NHS
South Yorkshire
Integrated Care Board

SY ICB Shared Care Protocol

For

Lithium for adults within mental health services in Sheffield and Barnsley*

Note – This protocol is based on the National Lithium Shared Care Protocol and incorporates guidelines from the Bipolar SCP in Sheffield (dated Feb 2018), Lithium Shared Care guideline from Barnsley (April 2022) and the Lithium SCP from Doncaster and Rotherham (July 2022).

It is intended for use exclusively within Sheffield and Barnsley

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*Doncaster and Rotherham have different monitoring arrangements in place and their SCP can be found here: Lithium

Review date – 5 years from approval

Lithium for adults within mental health services in Sheffield and Barnsley (please see Appendix 1: Framework for the management of initiation, monitoring and shared care responsibilities with primary care)

It is optional for the primary care clinician* to participate in taking on responsibility for shared care for the patient. Primary care clinicians will take on shared care only if they are willing and able.

* In this document, the term "primary care clinician" is used interchangeably with "GPs" to encompass all healthcare professionals involved in prescribing within primary care.

Specialist responsibilities

- 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.
- To prescribe as part of a treatment pathway, which will include psychological support.
- 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 book.
- If the purple lithium book is unavailable for any reason, an alternative method for monitoring serum plasma lithium levels could be through the NHS app, where the latest blood test results can be accessed.
- 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.
- Once treatment is optimised, complete the shared care documentation and contact patient's primary care prescriber to request prescribing and monitoring under shared care, detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required (Appendix 2). Include contact information (section 13). The target lithium range for the patient must be included.
- Transfer of monitoring and prescribing to primary care is at least after 12 weeks and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Inform GP of the brand being prescribed.
- Continue prescribing Lithium until a written agreement is received and primary care has confirmed their willingness to take over prescribing responsibilities.
- 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.
- Counsel patient regarding advice if planning to conceive or become pregnant and **reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.**
- Patients planning to become pregnant should be referred to the Sheffield Perinatal Mental Health Services or for Barnsley- the Barnsley Hospital for specialist support and care.
- Provide advice to primary care on the management of adverse effects if required and to be available to discuss any concerns with the GP regarding the patient's therapy.
- Discuss the long-term use of lithium with patients, advising them of its association with thyroid disorders and potential mild cognitive and memory impairments.

    - While the duration of treatment varies and cannot be precisely predicted, patients should be informed that lithium is typically continued long-term only if proven effective.
    - Discontinuation may be considered if the patient opts to stop or experiences significant side effects.
- The specialist will determine and communicate the expected duration of treatment on a case-by-case basis to both the patient and their GP.
- For stable patients, regular specialist reviews may not be required. However, any symptom deterioration or a desire to stop treatment should prompt a referral back to the specialist.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing Appendix 3 (agreement/refusal). It is asked that the GP practice should aim to complete this request within 14 days of receiving it, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialists request **(prescribe by brand)** 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 please see section 10 for further details.
- Inform the consultant if the patient discontinues treatment for any reason.
- Ideally, the GP should update the purple lithium book when practical and feasible. Alternatively, serum plasma lithium levels can be monitored via the NHS app, where patients can access their most recent blood test results.
- 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.
- In the event that the GP is not able to prescribe, or where the shared care is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems_ (sheffieldccg.nhs.uk)
- Any concerns about management should be discussed / referred to psychiatrist secondary care.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- If a patient would like to discontinue lithium therapy, please refer to specialist and stop treatment as and when advised by the specialist.
- Assess for interactions (section 7) with lithium when starting new medications.

Patient and/or carer responsibilities

- To be fully involved in, and in agreement with, the decision to move to shared care.
- 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 book 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.
- If the purple lithium book is unavailable or its use is considered impractical, serum plasma lithium levels can be monitored through the NHS app, allowing patients to access their most recent blood test results.
- 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, see 12. Pregnancy for further details.
- 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.
- Share the contents of the purple lithium book with healthcare professionals who may be involved in the management of the clinical condition or either the prescribing or dispensing of lithium preparations or use NHS app for the latest serum plasma lithium levels.
- To read the product information given to them, familiarise themselves with how to take lithium, common side effects and when to seek help or attend A&E if suspecting lithium toxicity.

1. Background

Back to top

The exact mechanism of action of lithium is unknown. 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 for 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. Indications

Back to top

Indications:

- Treatment and prophylaxis of mania
- Treatment and prophylaxis of bipolar disorder

- Treatment and prophylaxis of recurrent depression. NB: lithium should not be used as a sole agent to prevent recurrence, see Depression in adults: treatment and management | Guidance | NICE NG222
- Treatment and prophylaxis of aggressive or self-harming behaviour

3. Locally agreed off-label use Back to top

N/A

4. Contraindications and cautions Back to top

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

Contraindications:

- Hypersensitivity to lithium or any of the excipients
- Addison's disease
- Cardiac disease associated with rhythm disorder.
- Cardiac insufficiency
- Family or personal history of Brugada syndrome
- Patients with abnormal sodium levels, including dehydrated patients or those on low sodium diets.
- Untreated hypothyroidism
- Severe renal impairment
- Pregnancy (especially the first trimester), unless considered essential.
- Breastfeeding

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 is normalised. Discontinuation is not required prior to minor surgery, providing fluids and electrolytes are carefully monitored.
- Concurrent electroconvulsive treatment (may lower seizure threshold)
- Myasthenia gravis
- Avoid abrupt withdrawal

5. Initiation and ongoing dose regime Back to top

- Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 12 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.
- Levels should be taken 5-7days after a dose change or an initiation of a medication that interacts with lithium and affects the level.
- Before adjusting any dosage of lithium, specialist to ensure that the lithium level is measured at the appropriate time, i.e. for plasma lithium levels should be taken 10-14 hours (ideally 12 hours) post dose for once daily dosing. If on twice a day dosing the level should be taken prior to the morning dose. Verify that the patient is adhering to their medication regimen and check for any interacting medications and co-existing illnesses. Current lithium level will be checked against previous results.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

Lithium carbonate

Typically, 400 mg once daily, then adjusted according to patient response and 12-hour plasma levels. However, for patients who weight 50kg and under the usual starting dose is 200mg.

In some scenarios, such as acute mania, a higher starting dose may be preferable. The BNF outlines the typical starting doses by indication and brand.

Doses may initially be divided throughout the day but once-daily administration is preferred when plasma lithium concentration is stabilised in the target range (specified by specialist team).

Lithium carbonate tablets should be prescribed unless there is a specific problem with swallowing difficulties.

Lithium citrate

Typically, 509 mg or 520 mg twice daily (depending on brand), in the morning and evening, then adjusted according to patient response and 12-hour plasma levels.

Liquid formulations contain lithium citrate and **doses are not equivalent** to lithium carbonate; bioavailability is significantly different. **If a switch in formulation is considered, discuss with the specialist team.**

Extra care must be taken when prescribing lithium in liquid form, as some offer different strengths under the same brand names, and some brands are used for the liquid and tablet forms.

The initial period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

Individualised, to achieve plasma lithium levels in the range specified for the patient.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Lower doses may be required in older or physically frail/low body weight patients, in mild to moderate renal impairment and electrolyte imbalance. Dose adjustments may also be required in patients prescribed interacting medicines.

Stopping lithium treatment

The decision to stop treatment will be the responsibility of the specialist after a discussion has taken place with the patient. Clinicians, patients, and carers should be aware that abrupt discontinuation of lithium increases the risk of relapse. If lithium is to be stopped, the dose should gradually be reduced over a period of at least four weeks but preferably over a period of up to three months.

6. Pharmaceutical aspects

Back to top

Route of administration:	**Oral**
Formulation:	**Lithium is available as lithium carbonate (tablet formulations) and lithium citrate (liquid formulations). The patient should be maintained on the same brand and formulation of lithium. If a switch in brand or formulation is considered, refer to the specialist team. Lithium tablets and liquids are not interchangeable.** **Lithium Carbonate:** • Priadel® 200 mg and 400 mg prolonged-release tablets • Camcolit® 400 mg controlled release tablets • Liskonum® 450 mg controlled release tablets • Lithium carbonate Essential Pharma: 250 mg film-coated tablets (immediate release) **Lithium Citrate:** • Priadel® Liquid: 520 mg/5 mL strength sugar-free, pineapple flavoured syrup • Li-Liquid®: 509 mg/5 mL and 1,018 mg/5 mL strength cherry flavoured syrup Extra care must be taken when prescribing lithium in liquid form, as some offer different strengths (mg/ml) under the same brand name (Li-liquid®) and some brand names (Priadel®) are used for the liquid and tablet forms. **Always prescribe lithium by brand name. Switching preparation (either between brands of the same form or changing between tablets and liquid) requires 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.**
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 licence. Liskonum® 450mg tablets are licensed to be halved for the purposes of dose adjustment. Other brands may be scored to facilitate breaking for ease of swallowing, but 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.
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.

7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see Lithium Interactions or SPC for comprehensive information and recommended management.

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 (lithium toxicity made worse by sodium depletion).
    - Angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor antagonists.
    - Excretion of lithium reduced by aldosterone antagonists (spironolactone, eplerenone).
    - 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/ aminophylline (Excretion of lithium increased by theophylline by 20-30% Increased risk of hypokalaemia; Monitor lithium and potassium concentrations closely.)
    - Products which contain sodium bicarbonate e.g., antacids
    - Some SGLT2 inhibitors, such as empagliflozin and dapagliflozin (emerging evidence). Monitor levels frequently after starting empagliflozin and dapagliflozin and after dose changes.

- **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/Oxcarbazepine (increases the risk of neurotoxicity without increasing plasma concentration of lithium; Concurrent use can be advantageous)
- **Medicines associated with QT prolongation** (e.g. amiodarone, macrolides, tricyclic antidepressants) – potential for additive effects when co-administered with lithium.
    - Amiodarone has a long half-life; there is a potential for drug interactions to occur for several weeks (or even months) after treatment with it has been stopped. If concurrent use is unavoidable consider ECG monitoring recommended.

- **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.

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; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be requested to be transferred to primary care.

Back to top

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)
- 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 (bipolar disorder):

- 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:

To carry out an annual health check for patients under sole care of secondary care services and share results with patient's GP.

Specialists should be clear in their communication (letters) to GPs if they want GPs to take over prescribing or if the letter is just treatment progress information / feedback.

For patients still under secondary care (not discharged), conduct a review at least once every 12 months to assess their mental health, the effectiveness of their treatment, and the ongoing need for lithium therapy.

Levels should be taken 5-7days after a dose change (please refer to section 5) or an initiation of a medication that interacts with lithium and affects the level.

Prior to change of any dosing ensure that the level was taken at the appropriate time, i.e. for plasma lithium levels should be taken 10-14 hours (ideally 12 hours) post dose for once daily dosing. If on twice a day dosing the level should be taken prior to the morning dose. Check if patient is adherent with medication. Check for interacting medications and co-existing illness. Also compare to previous levels taken.

9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 10 for further guidance on management of adverse effects/responding to monitoring results.

When checking lithium levels please clarify with the initiating consultant the level the patient is aiming for. Higher levels are sometimes aimed for to help protect against manic symptoms. The target levels should also be recorded in the patient's purple lithium book, along with each reading. Alternatively, these levels should be recorded in the electronic patient record and made accessible through the NHS app. Prescribers and pharmacists should check blood levels are monitored regularly and that it is safe to issue a repeat prescription and/or dispense the prescribed item.

Blood samples for plasma lithium levels should be taken 10-14 hours (ideally 12 hours) post dose for once daily dosing. If on twice a day dosing the level should be taken prior to the morning dose. Please note that twice daily dosing usually gets lower peak lithium plasma levels.

Below is guidance only: please use professional judgment at all times. The specialist overseeing the patient can also be contacted for advice.

Monitoring	Frequency
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 book, or other suitable recording mechanism. It is advisable to document the actual time interval between the last dose and the blood sample	**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: Every 3 months for: • Older people (over 65yrs) • People taking drugs that interact with lithium (e.g. NSAIDS, diuretics, ACE inhibitors) • People who are at risk of impaired renal or thyroid function, raised calcium levels or other complications such as significant cardiac disease • At risk of significant changes in sodium or fluid intake • People who have poor symptom control • People with poor adherence or if most recent 12-hour plasma lithium level is at the threshold of target range. • If an adult with bipolar disorder or depression needs plasma lithium levels maintained above 0.8 mmol per litre, they should have their lithium levels monitored at least every 3 months.

	Consider additional monitoring whenever there is a change in the patient's circumstances, e.g. intercurrent illness.
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: **Serum creatinine and eGFR:** If evidence of impaired renal function e.g. eGFR less than 60ml/min (do whenever a serum lithium is done) If urea or creatine level increase or eGFR falls over 2 or more tests assess the rate of deterioration of renal function. If eGFR falls below 60ml/min, consider referring to specialist for review of the ongoing need for lithium seek further advice. Over 65yrs at least every 3-6 months **Serum Calcium:** Over 65yrs or cardiac disorder; at least every 6 months. More frequently if found that calcium level is raised and seek further advice. **Thyroid function test:** More frequently than 6 monthly if there is evidence of impaired thyroid function or an increase in mood symptoms that might be related to impaired thyroid function.
Signs of toxicity (please also see section 10) Enquire about and document signs and symptoms which might indicate toxicity, including diarrhoea, vomiting, loss 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	**At every consultation* with the prescriber regarding lithium treatment** ***Whenever a consultation is requested by the patient or deemed necessary by the prescriber
Additional monitoring – bipolar disorder	**Frequency**
Diet, nutritional status and level of physical activity. **Cardiovascular status including pulse and BP.** **Metabolic status including fasting blood glucose, HbA_{1c} and blood lipid profile.**	Annually as part of physical health check recommended in NICE CG185 Bipolar disorder: assessment and management.

LFTs. **Smoking status and alcohol use.**	

(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. Adverse effects and other management

Back to top

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

Common side effects include GI disturbances (e.g. nausea, vomiting, diarrhoea, dry mouth), sedation, fine tremor, metallic taste, polyuria, polydipsia, weight gain, oedema/swollen ankles. Significant side effects include hypothyroidism (rarely hyperthyroidism), parathyroid disease, renal impairment, hypercalcaemia, hypermagnesaemia, QT interval prolongation/arrhythmias, leucocytosis, exacerbation of skin conditions.

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
12-hour plasma lithium level. * NB: range for each patient to be determined by the specialist team. Note that local reference ranges may vary.	***Please note, the following is for reference/information only. All dose or formulation adjustments remain the responsibility of the initiating specialist unless explicitly discussed and agreed upon with the primary care clinician.** 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/too high.
<0.4mmol/L Levels as low as 0.4 mmol per litre can be adequate following approval by the clinician.	Increase dose by 200mg, recheck after 1 week
0.4-0.6mmol/L	A partial response maybe seen at this level, increase dose by 200mg/day. Recheck after 1 week.
0.6-0.8mmol/L	Maintain dose, no change.
0.8-1.0mmol/L	Check if aiming for higher level (previous relapse whilst on lithium/subthreshold symptoms). If not aiming for higher plasma levels, reduce dose by 200mg/day.
1.0-1.5mmol/L	Clarify if any toxic symptoms and severity. **Symptomatic and Severe:** Refer to A &E **Moderate**: Hold lithium for 48 hours, restart once symptoms resolved. Reduce dose by 200mg/400mg/day and recheck level after 1 week.

	Asymptomatic: Reduce dose by 200mg/400mg /day and recheck level after 1 week.
>1.5mmol/L	Check if toxic symptoms. **Symptomatic – Severe**: Refer to A & E. **Moderate**: Hold lithium until symptoms resolve. Check for causes of high level. Once resolved restart at 50% of original dose and recheck level after 1 week. **Asymptomatic** –Reduce dose by 400mg/day and recheck after 1 week. Ensure counsel for toxic symptoms.
Note: Dose changes based on lithium carbonate. Lithium carbonate 200mg equates to 509mg/520mg lithium citrate (dependent on brand used)	
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 overtly 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 or 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 than 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 of appetite, muscle weakness, lethargy, dizziness, ataxia, lack of coordination, tinnitus, blurred vision, coarse tremor of the extremities and lower jaw,	If 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

muscle hyper-irritability, choreoathetoid movements, dysarthria, and drowsiness	toxicity. Use clinical judgement to determine the urgency of referral.
Physical health check (bi-polar disorder)	Any physical health problems should be treated by the appropriate primary care health professional and communicated to the specialist team within 14 days.

11. Advice to patients and carers

Back to top

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.

The patient should be advised to report any of the following signs or symptoms to their GP without delay:

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 book supplies of which can be ordered from nhsforms@mmm.com or is accessible at Lithium patient info-ation booklet.

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 book 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. If NSAIDs are to be prescribed, these should be on a regular (not PRN) basis. The person should be monitored monthly until a stable lithium level is reached, and then every 3 months.
- 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. Lithium does not affect contraception, including the combined pill or emergency contraception. Please see Lithium – NHS. If they become pregnant while taking lithium they should not stop taking it, but should tell their doctor straight away. Breastfeeding should be avoided during treatment with lithium.
- For acute indications such as mania or augmentation, patients may respond within days to weeks of starting lithium. Depending on episode frequency, it may take months or even years to determine whether lithium has proven effective for relapse prevention.

Patient information on this medicine can be found at the following links:

- NHS: https://www.nhs.uk/medicines/lithium/
- MIND: https://www.mind.org.uk/information-support/drugs-and-treatments/lithium-and-other-mood-stabilisers/lithium/

12. Pregnancy, paternal exposure and breast feeding

Back to top

It is the responsibility of the specialist to provide advice on the need for contraception to patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding.

Pregnancy:

Seek specialist advice.

If a patient becomes pregnant whilst on lithium, the specialist team should be informed immediately (but do not stop the lithium).

Lithium should not be used during pregnancy where possible, **especially in the first trimester** (risk of teratogenicity, including cardiac abnormalities). **In cases where discontinuing treatment poses a severe risk to the patient, prescribing may continue. The specialist team is responsible for all prescribing for pregnant women.**

Second, third trimesters: Dose requirements increased (but on delivery return to normal abruptly); close monitoring of serum-lithium concentration advised (risk of toxicity in neonate)

There is a risk of relapse of bipolar disorder if lithium is withdrawn, particularly in the postnatal period.

Do not offer lithium to women who are planning a pregnancy or are already pregnant and discuss the following:

- The woman knows that there is a risk of foetal heart malformations when lithium is taken in the first trimester, but the size of the risk is uncertain.
- The woman knows that lithium levels may be high in breast milk with a risk of toxicity for the baby.
- Lithium levels are monitored more frequently throughout pregnancy and the postnatal period.

If a woman taking lithium becomes pregnant, consider stopping the drug gradually over 4 weeks if she is well. Explain to her that:

- Stopping medication may not remove the risk of foetal heart malformations.
- There is a risk of relapse, particularly in the postnatal period, if she has bipolar disorder.

If a woman taking lithium becomes pregnant and is not well or is at high risk of relapse, consider:

- Switching gradually to an antipsychotic or
- Stopping lithium and restarting it in the second trimester (if the woman is not planning to breastfeed and her symptoms have responded better to lithium than to other drugs in the past) or
- Continuing with lithium if she is at high risk of relapse and an antipsychotic is unlikely to be effective.

If a woman continues taking lithium during pregnancy:

- Check plasma lithium levels.
- Adjust the dose to keep plasma lithium levels in the woman's therapeutic range.
- Advise the woman maintains an adequate fluid balance.
- Advise the woman gives birth in hospital.
- Advise monitoring by the obstetric team when labour starts, including checking plasma lithium levels and fluid balance because of the risk of dehydration and lithium toxicity.
- Stop lithium during labour and check plasma lithium levels 12 hours after her last dose. Restart lithium at least 24 hours after last dose and only after reviewing the blood assay results (as dose may need to be readjusted).

Breastfeeding:

Lithium is secreted in breast milk and there have been case reports of neonates showing signs of lithium toxicity. Breastfeeding should be avoided during treatment with lithium.

Paternal exposure:

Animal studies have reported spermatogenesis abnormalities that may lead to impairment of fertility. It is unknown if this risk applies to humans.

Patients of child-bearing potential should be advised to use a reliable form of contraception. It is the responsibility of the specialist to provide advice on the need for contraception to patients on initiation of lithium, and at each review. Under shared care agreements, the ongoing responsibility for providing this advice rests with both the GP and the specialist.

Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-LITHIUM-IN-PREGNANCY/

Information resources for advice on medicines and breastfeeding – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Lithium - Drugs and Lactation Database (LactMed®) - NCBI Bookshelf (nih.gov)

Frontiers | Clinical Lactation Studies of Lithium: A Systematic Review (frontiersin.org)

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Lithium/

Lithium in pregnancy and breastfeeding (rcpsych.ac.uk)

Pregnancy, breastfeeding and fertility while taking lithium - NHS (www.nhs.uk)

Lithium - Mother To Baby | Fact Sheets - NCBI Bookshelf (nih.gov)

13. Specialist contact information

Back to top

Sheffield

Sheffield Health and Social Care NHS foundation Trust

Michael Carlisle Centre

Pharmacy Department

75 Osborne Road

Sheffield

Tel: 01142718633

Barnsley

Barnsley Single Point of Access (SPA)/ Barnsley CORE Team/ East Enhanced Team

01226 645000

SPA: BarnsleyMentalHealthSpa@swyt.nhs.uk

14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

Back to top

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- NHS UK leaflet: Lithium. Accessed via https://www.nhs.uk/medicines/lithium/ on 17/02/2021.
- National Patient Safety Agency. Safer Lithium Therapy. 2009. Archived resources available via: [ARCHIVED CONTENT] Safer lithium therapy (nationalarchives.gov.uk)
- Common questions about Lithium, NHS, available from Common questions about lithium - NHS (www.nhs.uk), accessed 21/6/24N
- National Shared Care Protocol, Lithium for patients within adult services, SPS, available from B1621_vi_lithium-for-patients-within-adult-services.docx (live.com) , accessed 7/9/2024

16. Other relevant national guidance

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from NHS England » Shared Care Protocols

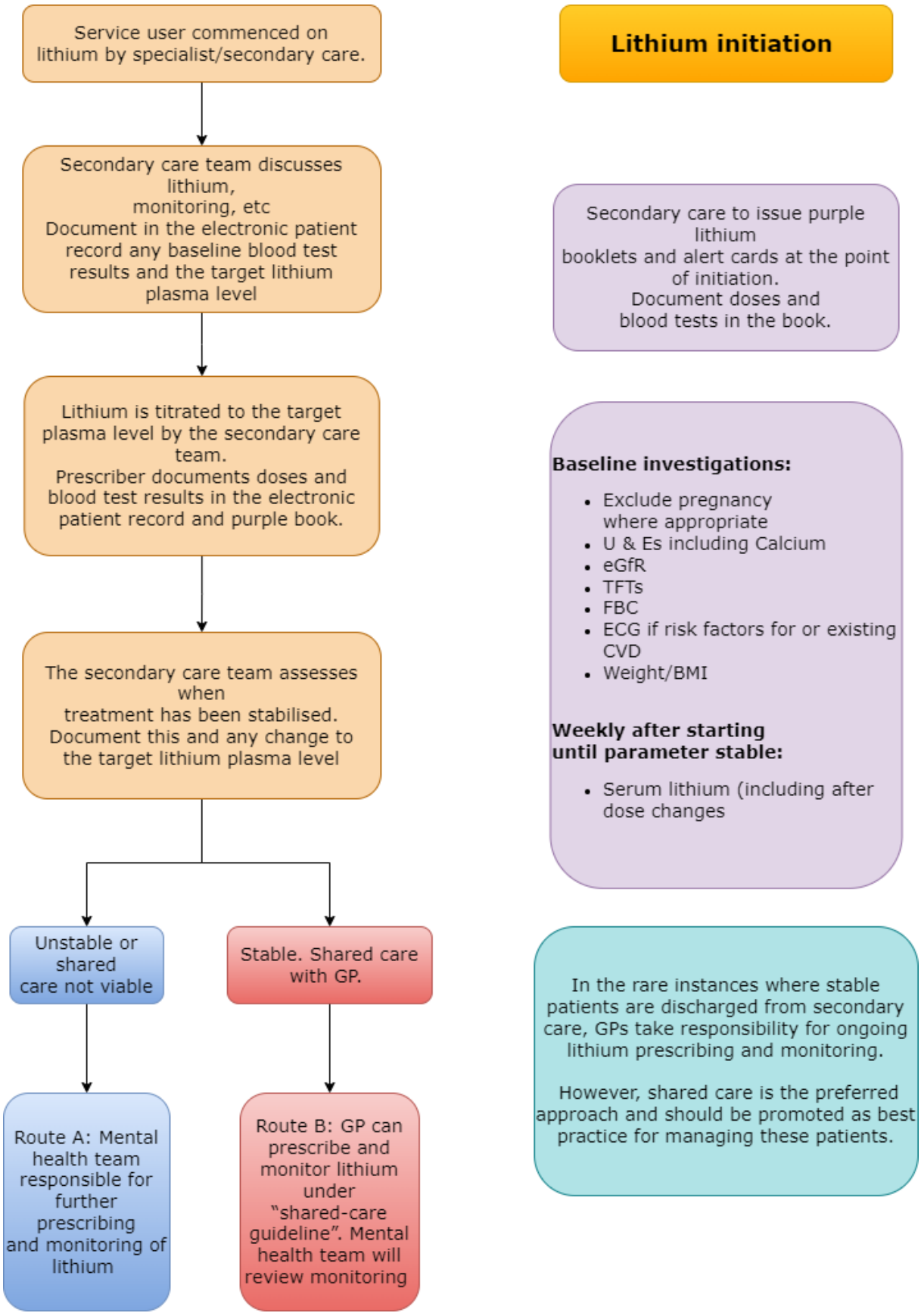
- NHSE policy – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and 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/.

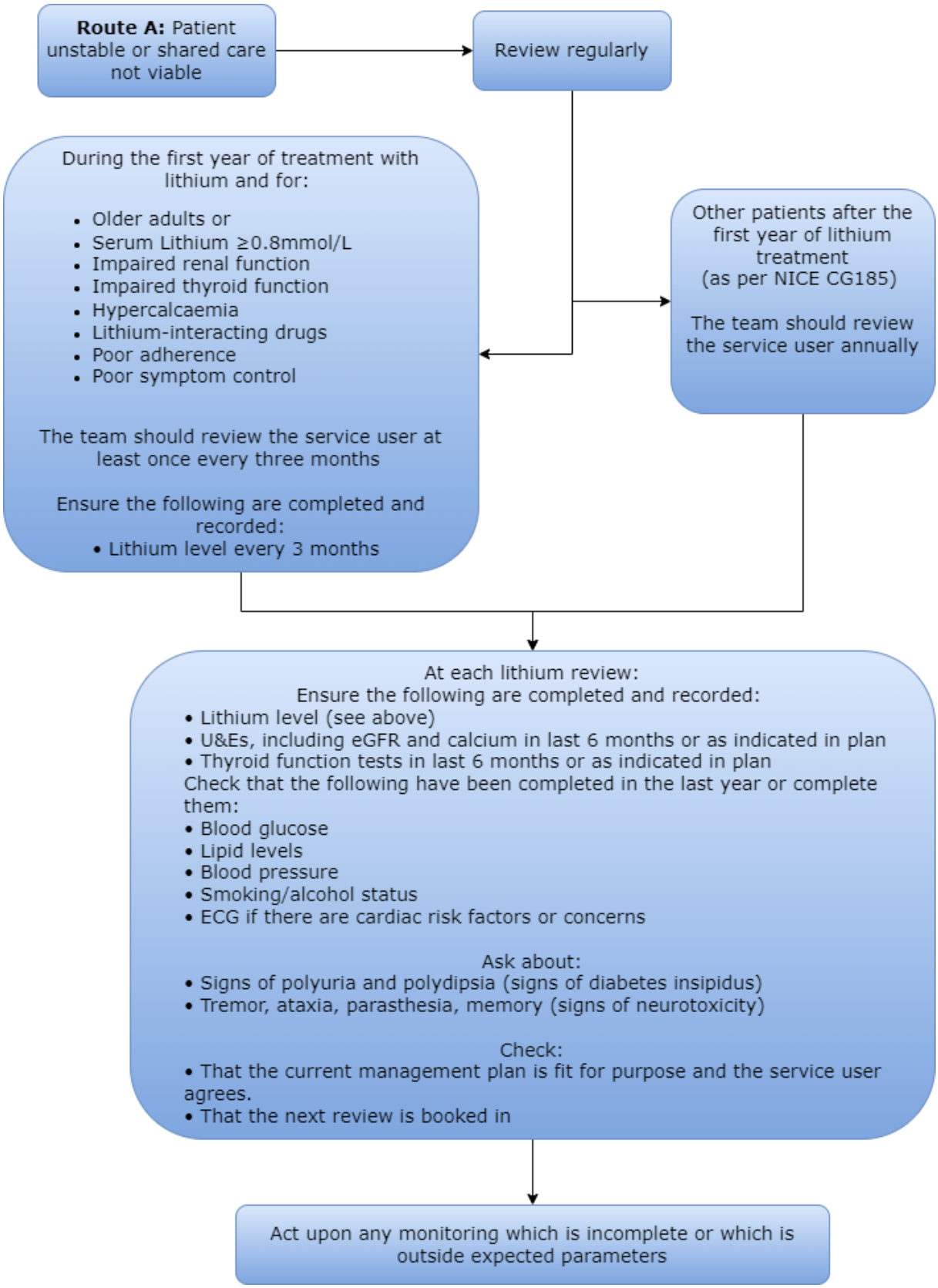
17. Local arrangements for referral Back to top

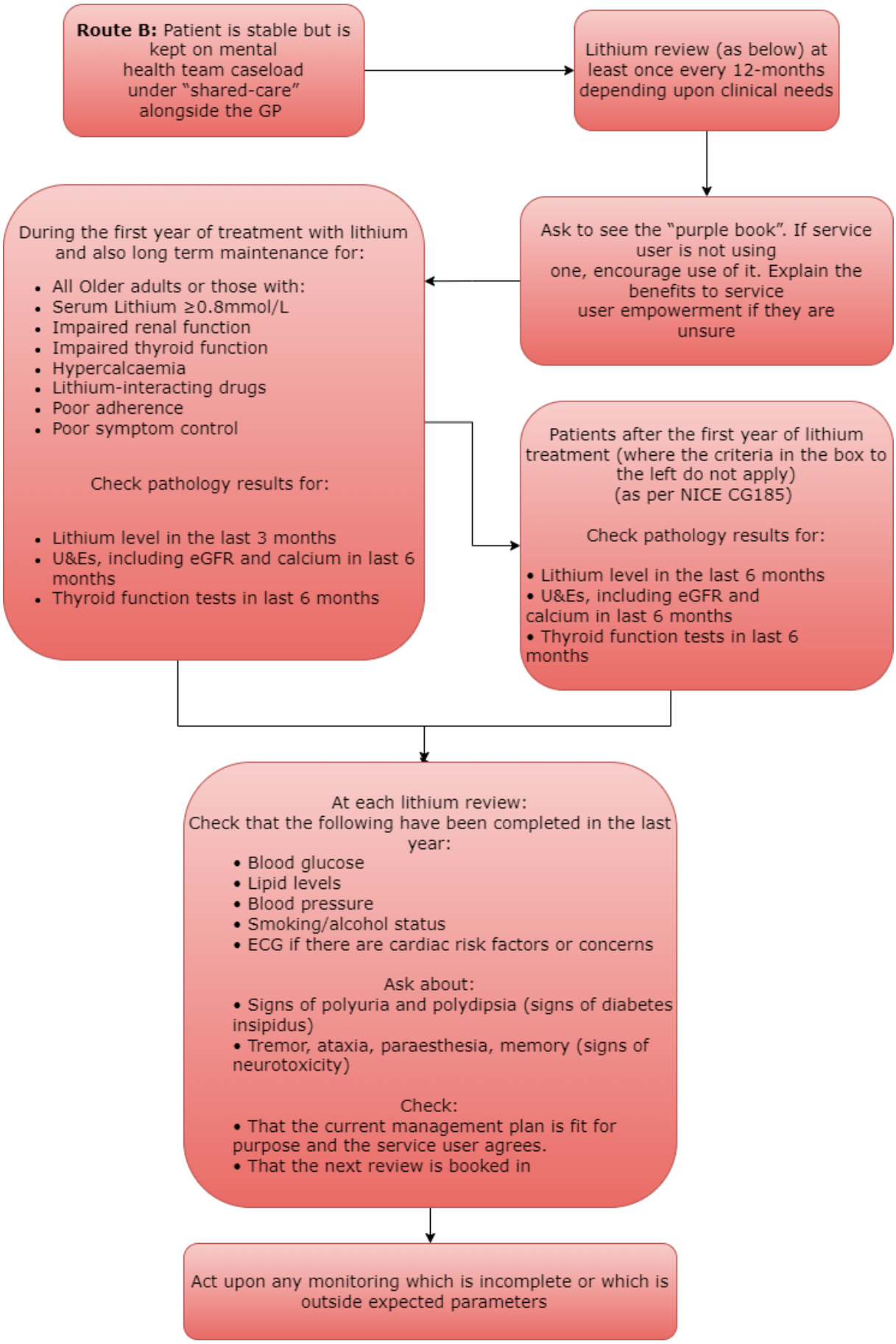
Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

- Specialist to primary care via SCP proforma (Appendix 2).
- Route of return via discussions between GP/specialist (Appendix 3-agreement/refusal)
- Appendix 4 is for patients, who are discharged from specialist services and no longer need specialist care. They can be safely managed by their GP with an individual care plan. This plan may allow quicker access to specialist advice and intervention without a new referral, outside of shared care arrangements. The mental health team should complete the proforma for patients discharged from mental health services and send it to the GP.
- Both the specialist and GP should sign the proforma with a record kept in the GP and specialist records. Full details will be given of the prescribing regime (brand, form, strength, and dose of medication) and follow-up plan. The patient will be asked to make arrangements with their GP for continued supply.

Appendix 1*. Assurance framework for the management of initiation, monitoring and shared care responsibilities with primary care.




Route A: Patient unstable or shared care not viable
Review regularly
During the first year of treatment with lithium and for:
• Older adults or
• Serum Lithium ≥0.8mmol/L
• Impaired renal function
• Impaired thyroid function
• Hypercalcaemia
• Lithium-interacting drugs
• Poor adherence
• Poor symptom control
The team should review the service user at least once every three months
Ensure the following are completed and recorded:
• Lithium level every 3 months
Other patients after the first year of lithium treatment (as per NICE CG185)
The team should review the service user annually
At each lithium review:
Ensure the following are completed and recorded:
• Lithium level (see above)
• U&Es, including eGFR and calcium in last 6 months or as indicated in plan
• Thyroid function tests in last 6 months or as indicated in plan
Check that the following have been completed in the last year or complete them:
• Blood glucose
• Lipid levels
• Blood pressure
• Smoking/alcohol status
• ECG if there are cardiac risk factors or concerns
Ask about:
• Signs of polyuria and polydipsia (signs of diabetes insipidus)
• Tremor, ataxia, parasthesia, memory (signs of neurotoxicity)
Check:
• That the current management plan is fit for purpose and the service user agrees.
• That the next review is booked in
Act upon any monitoring which is incomplete or which is outside expected parameters



* The flow chart from the Derbyshire Lithium shared care guidelines has been used as template with the consent of Derbyshire ICB [Policy and Procedures Template (derbyshiremedicinesmanagement.nhs.uk)]

Appendix 2: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear: *[insert Primary Care Prescriber's name]*

Patient name:*[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*: [insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *Sheffield and Barnsley* shared care protocol for *Lithium* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care, and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on *[insert date started]* and the brand prescribed is [*insert brand name*]. The current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]* NB: Transfer of monitoring and prescribing to primary care is at least after 12 weeks and when the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being received where possible.

Appendix 3: Shared Care Agreement/ Refusal Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

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

Medicine	Route	Dose & frequency

☐ I can confirm **that I am willing to take on** this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

☐ I regret to inform you that in this instance **I am unable to take on** responsibility for the requested prescribing.

Any feedback to secondary care (optional):

Primary Care Prescriber signature: _____ Date: _____

Primary Care Prescriber address/practice stamp

Appendix 4: Proforma for patients discharged from mental health services prescribed lithium therapy.

Only to be considered for patients stable on lithium for a minimum of 6 months.

From (Specialist): …… To (Primary Care Clinician): ……..

The following patient is deemed suitable for discharge and therefore no longer needs to be reviewed by the mental health team. The patient has been stable on lithium therapy for at least 6 months and there are no planned changes.

The consultant psychiatrist should also send a covering letter stating patient is suitable for discharge from mental health services.

Patient details

Name:
DOB:
NHS Number:
Address:

Lithium details

Brand name:
Formulation: ____
Dose and frequency:
Lithium level target range:

Monitoring

The following monitoring should be undertaken by the primary care clinician.

Monitoring should continue until directed otherwise.

Parameter	**Date next test due**	**Frequency**
Lithium serum level		
U+Es/eGFR and Creatine		
Calcium profile		
Thyroid function test (TFT): TSH/T4		
Weight/BMI		

Previous test results can be accessed from ICE.

Re-Referral guidance

If the primary care clinician has concerns regarding deteriorating mental state, please ring the contact telephone number provided. Please seek advice if aware of:

- Any new risks that may destabilise lithium levels (change in physical health status, new drug interaction etc)
- Patient develops new significant side effects.
- Lithium levels outside of target range
- If the patient is planning to become pregnant or is already pregnant (breastfeeding patients should be managed under specialist care).
- Kidney disease or progressive deterioration in renal function
- Patient had an acute episode of lithium toxicity.
- Patient would like to stop or has stopped lithium therapy for any reason.

Specialist can advise if appropriate to re-refer or if medication can be safety continued in primary care.

If a decision is made by the psychiatrist that the patient needs to be seen, then this appointment will be prioritised and organised by the medical secretary or relevant mental health team.

Contact telephone number:

Consultant:

Date: