

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**Proposed Health Technology Appraisal****Continuous positive airways pressure (CPAP) for the treatment of obstructive sleep apnoea/hypopnoea syndrome (OSAHS)****Final Scope****Appraisal objective**

To appraise the clinical and cost effectiveness of continuous positive airways pressure (CPAP) for the treatment of obstructive sleep apnoea/hypopnoea syndrome (OSAHS) and to provide guidance to the NHS for England and Wales¹.

Background

Obstructive sleep apnoea/hypopnoea syndrome (OSAHS) can be defined as the coexistence of excessive daytime sleepiness with irregular breathing at night. OSAHS occurs because the upper airway collapses intermittently. When the person falls asleep the muscle-tone in the upper pharyngeal airway decreases leading to upper airway narrowing. This produces an increase in inspiratory effort in an attempt to overcome this airway narrowing, which then leads to a transient arousal from deep sleep to wakefulness or a lighter sleep which allows restoration of normal airway muscular tone and calibre. These upper airway collapses occur repeatedly throughout the night leading to fragmentation of normal sleep architecture and a reduction in the quality of sleep with the generation of restless, disturbed and unsatisfying sleep.

Such upper airway collapses can be complete, with total obstruction of the airway lumen and no respiratory airflow (apnoea), or partial, with reduction in the cross-sectional area of the upper airway lumen causing hypoventilation (hypopnoea). An apnoea is arbitrarily defined in adults as a ten second breathing pause and a hypopnoea as a ten second event where there is continued breathing but ventilation is reduced by at least 50% from the previous baseline during sleep.

The apnoea/hypopnoea index (AHI) provides a measure of the severity of OSHAS, which is based on the frequency of apnoeas and hypopnoeas per hour of sleep as calculated from the results of a polysomnograph recording. Using this index, the varying degrees of breathing abnormality are subdivided into mild (AHI 5-14/hr), moderate (AHI 15-30/hr) and severe (AHI>30/hr). However, the AHI does not take into account severity of symptoms, which is considered to be important. One method of assessing this is using the Epworth Sleepiness Scale (ESS).

¹ DH remit: To appraise the clinical and cost effectiveness of continuous positive airways pressure (CPAP) for the treatment of obstructive sleep apnoea/hypopnoea syndrome.

The consequences of untreated sleep apnoea on daily activities include increased daytime sleepiness, impairment of cognitive function, mood and personality changes. This can result in a reduction in quality of life and impaired relationships between spouses and partners. Symptoms of sleepiness and impaired concentration resulting from untreated sleep apnoea are thought to have serious consequences during day-to-day activities, such as an increased risk of accidents. Additionally, it is thought that untreated sleep apnoea can be a risk factor for other chronic medical conditions such as myocardial infarction and stroke.

The prevalence of OSAHS is approximately 4% in men (30-65 years) and 2% in women of the same age. According to current workloads in sleep clinics, an annual incidence has been estimated at 150 referrals per typical health authority population of 500,000.

Due to factors that predispose the majority of people to OSAHS (such as obesity, sedative drugs and smoking and alcohol consumption) lifestyle management is usually an adjunct to treatment. Continuous positive airway pressure (CPAP) is the main current method of management of OSHAS. Other alternatives, used less often, include splints/oral appliances which advance the mandible (dental devices) and, less frequently, surgery. Drugs regimens have been tried, but their effectiveness is not established.

The technology

Continuous positive airway pressure (CPAP) consists of a flow generator, mask and headgear. It provides ventilatory assistance during the night for as long as it is used, and therefore requires the provision of a machine for long-term personal use. Several models are commercially available in the UK, for example SleepStyle (Fisher & Paykel Healthcare Ltd), REMstar (Respironics UK Ltd), S-Series (ResMed, UK), DeVilbiss Sleep solution (Sunrise Medical Ltd), GoodKnight 420 series (Tyco Healthcare Ltd) and Breas (Vital Signs Ltd). For the purpose of this appraisal the term CPAP will be defined as any CPAP (fixed) or autotitrating (APAP) regardless of make or whether additional features (such as humidifiers) are used.

Major side effects of CPAP are rare (such as, significant epistaxis, paranasal sinusitis), but minor side effects (including, rhinitis, nasal bridge sores, discomfort and noise) have been reported.

There are no routine data on current use. Expert opinion estimates that approximately 20,000 of the probable 180,000 patients with OSAHS are using CPAP.

Intervention(s)	Continuous positive airways pressure (CPAP) devices (fixed and autotitrating)
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Population(s)	Adults with obstructive sleep apnoea/hypopnoea syndrome (OSAHS) confirmed by an appropriate clinical expert
Standard comparators	<ul style="list-style-type: none"> • No treatment/ placebo (this may include lifestyle advice) • Dental devices (mild OSAHS)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • Severity of OSAHS measured via objective methods • Severity of OSAHS-related symptoms • Adverse effects of treatment • Health-related quality of life • Any other health effects
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 time horizon for the economic evaluation should reflect the fact that OSAHS is a chronic condition.</p> <p>The costs should include the initial set up and device fitting, subsequent assessment of appropriate airflow calibration and patient treatment compliance</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	If the evidence allows, the appraisal will attempt to identify criteria for selecting subgroups of people for which this treatment would be particularly appropriate.
Related NICE recommendations	<p>Related Technology Appraisals: None</p> <p>Related Guidelines: None</p>