Approved by Bath Clinical Area Partnership Prescribing & Therapeutics Committee Jan 2015 **FOR WILTS GPs ONLY**

Nalmefene for Alcohol Treatment Protocol for GPs

SCREEN

- Assess risk from alcohol consumption, using the AUDIT tool (see below)
- Identify WHO drinking risk level, based on the number of units drunk (see below)

ASSESS

- Check for presence of physical withdrawal symptoms from alcohol
- Exclude need for immediate detoxification - physical symptoms of alcohol withdrawal requiring medical treatment in someone who would benefit from a medically supported alcohol detox

ENGAGE

- Agree treatment goal – reduction or abstinence (Note: nalmefene is not licenced for abstinence)
- If reduction, offer brief advice, drinks diary and set next appointment in 2 weeks (if not already done)

↓ Wait minimum of 2 weeks

FOLLOW UP (at 2 weeks after initial assessment)

- Re-assess level of alcohol consumption
- Prescribe nalmefene as appropriate if patient exceeds WHO High drinking risk level
  - **Men ≥ 7.5 units/day** (60 g)
  - **Women ≥ 5 units/day** (40 g)
- **If the GP or Practice Nurse is confident in offering continuous PSS**, there would be no need to refer to other services.
- **If neither GP nor Practice Nurse is confident in delivering PSS** this can be provided by:
  - **Online** utilising barcode on nalmefene pack for log in at **www.reduceyourdrinking.com**
  - **Health Trainers** in Wiltshire can provide up to 6 sessions, meeting in libraries, leisure centres, children centres, and GP surgeries. Central referral number: 0300-0034566
  - **Wiltshire Substance Misuse Service** can provide guided self-help (Breaking Free Online) and other support Tel: 0345 603 6993

↓ Patient still drinking at High Drinking Risk level

INITIATION OF NALMEFENE (SELINCRO)

- Check patient is not taking any opioids, including tramadol and OTC medications e.g. Nurofen Plus. If unsure, do urine drug screen for opiates. Nalmefene is contra-indicated if the patient is on opiates.
- To aid compliance, ensure patient is aware that they may have transient side effects of nausea, dizziness, insomnia during initiation. In the majority of cases, these stop after 1 week
- Ensure patient has PIL and "opioid receptor antagonist card" supplied by the pharmacist (or with booklet)
- Prescribe 14 tablets, and advise to take 1st tablet when they do not have work the following day. Do not add as a repeat prescription item, only to be issued as an acute prescription every time.
- Patient to take a maximum of one tablet/day as needed (PRN) only on days when feeling at risk of drinking, ideally 1-2 hrs before anticipated drinking risk, but can be taken immediately after a drink
- Make follow up appointment two weeks later

↓ First review after 2 weeks

2 WEEK REVIEW and PSYCHOSOCIAL SUPPORT (PSS)

- Assess overall progress and efficacy of Nalmefene
- Re-assess alcohol consumption
- Check compliance with Nalmefene and side-effects
- Provide feedback/motivational support for alcohol reduction
- Revise treatment goal if appropriate
- Prescribe additional Nalmefene for a further 28 days

↓ Monthly reviews subsequently

CONTINUATION AND STOPPING TREATMENT

- Review **monthly** while patient is continuing Nalmefene
- **Continue** whilst patient is gaining benefit in reducing alcohol consumption, reducing cravings or maintaining control of their drinking, typically 6 to 12 months.
- **Discontinue and refer** to specialist services, if patient cannot tolerate or is not taking the Nalmefene or alcohol consumption is increasing

"High risk drinking" and physical health problems:

- "High risk drinking" is defined by the World Health Organisation (WHO), and relates only to the amount drunk, and does not relate to the presence of dependence on alcohol.
- High risk drinking is associated with many medical conditions in a dose-dependent way including liver disease, pancreatitis, essential hypertension, haemorrhagic stroke, various cancers (colon, oral, lip, pharangeal, oesophageal), and injuries (White et al 2002).
- Reduction of drinking will reduce the risk of these diseases. For example, alcohol is thought to cause 16% of all hypertension, and a 2mmg Hg reduction in diastolic BP may result in a 6% reduction in CHD and a 15% reduction in the risk of stroke and TIA's (Beilin and Puddey 2006, Xin et al 2001, Cook et al 1995).
- NICE hypertension guidelines state: "Ascertain people's alcohol consumption and encourage a reduced intake if they drink excessively, because this can reduce BP and has broader health benefits". (NICE 2011).

WHO Alcohol Consumption Categories	Average Daily Alcohol Intake in Units (g/day) for Men	Average Daily Alcohol Intake in Units (g/day) for Women
Very high-risk consumption	>12½ Units (>100 g)	>7½ Units (>60 g)
High-risk consumption	7½-12½ Units (60–100 g)	5-7½ Units (40–60 g)
Medium-risk consumption	5-7½ Units (40–60 g)	2½-5 Units (20–40 g)
Low-risk consumption	<5 Units (1–40 g)	<2½ Units (1–20 g)

Treatment recommendations for Nalmefene:

Recommendations for Nalmefene	
Benefits of nalmefene plus psychosocial support	• Reduces the number of heavy drinking days and total alcohol consumption compared with psychosocial intervention alone (NICE 2014). • It is a cost-effective use of NHS resources compared with psychosocial support alone. The incremental cost effectiveness ratio (ICER) is likely to be lower than £5100 per quality adjusted life year (QALY) gained (NICE 2014), where NICE considers an ICER of ≤ £2000 per QALY gained as cost effective for the NHS.
Psychosocial support (PSS)	• Should be in the form of continuous brief or extended brief intervention focused on treatment adherence and reducing alcohol consumption (NICE 2014) • The psychosocial support is similar to that provided to promote treatment adherence and compliance with other long term conditions, such as hypertension, diabetes and depression, and: o May be given in the Primary Care setting by GP, nurse, with assistance from Health Trainers or online computer programs (see "Nalmefene for alcohol treatment protocol for GPs" on previous page for contact details) o Would involve advice regarding medication compliance and alcohol reduction, and motivation and individual goals • Continuous PSS means being reviewed at least monthly, and extended brief intervention refers to having several brief intervention appointments.
Follow up appointments	• Would typically be reviewed 2 weeks after starting Nalmefene, and then monthly while treatment continues • Will occur in the Primary Care setting in the context of a routine clinical appointment with the GP or practice nurse • Would involve a review of: o Efficacy of the Nalmefene o Side-effects of the Nalmefene o Advice regarding medication compliance and alcohol reduction (PSS)

References:

1. NICE Pathway: Interventions for harmful drinking and alcohol dependence. Nov 2014.
2. NICE Technology Appraisal Guidance 325: nalmefene for reducing alcohol consumption in people with alcohol dependence. Nov 2014
3. White IR et al. Alcohol consumption and mortality: modelling risks for men and women at different ages. *BMJ* 2002 Jul 27;325(7357):191.
4. Beilin LJ and Puddey JB. Alcohol and hypertension - an update. *Hypertension* 2006, 47: 1035-8.
5. Xin et al. Effects of alcohol reduction on blood pressure: a meta-analysis of randomized controlled trials. Hypertension. 2001 Nov;38(5):1112-7
6. Cook et al. Implications of small reductions in diastolic blood pressure for primary prevention. Arch Intern Med. 1995 Apr 10;155(7):701-9.
7. NICE clinical guideline 127. Hypertension - Clinical management of primary hypertension in adults. August 2011

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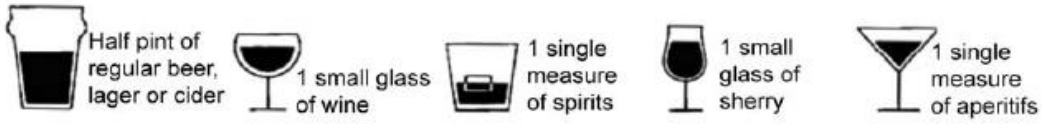
AUDIT-C and AUDIT and How to Respond

(the AUDIT measures the risk of psychological problems such as dependence developing)

This is one unit of alcohol…



…and each of these is more than one unit

AUDIT – C

Questions	Scoring system					Your score
	0	1	2	3	4	
How often do you have a drink containing alcohol?	Never	Monthly or less	2 - 4 times per month	2 - 3 times per week	4+ times per week	
How many units of alcohol do you drink on a typical day when you are drinking?	1 -2	3 - 4	5 - 6	7 - 9	10+	
How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	

Scoring:
A total of 5+ indicates increasing or higher risk drinking.
An overall total score of 5 or above is AUDIT-C positive.

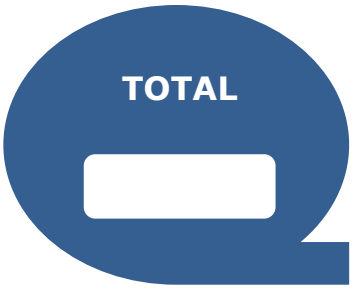
Score from AUDIT- C (from previous page)

Remaining 7 AUDIT questions

Questions	Scoring system					Your score
	0	1	2	3	4	
How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you failed to do what was normally expected from you because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you needed an alcoholic drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
Have you or somebody else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year	
Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested that you cut down?	No		Yes, but not in the last year		Yes, during the last year	

Scoring: 0 – 7 Lower risk, 8 – 15 Increasing risk,
16 – 19 Higher risk, 20+ Possible dependence

TOTAL Score equals
AUDIT C Score (above) +
Score of remaining 7 questions



How to Respond to the Full Audit Score

Full AUDIT Score	Risk Category for Dependence	Treatment
0-7	Lower risk	No action
8-15	Increasing risk	Brief (or repeated brief) advice ± Nalmefene
16-19	Higher risk	Extended (repeated brief) advice ± Nalmefene
≥20	Possible dependence	Consider treatment or referral for treatment ±Naltrexone, Acamprosate or Disulfiram post detox