Commissioning Support
Nalmefene (Selincro®)
For the treatment of alcohol dependence

Commissioning guidance:
Commissioners may wish to bear the following in mind when considering the commissioning of nalmefene:

- Patients receiving nalmefene treatment need effective and continuous psychosocial support during treatment, as described in the NICE pathway on alcohol-use disorders.
- The local care pathway for the treatment of alcohol dependence.
- The availability of community alcohol teams or similar services offering psychosocial support.
- 18 to 33% of participants in the trials were able to reduce their drinking after initial assessment, and before treatment. The NICE clinical pathway advises a motivational intervention as part of the initial assessment.

Prescribing guidance: Category B (Q4)
Nalmefene is suitable for prescribing in primary care in conjunction with continuous psychosocial support.

Category B: suitable for restricted prescribing under defined conditions

Q4 rating: The evidence for efficacy of nalmefene was strongest in the subgroup of patients described in the licensed indications: those with a high drinking risk level who did not manage to reduce their alcohol consumption before treatment. In pooled analyses from two RCTs, patients in this subgroup showed a mean reduction of 3 heavy drinking days (HDD) per month (from a baseline of 18 to 20 HDD/month), and a mean reduction of 66 g/day alcohol consumed vs. 51 g/day in placebo-treated patients.

The Q rating relates to the drug’s position on the effectiveness indicator grid. The strength of the evidence is determined by the quality and quantity of studies that show significant efficacy of the drug compared with placebo or alternative therapy. Its place in therapy in primary care takes into account safety and practical aspects of using the drug in primary care, alternative options, relevant NICE guidance, and the need for secondary care input.

Description of technology
Nalmefene is an opioid system modulator, and is thought to reduce alcohol consumption by modulation of the cortico-mesolimbic system (dopamine-mediated brain pathway related to feelings of reward).

It is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level, without physical withdrawal symptoms and who do not require immediate detoxification. It should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should only be initiated in patients who continue to have a high drinking risk level over two weeks after initial assessment.

At the initial visit, the patient’s clinical status, alcohol dependence and level of alcohol consumption (self-reported) should be evaluated. Thereafter the patient should be asked to record his or her alcohol consumption for two weeks. At the next visit, nalmefene may be initiated in patients who continue to have a high drinking risk level over this period, in conjunction with psychosocial support. One tablet should be taken as needed on each day the patient perceives a risk of drinking alcohol; preferably one or two hours before the anticipated time of drinking.1

The patient’s response to treatment, and the need for continued pharmacotherapy should be evaluated on a regular basis. The Summary of Product Characteristics advises caution if nalmefene is prescribed for more than one year.1

Background
Alcohol causes harm because of its inherent toxic effects on most organs of the body, which increase the risk of a variety of diseases, including cancers and liver disease. It also has addictive potential and is associated with a higher risk of mental health disorders. The NICE clinical guideline on harmful alcohol use and alcohol dependence (CG115, published 2011) states that “24% of the adult population in England consumes alcohol in a way that is potentially or actually harmful to their health or wellbeing” and 4% are alcohol dependent.2 Deaths from alcoholic liver disease have doubled in the UK since 1980, compared with a decrease in some other European countries.3 The prevalence of “hazardous drinking” among men (consumption of between 22 and 50 units per week) in the West Midlands was reported (in 2010) to be 24%.3

The NICE Pathway on alcohol-use disorders recommends offering a psychological intervention first in the case of harmful drinking and mild alcohol...
was a reduction of 3 more heavy drinking days per month for nalmefene treatment vs. placebo (p < 0.0001) in this patient population, and an estimated mean change from baseline in total alcohol consumption after six months’ treatment of -51 g/day in the placebo group and -66 g/day in the nalmefene group (treatment difference -14 g/day; 95% CI -20.8 to -7.8; p < 0.0001).7

**Adverse events**

In the two published trials,5,6 adverse events were reported for a higher proportion of nalmefene-treated patients than placebo-treated patients (68% vs. 59% of patients, and 81% vs. 67% of patients, in the two trials). Statistical significance was not reported in the articles for adverse events. The most common events included nausea, dizziness and insomnia (and also fatigue, vomiting and hyperhidrosis in one of the studies5), which occurred twice as frequently with nalmefene as with placebo. Overall drop-out rates due to treatment-emergent adverse events were 7% in the placebo group vs. 23% in the nalmefene group in one trial,5 and 6 to 7% of all patients in the second trial.6

**Considerations for cost impact**

 Ø At current prices, and assuming the use of one tablet per day, the cost of a year’s treatment with nalmefene 18 mg tablets is £1,106.

**References**


