Effective Shared Care Agreement (ESCA)

Lithium *(Priadel®)*

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

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of lithium can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with lithium are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis and the need for lithium therapy
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient Give appropriate written information including the NPSA patient-held record book and lithium alert card
3. Perform initial height & weight measurement, renal function tests, thyroid function tests. Full blood count and ECG should also be performed if there are risk factors for CVD (ref NICE) or existing CVD
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
5. Initiate lithium at an appropriate starting dose to attain target lithium serum levels; measured 5-7 days after first dose. Initiate lithium as a branded product to avoid problems with differences in bioavailability. BSMHT preferred brand :- Priadel preparation.
6. Review the patient every three to six months as indicated by the patient's clinical condition and **communicate promptly with the GP when the treatment is changed.**
7. Advise the patient on the importance of good adherence with the lithium prescription. Check adherence at each clinic appointment
8. Reassume prescribing responsibilities if a woman becomes, or wishes to become, pregnant
9. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
10. Report serious adverse events to the MHRA
11. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below)

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days
2. Prescribe lithium at the dose recommended. BSMHT preferred brand :- Priadel preparation.
3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care

4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist
5. Undertake routine monitoring of the patient's serum lithium levels every three months, renal/thyroid function every six months and weight, especially if the patient gains weight rapidly; **communicate the results to the specialist via the patient-held record book or directly if necessary.**
6. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment
7. Undertake annual physical health check, including weight monitoring, and communicate results to the specialist via the patient-held record. *(Note – physical health monitoring included in QOF and advised by NPSA)*
8. Undertake more frequent tests if there is a change in sodium intake, symptoms suggesting abnormal renal or thyroid function, or other risk factors eg the patient is starting medication such as ACE inhibitors/ARBs, NSAIDs or diuretics (which should be avoided if possible).
9. Monitor for symptoms of neurotoxicity, including paraesthesia, ataxia, tremor and cognitive impairment, which can occur at therapeutic levels.
10. Advise the patient on the importance of good adherence with the lithium prescription. Check adherence at each clinic appointment.
11. Refer the patient to the specialist if the patient's results are abnormal, side effects become apparent and cause problems or their condition deteriorates.
12. For women of child bearing age, refer prescribing responsibilities back to specialist immediately if patient becomes, or wishes to become, pregnant.
13. Report serious adverse events to specialist and MHRA
14. Stop treatment on advice of specialist

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Attend regularly for required blood tests and annual health check
3. Retain NPSA patient-held record and present to relevant health-care professionals on request.
4. Share any concerns in relation to treatment with lithium with the specialist, clinical nurse specialist or GP
5. Report any adverse effects to the specialist or GP whilst taking lithium
6. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

SUPPORTING INFORMATION

<table>
<tr><td>Indication</td><td colspan="2">Lithium is indicated for the treatment and prophylaxis of mania, bipolar disorder and recurrent depression; aggressive or self-mutilating behaviour. It is also prescribed as adjunctive therapy with antidepressants in resistant depression</td></tr>
<tr><td>Dosage and Administration</td><td colspan="2">Dose is adjusted to achieve a serum lithium concentration,12 hours post dose, in bipolar disorder of 0.6 – 0.8 mmol per litre normally or 0.8 - 1. 0 mmol per litre if the patient has relapsed previously on lithium or has subdromal symptoms
Lower levels may be considered in resistant depression
Lithium should always be prescribed by brand. eg. Priadel; changes to formulation or salt (carbonate or citrate) must be subject to the same monitoring as initiation</td></tr>
<tr><td rowspan="3">Renal Impairment</td><td>Mild</td><td rowspan="2">Serum lithium levels must be closely monitored and the dose should be adjusted accordingly to maintain serum lithium levels within the recommended range</td></tr>
<tr><td>Moderate</td></tr>
<tr><td>Severe</td><td>Lithium is contraindicated</td></tr>
<tr><td>Contra-indications / Special precautions</td><td colspan="2">Contraindications
• Hypersensitivity to lithium or to any of the excipients.
• Cardiac disease.
• Cardiac insufficiency.
• Severe renal impairment.
• Untreated hypothyroidism.
• Breast-feeding.
• Patients with low body sodium levels, including for example dehydrated patients or those on low sodium diets.
• Addison's disease.
• Brugada syndrome or family history of Brugada syndrome.
Cautions
• General
When considering lithium therapy, it is necessary to ascertain whether patients are receiving lithium in any other form. If so, check serum levels before proceeding.
The minimum clinically effective dose of lithium should always be used. Clear instructions regarding the symptoms of impending toxicity should be given by the physician to patients receiving long-term lithium therapy. They should be warned of the urgency of immediate action should these symptoms appear, and also of the need to maintain a constant and adequate salt and water intake. At the first sign of toxicity, the patient should consult a physician and lithium levels should be checked.
Treatment should be discontinued immediately on the first signs of toxicity.
• Monitoring recommendations
Before starting treatment with lithium, renal function, cardiac function and thyroid function should be evaluated. Patients should be euthyroid before initiation of lithium therapy. Lithium therapy is contraindicated in patients with severe renal insufficiency or cardiac insufficiency.
Renal, cardiac and thyroid functions should be re-assessed regularly during treatment with lithium.
• Renal Impairment
Since lithium is primarily excreted via the renal route, significant accumulation of lithium may occur in patients with renal insufficiency. Therefore, if patients with mild or moderate renal impairment are being treated with lithium, serum lithium levels should be closely monitored and the dose should be adjusted accordingly. If very regular and close monitoring of serum lithium levels and plasma creatinine levels is not possible, lithium should not be prescribed in this population. Lithium is contraindicated in patients with severe renal insufficiency.
The possibility of hypothyroidism and renal dysfunction arising during prolonged treatment should be borne in mind and periodic assessments made.
Patients should be warned to report if polyuria or polydipsia develop. In patients who develop polyuria and/or polydipsia, renal function should be monitored in addition to the routine serum lithium assessment.
• Fluid/electrolyte balance
If episodes of nausea, vomiting, diarrhoea, excessive sweating, and/or other conditions leading to salt/water depletion (including severe dieting) occur, lithium dosage should be closely monitored and dosage adjustments made as necessary. Drugs likely to upset electrolyte balance such as diuretics should also be reported. Indeed, sodium depletion increases the lithium plasma concentration (due to competitive reabsorption at the renal level). In these cases, lithium dosage should be closely monitored and reduction of dosage may be necessary.
Caution should be exercised to ensure that diet and fluid intake are normal in order to maintain a stable electrolyte balance. This may be of special importance in very hot weather or work</td></tr>
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	environment. Infectious diseases including colds, influenza, gastro-enteritis and urinary infections may alter fluid balance and thus affect serum lithium levels. Treatment discontinuation should be considered during any intercurrent infection. • **Risk of convulsions** The risk of convulsions may be increased in case of co-administration of lithium with drugs that lower the epileptic threshold, or in epileptic patients. • **Benign intracranial hypertension** There have been case reports of benign intracranial hypertension. Patients should be warned to report persistent headache and/or visual disturbances. • **QT prolongation** As a precautionary measure, lithium should be avoided in patients with congenital long QT syndrome, and caution should be exercised in patients with risk factors such as QT interval prolongation (e.g. uncorrected hypokalaemia, bradycardia), and in patients concomitantly treated with drugs that are known to prolong the QT interval. • **Brugada syndrome** Lithium may unmask or aggravate Brugada syndrome, a hereditary disease of the cardiac sodium channel with characteristic electrocardiographic changes (right bundle branch block and ST segment elevation in right precordial leads), which may lead to cardiac arrest or sudden death. Lithium should not be administered to patients with Brugada Syndrome or a family history of Brugada Syndrome. Caution is advised in patients with a family history of cardiac arrest or sudden death. • **Elderly patients** Elderly patients are particularly liable to lithium toxicity and may exhibit adverse reactions at serum levels ordinarily tolerated by younger patients. Caution is also advised since lithium excretion may be reduced in the elderly due to age related disease in renal function
Side Effects	GI disturbances, fine tremor, polyuria/polydipsia, also weight gain and oedema
Monitoring	Pre-treatment – height and weight RFTs, TFTs, full blood count, ECG Routine testing – serum lithium at least every 3 months, TFTs & RFTs at least every 6 months, weight Older adults should be monitored carefully for symptoms of lithium toxicity, because they may develop high serum levels of lithium at doses in the normal range, and lithium toxicity is possible at moderate serum lithium levels.
Drug Interactions	Diuretics, steroids, ACE inhibitors/ARBs and NSAIDs (incl. OTC) can all increase Lithium levels See also BNF Appendix 1 and SmPC

References

- Summary of Product Characteristics (SPC) Priadel 2009
- NICE Clinical Guideline 38 Bipolar Disorder 2006
- NICE Clinical Guideline 90 and 91 Depression 2009

I agree to participate in this shared care agreement for the treatment of the below named patient with lithium for the treatment and prophylaxis of mania, bipolar disorder and recurrent depression, aggressive or self-mutilating behaviour

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at:

Based on MTRAC template
Prepared by Satnaam Singh Nandra
Interface Lead Pharmacist
Birmingham CrossCity CCG

Medicines referral sheet – to be completed by specialist

Consultation date: **Consultant:** **Department:** **Telephone:**	**Surname:** **First name:** **DOB:** **Address:** **GP:**

Medical report

Diagnosis	**Rationale for treatment**

Investigations, test results and treatment – ***a copy of the latest laboratory report may be appended to the ESCA or clinical letter***

Pre-treatment	**At transfer to GP prescribing**
Date	Date
Initial TFT:	**Serum Lithium Concentration**
Initial RFT:	Target:
Sodium	Current:
FBC:	TFT:
ECG:	RFT:
Weight	Sodium
Height	Weight

On-going monitoring requirements

Serum Lithium Concentration: every three months

TFT: every six months **RFT**: every six months

Physical health check: every 12 months

Medication profile

Medication to be TRANSFERRED TO GP PRESCRIBING		
Drug name and form (NB Brand name prescribing essential)	**Dose and frequency**	**Commence on:**

Existing Medication known to specialist team	
Drug name and form	**Current dose and frequency**