NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

Daytime intraoral neuromuscular electrical stimulation of the tongue using a removable device, for obstructive sleep apnoea IP1906

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template, and ask if you would like to attend as a patient expert at the bottom of the form. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

About you	
1. Your name	**Kath Hope**
2. Name of organisation	Hope2Sleep Charity
3. Job title or position	Founder & CEO
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	We currently support over 19k patients with sleep apnoea, including all other forms of sleep disordered breathing, patients using CPAP and non-invasive ventilation, along with suspected sufferers of sleep apnoea, including benign snorers. Our primary funding comes from the sales of the products direct to patients and to the NHS clinics. We also receive funds via voluntary donations and grants/charity funding.

5. How did you gather the information about the experiences of patients and carers to help your submission?

   (For example, information may have been gathered from one to one discussions with colleagues, patients or carers, telephone helplines, focus groups, online forums, published or unpublished research or user-perspective literature.)

We have been involved with the eXciteOSA device (previously called 'Snoozeal') since its launch, and have also worked with the manufacture in carrying out some earlier testing – the results of which are on our website https://www.hope2sleep.co.uk/excite0sa-daytime-therapy-for-snoring-and-obstructive-sleep-apnoea.html I confirm that we do not receive any funding from Signifier Health, and any monies to our charity are gained only from sales of the product which we purchase from them.

As well as the earlier testing we helped with, due to selling the product we receive feedback direct from current and previous users of the eXciteOSA.

As an impartial registered charity, always working for the health of patients, we have also worked with another manufacturer of a similar electrical muscle stimulation device (Zeus) which differs as this is used as a therapy during sleep. Additionally we have also assisted Guy's & St Thomas during their TESLA trial (Randomised sham-controlled trial of transcutaneous electrical stimulation in obstructive sleep apnoea) https://pubmed.ncbi.nlm.nih.gov/27435610/

Living with the condition
6. What is it like to live with the condition or what do carers experience when caring for someone with the condition? Untreated sleep apnoea is a serious health risk for strokes, heart attacks and driving accidents, as well as causing or exacerbating many other health conditions, including mental health. However, in addition to these health risks, the symptoms of untreated sleep apnoea are hard to live with – the main ones being, constant daytime tiredness which can lead to depression, interrupted sleep and sleep deprivation leading to anxiety, brain fog, cognitive dysfunction, elevated blood pressure etc. As for carers and bed partners, a huge impact on them (especially if sleeping with the untreated patient) is that their own sleep is disturbed with both the snoring and the worry of laying next to someone they love hearing them repeatedly stop breathing.
Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are? Why do you consider it be to be innovative?

Advantages of the device, bearing in mind it will not work for everyone, are:-

- If a complete cure of sleep apnoea was achieved then CPAP would not be needed.
- If an improvement to the sleep apnoea was achieved rather than a cure, it could result in lower CPAP pressures or combination therapy of an alternative additional device, such as a mandibular advancement device (MAD) or positional therapy device etc.
- No CPAP or other therapy needed to sleep with.
- Daytime therapy (which is the eXciteOSA's main innovative feature), as well as treating the cause of the obstructive sleep apnoea (OSA) for those patients it will help.

8. Does this procedure have the potential to change the current pathway or patient outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

The actual pathway to diagnosis would not change, as patients will still need a sleep study for a diagnosis of sleep apnoea. However, if the device could be issued to patients from the NHS, then if a cure was achieved no other therapy would be needed, so patients would be pleased with the outcome and no regular hospital appointments would be required – just replacement mouthpieces supplied every 3 months and a new device when needed. However, a repeat sleep study would be recommended to check the device has actually cured the patient's OSA.

Disadvantages of the procedure or operation

9. What do patients (or carers) think the disadvantages of the procedure or operation are?

   The main disadvantages of the device are:-

   - The list of contraindications that may prevent a person using it.
   - It will only treat patients with OSA if the cause of sleep apnoea is the tongue or soft tissues at the back of the throat, whereas there are lots of different causes for sleep apnoea.
   - Unlike CPAP, there is no evidence on the eXciteOSA's app that apnoeas or hypopnoeas are not happening – or oxygen desaturations without a pulse oximeter, because a cease of snoring does not always mean no sleep apnoea. However, this is the same for many other alternative treatments such as MAD and sleep positional trainers etc.
   - It is expensive with ongoing costs if not supplied via the NHS.
   - Gagging and increased salivation in some patients.

Patient population
10. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why. Although CPAP is the gold standard treatment for OSA, there are some patients that struggle to use it, so this group would particularly benefit – as would those who find MAD or other therapies difficult.
Safety and efficacy
11. What are the uncertainties about how well this procedure works and how safe it is? Investigating the cause of the OSA would be advisable to ascertain if the device has a good chance of treating the patient. We can't comment on safety, which would be the responsibility of the manufacturer and hospital, but it is important a patient is not given the device if they have any of the contraindications listed.
Equality
10. Are there any potential equality issues that should be taken into account when considering this topic? If the device were to be approved as a viable therapy from the NHS, then it should be an option at all sleep clinics so that it can be accessed by all patients, irrespective of where they live.
Other issues
11. Are there any other issues that you would like the Committee to consider? If possible, any other similar devices would be worth considering under this Interventional Procedures Guidance - in particular the IQoro which is also a neuromuscular training device and a much cheaper device. We have no experience of the IQoro presently but NICE have undertaken two Medtech Innovative Briefings (MIB176 and MIB175) for its use for treating Hiatus Hernia and stroke-related Dysphagia, but we also understand it claims to treat snoring, sleep apnoea and reflux too.
Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.

1. Advantages of the device, bearing in mind it will not work for everyone; if a complete cure of sleep apnoea was achieved then CPAP would not be needed; if an improvement to the sleep apnoea was achieved rather than a cure, it could result in lower CPAP pressures or combination therapy of an alternative additional device, such as a mandibular advancement device (MAD) or positional therapy device etc; No CPAP or other therapy needed to sleep with; daytime therapy (which is the eXciteOSA's main innovative feature), as well as treating the cause of the obstructive sleep apnoea (OSA) for those patients it will help.

2. The main disadvantages of the device are; the list of contraindications that may prevent a person using it; it will only treat patients with OSA if the cause of sleep apnoea is the tongue or soft tissues at the back of the throat, whereas there are lots of different causes for sleep apnoea, unlike CPAP, there is no evidence on the eXciteOSA's app that apnoeas or hypopnoeas are not happening – or oxygen desaturations without a pulse oximeter, because a cease of snoring does not always mean no sleep apnoea. However, this is the same for many other alternative treatments such as MAD and sleep positional trainers etc; it is expensive with ongoing costs if not supplied via the NHS; gagging and increased salivation in some patients.

3. Although CPAP is the gold standard treatment for OSA, there are some patients that struggle to use it, so this group would particularly benefit – as would those who find MAD or other therapies difficult.

Committee meeting

13. Would you be willing to attend the interventional procedures committee meeting to provide the view from your organisation in person?

We understand this meeting is to be held online, and in this case we will be attending on Thursday, 13th October 2022.

Thank you for your time.

Please return your completed submission to helen.crosbie@nice.org.uk and ip@nice.org.uk.