National Institute for Health and Care Excellence

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

IPAC date: 9th February 2023

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 BSDSM, BADSM	1.1	From my clinical experience with this therapy, I would strongly recommend that this therapy be assigned to Standard or Special arrangement. Patients need more alternatives to CPAP and Physicians need more treatment options other than the mainstream therapies available (CPAP, MADs, Surgery).	Thank you for your comment. The committee makes recommendations based on the assessment of published, peer-reviewed evidence on the safety and efficacy of individual procedures. The committee only considers unpublished evidence if it raises significant safety issues that are not reported in the published literature. For this procedure, the committee considered that more evidence is needed on patient selection, duration of treatment and effect, effect on snoring, quality of life, and complications, before changing it from 'research'.
2	Consultee 1 BSDSM, BADSM	1.2 & 3.1	Here, I comment as President of BSDSM, BADSM, & Odontology section at RSM. I serve on the Executive Committee of ARTP and BSS. I have recently been appointed to the Scientific and Education Committee of World Dentofacial Sleep Society	Thank you for your comment and for highlighting your own clinical experience and how in your experience this treatment has been helpful for certain patients.

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			My experience in the field of dental sleep medicine and the broader aspects of non-CPAP therapies spans over 15 years and has made me appreciate the need for therapies beyond CPAP, OAT and Surgery. The complicated underlying pathophysiology of SDB which is so much better understood now than 15 years ago, explains why many of the mainstream therapies fail or are only partially successful in their outcome. Failures or limited success of various therapies (tolerance, adherence effectiveness and side effects) may be attributed to lack of understanding of individual patient's phenotypic cause of the problem. In this regard, NMES has certainly helped me deal with so many of those patients who may not be able to accept, afford or adhere and/or be suitable for OAT and CPAP or indeed surgery in its various forms (soft tissue and skeletal). There is relevant real world clinical experience and evidence of this therapy's effectiveness and safety that the Committee must take into consideration. NMES of the tongue muscle is an instantly available therapy which can see a large number of presenting/waiting patients at the lower end of the spectrum of disease treated quickly and effectively possibly even slowing the disease progression. The NHS is overwhelmed and overburdened with patients requiring treatment that can be easily offered in primary care. This type of treatment can help take care of a large number of patients waiting long periods of time for appointments in secondary care. GMPs and GDPs can be first line professionals that a patient can reach out to. The therapy certainly has a place as primary and adjuvant therapy in the armamentarium required to manage over a billion sufferers globally. Based on the very low risk profile of the therapy, in the patient's awake state, the clinical data at hand and the real world experience should be	The committee considered your comment but decided not to change the main recommendation. The committee also noted this procedure is currently only indicated for mild obstructive sleep apnoea (as described in section 3.5) and was aware of the unmet need. Please see response to comment 1.

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			sufficient for this therapy to be included in that which is offered to these patients in the NHS.	
3	Consultee 1 BSDSM, BADSM	3.1	A complete picture of evidence should include clinical research as well as real world experience. In regard to my own extensive clinical experience, prescribing over 75 patients this therapy, my patients have reported a much better quality of sleep, leading to waking feeling less fatigued and satisfied with the solution prescribed.	Thank you for your comment. Please see response to comment 1
4	Consultee 1 BSDSM, BADSM	2.3	device is used to deliver neuromuscular electrical stimulation	Thank you for your comment. 'neuromuscular' has been added to section 2.3, *"in this procedure, an intraoral removable device is used to deliver* ***neuromuscular*** *electrical stimulation to the intrinsic and extrinsic (genioglossus) muscles of the tongue."*
5	Consultee 1 BSDSM, BADSM	3.1	In my cllinical experience having prescribed this therapy to over 75 patients, I have had only one tangible side effect that was reported by 14 patients, namely excessive salivary pooling. This was reported to abate after the first week or two of the start of therapy. None of the patients reported any adverse reaction to metal fillings, tongue soreness or tingling, no tooth discomfort, nor gagging once shown how to position the mouthpiece correctly. This real world evidence, over the past two years, prescribing this therapy to my patients, should be considered important evidence as to the safety of this therapy.	Thank you for your comment. Please see response to comment 1.
6	Consultee 1 BSDSM, BADSM	3.1	Please add these relevant Societies: British Society of Dental Sleep Medicine	Thank you for your comment.

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			British Academy of Dental Sleep Medicine Royal Society of Medicine, Odontology World Dentofacial Sleep Society ARTP	The societies suggested by the consultee have been added to the list of professional societies in the overview.
7	Consultee 2 NHS professional	3.1	A useful novel device for treating sleep related breathing disorders especially mild OSA. Device is simple, user friendly and most importantly not required to be in-situ during sleep. I have used this device to treat more than 150 patients who have reported a good treatment outcome overall. Patients and partners both report improved sleep quality parameters as well as improved daytime function. There has been a general improvement in quality of life parameters and in many cases the Epworth sleepiness score has improved tremendously. In some patients where the sleep study has been conducted before and after therapy, an improvement in AHI has also been noted. No adverse effects have been reported by my patients except for mild tingling sensation in the tongue for a few minutes whilst using it for the 20 minute period. This is much better when compared to some of the adverse effects caused by oral appliances e.g. dental problems, TMJ dysfunction etc. The compliance and adherence they report is much better when compared to other treatment modalities such as oral appliances or CPAP therapy which have to be utilised throughout the sleep period. In my patients suffering from mild OSA, I highly recommend this device as a primary treatment option bearing in mind lack of adverse effects, simplicity in using it and its reported effctiveness. In patients treated with other modalities such as mandibular advancement device or surgery where the patient still has residual symptoms, I have	Thank you for your comment and for sharing your own clinical experience. Please see responses to comments 1 & 2.

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			suggested the use of this device as an adjunctive treatment and have found this to be very useful in improving the patient's symptoms. In a few patients who are on CPAP therapy and finding the pressure too high due to a very retractile, bulky and relaxed tongue base I have suggested the use of this device as adjunctive treatment to improve the tone of the tongue muscles in the hope of reducing the CPAP pressure and some have found this to be useful too. I have found this device to be safe and effective in treating many of my patients with sleep related breathing disorders particularly those with mild OSA	
8	Consultee 3 NHS professional	3.1	This document is well written, and has summarised the background and evidence base well. I have prescribed ExciteOSA for a small number of patients (9 in total) over the last 18 months. Patients are most impressed by the fact that the device needs to be used only in the day time. The proceudre is simple. None of my patients reported any side effects that concerned them. None stopped treatment. Snoring improved in all and sleepiness improved as well. My cohort of patients have been pleased with the outcome with the device.	Thank you for your comment and for sharing your own clinical experience. Please see response to comment 1.
9	Consultee 3 NHS professional	3.1	I have used the device for patients who presented with heavy snoring with and without mild OSA (as defiened in this document).	Thank you for your comment.
10	Consultee 3 NHS professional	3.1	My patients have have found it easy to use the equipment. The main attractonj is that the equipment needs to be used only during the day.	Thank you for your comment.
11	Consultee 3 NHS professional	3.1	I have used Epworth score and verbal report form partners to guage effetiveness of therapy. Only two out of the nine patients in my group had excessive daytime sleepiness interfering with daytime function. Both reported significant improvement in sleepiness to the extent that they were no longer experieincing problems at work. When snoring is no longer	Thank you for your comment and for sharing your own clinical experience. Please see response to comment 1.

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			bothering the parter and he/she is able to resume sleeping on the patient's bed, I consider it significant improvement. This has been the case with my patients.	
12	Consultee 3 NHS professional	3.1	This list inlcudes all the relevat professionla societies. I note that the Professional Expert Questionnaire was completed by a specialist with no experience in the use of this device and had not even heard of the device. I am not sure of the wisdom of seeking the opionon of those who have no knowledge of the device. The usefulness and validity of this opinon are doubtful.	Thank you for your comment. NICE seeks the opinions of as many professional experts as are deemed appropriate for the procedure to get balanced opinions. The committee considered all professional expert questionnaires alongside other evidence included in the overview in their deliberations.
13	Consultee 3 NHS professional	3.4	The submission form Hope2Sleep Charity presents a patient friendly viewpoint.	Thank you for your comment.
14	Consultee 4 NHS professional	1.1 & 3.1	I think it's fair to say there is inadequate evidence as yet to promote this treatment. Yet, I think because we are so poor at treating heavy snoring/mild OSA, it is very important that we explore other options. I have used the device clinically and have experienced no safety issues and very good results objectively (reduction in AHI) and subjectively (partners reported snoring). I accept this is anecdotal evidence.	Thank you for your comment and for sharing your own clinical experience. Please see response to comment 1.
15	Consultee 5 NHS professional	3.1	Recently, I recommended ExciteOSA to 12 patients up to date. This device uses electrical muscle stimulation to help improve sleep apnoea and reduce snoring. The device consists of a small unit that is connected to a mouthpiece. The mouthpiece is placed in the mouth and delivers electrical stimulation to the muscles in the tongue, which can help to strengthen and tone these muscles and improve airflow during sleep. Overall, all the patients found the device comfortable, efficacious, and safe. Four reported a noticeable reduction in snoring within a week of using the device. Some even said that their sleep partners noticed fewer breathing interruptions, and patients noticed better sleep quality after using	Thank you for your comment and for sharing your own clinical experience. Please see response to comment 1. Cost-effectiveness is not part of the remit of the IP programme.

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			ExciteOSA. Four patients with mild OSA were used before mandibular advancement devices. They found them uncomfortable or difficult to use, making it harder to stick with the treatment. After a trial with ExciteOSA, all four commented that they appreciated how easy the device was to use, with no complicated setup or preparation required. Additionally, many found ExciteOSA more convenient, as it is easy to use and can be taken with you when travelling. Overall, the group was pleased with their experience using the device and would recommend it to others looking for a safe and effective way to improve mild OSA and reduce snoring. Compared to other widely used alternatives, I find the device cost-effective and safe in indicated patients.	
16	Consultee 6 British Thoracic Society	1.1	BTS is in agreement with the recommendations proposed.	Thank you for your comment.
17	Consultee 6 British Thoracic Society	3.1	Page 4, in the paragraph defining ODI. On line 3 of this paragraph 'ODI is considered abnormal' is in our view wrong. Suggest 'oxygen saturation' instead.	Thank you for your comment. 'ODI' has been changed to 'oxygen saturation'.
18	Consultee 6 British Thoracic Society	3.1	British Thoracic Society (remove of England)	Thank you for your comment. 'of England' has been removed.
19	Consultee 7	3.1	Nokes et al, June 2022, study should be not be overlooked in the Appendix. The mechanistic study included 12 mild-mod OSA patients, measuring pre-/post- with in-clinic PSG. Secondary outcome data on AHI, including responder analysis, is similar to the multi-center trial results with >50%	Thank you for your comment.

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	Signifier Medical Technologies		average reduction in AHI. If interested, the investigator can provide data directly.	Studies in the appendix are also included and all evidence in the overview was considered by the committee in their deliberations. This was a mechanistic clinical investigation, assessing the physiological effects of transoral neurostimulation on genioglossus activity and markers of inspiratory flow limitation. Also, the paper did not clearly state the number of patients with mild OSA and did not report the relevant outcomes separately (as detailed in the appendix of the overview).
20	Consultee 7 Signifier Medical Technologies	3.2	The committee may wish to include "adherence" as an important variable to efficacy. Real-World Evidence: Signifier published an Adherence White Paper showing on >3,500 patients an 81% average adherence. https://exciteosa.com/wp-content/uploads/2022/09/eXciteOSA-AdherenceAnalysis_WhitePaper_2022_v3.pdf	Thank you for your comment. Section 1.2 states that further research should assess efficacy, safety and adherence. 'Adherence' as a variable has been added to the key efficacy outcomes.
21	Consultee 7 Signifier Medical Technologies	3.4	The committee can find UK patient reported outcomes on uk.trustpilot.com: https://uk.trustpilot.com/review/uk.exciteosa.com?utm_medium=trustbox&utm_source=MicroTrustScore	Thank you for your comment. The information provided by the consultee does not meet the inclusion criteria.
22	Consultee 7	3.4	Patient responses available via independent TrustPilot reviews of eXciteOSA -- https://uk.trustpilot.com/review/uk.exciteosa.com?utm_medium=trustbox&utm_source=MicroTrustScore.	Thank you for your comment.

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	Signifier Medical Technologies			The information provided by the consultee does not meet the inclusion criteria.
23	Consultee 8 NHS professional	2.2	Tongue base obstruction is a common cause of Obstructive Sleep Apnoea and its difficult to manage. The traditional methods like Mandibular Advancement device has not proved to be affective.	Thank you for your comment.
24	Consultee 8 NHS professional	3.1	The Excite OSA device can be used to treat patients with Mild OSA. I have trialed this device for 20 of my NHS patients with mild OSA. The device was tolerated well by all patients with no side effects. I reviewed all these patients again after they used the device for 12 weeks and there was significant improvement in these post-device scoring which showed that it has very good benefits in the treatment of OSA and quality of life.	Thank you for your comment and for sharing your own clinical experience. Please see response to comment 1.
25	Consultee 8 NHS professional	General	Based on this short trial and getting an encouragement from the results of my initial study I am now in the process of writing up a Business case to get this device available to all my NHS patients who have mild OSA	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."