Coastal West Sussex Clinical Commissioning Group

WORKING IN PARTNERSHIP WITH

Sussex Community NHS Foundation Trust

Sussex Partnership NHS Foundation Trust

Western Sussex Hospitals NHS Foundation Trust

EFFECTIVE SHARED CARE AGREEMENT (ESCA) – PART B

DRUG NAME: LITHIUM

INDICATION/S COVERED: (including whether for adults or children) Prophylaxis and treatment of mania; Prophylaxis of bipolar disorder; Prophylaxis of recurrent depression

Coastal West Sussex traffic light system classification: Amber

To be read in conjunction with PART A – CWS ESCA Core Documentation

Agreement for transfer of prescribing to GENERAL PRACTITIONER

Drug name and dose (standard or expected dose or dose range): <insert drug name and dosing>

The following tests and investigations have been carried out: <insert details of tests>

Date treatment initiated: <insert date>

At the last patient review the drug appeared to be effectively controlling symptoms / providing benefit: Yes/No

The patient has now demonstrated tolerability and effective clinical response on a dose of: <insert dose>

I will arrange to review this patient regularly. Date of next clinic appointment: <insert date>

Patient details	
Name:	
Address:	
Date of Birth:	
NHS number:	
Hospital No:	
Consultant details	
Name:	
Address:	
Email:	
Contact number:	
GP details	
Name:	
Address:	
Email:	
Contact number:	
Main Carer (if applicable):	
Name:	
Contact number:	
Key worker (if applicable):	
Name:	
Contact number:	

In the absence of written refusal within 14 days of shared care request, it will be assumed that prescribing responsibility will transfer and shared care arrangements commence.

The responsible Consultant and where differing, the requesting Health Care Professional must be informed in writing within 14 days of the initial request for shared care should the decline of the transfer of prescribing responsibility to the General Practitioner be necessary.

Information

Additional information to support but not replace the information provided within this document can be found within the current Summary of Product Characteristics (http://www.medicines.org.uk/emc/) and also the British National Formulary Online (https://www.medicinescomplete.com/mc/bnf/current/)

1. Link to relevant national or local guidance (e.g. NICE, CKS)

Summary of product characteristics: Lithium
http://www.medicines.org.uk/EMC/searchresults.aspx?term=lithium&searchtype=QuickSearch

2. Background for use

Both the Maudsley Prescribing Guidelines[5] and the Psychotropic Drug Directory[6] support the use of lithium for:

- the management of acute manic or hypomanic episodes
- management of episodes of recurrent depressive disorders where treatment with antidepressants has been unsuccessful,
- in the prophylaxis against bipolar affective disorders
- the control of aggressive behaviour or intentional self-harm.

All are licensed indications.

3. Dose (standard or expected dose or dose range), route of administration, frequency and duration of treatment

Dosage must be individualised depending on serum lithium levels and clinical response. The dosage necessary to maintain serum lithium levels within the therapeutic range varies from patient to patient.

The minimum effective dose should be sought and maintained.

In patients of average weight (70kg) treatment and prophylaxis - initially 400–1200mg daily as a single dose. Alternatively, the dose may be divided and given morning and evening, but ideally should revert to once daily once the dose is stable, though liquids must be given twice daily. The modified-release tablets should usually be given at the same time every day, usually at night, as the blood level needs to be taken 12 hours after the last dose. If the dosage is twice daily, and a blood test is due, the first dose of the day must not be taken until after the blood test has been done.

Prophylactic treatment of bipolar affective disorders and control of aggressive behaviour or intentional self-harm:
Dosage needed may vary from patient to patient. As a general rule, serum lithium levels should be maintained within the range of 0.5 to 1.0mmol/l and should not exceed 1.5mmol/l. Optimal maintenance serum lithium levels may vary from patient to patient.

Treatment of acute manic or hypomanic episodes and recurrent depressive disorders:
It is likely that a higher than normal (Priadel®) intake may be necessary during an acute phase and divided doses would be required. As a general rule, the monitoring should maintain serum levels at 0.8 - 1.2mmol/l until acute symptoms have been controlled. Dosage needed may vary from patient to patient. Serum lithium levels should be monitored and should not exceed 1.5mmol/l. Once clinical control is achieved, dosage should be reduced to prophylactic dose.[1,2]

4. Contraindications

Hypersensitivity to lithium or to any of the excipients, cardiac disease, cardiac insufficiency, severe renal impairment, Addison's disease, untreated hypothyroidism, breastfeeding, patients with low body sodium levels, e.g. dehydrated patients or those on low sodium diets, Brugada syndrome or family history of Brugada syndrome.

5. Cautions

The possibility of hypothyroidism and renal dysfunction arising during prolonged treatment should be borne in mind and periodic assessments made.

Any woman who is or planning pregnancy, or to breast feed whilst on lithium therapy, should be referred to a specialist.

Patients need to be made aware of what they should do if they become ill or find themselves in a situation that results in profuse sweating. The approved lithium treatment monitoring booklet includes advice covering this issue.

Patients should maintain an adequate fluid intake and should avoid dietary changes which might reduce or increase sodium intake.[2]

6. Side effects / adverse effects (including incidence, identification, importance and management)

Adverse effects are directly related to blood levels and their frequency increase dramatically at plasma levels above 1.0mmol/l[4]

- Fine tremor – often responds to low dose propranolol.
- Nephrotoxicity. Up to one third of patients may develop polyuria and polydipsia, which is usually reversible on withdrawal. Long term treatment may result in permanent changes and renal impairment.
- Gastrointestinal disturbances – often at start of treatment and usually transient.
- Weight gain and oedema (not to be treated by diuretics)
- Disturbances of thyroid function
- Exacerbation of psoriasis
- Raised antidiuretic hormone concentration
- Hypokalaemia
- ECG changes
- Mental dulling – reported in some patients, although others may report increase in creativity due to increased organisational ability.

  NOTE: periods of gastric illness with diarrhoea or vomiting may result in salt and water depletion – this can lead to an increase in lithium level.

  Signs of toxicity (levels above 2.0mmol/l) are normally considered dangerous – increased disorientation and seizures may lead to coma and death.

- Blurred vision
- Diarrhoea and vomiting
- Unsteadiness or clumsiness
- Difficulty in speaking
- Severe tremor or twitching limbs
- Greatly increased thirst and/or passing water
- Severe drowsiness and/or confusion

7. Interactions

- Diuretics (especially thiazides) = > increase lithium levels
- ACE-Inhibitors & Angiotensin-II-Antagonists = > increase lithium levels
- Non-Steroidal Anti-Inflammatory Drugs = > increase lithium levels
- SSRIs: may increase CNS toxicity; lower the epileptic threshold (although lithium levels may not be raised, increased monitoring should be considered).
- Antipsychotics = > may increase risk of neurotoxicity.
- Calcium channel blockers = > may increase risk of neurotoxicity and increase lithium levels.
- Drugs that prolong the QT interval.
- Many other interactions are possible – refer to current edition of BNF and the drug's SPC

8. Monitoring requirements

See "Roles and responsibilities" on page 4 & 5

9. Training requirements (patient and clinical) specific to the proposed treatment

Ensure that patient and/or carer has understanding of how this medicine is taken.

10. Any further information (e.g. supporting therapies)

- Brands of lithium are not bio-equivalent. They must be prescribed by brand name. If brands are changed the same precautions should be followed as when starting treatment. The preferred brand is Priadel® when initiating new patients.
- Lithium carbonate 200mg tablets contain 5.4mmol of lithium which is approximately equivalent to 509mg/5ml of the Li-Liquid® brand of lithium citrate liquid or 520mg/5ml of the Priadel® brand of lithium citrate liquid.
- Lithium levels can be affected by many other drugs. Please see Drug Interactions for further guidance.
- The full prophylactic effect of lithium may not occur for six to twelve months after the initiation of therapy.
- Dose reduction or discontinuation may be necessary in diarrhoea, vomiting or intercurrent infection.
- While there is no clear evidence of withdrawal or rebound psychosis, abrupt discontinuation of lithium increases the risk of relapse. If lithium is to be discontinued the dose should be reduced gradually over

a period of at least 4 weeks, preferably over a period of 3 months. Patients should be warned of the risk of relapse if lithium is discontinued abruptly. If treatment has to be stopped abruptly consider changing therapy to an atypical antipsychotic or valproate (avoid in women of child bearing potential).

11. References

1. Summary of Product Characteristics *Priadel 200 & 400mg prolonged release tablets,* updated June 2015, [Online], www.medicines.org.uk/emc/searchresults.aspx?term=Priadel&searchtype=QuickSearch last accessed via: on 13/10/17
2. British Medical Association, Royal Pharmaceutical Society of Great Britain, *British National Formulary (BNF)* ed 72 September 2016, London, BMJ Group & Pharmaceutical Press, 2016. www.bnf.org
3. NPSA alert, *Safer lithium therapy,* December 2009, [Online], last accessed via: www.nrls.npsa.nhs.uk/resources/?entryid45=65426 on 13/10/17.
4. Lancet. 2012 Feb 25;379(9817):721-8. doi: 10.1016/S0140-6736(11)61516-X. Epub 2012 Jan 20.Lithium toxicity profile: a systematic review and meta-analysis. McKnight RF, Adida M, Budge K, Stockton S, Goodwin GM, Geddes JR., last accessed via www.crd.york.ac.uk/crdweb/ShowRecord.asp?LinkFrom=OAI&ID=12012000520 on 13/10/17.
5. Taylor D, Paton C, Kapur S; The Maudsley Prescribing Guidelines, 10th Edition 2010
6. Bazire S; The Psychotropic Drug Directory 2010

RESPONSIBILITIES and ROLES

Consultants responsibilities	
Responsibilities in addition to those detailed within the core document.	
1	Undertake baseline tests. Renal, cardiac and thyroid function should be evaluated before starting treatment with lithium. Patients should be euthyroid before initiation of lithium therapy.
2	To ensure a patient information leaflet (available from the Choice & Medication website) and lithium treatment monitoring booklet (additional stocks are available from the Trust's Chief Pharmacist) are issued and discussed.
3	To initiate lithium and monitor lithium levels, four to seven days after starting treatment, and subsequently monitored weekly until the dosage is stabilised and ESCA is in place. A copy of the lithium levels should be requested for the primary care prescriber.
4	To provide the primary care prescriber with target serum levels of lithium and to advise on actions to take when the serum level is outside the range
5	To advise the patient and primary care prescriber on dose alterations, abnormal results, concurrent medication, and relevant action to be taken if adverse effects are experienced.
6	To advise and support the patient and / or carer.
7	To review the patient at least annually and when requested to by the primary care prescriber to assess response, the benefits of continued treatment and which treatment is most appropriate.
8	To document any changes and/or results in the patient's lithium treatment monitoring booklet.

GP's responsibilities	
Responsibilities in addition to those detailed within the core document.	
1	Monitoring to be undertaken by the primary care prescriber and a copy sent to the specialist for information and action as relevant. Results of routine monitoring should be recorded in a patient held lithium monitoring booklet. If the patient does not hold one, a copy should be provided for the patient and the importance of carrying the booklet for healthcare professionals to refer to should be stressed. a. Lithium levels – 3 monthly (or more frequently if indicated by a dose change or illness involving fluid loss) b. U&Es – 6 monthly. Lithium toxicity is made worse by sodium depletion and a dosage reduction may be necessary. c. eGFR – 6 monthly (3 months for elderly or where complicating factors). If there is evidence of new renal impairment or a sudden worsening of established mild or moderate impairment refer for reassessment of treatment. d. TSH – 6 monthly (every 4 to 6 weeks if TSH is raised) consider early thyroxine supplement in hypothyroid patients. e. Weight/BMI – 6 monthly. f. Corrected calcium – as appropriate (raised serum calcium may indicate hyperparathyroidism g. Regular cardiac function monitor is also recommended.
1.	To undertake routine monitoring and act upon the results, making necessary dose adjustments as advised by the specialist in addition to contacting the patient of the proposed action where appropriate / necessary.
2.	Additional frequency of monitoring should be made following alteration of dosage, on development of intercurrent disease, signs of manic or depressive relapse, following significant change in sodium or fluid intake,

	or if signs of lithium toxicity occur
2	To monitor the patient's overall health and wellbeing
3	To monitor the prescribing rate of lithium for individual patients.
4	To keep the care coordinator / mental health team informed e.g. any changes of medication prescribed for any indication.
5	To document any changes and / or results in the patient's lithium treatment monitoring booklet.

Patient's / Carer's role	
Responsibilities in addition to those detailed within the core document.	
1	Report to their primary care prescriber any such symptoms such as side-effects and situations that could affect their lithium levels
2	To inform the primary care prescriber if health problem arise
3	To be aware of side-effects, situations that could affect their lithium levels and report any relevant symptoms.
4	To present their lithium monitoring record whenever consulting a healthcare professional or on admission to hospital.

BACK-UP ADVICE AND SUPPORT

	Name / position	**Telephone**	**Email**
Specialist / Consultant:	Practice assigned team to be contacted, team will be dependent upon locality		
Alternative specialist (e.g. departmental contact):			
Out of hours (e.g. medical team on call):			
Mental health specialists:	Ami Hale – Coastal West Sussex locality Elizabeth Mailey – West Sussex Team leader	07823 789 216 07823 789 482	ami.hale@sussexpartnership.nhs.uk Elizabeth.Mailey@sussexpartnership.nhs.uk

Version History			
Document Name:		Effective Shared Care Agreement (ESCA) **PART B** – Lithium	
Document Type:		Effective Shared Care Agreement	
Relevant to:		All GPs working within CWS and all relevant clinicians at WSfHT. SPfT / SCT	
Version	Date	Author of original development or review	Details of document development
1	September 2011	Ray Lyon, Chief Trust Pharmacist, SPfT	Original development
2	May 2013	Cora Wukovich, (Medicines Management Technician), Coastal West Sussex CCG	Full review and re-draft
3	October 2016	Karen Gray, Senior Pharmaceutical Commissioning Technician. Coastal West Sussex CCG.	Re-formatted, no change of information
4	January 2018	Zara Butt, Pre-Registration Pharmacist **Checked by Ray Lyon – SPfT Chief Pharmacist*	Re-draft
Approval for organisational use			
ESCA authorised for use in Coastal West Sussex by		**Coastal West Sussex Area Prescribing Committee (APC):** January 2018	