SHARED CARE GUIDELINE FOR PRESCRIBING NALMEFENE (SELINCRO®) ▼ FOR REDUCTION OF ALCOHOL CONSUMPTION IN ADULT PATIENTS

INDICATION FOR USE

Nalmefene is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), 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.

NICE GUIDANCE

NICE Technology Appraisal 325 states:

Nalmefene (also known as Selincro®) is recommended as a possible treatment for people with alcohol dependence who:

- are still drinking more than 7.5 units per day (for men) and more than 5 units per day (for women) 2 weeks after an initial assessment **and**
- do not have physical withdrawal symptoms **and**
- do not need to either stop drinking straight away or stop drinking completely.

Nalmefene should only be taken if the person is also having ongoing support to change their behaviour and to continue to take their treatment, to help them reduce their alcohol intake.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines the responsibilities for managing the prescribing of nalmefene by the patient's GP whilst the patient is receiving psychosocial support from a specialist service. If the GP is not confident to prescribe the 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.

Sharing of care assumes communication. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION	
Specialist Services Responsibilities	
1	On receipt of self-referral of the patient with a diary of alcohol consumption for at least two weeks or a referral from the patient's GP 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 weekly appointments for the patient to receive psychosocial interventions. Patient signs up to weekly 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 participate in shared care in accordance with this shared care guideline. The request should also set out the anticipated duration of treatment.
4	The specialist service will provide the GP with monthly updates of the patient's adherence to treatment and alcohol consumption.
5	Compliance: The patient is required to attend weekly psychosocial support in order to receive their prescription. Medication will be stopped if the patient fails to comply with specialist psychosocial services. Should the patient fail to attend for 3 consecutive weeks the specialist 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	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	This medicinal product is subject to additional monitoring under the MHRA black triangle scheme ▼. The specialist service should report known or suspected adverse events to the GP, who will report to the MHRA via the Yellow Card scheme
General Practitioner Responsibilities	
1	Make an initial assessment of whether the patient would be a suitable candidate for treatment with nalmefene. If patient is suitable then he/she should • provide a Change4Life booklet on alcohol • advise the patient to record drinking habits for (at least) 2 weeks • recommend the patient attends or refer patient to local specialist service for alcohol, listed below: Bournemouth – Bournemouth Assessment Team (BAT) 01202 294888 Dorset – EDP Drug and alcohol services team 01305 760799 Poole – Substance misuse assessment and referral team (SMART) 01202 735777

2	After patient has been seen by specialist service, where nalmefene is appropriate based on triage and psychosocial interventions, GP will respond to request from the specialist service to initiate nalmefene. GP must ensure compatibility of nalmefene with concomitant prescribed medication. (Refer to 'interactions' section below). 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 Specialist service/ Specialist Team.
4	Monitor patient at regular intervals in conjunction with specialist service.
5	Compliance: The patient is required to attend weekly psychosocial support in order to receive their prescription. Medication will be stopped if the patient fails to comply with specialist psychosocial services. Should the patient fail to attend for 3 consecutive weeks the specialist 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 Specialist service regarding concerns about compliance or suspected drug misuse.
7	**Stopping prescriptions** • Stop treatment on the advice of the specialist 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	This medicinal product is subject to additional monitoring under the MHRA black triangle scheme▼. The GP should report known or suspected adverse events to the MHRA via the Yellow Card scheme and share this information with the specialist service.

Patient's role (or that of carer)	
1	Report to the specialist service or GP if he or she does not 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 or specialist service 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.

SUPPORTING INFORMATION

Dosage and Administration

Nalmefene is to be taken as-needed: on each day the patient perceives a risk of drinking alcohol, one tablet 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. Nalmefene can be taken with or without food.

Duration of treatment

The NICE guidance does not include clear information about when treatment should be stopped. Clinical data for the use of nalmefene under randomised controlled conditions are available for a period of 6 to 12 months. Caution is advised if nalmefene is prescribed for more than 1 year. During treatment, the GP and specialist service should continue to assess the patient's progress in reducing alcohol consumption, overall functioning, treatment adherence, and any potential side effects.

Contraindications to nalmefene treatment:

- Hypersensitivity to the active substance or to any of the excipients listed (refer to SPC).
- Patients taking opioid analgesics
- Patients with current or recent opioid addiction
- Patients with acute symptoms of opioid withdrawal
- Patients for whom recent use of opioids is suspected
- Patients with severe hepatic impairment (Child-Pugh classification)
- Patients with severe renal impairment (eGFR <30 ml/min per 1.73 m2)
- Patients with a recent history of acute alcohol withdrawal syndrome (including hallucinations, seizures, and delirium tremens).
- Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption (medicine contains lactose)

Cautions / special situations

- Nalmefene is not for patients for whom the treatment goal is immediate abstinence. Reduction of alcohol consumption is an intermediate goal on the way to abstinence.
- Nalmefene is not recommended for use in patients who are pregnant or breastfeeding
- Opioid administration
  - In an emergency situation when opioids must be administered to a patient taking nalmefene, the amount of opioid required to obtain the desired effect may be greater than usual. The patient should be closely monitored for symptoms of respiratory depression as a result of the opioid administration and for other adverse reactions.
  - If opioids are needed in an emergency, the dose must always be titrated individually. If unusually large doses are required, close observation is necessary.
  - Nalmefene should be temporarily discontinued for 1 week prior to the anticipated use of opioids, for example, if opioid analgesics might be used during elective surgery.
  - The prescriber should advise patients that it is important to inform their health care

professional of last Nalmefene intake if opioid use becomes necessary.

- Caution should be exercised when using medicinal products containing opioids (for example, cough medicines, opioid analgesics (see section 4.5)).

- Psychiatric disorders
  - Psychiatric effects were reported in clinical studies. If patients develop psychiatric symptoms that are not associated with treatment initiation with nalmefene, and/or that are not transient, the prescriber should consider alternative causes of the symptoms and assess the need for continuing treatment with Nalmefene.
  - Nalmefene has not been investigated in patients with unstable psychiatric disease. Caution should be exercised if Nalmefene is prescribed to patients with current psychiatric comorbidity such as major depressive disorder.
- Seizure disorders - there is limited experience in patients with a history of seizure disorders, including alcohol withdrawal seizures. Caution is advised if treatment aimed at reduction of alcohol consumption is started in such patients.
- Elderly patients (≥65 years of age) – limited clinical data are available on the use of Nalmefene in patients ≥65 years of age with alcohol dependence.

Potential side effects

Nausea, vomiting, dry mouth, weight loss, decreased appetite, tachycardia, palpitation, dizziness, headache, somnolence, tremor, disturbance in attention, paraesthesia, hypoaesthesia, malaise, sleep disorders, confusion, restlessness, decreased libido, muscle spasms, hyperhidrosis. Hallucinations and dissociation also reported.

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 (for example, certain types of cough and cold medicinal products, certain antidiarrhoeal medicinal products, and opioid analgesics), the patient may not benefit from the opioid agonist.

Simultaneous intake of alcohol and nalmefene does not prevent the intoxicating effects of alcohol.

The lists of potential side effects and potential drug interactions included within this document are not exhaustive. The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Drug costs (BNF 66):

Selincro® tablets, f/c, nalmefene (as hydrochloride dihydrate) 18 mg

- 14-tab pack = £42.42
- 28-tab pack = £84.84

DMAG approval date:	**January 2015**
For review:	**January 2017 (or earlier in the light of new guidance or changes to services)**

References

- Summary of Product Characteristics for Selincro® 18mg tablets (Lundbeck Limited, accessed 30/12/2014)
- NICE Technology Appraisal 325: Nalmefene for reducing alcohol consumption in people with alcohol dependence (accessed 30/12/2014)

TREATMENT PATHWAY FOR NALMEFENE PRESCRIBING IN DORSET

Patient requests/GP considers Nalmefene prescribing.

Considerations include:

- Concomitantly prescribed medication (particularly inhibitors of the UGT2B7 enzyme and UGT inducers) and opioid agonists
- Potential contraindications to treatment (renal or hepatic impairment)
- Factors that make treatment unsuitable, i.e. immediate abstinence desired

If nalmefene is potentially suitable, GP gives patient a copy of Change4Life booklet and informs patient that they should keep a diary of alcohol consumption for **2 weeks**

GP completes referral to specialist service (e.g. SMART, BAT and EDP) and informs patient that they should attend the service once they have kept the diary for at least 2 weeks. The diary must be taken to their appointment.

Specialist service carries out a full assessment of patient and arranges further appointments for psychosocial interventions.

A care co-ordinator/key worker is identified.

If patient attends appointments with service and engages with interventions over the next **2 weeks**, then specialist service sends a request to patient's GP for them to initiate and continue to prescribe nalmefene within Dorset shared care guidance.

In some cases psychosocial support will be sufficient and nalmefene is not required, the specialist service will advise the GP if this is the case.

Specialist service continues to review patient's progress weekly over the next three months, and routinely reports information on the patient's progress in reducing alcohol consumption, overall functioning, treatment adherence, and any potential side effects. back to the patient's GP

Specialist service may ask GP to continue to prescribe for up to a **further three months** if deemed appropriate for the individual patient.

Patient continues to access ongoing care and support for alcohol with specialist service or associated after care services .