose change or rv**	**After dose change**	**Weekly until 4/52 stable**	Transfer of care to GP if GP in agreement under ODSMSPG, seeking specialist advice as required	**3 monthly**	**At least 6 monthly**	**At least Annually**
								More frequently if indicated		
Serum lithium	12 hours post dose *continue 3 monthly if ≥65; taking drugs that interact with lithium; renal or thyroid impairment; poor adherence; last Li level >0.8mmol/l		✓	✓	✓	✓		For 12 months* then 6 monthly*	After 12 months ✓*	
Renal Function (U&Es, eGFR)	Risk of lithium toxicity in renal dysfunction. Trends may be more helpful, monitor lithium dose and plasma lithium levels more frequently if urea and creatinine levels become elevated, or eGFR falls over 2 or more tests, assess rate of deterioration of RF, seek advice from renal specialist if required	✓							✓CKS *	
Calcium	Risk of hypercalcaemia , hyperparathyroidism	✓							✓CKS	✓
Thyroid	Risk of hypothyroidism (greatest in 1st 2 years), treat with levothyroxine. Hyperthyroidism seek specialist advice	✓							✓CKS *	
Cardiac (ECG)	Arrhythmias and bradycardia	✓								✓
FBC		✓								✓
Weight/BMI		✓							✓CKS	
Pregnancy	Exclude prior to initiation, patient should inform if likelihood of pregnancy	✓								

All patients already taking lithium on admission to an inpatient area should have a serum lithium level taken

Appendix C References

1. National Institute for Health & Clinical Excellence (NICE): Bipolar disorder: Assessment and Management *Clinical Guideline* 185, 2014. http://www.nice.org.uk/guidance/cg185/chapter/introduction last accessed 23 February

2. National Institute for Health & Clinical Excellence (NICE): **Depression in adults: treatment and management**
   NICE guideline [NG222] Published: 29 June 2022 Replacing CG90
   https://www.nice.org.uk/guidance/ng222 last accessed 23 February 2023

3. NICE CKS: Bi-Polar Disorder Lithium Lithium | Prescribing information | Bipolar disorder | CKS | NICE https://cks.nice.org.uk/topics/bipolar-disorder/prescribing-information/lithium/

4. National Patient Safety Agency alert NPSA/2009/PSA005 (1st December 2009) [ARCHIVED CONTENT] Safer lithium therapy (nationalarchives.gov.uk) https://webarchive.nationalarchives.gov.uk/ukgwa/20180501163555/http:/www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=65426&p=2 last accessed 21st February 2023

5. Lithium Specialised Medicines Service prescribing guideline (Devon-wide) - One Devon https://onedevon.org.uk/download/lithium-specialised-medicines-service-prescribing-guideline-devon/

6. LSW Medicines Policy from LSW intranet. V8.2 as at February 2023

7. One Devon https://onedevon.org.uk last accessed 28 February 2023

8. British National Formulary https://bnf.nice.org.uk/search/?q=lithium

9. Electronic Medicines Compendium https://www.medicines.org.uk/emc#gref last accessed 21st February 2023

10. NPSA 2009/PSA005 “Lithium Therapy – Important Information for Patients” https://webarchive.nationalarchives.gov.uk/ukgwa/20180501163555mp_/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65431&type=full&servicetype=Attachment last accessed 21st February 2023

11. Lithium Record Book NRLS-0921-Lithium-record-_et-2009.12.01-v1.pdf.pdf https://webarchive.nationalarchives.gov.uk/ukgwa/20180501163555mp_/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65430&type=full&servicetype=Attachment last accessed 21st February 2023

12. South & West Devon Formulary & Referral Guideline 4.2.3 Drugs used for mania and hypomania (devonformularyguidance.nhs.uk) https://southwest.devonformularyguidance.nhs.uk/formulary/chapters/4.-central-nervous-system/4-2-psychoses-and-related-disorders/4-2-3-drugs-used-for-mania-and-hypomania Last accessed 21st February 2023

13. Devon Partnership Trust – Lithium Protocol Search - lithium | DPT https://www.dpt.nhs.uk/search?q=lithium Last accessed 1 March 2023

14 David M. Taylor, Thomas R. E. Barnes, Allan H. Young: Maudsley Prescribing Guidelines in Psychiatry 14th edition 2021