

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Nalmefene for reducing alcohol consumption in people with alcohol dependence

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness (allowing adoption of a wider perspective than the NHS and Personal and Social Services) 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 Alcohol Use Disorders Identification Test is an initial screen for alcohol related issues, and 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 (for example seizures and delirium tremens), gastrointestinal disorders (for example liver disease and acute and/or chronic pancreatitis), mental health disorders (for example depression and anxiety disorders) and Wernicke's encephalopathy. In 2010, there were 8589 alcohol related deaths in England and Wales.

NICE 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, controlled consumption, and to prevent relapse.

For people with mild alcohol dependence, CG115 states that assisted withdrawal programmes are usually not needed and recommends offering a psychological intervention (such as cognitive behavioural therapies, behavioural therapies, behavioural couples therapy or social network and environment-based therapies) focused specifically on alcohol-related cognitions, behaviour, problems and social networks. For people with moderate alcohol dependence assisted withdrawal programmes are usually needed but can be managed in a community setting and for people with severe alcohol dependence assisted withdrawal programmes are needed usually in an inpatient or residential setting. NICE CG115 also recommends specific pharmacological treatments for assisted withdrawal from alcohol and for the prevention of relapse after assisted withdrawal.

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	Nalmefene in conjunction with psychosocial support (as defined in NICE Clinical Guideline 115)
Population	Adults with mild alcohol dependence (as defined in NICE Clinical Guideline 115) who have a high drinking risk level (≥ 60 g/day of pure alcohol for men and ≥ 40 g/day for women) without physical withdrawal symptoms and who do not require immediate detoxification.
Comparators	<ul style="list-style-type: none"> • Psychological intervention such as cognitive behavioural therapies, behavioural therapies or social network and environment-based therapies alone (as defined in NICE Clinical Guideline 115). • Naltrexone (in conjunction with psychosocial support as defined in NICE Clinical Guideline 115)

Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • alcohol consumption • alcohol dependence symptoms • compliance/concordance with treatment • objective measures of alcohol consumption • hospitalisations • controlled drinking • change in number of heavy drinking days • morbidity • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs in the reference case will be considered from an NHS and Personal Social Services perspective.</p> <p>If evidence allows sensitivity analyses should be presented taking into account the wider impacts of alcohol dependence, specifically including:</p> <ul style="list-style-type: none"> • Social and crime issues, including impacts on domestic violence and prisons; • Social effects of alcohol dependence of adults on children; and • The effects of driving while under the influence of alcohol.
Other considerations	<p>Guidance will only be issued in accordance with the marketing authorisation.</p>

<p>Related NICE recommendations</p>	<p>Related Guidelines:</p> <p>Clinical Guideline No. CG120, March 2011, 'Psychosis with coexisting substance misuse', review proposal date tbc</p> <p>Clinical Guideline No. CG 115, February 2011, 'Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence', review proposal date tbc</p> <p>Clinical Guideline No. CG100, June 2010, 'Alcohol-use disorders: diagnosis and clinical management of alcohol-related physical complications', review proposal date tbc</p> <p>Related Public Health Guidance/Guidelines:</p> <p>Public health guidance No. PH24, June 2010, 'Alcohol-use disorders: preventing harmful drinking', review proposal date February 2014</p> <p>Public health guidance No. PH7, November 2007, 'School-based interventions on alcohol', review proposal date March 2014</p> <p>Public health guidance No. PH4, March 2007, 'Interventions to reduce substance misuse among vulnerable young people', review proposal date March 2014</p> <p>Related Quality Standards</p> <p>Quality Standard No. QS 11, August 2011, 'Alcohol dependence and harmful alcohol use quality standard', review proposal date tbc</p> <p>http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> <p>Related NICE Pathway:</p> <p>NICE Pathway: Alcohol-use disorders overview, Pathway created May 2011 and updated October 2013</p> <p>http://pathways.nice.org.uk/</p>
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