

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.

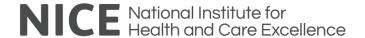


About you	
1. Your name	Chris Rogers
2. Name of organisation	Sleep Apnoea Trust
3. Job title or position	Managing Secretary
4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?)	The Sleep Apnoea Trust exists to improve the lives of sleep apnoea patients, their partners and families and is manages almost entirely by unpaid volunteers. We have 1500 members and their donations fund all our activities

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.)

Discussion with colleagues on the Committee.



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?

The majority sleep apnoea is generally treated by the patient using a CPAP machine and carers are only involved if they are very old, infirm or severely disabled. As a result of the new NICE guideline, we expect increasing numbers of those with moderate or mild OSA and intolerant to CPAP, to be treated using a mandibular advancement device or splint (MAD or MAS).

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?
 - If it works then it is minimally intrusive compared to current treatments of CPAP or MAD/MAS which have to be used continually when asleep. However, we understand from the manufacturers state that it is not suitable for moderate or severe OSA only mild.
- 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? If it works, yes.

Disadvantages of the procedure or operation

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

We have had no experience of this product at all.



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.

If it is effective for treating mild OSA it would benefit some of these patients

Safety and efficacy

11. What are the uncertainties about how well this procedure works and how safe it is? To our knowledge, there have not been any independent randomised controlled clinical trials to NHS standards carried out in the UK or EU. That means there is no peer reviewed published data on which to form an opinion.

Equality

10. Are there any potential <u>equality issues</u> that should be taken into account when considering this topic?

Cost

Other issues

11. Are there any other issues that you would like the Committee to consider?

As this product was formerly known as Snoozeal was publicised in 2018, we wonder why the manufacturer did not take the opportunity to comment during the evolution of the new NICE Guideline NG202. Two public consultation opportunities were provided, from May to June 2018 (maybe too early) and from 3rd Mar 2021 to 14th April 2021.

In addition, we have searched the European Respiratory Society and European Lung Foundation websites and cannot find any references at all to this product.

Finally, in the European Respiratory Society's Guideline on Non-CPAP therapies for OSA, again this product was not referred to at all. (*Randerath W, Verbraecken J, de Raaff CAL, et al. European Respiratory Society guideline on non-CPAP therapies for obstructive sleep apnoea. Eur Respir Rev 2021; 30: 210200 [DOI: 10.1183/16000617.0200-2021]*.

Key messages



- 12. In no more than 5 bullet points, please summarise the key messages of your submission.
 - 1. Are there any plans for an independent RCT to NHS standards on the eXcite OSA? Without that data, it is difficult for us to be convinced by the eXcite OSA's claims.
 - 2. We would like to know whether the company were aware of the NICE guideline NG202, that was published in Aug 2021 and the possibility of commenting on the draft guideline at its final public consultation from 03/03/2021 to 14/04/2021? If they were, why did they not comment?
 - 3. Was the company aware of the ERS guideline on Non-CPAP therapies that was in preparation during early 2021 for publication in Aug 2021? Again, why was their product absent?
 - 4. It seems that this device has been heavily promoted in the USA but the company has intentionally or unintentionally avoided two significant opportunities to subject its product to expert scrutiny in the UK and Europe
 - 5. The level of CPAP adherence on the UK is, we know from the "Getting it Right First Time" study, is widely variable between Sleep Clinics. This is being addressed with more focus on patient support during the first three months of commencement of CPAP therapy. Adherence rates are expected to rise to a significantly higher figure than at present.

Committee meeting

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

Yes, but preferably online with Covid infection rates on the rise again

Thank you for your time.

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