To be read in conjunction with the SPC, agreement signature sheet for lithium and lithium agreement.

Lithium (Priadel®, Camcolit®, Liskonum®, Li-Liquid®) (TLS Amber)

For the treatment and prophylaxis of mania, bipolar disorder, and recurrent depression; aggressive or self-mutilating behaviour

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AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing lithium might be shared between specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so and must inform the specialist within 3 weeks. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request within 3 weeks of receipt.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor or non-medical prescriber who prescribes this medication legally assumes clinical responsibility for lithium and the consequences of its use.

RESPONSIBILITIES and ROLES

AWP Specialist Team responsibilities
1. Assess patient, establish diagnosis and develop care plan. Ensure care plan contains correct contact details for care co-ordinator/ key worker and consultant psychiatrist; forward a copy of this care plan to the patients' GP.
2. To undertake physical health screen and assessment when patient is admitted to mental health services.
3. Ensure that arrangements for appropriate blood tests are made and the GP is in agreement with this. Blood test may be taken in primary care provided reliable systems are in place to ensure blood test results are communicated between the laboratories and prescribers. Secondary care is responsible for the interpretation and monitoring of these blood test results for the first 3 months of treatment. Agree with the GP how the relevant tests are to be communicated between themselves and the patient.
4. Be fully aware and understand the advice given as per the NPSA lithium alert issued in December 2009 http://www.nrls.npsa.nhs.uk/alerts/?entryid45=65426&p=2
5. Discuss the proposal of lithium agreement with the patient. If possible obtain consent (verbal is fine) and document in notes. If patient declines then please document this too. Provide written information on lithium to patient / carer so that an informed decision on taking lithium and consent to treatment can be made. Information on mental health conditions, treatments and medication can be found at: http://www.choiceandmedication.org/awp/ Inform patient of symptoms of toxicity and to report immediately any of these to doctor / healthcare professional. Treatment should be discontinued immediately on the first signs of toxicity.
6. Record in the care plan that the 'Checklists' as per page 14 and 17 of the Procedure for the prescribing and monitoring of lithium in AWP have been done. Record in progress notes that baseline monitoring has been done as per NICE guidance CG38 (see monitoring page 4)
7. To prescribe the first 3 months of lithium treatment, **prescribing by brand name and specifying formulation**.
8. Issue a lithium therapy patient pack (can be sourced from pharmacy or from NPSA website) and ensure it is completed and explained to the patient. Advise the patient to carry the lithium alert card at all times whilst on lithium treatment and to present the record book to healthcare professionals involved in the prescribing / dispensing of lithium. Document this is done in patient records on RiO.
9. Inform patients to tell community pharmacists that they take lithium before they purchase over the counter medicines
10. To ensure that the patient is fully informed about their treatment. For women of child bearing potential, this should also include a discussion about contraception and any plans they may have for pregnancy (as lithium is a known teratogen).
11. Inform patient to maintain adequate fluid intake and avoid dietary changes which reduce or increase sodium intake, particularly be aware of sweating (e.g. after exercise, hot climates, fever) or if they are immobile for long periods or in the case of the elderly, develop chest infections or pneumonia.
12. Inform patient to report any conditions leading to salt/water depletion e.g. vomiting or diarrhoea.
13. Obtain patients' agreement that he/she will attend clinic/GP practice for bloods/ tests to be done relating to lithium treatment and to sign the patient agreement monitoring form (see appendix 1)
14. Ensure that the GP has a copy of the 'lithium agreement' and a signed copy of the 'Agreement signature sheet for lithium'. The dose, formulation and brand of lithium must be given

15. Review results of any baseline tests and relay any abnormal findings to the GP with appropriate advice
16. Monitor for response and adverse drug reactions; to report ADRs to MHRA & GP
17. Communicate promptly with the GP when treatment is changed, advising GP on when to adjust dose, stop treatment or seek specialist advice.
18. To review the patient and treatment at least once a year until the patient is discharged from the mental health service where this is possible.
19. To review patient / provide advice as requested via the GP or Primary Care Liaison Service as necessary.
20. Inform GP of concurrent therapy (as this may interact with other medication patient gets from GP).
21. Inform GP if any appointments are not attended.
22. Ensure that clear backup arrangements exist for GPs to obtain advice and support. (See 'Back-up advice and support' for contact details).
23. Any verbal communication between primary and secondary care should be confirmed in writing

General Practitioner responsibilities	
1	Reply to the request for shared care within 3 weeks of receipt of request using the 'Agreement signature sheet'.
2	Be fully aware and understands the advice given as per the NPSA lithium alert issued in December 2009 http://www.nrls.npsa.nhs.uk/alerts/?entryid45=65426&p=2
3	Following initiation and first three months of treatment by the specialist team prescribe medicine at the dose, formulation and brand recommended by the specialist.
4	Undertake monitoring as per monitoring schedule on page 4. The prescriber signing the prescription is responsible for ensuring that relevant tests and monitoring are complete as per NICE CG38.
5	Ensure compatibility of lithium with other concomitant medication. See SPC and page 5 for details of interactions. Inform the specialist team of any changes in the patients' medication that may interact with medicines prescribed by the specialist.
6	Re-enforce the use of the lithium therapy record book, Re-issue if required.
7	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
8	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
9	Stop treatment/adjust dose on the advice of the specialist. Please note that lithium should not be stopped suddenly. It should be discontinued over 4 weeks. If it is stopped suddenly there is a 50% chance of relapse within 3 months.
10	Review patient as agreed in the care plan and lithium agreement.
11	Monitor patients' overall health and compliance.
12	Report adverse events to the specialist and MHRA.
13	Once the patient has been discharged from the specialist mental health services, advice may be sought from the Primary Care Liaison Service on any aspect of patients' mental health that is of concern.
14	Any verbal communication between primary and secondary care should be confirmed in writing.
15	If the GP decides not to prescribe lithium, it should still be added to the patients repeat medication as a "non issued' item for information and safety purposes. **For EMIS** The quantity should be set to *0 or 1. On the dose line it should read: *'Hospital prescribing only. Do not prescribe'*. **For TPP SystmOne**, it is entered using the red question mark icon on the medication screen. Once entered, this appears at the bottom of the repeat template screen in a separate in a separate section (and a different colour); however it does not appear on the repeat prescription screen which may be used by prescription clerks. For Vision Enter as a 1:1 repeat, put quantity as 1 tablet, on the dose line it should read: *'Hospital prescribing only. Do not prescribe'*.
This process should also be done during the stabilisation period before the GP takes over the prescribing.	

Patient's role	
1	Attend all appointments with GP and specialist, including appointments for blood tests and other monitoring.
2	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3	To be aware of the risks and symptoms of toxicity associated with lithium treatment.
4	Read the Lithium Therapy Patient Pack, carry the 'Lithium Alert Card' at all times and present to healthcare professionals involved in the dispensing or prescribing of any medications, including pharmacy staff if buying medicines over the counter.
5	Share any concerns in relation to treatment with lithium including adverse effects or warning symptoms with the GP or specialist team. .
6	Inform specialist or GP of any other medication being taken, including over-the-counter products.
7	Maintain adequate fluid intake and avoid dietary changes which may affect salt/water intake. Notify the specialist and GP if any diarrhoea, vomiting, severe dieting or sweating occurs.

Primary Care Liaison Service (PCLS) responsibilities	
1	Accept referrals by registered GPs in line with DoH guidance
2	To advise the GP on appropriate action regarding any issues they may have on patients' management regarding shared care.
3.	To try and resolve the issue(s) raised by the GP or to refer to the specialist team as appropriate.

4. Rapid & prioritised specialist mental health assessment with recommendation/s for care & treatment within multiple care pathways.
5. Determination of the nature & severity of mental health needs with consequent sign posting and pathway facilitation
6. Provide rapid and accessible ongoing support & advice to the non-specialist workforce
7. To advise the GP on appropriate action regarding any issues they may have on patients' management regarding shared care.

Primarily, this 'agreement for lithium' is between the Specialist consultant and the GP, with consent of the patient, but other healthcare professionals e.g. the community pharmacist, have roles in safe lithium therapeutic management:

Community pharmacist responsibilities
1. Be fully aware and understands the advice given as per the NPSA lithium alert issued in December 2009 http://www.nrls.npsa.nhs.uk/alerts/?entryid45=65426&p=2
2. Pharmacy staff are responsible for taking reasonable steps to ensure that it is safe to dispense lithium to a service user prescribed this drug in accordance with the above NPSA advice.
3. When a prescription for lithium is received, the pharmacist must ask the patient to see their lithium therapy record book and check that a lithium level has been done in the last three months and it is within the therapeutic range. This must be done prior to dispensing.
4. Counsel patient on safe use of lithium, to include potential signs of toxicity and side effects and the need to maintain a consistent fluid intake
5. The NPSA alert states that as a principle, therapy should not be withheld, in the absence of lithium levels if the service user is fit and well.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Email address:
Specialist Consultant		
Bethan Shepherd – Formulary Pharmacist	07775562391 Fax: 01225 362795	bethan.shepherd@awp.nhs.uk
Care Coordinator		
PCLS – Swindon (8am – 8pm then intensive service)	01793 835787 Fax: 01793 836817	
PCLS – North Wiltshire (Green Lane Hospital) (8am – 8pm then intensive service)	01380 7311341 Fax: 01380 731295	
PCLS – South Wiltshire (Fountain Way) 8am- 8pm then intensive service)	01722 820372 Fax: 01722 820376	
PCLS – B&NES (8am – 8pm then intensive service)	01225 371480 Fax: 01225 362799	
PCLS – South Gloucestershire (8am – 8pm then intensive service)	01173 787960 Fax: 0117 3787941	
PCLS – Bristol (8am – 8pm then intensive service)	0117 9195670 Fax: 0117 9195625	
PCLS – North Somerset (8am – 8pm then intensive service)	01934 836406 Fax: 01934 836405	

SUPPORTING INFORMATION

Indications

- Treatment and prophylaxis of mania
- Treatment and prophylaxis of bipolar disorder
- Treatment and prophylaxis of recurrent depression
- Aggressive or self-mutilating behaviour

Dosage and administration

- Dosage is adjusted based on serum-lithium concentration
- Lithium must be prescribed by **brand name** and **formulation** must be specified

Contra-indications and precautions for use

- Hypersensitivity to lithium or any of the excipients.
- Contraindicated in patients with dehydration

- Contraindicated in patients with untreated hypothyroidism.

Side-effects

Nausea, general GI discomfort and vertigo may occur initially but frequently disappear after the first few days of treatment.

Symptoms of neurotoxicty include; paraesthesia, ataxia, vomiting diarrhoea, increasing anorexia, tremor, cognitive impairment, nausea, uncontrolled eye movement, slurred speech and coma. Neurotoxicity can occur at therapeutic levels:

Refer patient back to the specialist if any of these side-effects cause concern. Refer to the SPC for a full list of adverse effects & further information http://www.medicines.org.uk.

This medicine does not have black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA.

Monitoring

Lithium levels - Lithium levels must be taken 12 hours post dose, otherwise clinical value is lost.
Lithium has a narrow therapeutic range necessitating blood levels between 0.4-1.2mmol/L. The lower end of this range is used for elderly and infirmed patients and the upper end for younger patients, particularly those being treated for an episode of mania. Clinicians should aim for levels of 0.6-0.8 mmol/L, with higher levels possibly being of benefit for patients with predominantly manic symptoms. Rarely 1.2mmol/L may be used.

Full blood count – only if clinically indicated.

Parameter	Frequency of monitoring	Action
Ca^{2+},TFTs,eGFR,Weight,	Pre-treatment	Monitoring and any action completed by specialist
Weight	Pre-treatment, annually and if the patient appears to gain weight rapidly.	See appendix 2 Drug treatments to promote weight loss are not recommended.
Lithium plasma level	4 – 7 days after starting treatment and when stable dose has been reached	Initial 3 months of monitoring and any action completed by specialist.
Lithium level every 3 months.	Every 3 months	See appendix 2
TFTs, Ca^{2+} and eGFR	Every 6 months	
Weight	Annually	
Lipid profile (in all those over 40 even if no other indication or risk), plasma glucose, smoking status and alcohol use & BP as part of annual review (NICE CG38)	Annually	
ECG & BP	ECG should be done at the start if there are risk factors for or existing cardiovascular disease; may need more frequent monitoring in those with cardiovascular disease or risk factors for it.	

Diet and concomitant minor illnesses which may increase lithium levels include: nausea/vomiting or other conditions leading to salt water depletion, excessive sweating leading to sodium loss and retention of lithium by the renal system.

Drug Interactions

Please note that some drug/drug interactions may result in lithium toxicity at therapeutic serum concentrations. Main interactions which may increase lithium levels are:

ACEI	Can reduce thirst which can lead to mild dehydration and increase renal sodium loss causing increased sodium reabsorption by the kidney and hence increased Li levels - up to a 4 fold increase (7-fold in the elderly). Can take several weeks to develop. Risk increased in those with heart failure, dehydration and renal impairment.
A2RAs	Care is needed when co-prescribed with lithium
Diuretics	Can reduce renal clearance of lithium. Thiazides are worse culprits than the loop diuretics: Li levels usually rise within 10 days of a thiazide being prescribed. Risk with loop diuretics can take up to a month for Li levels to rise.
NSAIDs	NSAIDs inhibit the synthesis of renal prostaglandins hence reducing renal blood flow and possibly increasing renal reabsorption of sodium and hence lithium. Aspirin does not usually affect serum lithium levels. Ibuprofen is usually safe for short term use on a 'when required' basis but should be used cautiously if other analgesics (e.g. paracetamol) are not appropriate. Check if patient is taking OTC products.

The following may also increase lithium levels: alcohol, dehydration, sodium chloride, systemic steroids.

Drugs that may decrease lithium levels include: theophylline, caffeine, sodium bicarbonate containing products (e.g. non-prescription antacids) and diuretics.

Interactions which may cause neurotoxicity include: antipsychotics (although the combination may be useful), methyldopa, triptan derivatives, SSRIs (although the combination can be useful), verapamil, diltiazem, carbamazaepine.

See SPC for full list of interactions.

Cost

Priadel 400mg Tablets £3.35 x 100
Priadel 200mg Tablets £2.30 x 100
Camcolit 250mg Tablets £3.22 x 100
Camcolit 400mg Tablets £4.30 x 100
Liskonium 450mg Tablets £2.88 x 60
Li-Liquid 509mg/5ml Liquid £5.79 x 150ml
Li-Liquid 1.018g/5ml Liquid £11.58 x 150ml
Priadel Liquid 520mg/5ml £5.61 x 150ml

(NHS Prescription Services 22nd April 2013)

References

1 Effective Shared Care Agreement (for the prescribing of lithium) Suffolk NHS Trust July 2010

2 Effective Shared Care Agreement for Lithium Therapeutic Management North Staffordshire NHS Trust, Stoke on Trent NHS Trust Dec 2010. Review Dec 2012.

3 Procedure for the prescribing and monitoring of lithium in AWP.

4 Shared Care Agreement Theresa Turner AWP Specialist Pharmacist for BNSSG Dec 2009

5 Patient Safety Alert, Safer Lithium Therapy, NPSA/2009/PSA005

6 NICE Clinical Guidance 38 The management of bipolar disorder in adults, children and adolescents, in primary and secondary care Issue date: July 2006

7 Summary Product Characteristics www.medicines.uk.org

8 BNF 63 March 2012

Date written: April 2013

Date of review: April 2015

Appendix 1

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Patient Agreement Monitoring Form

I **name of patient** **date of birth** agree to attend the clinic / GP practice to allow the necessary tests relating to lithium treatment to be taken.

I agree that if I cannot attend an appointment for whatever reason, I will let the specialist / GP practice know.

Signed:_____

PRINT:_____

Date: _____

Appendix 2
Results and referral for advice
Flow chart: