Standard Operating Procedure for Initiation Prescribing and Monitoring of Lithium

TARGET AUDIENCE	Prescribers within NHS Lanarkshire MHLD services Pharmacy team members within the Drug Initiation Service (DIS)
PATIENT GROUP	All new patients where lithium is to be initiated following recommendations by MHLD services

Summary

This document outlines the responsibilities of Mental Health & Learning Disabilities (MHLD) services and the **Drug Initiation Service (DIS)** to support the initiation of lithium as an outpatient within NHS Lanarkshire prior to lithium prescribing and monitoring transferring to Primary Care services.

The **DIS** is a pharmacy led prescribing and monitoring hub which facilitates the prescribing and monitoring of drugs on the High Risk Medicines Monitoring Local Enhanced Service (LES) including lithium **during the initiation phase**.

Following the initiation period, once a target lithium level is reached and the patient is established on a maintenance dose of lithium, prescribing and monitoring of lithium can be transferred to the patient's primary care team for ongoing management in line with the medicines monitoring LES.

The safe use of lithium has been a long-term national priority since the NPSA issued a Patient Safety Alert in 2009. In more recent years, the Chief Medical Officer issued national guidance for lithium in 2017 and 2019[1] which define the minimum standards for physical health monitoring for all individuals taking lithium in Scotland. NHS Lanarkshire's lithium drug specific monitoring document is in line with the CMO guidance and the most recent NICE guidance (CG185)[2].

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Purpose

The objective of this Standard Operating Procedure (SOP) is to describe the process for the prescribing and **monitoring of lithium during the initiation phase for outpatients** in NHS Lanarkshire, as well as outline the roles and responsibilities of the specialist mental health team as well as the DIS.

Inclusion criteria
Patients under the care of a community mental health team (CMHT)
Eligible to commence lithium

Exclusion criteria
Patients deemed not suitable to initiate lithium as an outpatient

Lithium is licensed for;

- Treatment and prophylaxis of mania
- Treatment and prophylaxis of bipolar disorder
- Treatment and prophylaxis of recurrent major depressive disorder
- Treatment and prophylaxis of aggressive or self-harming behaviour

Specialist mental health team responsibilities

1. Plan to initiate lithium as an outpatient.

2. Specialist mental health prescriber ensures patient meets eligibility criteria for prescribing of lithium via the DIS.

3. The specialist mental health team explains to patient process for lithium initiation prescribing and monitoring via the DIS and provides the patient with the DIS Information for patients letter (*Appendix 6 - Drug Initiation Service Patient Information Leaflet*)

4. Specialist mental health prescriber/ team arranges for all pre-initiation actions to be completed including:
    - assessment of contraindications/ cautions *(Appendix 2)*
    - assessment of relevant interactions with currently prescribed medication *(Appendix 3)*
    - discussion of benefits and risks of treatment* and obtaining/ documenting patient/ carer consent
    - all relevant baseline monitoring *(Appendix 7 – Lithium Drug Specific Monitoring Document*) either via the locality community mental health team (CMHT) or via a treatment room referral.

5. Once baseline actions and monitoring have been completed, a referral to the DIS can be made using the *Lithium initiation request* (*Appendix 1*) and sent via email to the DIS; lan.druginitiationhub@lanarkshire.scot.nhs.uk

6. The *Lithium initiation request* referral should be completed in full with initiation dosing instructions and target lithium level included in order for the DIS to titrate the dose of lithium appropriately. Failure to complete the request in full will potentially delay the initiation of lithium.

7. Patients must remain under the care of the specialist mental health team whilst prescribed lithium.

*** For accessible patient information on psychotropic medications including easy read versions and translations**

https://www.choiceandmedication.org/nhs24/

Drug Initiation Service responsibilities

Initial monitoring and prescription

8. On receipt of referral from the CMHT, the DIS confirms all relevant actions and baseline monitoring (in line with lithium drug specific monitoring document) have been completed and any potential outstanding actions are highlighted to the referring clinician.

9. The DIS will correspond with the specialist referrer to confirm receipt of referral as well as the patient and the patient's primary care team regarding their referral to the DIS via a DIS standard letter template.

10. Once the DIS are assured all relevant actions and baseline monitoring have been completed and results are satisfactory, the DIS will generate a prescription for one calendar month of lithium carbonate (Priadel®). Lithium carbonate will always be prescribed by the brand Priadel®, as the NHS Lanarkshire preferred formulary choice.

Lithium initiation dose	**Lithium carbonate (Priadel®) tablets supplied**	**Dosing instructions**
200mg	200mg x 30	*One tablet to be taken at night. Further dose changes will be communicated by the DIS following blood sample results.*
400mg	400mg x 30	*One tablet to be taken at night. Further dose changes will be communicated by the DIS following blood sample results.*

11. The prescription generated by the DIS will be posted directly to the patient and/or the patient's nominated community pharmacy for dispensing.

Follow up monitoring and prescription

12. DIS standard operating procedures will be followed for arranging phlebotomy appointments to arrange serum lithium levels to be taken (in line with lithium drug specific monitoring document) no sooner than seven days after lithium has been commenced. In practical terms, this is likely to be around two weeks after lithium has been commenced.

13. On receipt of the first lithium level, the DIS will contact the patient with instructions regarding any dose changes and subsequent blood tests. Further prescriptions will be issued in line with any adjustment in dose.

14. The DIS will arrange for serum lithium levels to be taken (in line with lithium drug specific monitoring document) no sooner than seven days after the lithium dose has been changed. In practical terms, this is likely to be around two weeks after the dose change.

15. Further dose changes and follow-up lithium levels will be made in line in with the lithium drug specific monitoring document until the target lithium level is reached.

16. In the event of patient non-engagement with the DIS and associated monitoring, the DIS will follow non-engagement procedures and correspond with the patient and the specialist via a DIS standard letter template.

17. In the event of repeated non-attendance, the DIS will follow Did Not Attend (DNA) procedures and correspond with the patient, the patient's primary care team and the referring specialist team via DIS standard letter templates.

18. Transfer of monitoring and prescribing to primary care should occur when the patient's dose has been optimised, a lithium level has been obtained within the target lithium level range and there are no anticipated further changes expected in immediate future.

19. The DIS will correspond with the patient, the referring specialist team and the patient's primary care team, when the responsibility for prescribing and monitoring will be taken over by the patient's primary care team (Appendix 5 – Lithium discharge letter to primary care). The DIS will ensure an adequate supply of the lithium maintenance dose is provided on discharge from the DIS to primary care to allow safe and timely transfer of care.

20. The patient will remain under the care of the specialist mental health team for ongoing review.

Lithium is available as two salts, lithium carbonate and lithium citrate, which are **not** dose equivalent.

Lithium carbonate is supplied in tablet form
Lithium citrate is supplied as a liquid
(both Priadel® preparations are the preferred NHS Lanarkshire formulary option)

5ml (520mg) lithium citrate is considered to be equivalent to 200mg lithium carbonate

In the event that the solid oral dosage form (lithium carbonate) is not suitable for the individual, the DIS will liaise with the NHS Lanarkshire mental health pharmacy team for bespoke arrangements for managing the prescribing of lithium solution as lithium citrate.

Advice regarding doses and lithium target levels[3]

- A serum lithium level of 0.6-0.8 mmol/l is suitable for most people who are being prescribed lithium for the first time.
- Dose adjustments may be required in patients prescribed interacting medicines. Where patients are prescribed medicines that can increase lithium levels (by reducing renal elimination), a lower starting dose may be advisable (refer to *Appendix 3– Lithium interactions with other medications*)
- Lower doses and low target lithium levels may be required in older or physically frail/ low body weight patients, in mild to moderate renal impairment and electrolyte imbalance. In these patients, a starting dose of 200mg and a lower target level is advisable.
- Higher serum lithium levels (0.8-1.0 mmol/l) are suitable for people who have relapsed previously while taking lithium, or who still have subthreshold symptoms with functional impairment while receiving lithium.
- Lithium toxicity is defined as any level greater than 1.2mmol per litre. However, toxic effects may develop within the normal range especially in older patients. Toxicity should be considered if there are signs suggestive of dehydration, any change in mental or physical state e.g. confusion, falls or increased tremor. (*Appendix 4– Lithium common side effects and signs of toxicity)*

Suggested lithium dose escalation			
Initiation dose	**Target level range**	**First level**	**Dose recommendation***
200mg (lower starting dose for older adults/ frail)	0.4-0.6 mmol/l (potentially lower target range for older adults)	0.1-0.2 mmol/l	400mg
		0.2-0.3 mmol/l	300- 400mg
		0.3-0.4 mmol/l	300mg
		0.4-0.6 mmol/l	Maintain at 200mg
		>0.6 mmol/l	100mg
200mg (lower starting dose for those Rx interacting meds)	0.6-0.8 mmol/l	0.1-0.2 mmol/l	400mg
		0.2-0.3 mmol/l	400mg
		0.3-0.4 mmol/l	400mg
		0.4-0.6 mmol/l	400mg
		0.5-0.6 mmol/l	300mg
		0.6-0.8mmol/l	Maintain at 200mg
400mg	0.6-0.8 mmol/l	0.1-0.2 mmol/l	800mg
		0.2-0.3 mmol/l	800mg
		0.3-0.4 mmol/l	800mg
		0.4-0.5 mmol/l	600mg
		0.5-0.6 mmol/l	500mg
		0.6-0.8 mmol/l	Maintain at 400mg
		>0.8mmol/l	300mg

* Priadel® 200mg and 400mg tablets have score lines and can be divided accurately to provide dosage requirements as small as 100mg within product licence.

Appendix 1- Drug Initiation Service – Lithium initiation request

Patient Name: NAME
Patient Address: ADDRESS
CHI: CHI

CMHT details
_____

Consultant Psychiatrist details
_____

I confirm I have completed and reviewed all clinically relevant actions and baseline monitoring (in line with the Lithium Drug Specific Monitoring Document) for this patient prior to referral to the Drug Initiation service and therefore satisfied it is appropriate to commence prescribing	
I understand that referral to this service is for prescribing and future blood monitoring for the period of lithium initiation.	
I confirm that this treatment is clinically appropriate for this patient in the context of allergies, past medical history and the patient has been provided with adequate patient education including a suitable patient information leaflet	
I have provided the patient with information about the Drug Initiation Service	

Baseline Actions and Monitoring (Ideally, baseline monitoring parameters should be captured within previous 4-6 weeks)	Date completed
• Assessment for contraindications/ cautions	
• Assessment for relevant interactions	
• Discussion of benefits and risks of treatment and obtaining/ documenting patient/ carer consent	
• Serum calcium	
• Thyroid function tests (patients should be euthyroid before initiation)	
• Urea and electrolytes including Sodium, Potassium, Urea, Creatinine & eGFR (patients must have adequate renal function (eGFR>60ml/min) before commencing lithium)	
• ECG for patients with existing cardiovascular disease (CVD) or risk factors	
• For women of childbearing potential, there should be a discussion of childbearing intentions and contraceptive status. Advice on risks and benefits must be discussed fully. Pregnancy must be excluded.	

Patient Name: NAME
Patient Address: ADDRESS
CHI: CHI

Patient diagnosis	
Is this a licensed indication for lithium treatment?	
Initiation dose instructions	
Target lithium level	
Any other relevant information?	

The DIS team will prescribe based on your instructions and arrange for these prescriptions to be sent to the patient or their community pharmacy. The DIS team will arrange phlebotomy appointments for the required blood tests for your patient and monitor these results.

If the bloods are within normal ranges further prescriptions will be issued to continue and/or titrate the drug based on your initiation instructions. In the event of an abnormal blood results the DIS team will contact you or an agreed member of your specialist team to seek advice on what action is to be taken.

Send this request via email to: lan.druginitiationhub@lanarkshire.scot.nhs.uk

Prescriber completing request

Name:	Signature:	Date:

Appendix 2 – Contraindications and Cautions [3, 4]

This information does not replace the Summary of Product Characteristics, and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Cardiac disease associated with rhythm disorder or heart failure
- Clinically significant renal impairment
- Untreated or untreatable hypothyroidism
- Brugada syndrome or family history of Brugada syndrome
- Low sodium levels, including dehydrated patients or those on low sodium diets
- Addison's disease
- Pregnancy (especially the first trimester), unless considered essential
- Breastfeeding
- Patients with a history of diabetes insipidus
- Patients who refuse regular bloods tests
- Patients who are at high risk of taking a lithium overdose (intentional or unintentional)
- Hypersensitivity to lithium or any of the excipients

Cautions:

- Mild to moderate renal impairment
- Use in elderly patients
- Cardiac disease
- QTc prolongation
- Myasthenia gravis
- May exacerbate psoriasis
- Adequate and stable sodium and fluid intake should be maintained. This may be of special importance in hot weather, or during infectious diseases, including influenza, gastroenteritis or urinary infections, when dose reduction may be required.
- Review lithium dose if diarrhoea and/or vomiting present and in cases where the patient has an infection and/or profuse sweating. Adjustments may be required.
- Risk of seizures may be increased if co-administered with drugs that lower the seizure threshold, or in patients with epilepsy.
- Surgery: discontinue 24 hours prior to major surgery and re-commence post-operatively once kidney function and fluid-electrolyte balance is normalised. Discontinuation is not required prior to minor surgery, providing fluids and electrolytes are carefully monitored.

Appendix 3- Lithium interactions with other medications [3, 4]

This information does not replace the Summary of Product Characteristics, and should be read in conjunction with it. Please see BNF & SPC as well as Stockley's Drug Interactions (accessible via Medicines Complete) for comprehensive information on interactions.

Medicines that may increase plasma lithium concentrations (by reducing renal elimination) and so risk toxicity:
• NSAIDs (including cyclo-oxygenase 2 inhibitors). If NSAID use is unavoidable, a dose reduction of lithium may be required and levels should be monitored more frequently; 'As required' use of NSAIDs should be avoided since it may cause fluctuations in lithium levels and makes monitoring levels challenging. • Diuretics, particularly thiazide diuretics • Angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor antagonists • Other drugs which alter electrolyte balance with the potential to alter lithium clearance e.g. steroids. • Certain antibiotics including metronidazole and tetracyclines
Medicines that may decrease plasma lithium concentrations (by increasing renal elimination) and so risk loss of efficacy:
• Theophylline • Products which contain sodium bicarbonate e.g. antacids
Medicines that may increase risk of neurotoxicity when co-administered with lithium:
• Calcium channel blockers with cardiac effects (e.g. verapamil, diltiazem) • Antipsychotics (e.g. haloperidol, olanzapine, clozapine, flupentixol, chlorpromazine) • Antidepressants with a serotonergic action (e.g. SSRIs, tricyclic antidepressants, venlafaxine, duloxetine) • Carbamazepine
Medicines associated with QT prolongation:
• e.g. amiodarone, macrolides, tricyclic antidepressants – potential for additive effects when co-administered with lithium
Medicines that lower seizure threshold
• e.g. SSRIs, tricyclic antidepressants, antipsychotics – increased risk of seizures

Appendix 4– Lithium common side effects and signs of toxicity [3]

COMMON SIDE EFFECTS OF LITHIUM	
Initial adverse effects	
• Upset stomach including nausea and diarrhoea • Metallic taste in the mouth • Weight gain • Swelling of ankles	these often resolve with continued treatment
• Fine tremor of hands • Polyuria • Polydipsia	these may persist
Longer-term adverse effects	
• Hypothyroidism • Hyperthyroidism • Hyperparathyroidism • Nephrotoxicity	

SYMPTOMS INDICATING POTENTIAL LITHIUM TOXICITY
• Gastric upset including vomiting and worsening diarrhoea • Coarse tremor • Muscle weakness • Muscle twitches • Unsteady gait • Slurred speech • Blurred vision • Confusion • Lethargy/ drowsiness

THE THREE MOST COMMON CAUSES OF LITHIUM TOXICITY ARE:

- Dehydration (e.g. through vomiting, diarrhoea, perspiration)
- Significant changes in the level of salt in the diet
- Drug interactions (refer to Appendix 5)

A lithium level should be checked urgently and lithium treatment suspended if there is evidence of signs and symptoms of lithium toxicity

Appendix 5– Lithium discharge letter to primary care

www.nhslanarkshire.org.uk
Drug Initiation Service
01355 584241

University Hospital
Hairmyres
Eaglesham Road
East Kilbride

Patient Name: NAME
Patient Address: ADDRESS
CHI: CHI
Date typed: DATE

Dear GP

This letter is to inform you that this patient has recently been initiated on lithium treatment following prescribing and monitoring by the Drug Initiation Service. The patient has now reached a target lithium level and is prescribed a maintenance dose of lithium carbonate.

Ongoing prescribing and monitoring of lithium is now transferred to your care.

	Date completed	**Result/Action**	**Next due**
Li Level		_____**mmol/l**	
U&Es			
Calcium			
TFTs			
Other tests (where applicable)			

Current dose of Lithium carbonate (Priadel)	_____**mg**
Target lithium level range	_____**mmol/l**

Please refer to the Lithium Drug Specific Monitoring Document for ongoing monitoring in primary care.

The patient has been advised of this transfer of care.

The patient has …….. supply of medication to allow arrangements to be made in primary care for ongoing supply.

Yours sincerely,

NHS Lanarkshire Drug Initiation Service
University Hospital Hairmyres | Eaglesham Road | East Kilbride | G75 8RG
Phone: 01355 584 241
Office hours: 09:00 to 13:00, Monday to Friday
CC CMHT specialist

Appendix 6 – Drug Initiation Service patient information leaflet
ttp://firstport2/resources/patient-info-leaflets/Documents/XS%20A4-PIL.DRUGIS.25_31060.L.pdf

Appendix 7 – lithium drug specific monitoring document
https://www.rightdecisions.scot.nhs.uk/media/pdgan5bs/lithium-drug-specific-monitoring-document.pdf

Appendix 8 - Governance information for Guidance document

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Distribution	• All prescribers in MHLD services • MHLD service managers for dissemination to ward and community mental health teams; all individuals involved with the Drug Initiation Service.

CHANGE RECORD			
Date	**Lead Author**	**Change**	**Version No.**
Jan 26	L Templeton	*New document*	1

References:

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