Humber Area Prescribing Committee

SHARED CARE FRAMEWORK for Lithium for Cluster Headache (neurology)

HUMBER AREA PRESCRIBING COMMITTEE

DATE APPROVED BY APC: 7TH DECEMBER 2022

REVIEW DATE: DECEMBER 2025

PATIENT NAME	*NHS NUMBER*	*DATE OF BIRTH*
ADDRESS		
GP'S NAME		

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:……..

Where prescriber is <u>not</u> a consultant:

Consultant's Name: …… GMC No ……..

Consultant's Signature ……..... ……. Date:……..

If the General Practitioner is unable to accept prescribing responsibility for the above patient the consultant should be informed within two weeks of receipt of this framework and consultant's / nurse specialist's letter. In such cases the GP are requested to update the consultant, by letter, of any relevant changes in the patient's medication / medical condition.

Shared Care Responsibilities

Specialists:

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet and means for the patient to keep a record of their serum plasma lithium levels, such as the purple lithium pack.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13). The target lithium range for the patient must be included.
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the required reviews and monitoring in section 8. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

General Practitioner and primary care team

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5, taking into any account potential drug interactions in section 7.
- Adjust the dose of lithium prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.

- Manage adverse effects as detailed in section 10 and discuss with specialist team when required.
- If toxicity is suspected, withhold lithium and discuss urgently with the specialist. Plasma lithium levels should be acquired immediately to aid interpretation and facilitate specialist advice
- If plasma lithium levels are above the specified range, check the dose, adherence, and timing of the sample (repeating if necessary). Determine whether toxicity is present and discuss with the specialist with an urgency determined by clinical judgement.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.
- Assess for interactions with lithium when starting new medications.

Pharmacists

- Pharmacists must check that blood results are being monitored regularly and that it is safe to dispense lithium and check the lithium book as per pharmacy procedures
- Where it is not possible to assess monitoring, lithium therapy should not be withheld. The pharmacist responsible for dispensing a prescription should communicate to the prescriber that lithium medication has been provided with without checking this lithium book. This is especially important if not seen the lithium book for multiple dispensing i.e. >3 months.

Patient and/or carer responsibilities

- Take lithium as prescribed and avoid abrupt withdrawal unless advised by their prescriber.
- Attend regularly for monitoring and review appointments with primary care and specialist, and bring their purple lithium pack to keep a record of lithium levels. Keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of lithium with their pharmacist before purchasing any over-the-counter medicines.
- Moderate their alcohol intake to no more than 14 units per week. Avoid recreational drugs.
- Not to drive or operate heavy machinery if lithium affects their ability to do so safely.
- Use an appropriate form of contraception, as agreed with their doctor/nurse/sexual health service.

- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

Shared Care Framework for *Lithium in cluster headache*

1. Introduction:	Lithium is licensed for the treatment and prevention of mania, bipolar depression, recurrent depression (unipolar) and aggressive/self-mutilating behaviour. Not all patients respond to lithium, so the benefits and risks should be regularly and individually assessed. Lithium treatment should not be stopped suddenly, as this can cause relapse. Lithium has a narrow therapeutic window of between 0.4 and 0.8 mmol/L for most indications, although a narrower range is usually specified on an individual patient. Higher target plasma levels (0.8–1 mmol/L) are occasionally recommended for acute episodes of mania, for patients who have previously relapsed or when subthreshold symptoms of illness are associated with functional impairment. **The specialist service will determine the target range for each patient and advise the primary care prescriber accordingly.** Lithium has numerous mild side effects but can be toxic if the dose is too high. Toxicity usually occurs with levels above 1.5 mmol/L but can emerge at lower levels in susceptible patients such as the elderly or those with renal impairment. Toxicity can also occur when levels are in the 'therapeutic range'. Excluding excessive ingestion, toxicity most commonly arises due to a reduced elimination of lithium. Elimination of lithium is almost exclusively renal and is sensitive to the handling of sodium by the kidneys. Lithium toxicity can itself impair renal function, so rapid escalations in plasma lithium levels may occur. With long-term use, lithium can have adverse effects on the kidneys, the thyroid, and the parathyroid glands. **Lithium should always be prescribed by brand and form**; tablets and liquids are not interchangeable. Extra care must be taken when prescribing liquid forms, with clarity over the name and strength of the preparation. Patients should be involved in treatment decisions and understand the importance of lithium monitoring. This shared care protocol applies to all adults aged 18 and older.	
2. Indication:	*Prophylaxis of cluster headache*	
3. Licensing Information	*Lithium is not licensed for prophylaxis of cluster headache*	
4. Pharmaceutical Information	Route	Oral
	Formulation	Lithium carbonate: Priadel® prolonged-release tablets 200mg and 400mg Camcolit® 400mg controlled release tablets Lithium Citrate: Priadel® liquid 520mg in 5ml (equivalent to 204mg lithium carbonate)

	Administration details	Consistency is paramount in lithium treatment and monitoring. Doses should be taken regularly, at the same time every day. Lithium carbonate tablets should not be crushed or chewed. Priadel® 200mg and 400mg tablets have score lines and can be divided accurately to provide dosage requirements as small as 100mg within product license. Other brands may be scored to facilitate breaking for ease of swallowing, and not to divide into equal doses. Breaking these tablets is not expected to alter their release properties but the accuracy of the division is not established
	Additional information	Always prescribe lithium by brand name. Switching preparation (either between brands of the same form or changing between tablets and liquid) additional monitoring to ensure that the 12-hour plasma lithium level remains in the desired range. Particular care should be taken if prescribing liquid preparations; lack of clarity may lead to the patient receiving a sub-therapeutic or toxic dose.
	Other important information:	If a dose is missed, then the next scheduled dose should be taken as usual; a double dose should not be taken to make up for a missed dose. For a given total daily dose, 12-hour plasma lithium levels will differ for once versus twice daily dosing schedules. The schedule should be determined by the specialist and not altered without their advice.
5. Supporting evidence	BASH Guideline 2019 (headache.org.uk)	
6. Initiation on ongoing dosage regimen	• Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks. • The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability. • All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician. • Termination of treatment will be the responsibility of the specialist. Starting dose for Lithium carbonate for cluster headache is normally 200mg/week. This dose is increased at increments of 200mg every week. Until levels in range.	

	The duration of treatment will vary according to the individual patient, specific information will be provided to the GP on dose alterations and on length of treatment. There is a significant risk of relapse if patient therapy is suddenly discontinued. **Greater caution must be taken in older adults (over 65 years) or frail adults or patients with renal impairment who may require a third to a half less lithium due to reduced clearance.**
7. Contraindications and Warnings:	**Contraindications** • Hypersensitivity to lithium or excipients. • Cardiac disease associated with rhythm disorder (Cardiac arrhythmia). • Cardiac insufficiency (Heart failure). • Severe renal impairment. • Untreated hypothyroidism. • Breast-feeding. • Low body sodium levels, e.g. in dehydrated patients or those on low sodium diets. • Addison's disease. • Pregnancy (especially the first trimester, unless considered essential • Brugada syndrome or family history of Brugada syndrome **Cautions** • Mild to moderate renal impairment • Use in elderly patients • 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, gastro-enteritis 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. • Cardiac disease • May exacerbate psoriasis • Surgery: discontinue 24 hours prior to major surgery and re-commence post-operatively once kidney function and fluid-electrolyte balance are normalised. Discontinuation is not required prior to minor surgery, providing fluids and electrolytes are carefully monitored. **Lithium therapy should not be used during pregnancy, especially during the first trimester, unless considered essential.**
8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist	**Monitoring at baseline and during initiation is the responsibility of the specialist.** Recent and relevant investigation results must be documented in the corresponding letter from specialist **Baseline (all indications):** • Urea and electrolytes (U&Es), including estimated glomerular filtration rate (eGFR)

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- Calcium
- Thyroid function tests (TFTs)
- Electrocardiogram (ECG) recommended for patients with existing cardiovascular disease (CVD) or risk factors
- Full blood count (FBC)
- Height, weight and body mass index (BMI)
- Exclude pregnancy

Additional baseline investigations (specialists discretion):

- Cardiovascular status including pulse and blood pressure (BP)
- Metabolic status including fasting blood glucose, glycosylated haemoglobin (HbA_{1c}) and blood lipid profile.
- Liver function tests (LFTs)

Initial monitoring:

- 12-hour plasma lithium levels one week after initiation and one week after any change in dose or formulation; lithium levels take 4-7 days to reach steady state concentrations. Typically, this means levels will be monitored weekly until the desired level and clinical effect is achieved. Following a dose, levels fluctuate during absorption/distribution, so measurements are made 12 hours post-dose for monitoring purposes.

Ongoing monitoring:

Review patient at least every 12 months to assess their mental health, effectiveness of treatment and the ongoing need for lithium.
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<tr><td rowspan="2">9. Ongoing monitoring requirements to be undertaken by primary care</td><td>Monitoring</td><td>Frequency</td></tr>
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Plasma lithium level taken 10-14 hours post-dose. NB: samples should be taken as close to 12-hours post-dose as possible.

- Record results in the patient's record as well as patient-held purple lithium pack, or other suitable recording mechanism.
- It is advisable to document the actual time interval between the last dose and the blood sample
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At least every 12 weeks for the first year, then every 6 months.
More frequent long-term monitoring may be advised by the specialist team in some circumstances (e.g. elderly, renal impairment, altered laboratory parameters, poor symptom control or adherence, concurrent interacting medicines) or if most recent 12-hour plasma lithium level is at the threshold of target range. **Consider additional monitoring whenever there is a change in the patient's circumstances, e.g. intercurrent illness.**
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	U&Es, including eGFR **Calcium** **TFTs** **Height, weight, and BMI.**	**Every 6 months.** More frequent monitoring (particularly renal function) may be advised by the specialist team in some circumstances (e.g. elderly, renal impairment, altered TFTs, concurrent interacting medicines).
	Signs of toxicity Enquire about and document signs and symptoms which might indicate toxicity, e.g. paraesthesia, ataxia, tremor, cognitive impairment.	**At every consultation with the prescriber regarding lithium treatment**
	(If relevant) 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.	
10. Interactions	The following drugs are known or suspected interactions and the GP may wish to discuss with the initiating specialist before commencing: 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. If medicines that interact with lithium must be prescribed, this should be on a regular (not p.r.n.) basis and monitoring should be undertaken monthly until a stable lithium level is reached and then every 3 months	
	The following medicines must not be prescribed without consultation with specialists: • **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; discuss with specialist team. '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

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

Less commonly encountered interactions are possible with the following drugs; therefore, it is prudent to be aware and check lithium levels soon after starting treatment for:

Drug/Drug group	Interaction type
Diuretics*: loop diuretics safer than thiazides	Excretion of Lithium reduced; increased plasma concentration and risk of toxicity
Tricyclics*	Risk of toxicity
Antipsychotics: clozapine, haloperidol, phenothiazines, sulpiride, flupentixol, quetiapine, risperidone, zuclopenthixol	Increased risk of extrapyramidal side effects
Antipsychotics: Clozapine, flupentixol, haloperidol, phenothiazines, risperidone, zuclopenthixol	Possible neurotoxicity
Antipsychotics: amisulpride	Increased risk of adverse effects of amisulpride
Antipsychotics: olanzapine	Possible risk of lithium toxicity

	Amiodarone	Increased risk of hypothyroidism, risk of ventricular arrhythmias
	Antiepileptics: carbamazepine, phenytoin.	Possible neurotoxicity without increased lithium plasma concentration
	Calcium channel blocker: diltiazem, verapamil	Possible neurotoxicity without increased lithium plasma concentration
	Methyldopa	Possible neurotoxicity without increased lithium plasma concentration
	Dapoxetine	Increased risk of serotonergic effects
	SSRIs	Increased risk of CNS toxicity
	Sodium containing antacids*	Lithium excretion increased – reduced plasma concentration
	Theophylline *	Lithium excretion increased – reduced plasma concentration
	*Prudent to be aware and check lithium levels soon after starting or stopping treatment	
	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.	
	For full list see SPC at www.medicines.org.uk/emc and BNF	
11. Adverse effects, abnormal results and management	Adverse effects	Action for GP
	Renal function: Polyuria and polydipsia	Polyuria is common and often well tolerated. Advise the patient to maintain adequate fluid intake and advocate excellent oral hygiene. Contact specialist team for advice, which may include input from nephrology services.
	Risk of arrhythmia. Lithium can cause cardiac arrhythmia, mainly bradycardia, sinus node dysfunction and ECG changes such as reversible flattening or inversion of T-waves and QT prolongation, or unmask Brugada syndrome. Concurrent prescribing of other drugs with a risk of prolonging the QT interval	ECG* should be performed shortly after initiation of treatment by the specialist team. Also, at any point where the patient develops symptoms such as blackouts, fainting, dizziness, laboured breathing, palpitations, or seizures. Also, if any new medication is added which may increase the risk of arrhythmia. Seek advice from initiating specialist regarding the risks and benefits of ongoing prescribing.
	Possible signs of lithium toxicity Typical signs and symptoms include diarrhoea, vomiting, loss of appetite, muscle weakness, lethargy, dizziness, ataxia, lack of	f lithium toxicity is suspected, do an urgent lithium level immediately and seek specialist advice. Referral to secondary care may be required depending on the severity of symptoms and the certainty of toxicity. Use

	coordination, tinnitus, blurred vision, coarse tremor of the extremities and lower jaw, muscle hyper-irritability, choreoathetoid movements, dysarthria, and drowsiness	clinical judgement to determine the urgency of referral.
	Result	Action for GP
	Thyroid function Altered TFTs without symptoms	Contact specialist team for advice. During lithium treatment, TFTs are commonly abnormal; the TSH can rise early in treatment but settle with time. Note that the symptoms of hypothyroidism can be difficult to discriminate from depression and the common side effects of lithium
	Subclinical hypothyroidism • Raised TSH • Normal T4 Clinical features not overly manifest	Contact specialist team for advice, which may include input from endocrinology services. The optimal management of subclinical hypothyroidism during lithium treatment remains controversial, with different thresholds for treatment advocated. Anticipate the need for additional monitoring, investigations and potentially thyroid hormone replacement based on specialist recommendations.
	Overt hypothyroidism • High TSH • Low T4 Symptomatic	Contact specialist team for advice, which may include input from endocrinology services. Thyroid hormone replacement is usually indicated and often continued throughout the course of lithium treatment.
	Hyperthyroidism	Contact specialist team for advice, which may include input from endocrinology services.
	Renal function Polyuria and polydipsia	Polyuria is common with lithium and often well tolerated. Advise the patient to maintain adequate fluid intake and advocate excellent oral hygiene. Contact specialist team for advice, which may include input from nephrology services. In some instances, dose adjustment or specific treatments may be advocated.
	U&Es (including calcium) out of range	Check that the most recent 12-hour plasma lithium level is in the desired range and act accordingly if not. Determine whether there are symptoms and signs related to the electrolyte disturbance or lithium toxicity.

		Consider arranging an ECG in those at risk for QT prolongation. Contact specialist team for advice. Changes in calcium levels may reflect parathyroid dysfunction and input from endocrinology services may be indicated.
	eGFR <45ml/min rapidly falling eGFR gradual decline in eGFR	The response to impaired or deteriorating renal function should be individualised. Contact specialist team for advice, which may include input from nephrology services. A cardiovascular risk profile may guide specialist advice and should be provided if available. Use clinical judgement to determine the urgency of consultation. Anticipate the need for increased monitoring as trends in renal function are more useful than absolute values. In the elderly or those at the extremes of muscle mass, creatinine clearance provides a better estimate of renal function that eGFR. Adjustments to dose may be advised. If renal function is significantly compromised, lithium may no longer be an appropriate treatment and specialists will advise accordingly
	Weight and BMI Outside healthy range	Provide appropriate support on multicomponent interventions to increase physical activity levels, improve eating behaviour and quality of diet. Remind patient of the importance of maintaining adequate fluid intake and avoiding dehydration while exercising. Consider measuring waist circumference for individualised monitoring. Patients should be instructed to avoid sudden changes in diet, especially avoiding low sodium diets. Lithium levels are influenced by body weight and so for patients being supported to lose weight, lithium levels may need to be checked more frequently (akin to other situations of caution). Use clinical judgement, lithium levels and the rate of weight loss when determining the frequency of blood tests.
	Signs of toxicity Typical signs and symptoms include diarrhoea, vomiting, loss	If lithium toxicity is suspected, do an urgent lithium level immediately and seek specialist advice.

	of appetite, muscle weakness, lethargy, dizziness, ataxia, lack of coordination, tinnitus, blurred vision, coarse tremor of the extremities and lower jaw, muscle hyper-irritability, choreoathetoid movements, dysarthria, and drowsiness	Referral to secondary care may be required depending on the severity of symptoms and the certainty of toxicity. Use clinical judgement to determine the urgency of referral.
	Lithium level	Action
	12-hour plasma lithium level. Below target range NB: range for each patient to be determined by the specialist team. Note that local reference ranges may vary	Assess adherence, including discussion with patient and check of GP clinical systems. Offer advice on adherence if appropriate (e.g. daily routines, reminders). Ensure level was taken 12 hours after lithium dose. Contact specialist team for advice if suspected that the dose is too low.
	Above target range NB: range for each patient to be determined by the specialist team. Note that local reference ranges may vary	Ensure level was taken 12 hours after lithium dose and that the correct dose has been prescribed and taken. Check for interactions, hydration, patient's physical and mental status, and features of toxicity. Repeat level if necessary. **Withhold lithium if there are features of toxicity.** Contact specialist team for advice in all cases. If ≥2.0mmol/L – consider sending patient to A&E, based on clinical presentation (e.g. features of toxicity) and inform specialist team.
	Within range but patient has signs of toxicity	Contact specialist team for advice. Referral to secondary care may be required depending on the severity of symptoms and the certainty of toxicity. Use clinical judgement to determine the urgency of referral.
	Within target range but marked change since last level (and there has been no dose change) NB: range for each patient to be determined by the specialist team. Note that local reference ranges may vary	Establish whether level was taken 12 hours after lithium dose. Repeat level with an urgency determined by clinical judgement. Assess adherence, including discussion with patient and check of GP clinical systems. Offer advice on adherence if appropriate (e.g. daily routines, reminders). More frequent monitoring may be required.
	. Record all episodes of toxicity along with any remedial action	
12. Advice to patients and	**The patient should be advised to report any of the following signs or symptoms to their GP without delay:**	

carers The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.	• Lithium toxicity (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). • Signs of hypothyroidism (e.g. fatigue, cold intolerance, weight gain, constipation, and depression), renal dysfunction (including polyuria and polydipsia), and benign intracranial hypertension (persistent headache and visual disturbance). **At the start of treatment patients should be given suitable information on lithium and means to keep a record of their plasma lithium levels, such as a** purple lithium pack supplies of which can be ordered from nhsforms@mmm.com or accessible at [ARCHIVED CONTENT] Safer lithium therapy (nationalarchives.gov.uk) **.** **Additional advice for patients/ carers:** • Patients must attend regularly for monitoring and review appointments to ensure their lithium dose remains safe and effective, and bring their purple lithium pack to keep a record of their lithium levels. • Patients should notify their primary care prescriber straight away if there is any change in their health, e.g. an infection, or significant weight loss. Additional lithium monitoring may be required. • Lithium should be taken regularly, as prescribed. If doses are missed, patients should not attempt to catch up or double dose. • Patients should not stop taking lithium suddenly – doing so increases the chance of relapse. If lithium is to be stopped, it should be reduced over at least four weeks and preferably three months. • The same brand of lithium should always be taken unless otherwise instructed. Patients should become familiar with their brand and check they have received the correct one before taking. • Changes in hydration and sodium balance can affect plasma lithium levels. Patients should maintain adequate fluid intake, particularly in hot weather or when activity levels change (such as increases in exercise or immobility). Large changes in dietary sodium should be avoided – changing dietary regime may inadvertently alter sodium intake.

	• Substantial changes in plasma lithium levels can occur if patients develop diarrhoea or vomiting, or if they become acutely ill for any reason. Patients should seek medical advice in such instances. • Excessive alcohol consumption should be avoided as it can lead to dehydration, increasing plasma lithium levels and so risk of toxicity. • Patients should be warned about common drug interactions and advised to present their 'Lithium alert card' whenever they redeem a new prescription. They should specifically be advised not to take OTC NSAIDs as these can increase plasma lithium levels and so risk toxicity. • Lithium may impair performance of skilled tasks (e.g. driving, operating machinery). Patients with a diagnosis of bipolar disorder must notify the Driver and Vehicle Licensing Agency (DVLA); see https://www.gov.uk/bipolar-disorder-and-driving. • Patients of childbearing potential should be advised that lithium carries additional risks in pregnancy and is a potential teratogen. They should be aware of the need to use reliable contraception. If they become pregnant while taking lithium they should not stop taking it, but should tell their doctor straight away if they become pregnant while taking lithium. Breastfeeding should be avoided during treatment with lithium.
13. Preconception, Pregnancy, paternal exposure and breast feeding It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.	**Preconception** Patients of child-bearing potential should be advised to use a reliable form of contraception. **Pregnancy:** Lithium should not be used during pregnancy, especially in the first trimester (risk of teratogenicity, including cardiac abnormalities). In certain cases where a severe risk to the patient could exist if treatment were stopped, lithium has been continued during pregnancy; under these circumstances prescribing is the responsibility of the specialist team. If a patient becomes pregnant whilst on lithium, the specialist team should be informed immediately (but do not stop the lithium). Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-LITHIUM-IN-PREGNANCY/ Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Lithium/ **Breastfeeding:**

	Lithium is secreted in breast milk and there have been case reports of neonates showing signs of lithium toxicity. Lithium should be avoided during breastfeeding. Information for healthcare professionals: https://www.sps.nhs.uk/medicines/lithium/ **Paternal Exposure** Animal studies have reported spermatogenesis abnormalities that may lead to impairment of fertility- it is unknown if this risk applies to humans
14. Specialist contact information	Name: Prof Ahmed/Dr Dorsey – as per clinic letter Role and specialty: *Consultant Neurologist (Humber Neurology Service)* Daytime telephone number: *As per clinic letter* Email address: *As per clinic letter* Alternative contact: *Priscilla Kanyoka – Neurology Specialist Pharmacist HUTH – Priscilla.Kanyoka1@nhs.net* Out of hours contact details: *01482 875875 (HUTH switchboard and speak to Consultant Neurologist on call).*
15. Local arrangements for referral .	Triggers for advice and guidance to secondary care: • Lithium level outside the optimum target blood level or features of toxicity occur • Lithium level above 1mmol/l • Lithium level below 0.4mmol/L • If trend in decreasing lithium dose to keep lithium blood level maintained (indication of impaired renal function) • Deterioration of renal function o Monitoring trend in function is more useful than absolute value of test result • Consecutive results indicating reduction of renal function (increase in creatinine level or decreased e-GFR – less than 60ml/minute should prompt referral for consideration of lithium review • Service user becomes mentally unwell • Non-compliance or suspected non-compliance with treatment or monitoring • Pregnancy or planning pregnancy • Breast feeding • Initiation of interacting medication • Acute infection or other medical condition which may impact on lithium levels or renal function
16. To be read in conjunction with the following documents	• Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/ • NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/

	• General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care • NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

Document and version control	**This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.**		
	Date approved by Guidelines and SCF Group:		16/11/2022
	Date approved by APC:		7/12/2022
	Review date:		December 2025
Version number	Author	Job title	Revision description:
1	Jane Morgan	Principal pharmacist – Interface	New document. Adapted from SPS document