NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Nalmefene for reducing alcohol consumption in people with alcohol dependence

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of nalmefene within its licensed indication for reducing alcohol consumption in people with alcohol dependence.

Background

Alcohol dependence is characterised by craving, tolerance and a preoccupation with alcohol. It is defined as a maladaptive pattern of alcohol use, leading to clinically significant impairment or distress. Severity may be defined using measures of symptoms and behaviours and/or amount of alcohol consumed. The Severity of Alcohol Dependence Questionnaire measures alcohol related symptoms, behaviours and consumption (mild, moderate or severe alcohol dependence). The World Health Organisation categorise alcohol consumption in different health risk levels. High drinking risk level is ≥ 60 g/day of pure alcohol for men and ≥ 40 g/day for women.

In England, alcohol dependence affects approximately 4% of people aged 16-65 years (6% of men and 2% of women), about 1.1 million people, of whom 6% seek treatment. It is estimated that around 85,000 people with moderate or severe dependence receive specialist treatment each year. Alcohol dependence is associated with an increased rate of significant mental and physical disorders, including cardiovascular disease, neurological disorders (e.g. seizures and delirium tremens), gastrointestinal disorders (e.g. liver disease and acute and/or chronic pancreatitis), mental health disorders (e.g. depression, anxiety disorders and drug misuse) and Wernicke's encephalopathy. In 2010, there were 8,589 alcohol related deaths in England and Wales.

Clinical guideline 115 'Alcohol dependence and harmful alcohol use' states that for most people the goal of treatment for alcohol dependence will be abstinence. However, for some people a goal of reducing alcohol consumption may be appropriate. Interventions should aim to support abstinence or reduction in consumption and prevent relapse.

For people with mild alcohol dependence, CG115 recommends offering a psychological intervention focused specifically on alcohol-related cognitions, behaviour, problems and social networks. For people with moderate and severe alcohol dependence who have limited social support, complex comorbidities, or who have not responded to initial community-based

interventions, CG115 recommends offering intensive structured community-based interventions including psychological interventions (individual treatments, group treatments, psycho-educational interventions, help to attend self-help groups and family and caregiver support and involvement). NICE CG115 also recommends specific pharmacological treatments for assisted withdrawal from alcohol and for the prevention of relapse.

The technology

Nalmefene (Selincro, Lundbeck) is an opioid receptor modulator, which exhibits antagonist activity at μ and δ opioid receptors, and partial agonist at κ opioid receptors. It is administered orally.

Nalmefene has a UK marketing authorisation 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.

Intervention(s)	Nalmefene in conjunction with psychosocial support
Population(s)	Adults with alcohol dependence who have a high drinking risk level without physical withdrawal symptoms and who do not require immediate detoxification.
Comparators	Psychological intervention such as cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies.
Outcomes	The outcome measures to be considered include: • alcohol consumption • alcohol dependence symptoms • mortality • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. If the evidence allows subgroups by level of dependence will be considered.

Related NICE recommendations	Related Guidelines: Clinical Guideline No. CG120, March 2011, 'Psychosis with coexisting substance misuse', review proposal date tbc Clinical Guideline No. CG 115, February 2011, 'Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence', review proposal date tbc Clinical Guideline No. CG100, June 2010, 'Alcohol-use disorders: diagnosis and clinical management of alcohol-related physical complications', review proposal date June 2013 Related Public Health Guidance/Guidelines: Public health guidance No. PH24, June 2010, 'Alcohol-use disorders: preventing harmful drinking', review proposal date tbc Public health guidance No. PH7, November 2007, 'School-based interventions on alcohol', review proposal date tbc Public health guidance No. PH4, March 2007, 'Interventions to reduce substance misuse among vulnerable young people', review proposal date tbc Related Quality Standards Quality Standard No. QS 11, August 2011, 'Alcohol dependence and harmful alcohol use quality standard', review proposal date tbc http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp

Questions for consultation

In which patients would nalfemene be used in clinical practice? How would a population with a high drinking risk level be defined in NHS clinical practice?

Has the most appropriate comparator for nalmefene for the reduction of alcohol consumption in people with alcohol dependence been included in the scope? Should any pharmacological comparators be included?

Is the subgroup suggested in 'other considerations appropriate? Are there any other subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which nalmefene will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)