Manchester Mental Health and Social Care Trust

Shared Care Guideline for	Reference Number
Prescription and monitoring of Acamprosate Calcium	
Author(s)/Originator(s): (please state author name and department)	**To be read in conjunction with the following documents:** Current Summary of Product characteristics (http://www.medicines.org.uk)
Dr Daly - Consultant Psychiatrist, Alcohol Services Dr Donnelly – Consultant Psychiatrist MMHSCT	BNF
Date approved by Medicines Management Committee: 10th September 2013	**Review Date: 31st November 2016**

1. Licensed Indications	Maintenance of abstinence in alcohol dependence
2. Therapeutic use & background	Acamprosate (active ingredient calcium acetylhomotaurinate, brand name Campral) is licensed for use in alcohol dependent individuals who are attempting to maintain abstinence from alcohol as an adjunct to appropriate psychosocial interventions and support. Its mechanism of action is not clearly defined, it is believed to act by stimulating GABAergic inhibitory neurotransmission, antagonising glutamic acid and other excitatory amino acids. It may be neuroprotective and reduce the kindling effect observed in repeated alcohol withdrawals. There is no clear evidence of reducing craving as the mechanism of action although this is often described to patients. Acamprosate does not interact with alcohol. Large series of placebo controlled trials in Europe have demonstrated efficacy and a dose related effect. Abstinence rates for those treated with Acamprosate were increased by 10-40% compared with placebo. Meta-analysis of studies involving over 4,000 patients demonstrated a 13.3% superiority over placebo (Mann et al 2004) Chick et al have estimated a 50% reduction in drinking in those taking Acamprosate. The duration of response has been detected for up to 12 months of treatment. The UKMAS study showed no benefits over placebo one of the reasons for these findings was felt to be the delay in instigating treatment. Acamprosate is recommended in a review of the effectiveness of treatment for alcohol problems by the NTA 2006. NICE Alcohol use disorder : Diagnosis, assessment and management of harmful drinking and alcohol dependence (NICE Clinical Practice

<table>
<tr><td></td><td>Guideline 115 Feb 2011) recommend the use of acamprosate as first line treatment after successful withdrawal from alcohol (Recommendation 7.15.1.1). Acamprosate is thought to be less effective in those who stopped drinking >2 weeks before commencing the medication, also in those with a personality disorder.

Acamprosate works best in those who are abstinent but may be effective in reducing the risk of a lapse becoming a full relapse. Therefore continue in these individuals unless a full relapse to heavy drinking is obvious.

Acamprosate works best in those who are abstinent but may be effective in reducing the risk of a lapse becoming a full relapse. Therefore continue in these individuals unless a full relapse to heavy drinking is recommended.</td></tr>
<tr><td>3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).</td><td>Established hypersensitivity to Acamprosate.
Renal insufficiency (creatinine >120 mmol/l)
Severe hepatic failure (Childs-Pugh classification C)
Pregnancy (discuss risks in women of child bearing age)
Breast-feeding
Children</td></tr>
<tr><td>4. Prescribing in pregnancy and lactation</td><td>This drug cannot be prescribed in the pregnant/breastfeeding patient. It should be discontinued if pregnancy occurs.</td></tr>
<tr><td>5. Dosage regimen for continuing care</td><td>
<table>
<tr><td>Route of administration</td><td>Oral</td></tr>
<tr><td colspan="2">Preparations available

Acamprosate calcium, 333mg, enteric-coated tablets
(Campral EC®).</td></tr>
<tr><td colspan="2">Please prescribe:

Adult >60kg: 666mg (2 tablets) three times daily

Adult <60kg: 666mg mane, 333mg midday and 333mg 6pm

Acamprosate taken with food reduces its bioavailability.</td></tr>
<tr><td>Is titration required</td><td>Yes</td><td>No ✓</td></tr>
<tr><td colspan="2">Adjunctive treatment regime

Adjunctive psychosocial intervention</td></tr>
<tr><td colspan="2">Conditions requiring dose reduction

None</td></tr>
<tr><td colspan="2">Usual response time

Should be initiated as soon as possible after detoxification, there is some evidence to suggest that suggest that starting Acamprosate 2 weeks before a detoxification may reduce the risk of kindling and worsening subsequent withdrawals.</td></tr>
</table>
</td></tr>
</table>

	Duration of treatment Treatment should be continued for 6-12 months
	Treatment to be terminated by Either GP or the specialist. Treatment should be terminated if a full relapse has happened, lack of efficacy or intolerable side effects.
6.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	The following drugs may be prescribed:
	No significant interactions have been associated with the use of Acamprosate. Concomitant intake of alcohol does not affect the pharmacokinetics of either agent Acamprosate can be used safely with benzodiazepines (e.g. as part of a detoxification).

7. Adverse drug reactions

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF

Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.

Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
In up to 10% of patients diarrhoea may occur, less frequently nausea, vomiting or abdominal pain.	Generally self limiting and does not require cessation of the drug, If severe and persistent then withdraw medication.	GP or specialist.
Pruritus may occur and occasionally a maculopapular rash	Generally self limiting and does not require cessation of the drug, If severe and persistent then withdraw medication.	GP or specialist
Fluctuation of libido	If severe and patient wishes discontinue.	GP or specialist
Bullous rash (rare)	Discontinue, consider referral to dermatology	GP or specialist

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

Bullous rash

Other important co morbidities:

	None
	Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme.
8.Baseline investigations	**List of investigations / monitoring :** Blood tests - Renal function tests – it has predominant renal excretion - Liver function tests – prescribing is only unsafe if Child Pugh C
9. Ongoing monitoring requirements to be undertaken by GP	**Is monitoring required?** **Yes or No (if yes complete following section)**

Monitoring	Frequency	Results	Action	By whom
Efficacy and side effects	6 weekly	Ensure engagement with psychosocial intervention and CAT.	Contact CAT	CAT/GP

10. Pharmaceutical aspects	No special considerations required.
11. Secondary care contact information	**If stopping medication or needing advice please contact:**
	Dr _____
	Contact number: _____
	Hospital: _____
12. Criteria for shared care	Prescribing responsibility will only be transferred when ▪ Treatment is for a specified indication and duration. ▪ Treatment has been initiated and established by the secondary care specialist. ▪ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements

13. Responsibilities of initiating specialist	Initiate treatment or to advise the GP to initiate treatment as appropriate . Establish dose relating to weight. Monitor patient's initial reaction to and progress on the drug. Ensure that the patient has an adequate supply of medication until GP supply can be arranged (Unless GP is initiating treatment after advice from specialists). Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before review. Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient *or* inform GP if the patient does not attend appointment Provide GP with advice on when to stop this drug. Provide patient with relevant drug information to enable Informed consent to therapy Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action .
----------	**----------**
14. Responsibilities of the GP	Initiate treatment as directed by the specialist To monitor and prescribe in collaboration with the specialist according to this protocol To ensure that the monitoring and dosage record is kept up to date To discontinue medication if lack of efficacy, full relapse or side effects. Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary.
----------	**----------**
15. Responsibilities of the patient	To take medication as directed by the prescriber, or to contact the GP if not taking medication To attend hospital, CAT and GP clinic appointments To report adverse effects to their Specialist or GP.

16.Additional Responsibilities	**List any special considerations**	**Action required**	**By whom**	**Date**
17. Supporting documentation	The SCG must be accompanied by a patient information leaflet.			
19. Shared care agreement form	Attached below			

Shared Care Agreement Form

Specialist request

***IMPORTANT: ACTION NEEDED**

Dear Dr *[insert Doctors name here]*

Patient name: *[insert Patients name here]*
Date of birth: *[insert date of birth]*

Diagnosis: *[insert diagnosis here]*

This patient is suitable for treatment with *[insert drug name]* for the treatment of *[insert indication]*

This drug has been accepted for Shared Care according to the enclosed protocol (as agreed by Trust / LHB / AWMSG). I am therefore requesting your agreement to share the care of this patient.

Treatment was started on [insert date started] [insert dose].

If you are in agreement, please undertake monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

Baseline tests: *[insert information]*

Next review with this department: *[insert date]*
You will be sent a written summary within 14 days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking *[insert text here]*.

Please use the reply slip overleaf and return it as soon as possible.

Thank you.

Yours

[insert Specialist name]

Shared Care Agreement Form

GP Response

Dear Dr *[insert Doctors name]*

Patient *[insert Patients name]*

Identifier *[insert patient date of birth/address]*

I have received your request for shared care of this patient who has been advised to start *[insert text here]*

A I am willing to undertake shared care for this patient as set out in the protocol

B I wish to discuss this request with you

C I am unable to undertake shared care of this patient.

GP signature Date

GP address/practice stamp