Royal Cornwall Hospitals NHS Trust

Policy Under Review

Please note that this policy is under review. It does, however, remain current Trust policy subject to any recent legislative changes, national policy instruction (NHS or Department of Health), or Trust Board decision. For guidance, please contact the Author/Owner.

Information Category	Detailed Information
Document Title:	Acamprosate Shared Care Guideline V3.0
This document replaces (exact title of previous version):	Shared Care Guideline Acamprosate V2.0
Date Issued / Approved:	May 2023
Date Valid From:	November 2022
Date Valid To:	May 2026
Author / Owner:	Mike Wilcock - Head of Prescribing Support Unit
Contact details:	01872 253548
Brief summary of contents:	To guide medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of Acamprosate To provide information on prescribing of acamprosate to enable General Practitioners to take over prescribing responsibility from secondary care. This shared care guideline sets out details for sharing care of adult patients undergoing 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.
Suggested Keywords:	Acamprosate, shared care.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer

Information Category	Detailed Information
Approval route for consultation and ratification:	Medicines optimisation and safety committee
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	None required
Related Documents:	
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Acamprosate Shared Care Guideline V3.0

Document reference code: MM/023/24

This is a joint policy between Cornwall Partnership NHS Foundation Trust and Royal Cornwall Hospitals NHS Trust.

Purpose: To guide medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of Acamprosate To provide information on prescribing of acamprosate to enable General Practitioners to take over prescribing responsibility from secondary care. This shared care guideline sets out details for sharing care of adult patients undergoing 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

Target audience: Medical, nursing and pharmacy staff

Document author and role: Chief pharmacist
Document author contact details:01208 834265

Document definition: Guidelines

Supporting committee and chairperson: Medicines optimisation and safety committee
Executive director responsible for the policy: Chief medical officer

Freedom of information: Can be released under the Freedom of Information Act 2000

Audience:
☒ Royal Cornwall Hospitals NHS Trust
☒ Cornwall Partnership NHS Foundation Trust

Key words: Acamprosate, shared care, SCG,

Approval process

Approved at: Area Prescribing committee, Medicines Optimisation and Safety Committee
Date approved: 16 December 2024

Executive approval: Adrian Flynn Chief Medical Officer.
Date approved by: 22 December 2024

RCHT General manager confirming approval processes: Richard Andrzejuk
RCHT Governance lead confirming approval process: Kevin Wright

Review date: 30 June 2025 (6 months prior to the expiry date)

Expiry date: 30 November 2025 (normally 3 years after ratification unless there are changes in legislation, NICE guidance or national standards or the document should only be valid for a specified period)

Publication location:
☒ Internet and intranet ☐ Intranet only

RCHT Document Library folder and sub-folder: Clinical / Pharmacy

CFT Document section: Clinical, medication management

Version control

Author to complete the table below with all changes made. Add more rows as required and make sure any deleted empty rows). Delete this paragraph when policy published.

Version	Date	Author and/or reviewer	Section	Changes (key points)
1	November 2013	M. Wilcock RCHT		New version in this format.
1.1	November 2016	M. Wilcock RCHT		Minor amendments.
2	November 2019	M. Wilcock		New version in this format.
2.1	March 2020	Demi Louise Kent, Corporate Records Manager RCHT		Appendix 3 added following FRG approval - CHA4215 Shared Care Agreement Letter Consultant Request
2.2	September 2021	M. Wilcock		Substitution of Shared Care Agreement Letter with suggested wording template
V2.3	September 2021	M Wilcock		Change from Addaction to 'We Are With You' and removal of hyperlink in related documents section

Version	Date	Author and/or reviewer	Section	Changes (key points)
V3.0	November 2022	M Wilcock		Addition of specialist responsibility re assess suitability with named tests, and inclusion of RCHT non-medical prescribers Alcohol Liaison Team
3.0	September 2024	M. Wilcock		Addition of specialist responsibility re assess suitability with named tests, and inclusion of RCHT non-medical prescribers Alcohol Liaison Team.

This document replaces: MM/023/21 – Shared Care Guideline Acamprosate

Contents

Data Protection Act 2018 (UK General Data Protection Regulation Legislation

The Trusts have a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opted in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679, contact the Information Governance team.

- Cornwall Partnership NHS Foundation Trust: Email cpn-tr.infogov@nhs.net
- Royal Cornwall Hospitals NHS Trust: Email rch-tr.infogov@nhs.net

1. Introduction

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

1.2. This shared care guideline sets out details for sharing care of adult patients undergoing 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.

1.3. This version supersedes any previous versions of this document.

2. Scope

Medical, nursing and pharmacy staff.

3. Definitions and glossary

GABAergic: affects the neurotransmitter gamma-aminobutyric acid (GABA).
GPWSI: GP with special interest.
SPC: Summary of product characteristics.
BNF: British National Formulary.
MHRA: Medicines and Healthcare Product Characteristics regulatory agency.
RCHT: Royal Cornwall NHS Trust.
CFT: Cornwall Partnership NHS Trust.

4. Ownership and responsibilities

4.1. Ownership

Chief Pharmacist Cornwall Partnership NHS Trust.
Chief Pharmacist Royal Cornwall NHS Trust.
Head of Prescribing Support unit RCHT and ICB.
We are with you.
RCHT Hepatology.
Ward and community staff in CFT and RCHT.
Pharmacy staff in CFT and RCHT.
Alcohol liaison team RCHT/CFT.
All prescribers in CFT/RCHT.
GPs.

4.2. Responsibilities

Lead executive

- Adrian Flynn.

Responsible reporting group

- Cornwall Area Prescribing Committee.

Lead professional

- Mike Wilcock Head of Prescribing Support Unit RCHT, Helen Woods Chief Pharmacist CFT.

Sub-groups

- Medicines Optimisation and Safety Committee CFT.

Specialist staff

- We are with you staff.
- Representatives from RCHT Hepatology.

4.3. Groups and committees

- Cornwall Area Prescribing Committee.
- Medicines Optimisation and Safety Committee CFT.
- Medicines Practice Committee RCHT.

5. Standards and practice

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.

6. Related legislation, national and local guidance

- 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.

7. Training requirements

All prescribers to be made aware of shared care guideline by community and inpatient clinical directors and promoted via medicine matters newsletter.

8. Implementation

Clinical Director for Community and Inpatient service lines to implement with all prescribers within the Community and Inpatient service lines.

Promoted via medical directors' bulletin and Meds matters newsletter.

9. Document Monitoring arrangements

All patients on Acamprosate treatment initiated by secondary care must have a completed shared care guideline agreed with GP and evidence of this must be recorded on RiO.

Information category	**Detail of process and methodology for monitoring compliance**
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit RCHT
Tool	Audit and review tool using patient documentation.
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee RCHT/ Medicines Optimisation and Safety Committee CFT
Acting on recommendations and lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff

10. The guidance

10.1. 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.

10.2. Preparations and Dosage

- Acamprosate calcium is prepared in 333mg gastro resistant tablets.
- 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.

10.3. Initiation and monitoring

- Acamprosate should be initiated by We Are With You, a GPWSI in Substance Misuse, a Substance misuse Shared Care GP, a Home and Dry Detox Trained GP or Consultant Hepatologist or Consultant Nurse in 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 We Are With You.
- On-going monitoring should include monthly medical review for at least the first 6 months together with support from We Are With You.
- 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.

10.4. Contraindications and Precautions

10.4.1. Contraindications are:

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

10.4.2. Precautions - caution is advised as follows

- Pregnancy (discuss risks in women of childbearing 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.

10.5. Side Effects

10.5.1. 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.

10.5.2. 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.

10.5.3. Should not impair ability to drive or operate machinery.

10.6. Common / significant drug interactions

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

10.6.2. 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.

10.7. Contacts

We Are With You 01872 263001.

10.8. Areas of Responsibility for the Sharing of Care

10.8.1. 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.

10.8.2. In the NHS E guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

10.8.3. Specialist:

- Acamprosate will usually be initiated by We Are With You, a GPWSI in Substance Misuse, a substance misuse Shared Care GP, a Home and Dry Detox Trained GP or Consultant Hepatologist or Consultant Nurse Hepatology.
- Decision to prescribe acamprosate, and establish dose relating to weight.
- Assess suitability for Acamprosate (physical/mental health, social issues, alcohol use, UandE's, LFT's (including GGT), breathalyse) where appropriate.
- 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 using the suggested wording template (Appendix 1).
- 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.

10.8.4. General Practitioner:

- To respond to the shared care request from the consultant in writing without undue delay.
- 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.
- Continue the prescribing only if the patient is receiving regular support from We Are With You.
- Prescribing of acamprosate to help maintain abstinence (acamprosate is normally stopped at the end of 12 months).
- Promote patient adherence to acamprosate.
- Liaise with We Are With you 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.

10.8.5. Patient / parent / guardian / carer:

- 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.

10.8.6. BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM WE ARE WITH YOU.

11. Updating and review

The shared care agreement will be reviewed every three years via the Cornwall Partnership NHS Foundation Trust medicines optimisation and safety committee and the Royal Cornwall Hospitals NHS Trust medicines practice committee with system wide approval at the Area Prescribing Committee.

12. Equality and diversity

This document complies with the Cornwall Partnership NHS Foundation Trust and Royal Cornwall Hospitals NHS Trust equality and diversity statements. The statements can be found in the RCHT Equality Diversity And Inclusion Policy and CFT Equality, Diversity and Inclusion Statement.

The initial equality impact assessment screening form is at appendix 1.

Appendix 1: Equality Impact assessment Form

Title of policy or document for assessment: Acamprosate Shared Care Guideline V3.0

Document library section: Clinical: medication management

Is this a new or existing document? Existing

Date of assessment: 22 November 2024

Person responsible for the assessment: Helen Woods Chief Pharmacist

What is the main purpose of the document?
To provide information on prescribing of acamprosate to enable General Practitioners to take over prescribing responsibility from secondary care.

Who is affected by the document?
☒ Staff ☒ Patients ☐ Visitors ☐ Carers ☐ Other ☐ All

The document aims to improve access, experience and outcomes for all groups protected by the Equality Act 2010.

Concerns
Are there concerns that the procedural document could have a differential impact on the following areas?
If a negative impact has been identified, please complete a full EIA by contacting the Equality, Diversity, and Inclusion Team. For RCHT please contact rcht.inclusion@nhs.net and for CFT please contact cft.inclusion@nhs.net

Concern area	Response	If yes, what existing evidence (either presumed or otherwise) do you have for this?
Age	☐ Yes ☒ No	
Disability	☐ Yes ☒ No	
Sex	☐ Yes ☒ No	
Gender reassignment	☐ Yes ☒ No	
Pregnancy and maternity	☐ Yes ☒ No	
Race	☐ Yes ☒ No	
Religion and belief	☐ Yes ☒ No	
Sexual orientation	☐ Yes ☒ No	
Marriage and civil partnership	☐ Yes ☒ No	

Concern area	Response	If yes, what existing evidence (either presumed or otherwise) do you have for this?
Groups at risk of stigma or social exclusion such as offenders or homeless people	☐ Yes ☒ No	
Human rights	☐ Yes ☒ No	

Are there any associated objectives of the document? If yes, what existing evidence (either presumed or otherwise) do you have for this?
None

Signature of person completing the equality impact assessment:
Name: Helen Woods
Date: 22 November 2024

Appendix 2: Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you agree, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.)

Baseline tests: (insert information)

Next review with this department: (insert date)

You will be sent a written summary within (XX) days. The medical staff of the department are always available to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.