Sandwell, Wolverhampton, Walsall/Dudley Shared Care Agreement

Lithium (Priadel®)

ESCA: For the management of acute manic or hypomanic episodes, for prophylaxis against bipolar affective disorders, for episodes of recurrent depressive disorders where treatment with other antidepressants has been unsuccessful and for the control of aggressive behaviour or self harm.

SECONDARY CARE SECTION TO BE COMPLETED BY INITIATING DOCTOR

Patient's name……Date of birth…….

Address……..

NHS number……..MH number……..

Date treatment commenced……

	Tick box
One copy of agreement sent to general practitioner (One copy filed in patient's notes)	☐
Lithium therapy patient information booklet, alert card, record book and patient information leaflet given to patient	☐

Name of initiating doctor……..

Consultant……..

Speciality…….

Fax number: ……..

Telephone number: ……..

Consultants may decide to take full clinical responsibility in case of clinical need and monitor the patient within secondary care. A shared care agreement may not be requested in such cases and the consultant will notify this arrangement to the General Practitioner.

PRIMARY CARE SECTION: TO BE COMPLETED BY GENERAL PRACTITIONER

I agree*/don't agree* to enter into a shared care arrangement for the treatment of the above patient with this medicine (*delete as appropriate)

G.P. Name……

Signature…….. Date…….

Once signed please detach this sheet and fax to the number shown above.

Lithium (Priadel®)

Monitoring by General Practitioner

Shared Care Agreement for the management of acute manic or hypomanic episodes, for prophylaxis against bipolar affective disorders, for episodes of recurrent depressive disorders where treatment with other antidepressants has been unsuccessful and for the control of aggressive behaviour or self harm

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Patient's name……Date of birth……..

Address……..

NHS number……MH number……

Date treatment commenced…….

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

The aim of an Effective Shared Care Agreement (ESCA) is to provide information to general practitioners (GPs) and hospital staff about complex or high cost therapies that their patients may receive following specialist referral. An ESCA will only be written when it has been agreed that shared care is an appropriate option and will include a statement of Specialist Unit / GP responsibilities.

Shared Care Guidelines will ensure that all GPs have sufficient information to enable them to undertake prescribing responsibility for specialist therapies and other therapies that may affect / interact with specialist therapies.

It is not the intention to insist that GPs prescribe this therapy and any doctor who does not wish to undertake the clinical and legal responsibility for this drug is not so obliged. Acceptance of the Effective Shared Care Agreement will be endorsed by the appropriate commissioning medicines management meeting and drugs will, where appropriate, be added to the list of high cost drugs used when setting prescribing budgets.

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 diagnosis and need for lithium therapy.
2	Discuss with patient the need for pre-treatment tests and continued monitoring. Discuss the dangers of continuing treatment without adequate monitoring and possibility of discontinuing treatment.
3	Explain possible side effects, signs of toxicity, interactions (including over-the-counter medication such as NSAIDs) and the importance of maintaining fluid and salt intake. Discuss the risk factors for toxicity.
4	In female patients consider need for pregnancy test and contraceptive advice. If appropriate, discuss breastfeeding contra-indication.
5	Provide the patient/carer with a copy of the lithium therapy patient information booklet, alert card, record book and patient information leaflet. Explain the importance of bringing the record book to each appointment and hospital admission.
6	Undertake pre-treatment monitoring tests (see "Monitoring" section of this agreement) and communicate results to GP.
7	Send a letter and shared care agreement form to the GP to obtain consent to share prescribing and monitoring responsibilities.
8	Initiate treatment with lithium until the dose is stable *and GP formally agrees to shared care*. Always specify brand of lithium on prescription (BCPFT will only initiate patients on the Priadel® brand).
9	Initiate and continue routine blood tests *until GP agrees to share care*. See "Monitoring" section of this agreement for details of blood tests.
10	Ensure the patient's lithium therapy record book is kept up-to-date.

11 Once stable, review the patient's condition and monitor response to treatment every 12 months or sooner if clinically indicated.
12 Communicate promptly with GP when lithium treatment is changed or if other interacting medicines are prescribed/recommended.
13 Communicate blood levels and results of tests to GP as soon as possible.
14 Advise GPs of any dosage adjustments required, when to refer back, and when and how to stop treatment.
15 Accept patients back to secondary care if refusing monitoring tests in the communiity.
16 Ensure clear arrangements for back up, advice, and support.
17 Report adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card system.

General Practitioner responsibilities
1 Initiate referral to specialist if lithium therapy is thought to be indicated.
2 Reply to the specialist requesting shared care and sign the shared care agreement form.
3 Provide repeat prescriptions after dose is stable. Any increase in lithium dose (even if serum lithium level is low) must be made only after consultation with the consultant psychiatrist. Always specify brand of lithium on prescription and on patient's record (BCPFT will only initiate patients on the Priadel® brand).
4 Ensure patient is aware of possible side effects, risk factors for toxicity and drug interactions (including over-the-counter medication such as NSAIDs).
5 Ensure patient is aware of signs of lithium toxicity and understands the importance of reporting these signs to their GP and/or specialist.
6 Continue routine monitoring as detailed in "Monitoring" section of this agreement. Communicate results to the secondary care consultant as soon as possible.
7 Ensure the patient's lithium therapy record book is kept up-to-date.
8 Monitor the patient for side effects and signs of toxicity.
9 Monitor the patient for drug interactions, arranging blood tests if interacting medicines are prescribed.
10 Refer back to specialist if condition deteriorates or if a patient refuses to have any monitoring tests.
11 Report adverse events to the MHRA, using the yellow card system and keep specialist informed.
12 Stop treatment on advice of specialist.

Patient's role
1 Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2 Ensure regular attendance for review and blood monitoring tests.
3 Take lithium therapy record book to all appointments and hospital admissions and keep it up-to-date.
4 Be aware of side effects and potential for drug interactions. Seek medical attention if they develop diarrhoea and/or vomiting
5 Be aware of risk factors and signs of toxicity and understand the importance of reporting these signs to their GP and/or specialist.
6 Be aware that erratic compliance or stopping the drug suddenly may increase the risk of relapse.
7 Report any adverse effects to the specialist or GP.

SUPPORTING INFORMATION

See current edition of the British National Formulary (BNF) and Summary of Product Characteristics (SPC) for Priadel® for full details of licensed indications, dosage and administration, contraindications, cautions, side-effects and drug interactions.

Licensed indications

- Management of acute manic or hypomanic episodes
- Prophylaxis against bipolar affective disorders
- Episodes of recurrent depressive disorders where treatment with other antidepressants has been unsuccessful
- Control of aggressive behaviour or intentional self harm

Dosage and Administration

- Dose is adjusted to achieve a 12 hours post dose serum lithium concentration of 0.4-1.0 mmol/L in adults and 0.4-0.8 mmol/L in the elderly. (NICE Guideline 38 Bipolar disorder July 2006 states aim for 0.6–0.8 mmol/L normally or 0.8-1.0 mmol/L if the patient has relapsed previously on lithium or has sub-syndromal symptoms)
- Starting dose 400mg at night (200mg in the elderly). Normal dose range 400-1200mg at night.
- Prescribe lithium by brand only as preparations vary widely in bioavailability. BCPFT will only initiate patients on the Priadel® brand
- If lithium liquid (Priadel® liquid) is required it should be prescribed in 2 divided doses. Priadel® tablets contain lithium carbonate;
- Priadel® liquid contains lithium citrate 520mg/5mL. A 5mL dose of lithium citrate is equivalent to 204mg of lithium carbonate
- Li-Liquid® contains lithium citrate 509mg/5ml. A 5ml dose of lithium citrate is equivalent to 200mg of lithium carbonate
- For all practical purposes 5ml of either liquid preparation is equivalent to 200mg of the carbonate salt.

Contraindications

- Hypersensitivity to lithium or to any of the excipients
- Clinically significant renal impairment
- Untreated hypothyroidism
- Breast-feeding
- Patients with low sodium levels, including, for example, dehydrated patients or those on low sodium diets
- Addison's disease

Cautions

- Measure serum-lithium concentration every 3 months on stabilised regimens
- Measure renal function and thyroid function every 6 months on stabilised regimens and advise patients to seek attention if symptoms of hypothyroidism develop
- Cardiac disease
- Diarrhoea, vomiting and intercurrent infections
- Elderly
- Psoriasis
- Diuretic treatment
- Myasthenia gravis
- Pregnancy and women of child-bearing potential

Side Effects

- GI disturbances, fine tremor, polyuria/polydypsia, weight gain, oedema. See the latest edition of the BNF or SPC for Priadel® for further details

Drug Interactions

- Diuretics (especially thiazides), angiotensin converting enzyme (ACE) inhibitors, non-steroidal anti-inflammatory drugs (NSAIDs) (including OTC), steroids and metronidazole increase lithium levels. For a full list of interactions see the latest edition of the BNF or SPC for Priadel®

Signs of intoxication

- Blurred vision, increasing GI disturbances (anorexia, vomiting, diarrhoea), muscle weakness, increased CNS disturbances (mild drowsiness and sluggishness, increasing to giddiness with ataxia, coarse tremor, lack of co-ordination and dysarthria)

Monitoring

- **Pre-treatment -** thyroid function, renal function, full blood count (if clinically needed), ECG (if there are risk factors for or existing cardiovascular disease), weight and height, contraception advice/pregnancy test (if applicable).
- **At beginning of treatment -** weekly serum lithium levels until level stable. The blood sample should be taken 12 hours after a lithium dose. If the patient is taking Priadel® liquid, the morning dose will need to be delayed until the blood sample is taken.
- **After any change of dose/formulation or introduction of interacting medication -** serum lithium level after 7 days, then weekly until level stable.
- **Routine testing -** serum lithium every 3 months once level stable, thyroid function and renal function every 6 months, full blood count (if clinically needed), ECG (if risk factors for or existing cardiovascular disease), weight when needed if the patient gains weight rapidly. In addition, yearly health checks and monitoring of weight are recommended.
- **Do tests more frequently** if there is clinical deterioration, abnormal results, a change in sodium intake, symptoms of abnormal renal or thyroid function or other risk factors such as starting ACE inhibitors, NSAIDs or diuretics.
- **If urea and creatinine levels rise** monitor lithium dose and blood levels more closely and assess the rate of deterioration of renal function. The decision on whether to continue the drug depends on clinical efficacy and the degree of renal impairment. Consider consulting a renal specialist
- **Monitor for symptoms of neurotoxicity** including paraesthesia, ataxia, tremor and cognitive impairment.
- **NB: Always be aware of the time a sample was taken in relation to the last dose. Samples taken more than 1.5-2 hours more or less than the standard 12-hr lithium can lead to misleading interpretation.**

<u>If lithium serum levels above normal range for patient</u>:

- Usually, for levels between 1.0 and 1.5 mmol/L and if no serious signs of toxicity, reduce dose and recheck lithium level
- In cases of suspected lithium toxicity, lithium should be stopped and an urgent serum lithium level taken. In all cases of lithium toxicity advice should be obtained from a specialist
- Monitor older adults carefully for symptoms of toxicity

<u>If lithium serum level is between 1.5 and 2 mmol/L:</u>

Stop lithium and re-check serum level. GP should seek further advice from consultant (on call consultant if out of hours) as soon as possible

<u>If lithium serum level above 2 mmol/L:</u>

Serious toxicity is likely – refer to hospital for emergency treatment of lithium poisoning

If renal or cardiac changes are noticed during the monitoring the GP should take opinion from the nephrology and/or cardiology consultant and also inform the consultant psychiatrist.

Patients non-compliant with monitoring

This requires prompt attention and may indicate that the patient's illness is relapsing. Therefore, to stop the prescription of lithium without investigating the reason for the default from monitoring may be detrimental. Those with the responsibility for prescribing lithium will be expected to have a reactive monitoring system in place to follow up the patient who has defaulted (e.g. a recall letter). This should equally apply in the situation when a patient is found not to collect their prescription of lithium.

This Shared Care Agreement should be read in conjunction with the current edition of the BNF, the SPC for Priadel® and Trust guidelines for the prescribing and monitoring of lithium. This format is based on an original template developed by the Midlands Therapeutic Review and Advisory Committee (MTRAC)

References:

- *British National Formulary*. No. 59. British Medical Association/Royal Pharmaceutical Society of Great Britain March 2010
- Summary of Product Characteristics (SPC) for Priadel® Priadel 200mg & 400mg prolonged release tablets - Summary of Product Characteristics (SPC) - electronic Medicines Compendium (eMC) Priadel Liquid - Summary of Product Characteristics (SPC) - electronic Medicines Compendium (eMC)
- National Institute for Health and Clinical Excellence Clinical Guideline 39. *Bipolar disorder. The management of bipolar disorder in adults, children and adolescents, in primary and secondary care.* July 2006 CG38 Bipolar disorder: quick reference guide

Taylor D, Paton C, Kapur S. *The Maudsley Prescribing Guidelines*. Tenth Edition. The South London and Maudsley NHS Foundation Trust, Oxleas NHS Foundation Trust. Informa Healthcare. 2009

This shared care agreement has been approved for use in Dudley & Walsall, Sandwell, and Wolverhampton by:		**Signature**	**Date**
BCPFT Medicines Management Committee Chairman	Dr. S. Edwards		1/1/14
Head of Medicines Management Sandwell PCT	Ms E. Walker		
Wolverhampton City PCT Prescribing Board Chairman	Dr. J. Parkes		1/1/14
Specialist in Pharmaceutical Public Health, Office of Public Health, Dudley MBC on behalf of Dudley CCG	Dr Duncan Jenkins		
Head of Medicines Management Walsall PCT	Bharat Patel		

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Fax:
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Consultant: Dr Regmi	01902 445371	01902 444514
Consultant: Dr Tungaraza	01902 445395	01902 444514
Consultant: Dr Kar	01902 553798	01902 553383
Consultant: Dr Akhtar	01902 553807	01902 553383
Consultant: Dr Black	01902 445991	
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Consultant: Dr Ahmed	0121-612 8658	0121-612 8658
Consultant: Dr Mahbouba	0121-612 8960	0121-612 8960
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Consultant: Dr Curran	0121-612 8205	0121-612 8205
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