NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

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

This guidance was issued in March 2008

The review date for this guidance is mid-2011 to coincide with publication of the MOSAIC trial

1. Recommendation

The guidance should be transferred to the 'static guidance list'. That we consult on this proposal.

2. Original remit(s)

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

3. Current guidance

1.1 Continuous positive airway pressure (CPAP) is recommended as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

1.2 CPAP is only recommended 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.

1.3 The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.

4. Rationale[1]

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,

[1] A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper

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.

5. Implications for other guidance producing programmes

There is no proposed or ongoing guidance development that overlaps with this review proposal.

6. New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from October 2010 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

7. Summary of evidence and implications for review

The CE marking for CPAP devices listed in TA139 remain largely unchanged since its publication in March 2008. Two devices are currently in development (Appendix 2). As mentioned in TA139, currently available CPAP devices are broadly similar and the selection of a CPAP device should be based on patient preferences and requirements.

Since TA139 was published in March 2008, no new evidence has been reported that would significantly impact the clinical management of obstructive sleep apnoea/hypopnoea syndrome in the UK. The evidence base for recommending CPAP in TA139 was based on RCTs comparing CPAP to placebo, usual care or dental devices. TA139 found CPAP to be cost effective for the treatment of moderate and severe OSAHS when compared to dental services and conventional treatment, and that CPAP therapy improved quality of life (measured as reductions in sleepiness). The Committee heard that CPAP was considered not to be appropriate for people with mild symptomatic CPAP because the inconvenience associated with use of the device would outweigh benefits in reduction of OSAHS symptoms. However, as mild OSAHS patients also suffer from considerable symptoms, the Committee was persuaded that mild OSAHS patients could benefit from CPAP therapy if symptoms affect their quality of life and if alternative options are deemed inappropriate (based on the ICER of £20,585 per QALY gained).

In TA139, the analysis by different severity grades of OSASH excluded cardiovascular events and its exclusion did not have a material effect on the reported ICERs. It was also understood by the Committee that there was insufficient evidence available to conclude a beneficial effect of CPAP on blood pressure. To address the potential of CPAP therapy in improving cardiovascular outcomes, interim results of a recent trial (MOSIAC I) evaluating CPAP to standard of care in patients with obstructive sleep apnoea (but presenting with insufficient symptoms to warrant CPAP therapy) found patients 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). The primary results of the MOSIAC I trial support the current recommendation for mild OSASH and would therefore not alter the recommendations outlined in TA139.

Given that there is no substantial new evidence that would impact on the recommendations, it is proposed that TA139 should be transferred to the static guidance list.

8. Implementation

A submission from Implementation is included in Appendix 3.

Using data for non-invasive ventilation procedures performed on patients with sleep apnoea as a proxy for CPAP procedures, the number of episodes procedures has nearly doubled from 2500 in March 2008 to approximately 4500 in 2009/10. Based on this proxy (as CPAP does not currently have a procedure code), the use of CPAP in the treatment of sleep apnoea is in-line with current NICE guidance.

9. Equality issues

No equality issues were raised when the scope for this appraisal was developed, or during the course of the appraisal.

GE paper sign off: Helen Knight, 14 November 2011

Contributors to this paper:

Information Specialist:	Mike Raynor
Technical Lead:	Kumar Perampaladas
Implementation Analyst:	Rebecca Lea
Project Manager:	Andrew Kenyon

Appendix 1 – explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
A review of the guidance should be planned into the appraisal work programme.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred to [specify date or trial].	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No
The guidance should be updated in an on-going clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	No

Options	Consequence	Selected – 'Yes/No'
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes

NICE would typically consider updating a technology appraisal in an ongoing guideline if the following criteria were met:

i. The technology falls within the scope of a clinical guideline (or public health guidance)

ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement

iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment

iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;

- Spending on a treatment for the indication which was the subject of the appraisal continues to rise
- There is evidence of unjustified variation across the country in access to a treatment
- There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed
- The treatment is excluded from the Payment by Results tariff

v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

Appendix 2 – supporting information

Relevant Institute work

Published

Soft-palate implants for simple snoring. Interventional Procedures Guidance IPG240. Published: November 2007.

Soft-palate implants for obstructive sleep apnoea. Interventional Procedures Guidance IPG241. Published: November 2007.

Soft-palate implants for simple snoring. Interventional procedures Guidance IPG240. Published November 2007.

Radiofrequency ablation of the soft palate for snoring. Interventional Procedures Guidance IPG124. Published: May 2005. Static guidance

In progress

None

Suspended/terminated

None

In topic selection

None

In topic selection[2]

[redacted]

[2] Information held by the NICE Topic Selection Team is treated as being potentially commercially sensitive by default. Details of the topics considered by NICE's Consideration Panels may be available on the NICE website, providing the manufacturers of the technologies under discussion have consented to the release of this information.

Details of changes to the indications of the technology

Indication considered in original appraisal	Proposed indication (for this appraisal)
A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the person must always wear their device when they go to sleep.	Unchanged.

Details of new products

Drug (manufacturer)	Details (phase of development, expected launch date,)
System One (Phillips Respironics)	Currently in clinical trials (System One study ISRCTN19824122). Due to complete Oct 2012.
Smartflex (DeVibliss)	Clinical trial completed May 2011 (DeVilbiss AutoAdjust With SmartFlex Comparative Study NCT01203956)

Registered and unpublished trials

Trial name	Details
MOSAIC I - Multi-centre randomised controlled trial to investigate the efficacy of nasal continuous positive airway pressure treatment to reduce cardiovascular risk and symptoms in mild to moderate sleep apnoea	Currently in follow-up. NICE has contacted the trial lead. [redacted] Abstract published in Thorax (2010).

PREDICT - A randomised controlled trial of continuous positive airway pressure treatment in older people with obstructive sleep apnoea/hypopnoea syndrome ISRCTN 90464927	Estimated completion date: October 2011
Continuous Positive Airway Pressure Treatment of Obstructive Sleep Apnea to Prevent Cardiovascular Disease	Currently recruiting Estimated completion date: September 2015
Continuous Positive Airway Pressure (CPAP) Treatment in Coronary Artery Disease and Sleep Apnea (NCT00519597)	Currently recruiting Estimated completion date: October 2012
Effect of Continuous Positive Airway Pressure (CPAP) on Cardiovascular Biomarkers in Patients With Obstructive Sleep Apnea (OSA) (NCT01138865)	Currently recruiting Estimated completion date: March 2011
Antihypertensive Effect of Continuous Positive Airway Pressure (CPAP) in Resistant Hypertensive Patients With Sleep Apnea (NCT00929175)	Currently recruiting Estimated completion date: December 2011
Effect of Continuous Positive Airway Pressure (CPAP) Versus Auto-titrating Continuous Positive Airway Pressure (APAP) on Resistant Hypertension (HTN) and Arterial Stiffness (NCT01044355)	Currently recruiting Estimated completion date: January 2011
Continuous Positive Airway Pressure (CPAP) in Patients With Acute Coronary Syndrome and Obstructive Sleep Apnea (OSA) (ISAACC) (NCT01335087)	Currently recruiting Estimated completion date: April 2014
CPASMA: Is There an Improvement in Asthma in Patients With Both Asthma and OSAS Treated With CPAP? (NCT01374932)	Not yet recruiting. Estimated completion date: December 2013
Reversibility of Cardiovascular Injury With CPAP Use: Mechanisms Involved (NCT01317329)	Enrolling participants (by invitation only) Estimated completion date: December 2014
Nasal Continuous Positive Airway Pressure (CPAP) in Chronic Fatigue and Sleep-disordered Breathing (NCT01368718)	Not yet recruiting Estimated completion date: December 2012

System One™ study: evaluation of the System One™ REMstar® Auto A-Flex for the treatment of obstructive sleep apnoea (OSA) (ISRCTN19824122)	Ongoing. Estimated completion date: October 2012
Evaluation of fixed continuous positive airway pressure (CPAP) with C-Flex+ against fixed CPAP (ISRCTN04363711)	Ongoing. Estimated completion date: January 2012

References

N/A

Appendix 3 – Implementation submission

Implementation feedback - review of technology appraisals: report for guidance executive

Technology Appraisal	**TA139 – Sleep apnoea – continuous positive airway pressure**
Implementation input required by date	**08/08/2011**

1. Routine healthcare activity data

1.1 Hospital Episodes Statistics data

This section provides information on the uptake of continuous positive airway pressure (CPAP) for people diagnosed with sleep apnoea in England. CPAP does not currently have a procedure code; we have therefore used the data for non-invasive ventilation procedures. This data needs to be treated with caution as we have not been able to identify an exact procedure code for CPAP. Thus, the data could include other procedures that come under the heading 'non-invasive ventilation procedures'.

Figure 1 below shows the number of people diagnosed with sleep apnoea who have had a non-invasive ventilation procedure. The data are obtained from Hospital Episode Statistics (HES). The total number of episodes has been calculated from the main procedure, the first secondary procedure, the second secondary procedure and the third secondary procedure for each of the 4 years from 2006 to 2010.

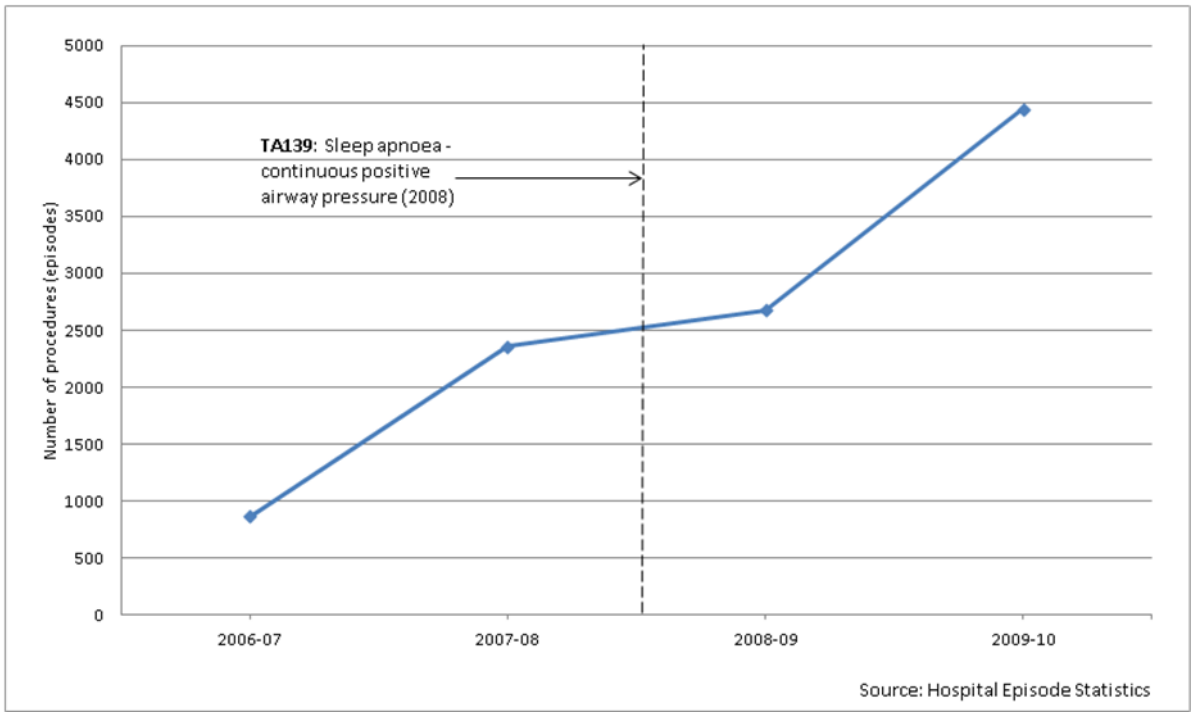

Figure 1 Number of non-invasive ventilation procedures (finished consultant episodes) performed for patients diagnosed with sleep apnoea in secondary care within the NHS

2. Implementation studies from published literature

Information is taken from the ERNIE website

Nothing to add at this time.

3. Qualitative input from the field team

The implementation field team has recorded the following feedback in relation to this guidance:

Nothing to add at this time.