

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Health Technology Appraisal**

**Varenicline for smoking cessation**

**Final scope**

**Appraisal objective**

To appraise the clinical and cost effectiveness of varenicline for smoking cessation and to provide guidance to the NHS in England and Wales<sup>1</sup>.

**Background**

Tobacco smoking is associated with a range of medical conditions that kill millions of people worldwide each year. Tobacco smoke contains nicotine, a highly addictive alkaloid that acts by binding to a subset of receptors for the neurotransmitter acetylcholine. The smoke also contains a number of other substances that increase the risk of lung cancer and cancers of the mouth and throat. Prolonged smoking also increases the risk of other lung and cardiovascular conditions. It has been estimated that smoking contributes to the premature death of about half of all people who smoke for 20 years or more. It is suggested that prolonged smoking reduces life expectancy by about 3 years in men and about 10 years in women.

The proportion of adults who currently smoke is approximately 25% in England and about 27% in Wales. Approximately equal numbers of men and women smoke. Smoking prevalence declines with age, because more older people quit than begin, and older smokers die at a younger age than non-smokers. About 2% of children aged 11 smoke, rising to 22% at age 15 and 40% in the age-range 20-24, declining to 16% of people over the age of 60. Smoking prevalence is about 50% higher among manual workers and unemployed people, compared with of the general adult population.

In July 2004 the Government set a new target to reduce the overall proportion of cigarette smokers in England from 26% in 2002 to 21% or less by 2010 with a reduction from 31 to 26% or less among routine and manual occupation groups. In 2002, in the Department of Health Priorities and Planning Framework (2003-2006) the government set targets to "reduce the rate of smoking contributing to the national target of reducing the rate in manual groups from 32% in 1998 to 26% by 2010; 800,000 smokers from all groups successfully quitting at the 4 week stage by 2006."

To this end, the government has set up a comprehensive set of anti-smoking policies, including smoking cessation units within the NHS. NICE public health guidance No. 1 recommends that pharmacotherapy is recommended to patients who have indicated they wish to quit but have declined referral to an intensive support programme. NICE technology appraisal guidance (TA 39)

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<sup>1</sup> DH remit: To prepare a technology appraisal on the clinical and cost effectiveness of varenicline for smoking cessation

recommends that nicotine replacement therapy (NRT) and bupropion should be available on prescription for smokers who have said that they want to quit smoking and that they should also be offered advice and encouragement. NRT is now also available over-the-counter.

**The technology**

Varenicline tartrate (Champix Pfizer Ltd) is an oral neuronal nicotinic receptor partial agonist which binds to nicotinic acetylcholine receptors in the brain. In contrast to a nicotine derivative or an antidepressant, varenicline was designed to selectively target the alpha 4-beta 2 nicotinic receptors in the brain and thereby to reduce craving and the related withdrawal symptoms of quitting and block rewards from smoking. Varenicline has a marketing authorisation in the UK for smoking cessation in adults.

<b>Intervention(s)</b>	Varenicline
<b>Population(s)</b>	Adults who smoke tobacco products and have indicated a desire to quit smoking
<b>Standard comparators</b>	<ul style="list-style-type: none"> <li>• Bupropion</li> <li>• NRT</li> <li>• Other smoking cessation interventions, as appropriate without varenicline</li> <li>• No therapy (placebo)</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• Survival</li> <li>• Morbidity related to smoking</li> <li>• Quit rates at 4 weeks, 6 months, 12 months and at longer periods</li> <li>• Adverse effects of treatment</li> <li>• Health-related quality of life</li> </ul>
<b>Economic analysis</b>	<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 time horizon for the economic evaluation should be sufficiently long so as to incorporate all the important costs and benefits.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>

<b>Other considerations</b>	<p>Guidance will be issued in accordance with the marketing authorisation.</p> <p>If evidence permits, subgroups based on age, gender, socioeconomic status or other parameters will be considered.</p> <p>If evidence permits, considerations of the effectiveness of varenicline in patients with other chronic conditions such as asthma, COPD and diabetes</p> <p>If evidence permits combination and sequential therapy will be considered.</p> <p>If evidence permits the role of accompanying advice will be considered.</p>
<b>Related NICE recommendations</b>	<p>Related Technology Appraisals:</p> <p>NICE Appraisal Guidance No 39 - <i>NRT and bupropion for smoking cessation</i>, March 2002</p> <p>Related Guidance</p> <p>NICE public health intervention guidance No 1 – <i>Brief interventions and referral for smoking cessation in primary care and other settings</i>, March 2006</p>