

## NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Health Technology Appraisal

## Naltrexone as a treatment for relapse prevention in drug misusers

## Draft scope

**Appraisal objective**

To appraise the clinical and cost effectiveness of naltrexone (Nalorex, Bristol-Myers Squibb Pharmaceuticals Ltd) as a treatment for relapse prevention for drug misusers, and to provide guidance to the NHS in England and Wales<sup>1</sup>.

**Background**

Opiate is a collective term for analgesics that are derived from the naturally occurring compound opium. This includes diamorphine (heroin), morphine and codeine. The term 'opioid' denotes a broader group that includes opiates plus synthetic analgesics with agonist, partial agonist, or mixed agonist and antagonist activity at opioid receptors.

Opiates are used therapeutically as painkillers, but also produce euphoria and are therefore abused. Dependence can also develop within a relatively short period of continuous use (2-10 days), and is characterised by an overwhelming need to continue taking the drug in order to avoid withdrawal symptoms (such as sweating, anxiety, muscle tremor, disturbed sleep, anorexia, and raised heart rate, respiratory rate, blood pressure and temperature). The body also becomes tolerant to the effects of opiates and therefore the dose taken needs to be increased to maintain the effect.

Opiate misuse can be defined as the compulsive use of opiates despite physical, psychological, and social harm to the user. Most individuals who meet the criteria of opiate misuse and continue to use opiates go on to fulfil the criteria of opiate dependence.

Opiate dependence can cause a wide range of health problems, such as liver and neurological disorders, and is associated with simultaneous abuse of a number of drugs (including alcohol). Mortality risk of heroin abusers is estimated to be around twelve times that of the general population. Associated social problems include marital and relationship breakdown, unemployment, homelessness, and criminal activity.

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<sup>1</sup> The Department of Health and Welsh Assembly Government remit to the Institute: To appraise the clinical and cost effectiveness of naltrexone as a treatment for relapse prevention for drug misusers and to identify those groups of drug misusers (in the community and prison settings) who are most likely to benefit from being prescribed naltrexone. Also to advise on the optimum care package that needs to be available to those prescribed naltrexone to secure effective outcomes, and to provide guidance to the NHS in England and Wales.

Estimates suggest there are around 250,000 dependent drug users in the UK, with approximately 160,000 in treatment at some point during the year. The scale of opiate misuse in prisons is not easy to estimate. General drug misuse in prisons in England and Wales is estimated to be between 15% and 29%. In one UK survey, 20% of prisoners had used opiates at some point during their sentence, and 10% during the previous week.

There are two main strategies for the treatment of opiate dependence. One is harm reduction (taking the individual off illicit street drugs and administering an opiate substitute in a maintenance regimen) to enable the individual to achieve social stability. The second is abstinence (taking the individual off the drug altogether using detoxification and withdrawal). Choice of strategy is influenced by individual preference and circumstances. To improve prognosis, both strategies are used in conjunction with other psychological, social and medical interventions.

**The technology**

Naltrexone is an opioid antagonist which blocks the action of opioids and precipitates withdrawal symptoms in opioid-dependent subjects. Because the euphoric action of opioid agonists is blocked by naltrexone, it is given to former addicts to aid continued abstinence. It is licensed as an adjunct to prevent relapse in detoxified formerly opiate-dependent individuals who have remained opiate-free for at least 7 to 10 days.

<b>Intervention(s)</b>	Naltrexone
<b>Population(s)</b>	Detoxified, formerly opiate-dependent individuals
<b>Standard comparators</b>	The intervention is an adjunct to current treatment strategies and therefore the comparator is treatment strategies without naltrexone.
<b>Outcomes</b>	<p>Outcome measures include:</p> <ul style="list-style-type: none"> <li>• Relapse rates</li> <li>• Mortality</li> <li>• Compliance with treatment</li> <li>• Adverse effects of treatment</li> <li>• Health-related quality of life</li> <li>• Criminal activity</li> <li>• Unemployment.</li> </ul>

<p><b>Economic analysis</b></p>	<p>Ideally, the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>Costs and benefits for the base case will be considered from an NHS and Personal Social Services perspective. Sensitivity analysis will also be undertaken to include the wider societal costs/benefits including unemployment, criminal activity and costs to the prison service.</p>
<p><b>Other considerations</b></p>	<p>Where the evidence allows, the appraisal will examine subgroups of individuals for whom naltrexone may be particularly appropriate or inappropriate.</p> <p>Where the evidence allows, the appraisal will consider the use of naltrexone in both community and prison settings.</p> <p>Where the evidence allows, the appraisal will consider the impact on the clinical and cost-effectiveness of the prescribed dose and the context of care.</p>
<p><b>Related NICE recommendations</b></p>	<p>Related Technology Appraisals:</p> <p>None</p> <p>Related Guidelines:</p> <p>Drug misuse: psychosocial management of, drug misusers in the community and prison settings.</p> <p>Drug misuse: opiate detoxification management of, drug misusers in the community, hospital and prison settings.</p>