Nalmefene Prescribing Guidance

Section 1: Indication

Indication	Nalmefene is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL) of more than 7.5 units per day (for men) and more than 5 units per day (for women), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.
Speciality / Department	For Bristol ROADs alcohol service and Primary Care where patients are receiving support from the Bristol Roads alcohol service. See Remedy Alcohol Misuse page for information about local services.

Section 2: Treatment Schedule

Usual dose and frequency of administration	Nalmefene is to be taken as-needed: on each day the patient perceives a risk of drinking alcohol; one tablet (18mg) should be taken, preferably 1-2 hours prior to the anticipated time of drinking. If the patient has started drinking alcohol without taking nalmefene, the patient should take one tablet as soon as possible. The maximum dose of nalmefene is one tablet per day (18mg). Nalmefene is an opioid system modulator with a distinct mu, delta, and kappa receptor profile.
Route and formulation	Oral, tablet
Duration of treatment	6 months

Section 3: Monitoring

Baseline tests - where appropriate
Patient's clinical status, alcohol dependence and level of alcohol consumption (based on patient reporting) should be evaluated. Patients should be assessed for current use, or withdrawal from opioids. LFTs (patients with severe hepatic impairment are not appropriate for treatment). Renal function (patients with eGFR <30ml/min are not appropriate for treatment).
Subsequent tests and Psychosocial support
The patient should be asked to record his or her alcohol consumption for approximately two weeks. At the next visit, nalmefene may be initiated in patients who continue to have a high DRL over this two-week period, in conjunction with psychosocial intervention focused on treatment adherence and reducing alcohol consumption. **Psychosocial support**

Nalmefene Prescribing Guidance

The NICE guidance (TA 325) and product license for nalmefene state it should only be used in conjunction with psychosocial support (in the form of BRENDA[4]) or in the form of brief or extended brief interventions, focusing on treatment adherence and reduction of alcohol consumption.

Section 4: Side Effects

Side effects and management	The incidence of nausea (22%) and dizziness (18%) were high in the first month of treatment but decreased to approximately 1–2% in subsequent months. Other side-effects include insomnia and headaches. For full details of adverse reactions, see the manufacturer's summary of product characteristics.

Section 5: Drug Interactions

Significant Drug Interactions	Co-administration with medicinal products that are potent inhibitors of the UGT2B7 enzyme (for example, diclofenac, fluconazole, medroxyprogesterone acetate, meclofenamic acid) may significantly increase the exposure to nalmefene. This is unlikely to present a problem with occasional use, but if long-term concurrent treatment with a potent UGT2B7 inhibitor is initiated, a potential for an increase in nalmefene exposure cannot be excluded. Conversely, concomitant administration with a UGT inducer (for example, dexamethasone, phenobarbital, rifampicin, omeprazole) may potentially lead to subtherapeutic nalmefene plasma concentrations. **If nalmefene is taken concomitantly with opioid agonists the patient may not benefit from the opioid agonist.** For full details of interactions, see the manufacturer's summary of product characteristics.
Reminder to ask patient about specific problems	Check compliance with psychosocial support. Check efficacy of medication in reducing alcohol consumption.

Section 6: Contra-indications, Cautions and Special Recommendations

1. Patients taking opioid analgesics.
2. Patients with current or recent opioid addiction.
3. Patients with acute symptoms of opioid withdrawal.
4. Patients for whom recent use of opioids is suspected.
5. Patients with severe hepatic impairment (Child-Pugh classification).
6. Patients with severe renal impairment (eGFR <30 ml/min per 1.73 m2).
7. Patients with a recent history of acute alcohol withdrawal syndrome (including hallucinations, seizures, and delirium tremens).
8. Caution should be exercised if nalmefene is prescribed to patients with current psychiatric comorbidity such as major depressive disorder.
9. In emergency situations larger doses of opioids may be required. Nalmefene should be discontinued 1 week prior to elective surgery.
10. There is limited experience in patients with a history of seizure disorders, including alcohol withdrawal seizures.
11. Caution should be exercised when prescribing nalmefene to patients ≥65 years of age
12. Caution is advised if nalmefene is co-administered with a potent UGT2B7 inhibitor
13. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product.
14. Nalmefene is not recommended during pregnancy or breastfeeding.

For full details of contra-indications and cautions, see manufacturer's summary of product characteristics.

Section 7: Advice to the patient

Information to be provided to the patient (or carer)	
1	Report to the GP or the alcohol service if they don't have a clear understanding of the treatment.
2	Attend appropriate psychological support and GP appointments.
3	Share any concerns in relation to treatment.
4	Use written and other information on the reduction of alcohol and nalmefene.
5	Seek help urgently from the GP if suffering with suspected side effects or otherwise unwell during treatment.
6	If the patient is seen by another service, clinic or hospital, they should advise the healthcare professionals offering treatment about their use of nalmefene, particularly if new medicines are administered or prescribed.

Section 8: Information for GP & Alcohol Service

This guidance provides information for managing prescribing of nalmefene by the patient's GP whilst the patient is receiving psychosocial support from an alcohol service. If the GP is not confident to prescribe nalmefene the patient may still be referred for psychosocial support but these services are unable to prescribe. If the service asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable and ensure the patient stays in contact with the support service during the prescribing of the drug. The prescriber who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Referral and initiation	
Information for GP / Primary Care	
1	Make an initial assessment of whether the patient would be a suitable candidate for treatment with nalmefene. If patient is suitable then you should • Advise the patient to record drinking habits for (at least) 2 weeks. • Once drink diary is completed: refer patient to local alcohol service. In Bristol contact ROADS Tel:0117 440 0540 Email: roads@dhi-services.org.uk • See Remedy Alcohol Misuse page for information about local services in North Somerset and South Gloucestershire.
2	After patient has been seen by alcohol service, where nalmefene is appropriate based on triage and psychosocial interventions, GP will respond to request from the alcohol service to initiate nalmefene. GP must ensure compatibility of nalmefene with concomitant prescribed medication. It is expected that prescribers will prescribe 14 tablets per prescription as NICE predicts that patients will use nalmefene on 50% of days. It is recommended that this prescribing is maintained as an 'acute' prescription.
3	Continue to prescribe nalmefene in the community under guidance of the alcohol service.
4	Monitor patient at regular intervals in conjunction with the alcohol service.
5	Compliance: The patient is required to attend psychosocial support in order to receive their prescription. Medication will be stopped if the patient fails to comply with psychosocial services. Should the patient fail to attend, the alcohol service is required to inform the GP. The GP should withhold further prescriptions, other than in exceptional circumstances. A contract between GP and patient can be used if desired to formalise this arrangement.
6	Liaise with the alcohol service regarding concerns about compliance or suspected drug misuse.
7	**Stopping prescriptions** • Stop treatment on the advice of the alcohol service. • Prescribing will normally terminate when the patient disengages from psychosocial treatment. • Prescribing should continue for no longer than 6 months, in line with the current evidence base.
8	The GP should report adverse events to the MHRA via the Yellow Card scheme and share this information with the alcohol service.

Information on Alcohol Services for GP	
1	On receipt of GP referral of the patient with a completed diary of alcohol consumption for at least two weeks, the patient should be triaged and assessed as a candidate for treatment with nalmefene in line with NICE guidance and local pathways.
2	Arrange subsequent monthly appointments for the patient to receive psychosocial interventions. Patient signs up to monthly sessions of support and understands that the prescribing of nalmefene is contingent upon compliance with this support.
3	Where nalmefene is an appropriate treatment, a written request should be made to the patient's GP requesting them to prescribe nalmefene in accordance with this guideline. The request should also set out the anticipated duration of treatment, usually 6 months.
4	The alcohol service will provide the GP with updates of the patient's adherence to treatment and alcohol consumption.
5	Compliance: The patient is required to attend psychosocial support in order to receive their prescription. Should the patient fail to attend, the alcohol service will inform the GP. The GP should withhold further prescriptions, other than in exceptional circumstances. A contract between GP and patient can be used if desired to formalise this arrangement.
6	Notifying the patient's GP if treatment is to be discontinued and the reason for this.
7	Ensure clear arrangements are in place for GP back up, advice and support.
8	Promoting access to any appropriate supporting therapies and services.
9	The alcohol service should report adverse events to the MHRA via the Yellow Card scheme and share this information with the GP.

Section 9: Contact Details

Name	Organisation	Telephone Number	Email
DHI	ROADS	0117 440 0540	roads@dhi-services.org.uk

Section 10: Document Details

Date prepared	23/06/23
Prepared by	Dr Rosie Garbutt. Adapted from previous SCP guidance.
Date approved by ICB	August 2023
Date of review	August 2026
Document Identification: Version	V1.0

Section 11: References

1. NICE TA 325 Nalmefene for reducing alcohol consumption in people with alcohol dependence
2. Shared Care guideline for prescribing nalmefene (Selincro) for reduction of alcohol consumption in adult patients. Dorset Medicines Advisory Group.
3. SPC – Nalmefene. Accessed 23/06/2023 https://www.medicines.org.uk/emc/medicine/27609/SPC/Selincro+18mg+film-coated+tablets/
4. van den Brink W, Aubin H-J, Bladström A, et al. Efficacy of as-needed nalmefene in alcohol-dependent patients with at least a high drinking risk level: results from a subgroup analysis of two randomized controlled 6-month studies. Alcohol Alcohol 2013;48:570–78.