

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA139; Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome**

This guidance was issued in March 2008.

**Background**

At the GE meeting of 22 November 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list'
<b>Rationale for selecting this proposal</b>	No new evidence has emerged that would change the recommendations of TA139. The results of MOSAIC study showed patients with mild OSAHS treated with CPAP did not experience a reduction in vascular risk at the five-year mark. CPAP therapy, however, was found to be effective in reducing daytime sleepiness (measured by the Epworth Sleepiness Score). This result would not impact on the current recommendation for patients with OSAHS.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

**Recommendation  
post  
consultation:**

The guidance should be transferred to the 'static guidance list'.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Association for Respiratory Technology & Physiology	Agree	<p>After some consideration, the Association for Respiratory Technology &amp; Physiology (ARTP) expert group on Sleep (ARTP SLEEP) have decided that they are unaware of any substantial new evidence to consider moving TA139 to the active list to undertake a full review appraisal in 2012. Sleep apnoea and its treatment with CPAP is however, still an active area of development. Furthermore, we feel that more evidence will emerge in the interaction of sleep apnoea, heart disease/hypertension and improvements in CPAP therapy in the next few years. We would hope that re-consideration of a full review appraisal is performed before 2015.</p> <p>Our main concern still remains that many primary care centres are still not fully aware of the clear evidence base for the efficacy of CPAP treatment and they are reluctant to promote the diagnosis and treatment of the condition with CPAP. We are encouraged that current public campaign of awareness of OSA is being spearheaded by the British Lung Foundation.</p>	Comment noted. Topics on the static list may be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a material effect on the last guidance issued.
British Thoracic Society	No comment	The British Thoracic Society is not aware of any new evidence in relation to this guidance and notes the plans to place the guidance on the static list.	Comment noted.
Healthcare Improvement	No comment	Healthcare Improvement Scotland has no comment to make on the proposal to move TA139 to the static list.	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Scotland			
Oxford Sleep Unit	Agree	<p>You are right that MOSAIC showed no cardiovascular benefit using conventional vascular risk factors (still abstract only, to our annoyance).</p> <p>A subset who had endothelial function showed CPAP treatment effect – but again only in abstract at present.</p> <p>Also value of endothelial function as a predictor of vascular state in this setting is speculative.</p> <p>However, the other MOSAIC primary endpoint was the ESS which showed a clear and highly significant improvement.</p> <p>One of the comments in the TA was that there was little data at the milder end of the spectrum – well now there is and it showed clear benefit.</p> <p>Therefore you might consider an altered word when referring to milder disease saying there is some evidence of benefit and CPAP can be tried.</p> <p>So not a major change, more a change of emphasis.</p>	<p>Comment noted. Interim results of the MOSIAC trial support the current guidance for mild OSAHS in section 1.2, which recommends CPAP as a treatment option for adults with mild OSAHS if they: have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate.</p>
Oxford Sleep Unit (2)		<p>Second response – apologies</p> <p>MOSAIC was 6 months, not 5 years!</p> <p>We will have some 5 year data but not yet.</p>	<p>Comment noted.</p>

Respondent	Response to proposal	Details	Comment from Technology Appraisals
ResMed	Agree	I can confirm that ResMed does do intend to submit new data that would impact on the current recommendation for patients with OSAHS and therefore support the proposal that the guidance be placed on the static list until such a time as new data emerges.	Comment noted.
Weinmann Medical Technology	Disagree	<p>We ask NICE to consider point 4.3.13.</p> <p>You stated in the document that the committee heard from specialists that CPAP is not appropriate for people suffering from mild OSAHS “because the inconvenience of use of the device would outweigh the benefits” of treatment. Other specialists, however, told the committee that people with mild OSAHS can benefit from CPAP with respect to quality of life. Advice and support on lifestyle changes should be included from the very beginning of treatment and should always be followed by a CPAP trial. It has been shown that CPAP treatment of mild OSA reduces cardiovascular risk and could therefore result in a positive ICER (incremental cost-effectiveness ratio). Furthermore, we cannot ignore the fact that even patients with mild cases of Obstructive Sleep Apnoea face an increased cardiovascular risk (Am J Respir Crit Care Med, Vol 176, 1274-1280, 2007).</p>	<p>Comment noted. Section 1.2 of the guidance recommends the use of CPAP as a treatment option for adults with mild OSAHS if they: have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate; as concluded in section 4.3.13. CPAP’s purported benefit on cardiovascular risk is unclear in light of the interim results from the MOSIAC trial. There is no substantial new evidence that would impact on the current recommendations, or indicates a review of the guidance would be of value for the NHS.</p>

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Royal College of Nursing	Agree	Nurses caring for people with this condition were invited to comment on the above proposal to move this guidance to the static list. This seems appropriate. There are no further comments to make at this stage on behalf of the Royal College of Nursing.	Comment noted.
Association of Respiratory Nurse Specialists	Agree	We have consulted with ARNS members' expertise in this area and are in full support of Oxford Sleep Unit's views which have been submitted to NICE.  If in the event that the NICE Appraisal is altered, ARNS would support any need to disseminate information to our members, who are involved in the treatment of sleep apnoea.	Comment noted.
Royal College of Physicians	Agree	The RCP wishes to endorse the response of the BTS to the above consultation	Comment noted.

**No response received from:**

<u>Manufacturers/sponsors</u> <ul style="list-style-type: none"> <li>• Apex Medical (CPAP devices)</li> <li>• Breas Medical AB (CPAP devices)</li> <li>• Carefusion (CPAP devices)</li> </ul>	<u>General</u> <ul style="list-style-type: none"> <li>• Association of British Healthcare Industries</li> <li>• Board of Community Health Councils in Wales</li> <li>• Care Quality Commission</li> </ul>
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- DeVilbiss Healthcare (CPAP devices)
- Fisher & Paykel Healthcare (CPAP devices)
- Philips Respironics (CPAP devices)
- Covidien (CPAP devices)

Patient/carer groups

- Afiya Trust
- Black Health Agency
- British Lung Foundation
- British Snoring and Sleep Apnoea Association
- Counsel and Care
- Equalities National Council
- Muslim Council of Britain
- Muslim Health Network
- Sleep Apnoea Trust
- South Asian Health Foundation
- Specialised Healthcare Alliance

Professional groups

- British Association for Services to the Elderly
- British Geriatrics Society
- British Sleep Society
- British Society of Dental Sleep Medicine
- Primary Care Respiratory Society UK
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal Pharmaceutical Society
- Royal Society of Medicine
- United Kingdom Clinical Pharmacy Association

- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- EUCOMED
- Healthcare Improvement Scotland
- Medicines and Healthcare products Regulatory Agency
- National Association of Primary Care
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Comparator manufacturer(s)

- None

Relevant research groups

- Cochrane Airways Group
- Loughborough University Sleep Research Centre
- MRC Clinical Trials Unit
- National Institute for Health Research
- Research Institute for the Care of Older People
- Sleep Research Group, Section of Psychological Medicine, University of Glasgow

Assessment Group

- National Institute for Health Research Health Technology Assessment Programme

<u>Others</u> <ul style="list-style-type: none"><li>• Department of Health</li><li>• NHS Bradford and Airedale</li><li>• NHS Hertfordshire</li><li>• Welsh Government</li></ul>	<u>Associated Guideline groups</u> <ul style="list-style-type: none"><li>• None</li></ul> <u>Associated Public Health groups</u> <ul style="list-style-type: none"><li>• None</li></ul>
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**GE paper sign-off:** Helen Knight, Associate Director – Technology Appraisals Programme

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