BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Acamprosate
Amber *3 months*	
Indication	Acamprosate is indicated as therapy to maintain abstinence in alcohol-dependent patients. It should be combined with counselling.
Speciality / Department	Specialist Drug and Alcohol Services (SDAS)
Trust(s)	Avon and Wiltshire Mental Health Partnership NHS Trust
	Click here to enter details
	Click here to enter details

Section 2: Treatment Schedule

Usual dose and frequency of administration	Acamprosate should be started as soon as possible after the patient has stopped drinking alcohol and should be maintained if the patient relapses. Treatment with acamprosate will start to have an effect after about a week or so and should build steadily over the next few months. **Dose:** Adults (age between 18-65 years) - Weighing 60kg or more: Six tablets (1998mg daily) divided into three daily doses with meals as two tablets (666mg) three times daily (morning, noon and night). Weighing less than 60kg: Four tablets divided into three daily doses with meals (Two tablets (666mg) in the morning, One tablet (333mg) at noon and One tablet (333mg) at night).
Route and formulation	Oral. Tablets.

Duration of treatment	Acamprosate should usually be prescribed for up to 6 months, or longer for those benefiting from the drug who want to continue with it (SPC recommends one year). Acamprosate does not prevent the harmful effects of continuous alcohol abuse. Continued alcohol abuse negates the therapeutic benefit, therefore acamprosate treatment should only be initiated after weaning therapy, once the patient is abstinent from alcohol.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
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. See responsibilities for primary and secondary care for monitoring.
Subsequent tests - where appropriate
Please see above

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	For a full list, please refer to manufacturer's summary of product characteristics (SPC) www.medicines.org.uk and also the current BNF www.bnf.org/bnf/. The following definitions relate to the frequency: very common (1/10), common (1/100, <1/10), uncommon (1/1,000, < 1/100), rare (1/10,000, < 1/1,000), very rare (< 1/10,000). Acamprosate is usually well tolerated, however, diarrhoea has been reported to be a very common side effect. If this persists, contact the specialist. Common side effects Include abdominal pain, nausea, vomiting, flatulence loss of appetite trouble sleeping, maculo papular rash, pruritis, impotence, decreased libido, Frigidity or impotence. Contact the specialist for advice. Uncommon: Increased libido. Very rare: Hypersensitivity reactions including urticaria, angio-oedema or anaphylactic reactions. Contact the specialist for advice. Not known: Vesiculo-bullous eruptions. If a patient is unduly troubled by these symptoms it would be reasonable to discontinue the medication. Serious side-effects are very rare and include allergic reactions upon initiation and cardiovascular effects. Cardiovascular effects include palpitations, vasodilation, hypertension and syncope. Urgent medical attention should be sought if these develop.

Referral back to specialist	Side effects which persist and/or are of concern to the prescriber / service user. Service user starts drinking alcohol again. Service user becomes pregnancy or starts to breastfeed. Development of severe renal / hepatic impairment.

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	The concomitant intake of alcohol and acamprosate does not affect the pharmacokinetics of either alcohol or acamprosate. The administration of food diminishes the bioavailability of the drug compared with its administration in the fasting state. Acamprosate is excreted by the kidneys and therefore is not affected by drugs that alter liver metabolism. There are no dangerous drug interactions reported. Co-administration of naltrexone with acamprosate produces an increase in acamprosate levels, however, no adjustment of dosage is necessary. Other concomitant therapies: Patients taking acamprosate concomitantly with antidepressants more commonly reported both weight gain and weight loss, compared with patients taking either medication alone.
Reminder to ask patient about specific problems	Ask about emergence of any possible side effects / compliance to treatment.

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

Contraindications:
Patients with a known hypersensitivity to acamprosate or to any of the excipients
Lactating women
Renal insufficiency of serum creatinine >120 micromol/L. Please also see below.

Cautions and special recommendations:
Patient group -
Acamprosate is not recommended for use in patients younger than 18 or older than 65 years as its safety and efficacy has not been established in these patient groups.

Renal Impairment:
For patients with moderate renal impairment (GFR 30 – 50mL/min), a dose of one 333 mg tablet taken three times daily is recommended.
Patients with a GFR 10 – 30 mL/min, a dose of one 333mg tablet should be taken twice a day.
Patients with a GFR of <10mL/min a dose of one 333mg tablet should be taken once a day.

Liver impairment:
The safety and efficacy of acamprosate has not been established in patients with severe liver insufficiency (Childs-Pugh Classification C).

Suicidality:
Acamprosate is very unlikely to be responsible for any change in suicidal ideation. In controlled clinical trials of acamprosate, adverse events of a suicidal nature (suicidal ideation, suicide attempts, completed suicides) were infrequent overall, but were more common in acamprosate treated patients than in patients treated with placebo (1.4% vs. 0.5% in studies of 6 months or less; 2.4% vs. 0.8% in year-long studies).

Abuse and dependence
Non-clinical studies suggest that acamprosate has little or no abuse potential. No evidence of dependence on acamprosate was found in any clinical study demonstrating that acamprosate has no significant dependence potential.

Pregnancy
Avoid in pregnancy and breast feeding. Animal data suggests there may be a risk of teratogenicity in humans.

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Report to the specialist or GP if s/he does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with acamprosate medication.
3. Patients should be advised to notify their doctor if they become pregnant or intend to become pregnant during therapy or wish to breast feed.
4. Patients should be advised to continue acamprosate therapy as directed, even in the event of relapse and should be reminded to discuss any renewed drinking with their doctor.
5. Patients should inform their primary care prescriber/ consultant if they develop any adverse effects e.g. diarrhoea, vomiting etc
6. Notify their GP/specialist/NMP if /when acamprosate is stopped.

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first three months.
2. Undertaking the clinical assessment and monitoring for the first three months.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of acamprosate..
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Explain at initiation the indication for the medication and how to use it, to allow for informed consent. Explain the risks and potential benefits and what to do in a minor relapse of drinking - provide the patient with information on acamprosate, including a PIL . Information on mental health conditions, treatments and medication can be found at www.choiceandmedication.org/awp/
2. To ensure the patient is fully informed about their treatment – for women of child bearing potential this should also include a discussion about plans for pregnancy and effective contraception.
3. Discuss the proposal of shared care agreement with the patient. Document outcome in notes.
4. If the patient agrees to shared care, ask the GP whether s/he is willing to participate in shared care once patient has been stabilised on treatment and issued with one month supply of medication. This must be done using the Shared Care Agreement form for acamprosate. Details of dose prescribed must be given.
5. Ensure that the GP has a copy of the shared care agreement and a signed copy of the shared care agreement form.
6. To ensure that the care plan contains correct contact details for the care co-ordinator/ key worker and specialist/NMP.
7. To forward a care plan to the GP.
8. Blood tests may be taken at the GP surgery providing there is appropriate communication with the GP and the GP is in agreement with this. Secondary care is responsible for the interpretation and monitoring of these blood test results for the first 3 months of treatment.

9. Secondary care is responsible for reviewing all baseline tests and relay any abnormal findings to the GP with any appropriate advice.
10. Communicate promptly with the GP when treatment is changed.
11. To review patient / provide advice as requested via the GP or Primary Care Liaison Service as necessary
12. To provide psychosocial support for the first 3 months of treatment.
13. To review patient regularly (minimum monthly) for first 3 months of treatment ensuring psychosocial needs are met.
14. Inform GP if any appointments are not attended.
15. Ensure that clear backup arrangements exist for GPs to obtain advice and support.
16. Any verbal communication between primary and secondary care should be confirmed in writing.

Section 9: Responsibilities for Primary Care

Core responsibilities

1. Responsible for taking over prescribing after the first three months
2. Responsible for the clinical assessment and monitoring after the first three months
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Reply to the request for shared care within 3 weeks of receipt of request using the shared care agreement form for acamprosate.
2. If the GP decides not to prescribe acamprosate, it should still be added to the patients repeat medication as a 'non issued item'' for information and safety purposes. The quantity should be set to *0 or 1. On the dose line it should read 'Hospital prescribing only. Do not prescribe' This should also be done during the 'stabilisation' period before GP takes over the prescribing.
3. Prescribe acamprosate at the dose requested by the specialist.
4. Review patient regularly (minimum monthly) then at extended but regular intervals if treatment is continued beyond 6 months.
5. Review patient as agreed in the Shared Care Agreement & care plan.
6. Adjust the dose / stop drug as advised by the specialist.
7. Check patient for adverse effects (see Section 4) at each appointment and inform of any significant adverse effects to the specialist.
8. Monitor patients overall health and compliance.
9. To notify specialist of any relevant changes in other medications or clinical status.
10. Review at least 6 monthly whether patient should be referred to specialist for assessment regarding need for continuing therapy.
11. Monitor treatment effectiveness with the patient. Recommendation would be for at least 6 months and up to a year of continued abstinence from alcohol. However, acamprosate could be continued beyond this time if there was felt to be a significant risk of relapse after this time.
12. 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. Any necessary monitoring to be agreed with the specialist team and any clinically significant results fedback for advice / action.
13. Once the patient has been discharged, advice may be sought from the Primary Care Liaison Service on any aspect of patients mental health that is of concern to the GP
14. Any verbal communication between primary and secondary care should be confirmed in writing.

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address

Dr T Williams	AWP Mental Health NHS Trust	0117 919 2345	tim.williams6@nhs.net
Care co-ordinator	Click here to enter details	Click here to enter details	Click here to enter details
Primary Care Liaison Service, BRISTOL	AWP Mental Health NHS Trust – Callington Road	0117 919 5670	Click here to enter details
Primary Care Liaison Service, NORTH SOMERSET	AWP Mental Health NHS Trust – Long Fox Unit	01934 836406	Click here to enter details
Primary Care Liaison Service, SOUTH GLOUCESTERSHIRE	AWP Mental Health NHS Trust – Bybrook Lodge, Blackberry Hill Hospital.	01173 787960	Click here to enter details
Click here to enter details	Click here to enter details	Click here to enter details	Click here to enter details
Click here to enter details	Click here to enter details	Click here to enter details	Click here to enter details

Section 11: Document Details

Date prepared	Revised July 2014 (from previous version July 2012)
Prepared by	Bethan Shepherd, Formulary Pharmacist on behalf of Dr T Williams, from previous version.
Date approved by JFG	14th October 2014
Date of review	July 2016
Document Identification: Version	Acamprosate SCP AWP Version 2.9

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

The original shared care (July 2012) was prepared after discussion with prescribers in primary care to understand the common problems associated with on-going prescribing in the community.

Section 13: References

Please list references

1. NICE clinical guideline 115: February 2011 Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence.
2. Summary of Product Characteristics www.medicines.org.uk
3. BNF.org 67
4. The Renal Drug Handbook, Fourth Edition 2014. Caroline Ashley and Aileen Dunleavey