SHARED CARE GUIDELINE FOR ACAMPROSATE

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of acamprosate.

2. The Guidance

2.1. See below for the Shared Care Guideline.

ACAMPROSATE

This shared care guideline sets out details for sharing care of adult patients alcohol abstinence maintenance prescribed Acamprosate. These guidelines provide limited information necessary to aid in the treatment of these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with the BNF, ABPI summary of product characteristics and do not replace them

BACKGROUND / INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE:

Acamprosate is indicated as therapy to maintain abstinence in alcohol-dependent patients. It should be combined with psychosocial interventions. It is believed to act by stimulating GABAergic inhibitory neurotransmission and antagonising excitatory amino acids, particularly glutamic acid, which may underlie some aspects of CNS vulnerability to relapse.

The product is used to maintain abstinence in people who are dependent on alcohol.

Acamprosate does not constitute treatment for the symptoms of alcohol withdrawal.

DOSAGE

Adults >60kg 2 tablets three times daily with meals,

Adults < 60kg 2 tablets morning, 1 at noon and 1 at night with meals.

Not recommended for the elderly and children.

INITIATION & MONITORING

- Acamprosate should be initiated by an Addaction, a GPWSI in Substance Misuse, a Substance misuse Shared Care GP, a Home & Dry Detox Trained GP or Consultant Hepatologist or Consultant Nurse Hepatology.
- Subsequent prescribing can be continued by the patient's own GP supported by clear handover information from the initiator.
- Treatment should be commenced as soon as possible around the time of alcohol detoxification, and can be maintained if patient relapses.
- Recommended treatment period is one year.
- The medication forms part of an integrated programme that includes continuing psychosocial intervention provided by Addaction.
- On-going monitoring should include monthly medical review for at least the first 6 months together with support from Addaction.
- Reviews should determine whether or not the patient is continuing to take the medication as prescribed; their level of alcohol consumption (if any); any relevant health problems (such as liver disease); their continuing use of support services; and the patient's views on the effectiveness of the medication.
- In the event of a relapse:
  - Acamprosate does not interact with alcohol so treatment should be continued.
  - Acamprosate does not interact with diazepam, so they can be used together if necessary.

CONTRAINDICATIONS

- Known hypersensitivity to the drug
- lactation
- Renal insufficiency (serum creatinine >120 micromol/L)

PRECAUTIONS - caution is advised as follows:

- Pregnancy (discuss risks in women of child bearing age).
- Acamprosate does not prevent the harmful effects of continuous alcohol abuse.
- Because the interrelationship between alcohol dependence, depression and suicidality is well-recognised and complex, it is recommended that alcohol-dependent patients, including those treated with acamprosate, be monitored for such symptoms.
- Severe hepatic failure.

SIDE EFFECTS

Below are some of the more common side effects please note that this list is NOT exhaustive and that it is recommended that the SPC and BNF should be consulted for a more comprehensive list.

Initially diarrhoea may occur, less frequently nausea, vomiting or abdominal pain. Pruritus may occur and occasionally a maculopapular rash. Rarely a bulbous skin reaction occurs. There may be fluctuations in libido.

Should not impair ability to drive or operate machinery.

COMMON / SIGNIFICANT DRUG INTERACTIONS

This list is NOT exhaustive, the SPC and BNF should be consulted for a more comprehensive list of potential drug interactions.

Acamprosate taken with food has lower bioavailability than in the fasting state. However some patients are more comfortable taking the tablets with food. No interactions have been shown between acamprosate and diazepam, disulfiram or imipramine. Concomitant intake of alcohol does not affect the pharmacokinetics of either agent.

PRODUCT INFORMATION

- Acamprosate calcium is prepared in 333mg enteric-coated tablets (Campral EC).

REFERENCES

- Summary of Product Characteristics http://emc.medicines.org.uk/
- British National Formulary www.bnf.org.uk
- NICE clinical guideline 115: February 2011 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence.
- http://www.choiceandmedication.org/addaction/

CONTACTS (in hours)

- RCHT medicine information: 01872 252587
- Addaction 0333 2000 325

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of patients undergoing alcohol abstinence maintenance who are prescribed *acamprosate* can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

In its guidelines on responsibility for prescribing (circular EL(91)127) between hospitals and GPs, the DH has advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

Specialist:

- Acamprosate will usually be initiated by Addaction, a GPWSI in Substance Misuse, a substance misuse Shared Care GP, a Home & Dry Detox Trained GP or Consultant Hepatologist or Consultant Nurse Hepatology.
- Decision to prescribe acamprosate, and establish dose relating to weight.
- Discussion with the patient regarding the benefits and side effects of treatment.
- Arrangement of psychosocial interventions.
- Initiate *acamprosate* and stabilise patient on a therapeutic dose *before* referral to the GP. Prescribing will remain in secondary care for usually 3 months or until the patient is stable on the dose.
- Ask the GP whether they are willing to participate in shared care.
- Prompt communication with GP of any changes in treatment, results of monitoring undertaken and assessment of adverse events.
- Specify review dates at clinically relevant time intervals for both the GP and the specialist prescriber.
- Advice to GPs on when to stop treatment.
- Ensure clear arrangements for back-up advice and support.
- Reporting adverse events to the MHRA.

General Practitioner:

- Reply to request for shared care as soon as practical.
- Prescribing of *acamprosate* after communication with specialists regarding the need for treatment and upon confirmation that the patient's dose is stabilised.
- Resume contact with patient at monthly intervals.
- Do not use blood tests routinely, but consider them to monitor for recovery of liver function and as a motivational aid for patient to show improvement.
- Ensure the patient is receiving regular support from Addaction, or GP during the prescribing period.
- Prescribing of acamprosate to help maintain abstinence (acamprosate is normally stopped at the end of 12 months).
- Promote patient adherence to acamprosate.
- Liaise with Addaction regarding any complications and prompt referral to a specialist if there is a change in the patient's status.
- Reporting adverse events to specialist and MHRA.
- Stopping treatment in the case of a severe adverse event or as per shared care guideline.

Patient:

- Report any adverse effects to their GP and/or specialist whilst being treated with *acamprosate*
- Attend appropriate GP and other follow up appointments
- Willing to complete a statement to confirm use and understanding of written and other information on the medication.
- Address their overall needs in overcoming alcohol dependence.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM ADDACTION

Request for other formats

Please ask if you would like to receive this leaflet in large print, braille, on CD or in any other languages. If you would like the leaflet in an alternative format please contact the NHS Kernow Communications Team at communications@kernowccg.nhs.uk or call 01726 627800

3. Monitoring compliance and effectiveness

Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	No specific tool
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Medicines Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Relevant Clinical Staff

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Shared Care Guideline for Acamprosate					
Date Issued/Approved:	November 2016					
Date Valid From:	November 2016					
Date Valid To:	December 2019					
Directorate / Department responsible (author/owner):	M Wilcock, Head of Prescribing Support Unit, Pharmacy Department, RCHT					
Contact details:	01872 253548					
Brief summary of contents	Some clinical issues and details of prescribing responsibilities for GP and specialists					
Suggested Keywords:	Shared care					
Target Audience	RCHT	CCG	CFT			
	✓	✓	✓			
Executive Director responsible for Policy:						
Date revised:	November 2016					
This document replaces (exact title of previous version):	Acamprosate shared care guideline					
Approval route (names of committees)/consultation:	Cornwall Area Prescribing Committee					
Divisional Manager confirming approval processes	M Wilcock					
Name and Post Title of additional signatories	Not Required					
Signature of Executive Director giving approval	{Original Copy Signed}					
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only			
Document Library Folder/Sub Folder	Clinical / Pharmacy					
Links to key external standards	None					
Related Documents:	None					
Training Need Identified?	No					

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
20 Nov'13	V1.0	New version in this format	M Wilcock
Nov-16	V1.1	Minor amendments	M Wilcock

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

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Appendix 2.Initial Equality Impact Assessment Screening Form

Name of service, strategy, policy or project (hereafter referred to as *policy)* to be assessed: Shared Care Guideline for acamprosate	
Directorate and service area: Pharmacy	Is this a new or existing Procedure? Existing
Name of individual completing assessment: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow	Telephone:01726 627953
1. Policy Aim* Who is the strategy / policy / proposal / service function aimed at?	To provide information on prescribing of acamprosate to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives*	To promote a consistent level of shared care between primary, secondary care and other specialist services
3. Policy – intended Outcomes*	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. *How will you measure the outcome?	If the guideline is not well received, publicised and adopted, then some GPs may not enter into shared care arrangements.
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.
6a) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? b) If yes, have these *groups been consulted? C). Please list any groups who have been consulted about this procedure.	No Cornwall & IoS Area Prescribing Committee

7. The Impact Please complete the following table.			
Are there concerns that the policy **could** have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		**No**	
Sex (male, female, trans-gender / gender reassignment)		**No**	
Race / Ethnic communities /groups		**No**	

Disability - learning disability, physical disability, sensory impairment and mental health problems		**no**	
Religion / other beliefs		**no**	
Marriage and civil partnership		**no**	
Pregnancy and maternity		**no**	
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**no**	

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.		**No**
9. If you are not recommending a Full Impact assessment please explain why.		
Signature of policy developer / lead manager / director	Date of completion and submission	
Names and signatures of members carrying out the Screening Assessment	1. Dan Thomas 2. Mike Wilcock	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust's web site.

Signed _____

Date _____