NICE advice

Noctura 400 Sleep Mask for diabetic retinopathy and diabetic macular oedema

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Noctura 400 Sleep Mask. It is used for treating diabetic retinopathy (DR) and diabetic macular oedema (DMO).
- The **innovative aspects** are that it is a non-invasive treatment that delivers light to the backs of the eyes while a person is sleeping or in a darkened room.
- The intended **place in therapy** would be as an add-on treatment, alongside intravitreal injections of anti-vascular endothelial growth factor hormones or laser photocoagulation in people with late-stage DR or DMO, or as a preventative measure in people with early-stage DR.
- The **main points from the evidence** summarised in this briefing are from 4 observational studies using different versions of the device (2 in the UK, 2 in Europe) including 151 adults in secondary care. They show that Noctura 400 Sleep Mask is a usable technology for people with DMO and mild to advanced non-proliferative DR, as

well as early proliferative DR.

- **Key uncertainties** around the evidence are that it is very limited in quantity and quality, with no randomised comparative studies assessing the effectiveness of Noctura 400 Sleep Mask compared with standard care. Cost-effectiveness studies are also needed.
- The **cost** of Noctura 400 Sleep Mask is up to £1,250 per patient per year (excluding VAT). The overall **resource impact** is uncertain compared with standard care because of the lack of comparative evidence. There is no published evidence assessing the cost effectiveness of Noctura 400.

The technology

Noctura 400 Sleep Mask (Polyphotonix Medical) is for people with DR and DMO. The mask should be worn over the eyes during sleep for as long as the person is in darkened conditions, up to a maximum of 8 hours each night. It contains 2 organic light-emitting diodes (OLEDs) in thick glass behind acrylic lenses. The OLEDs emit a dose of light at a particular wavelength into the wearer's eyes.

The main purpose of the mask is to stop or slow the production of vascular endothelial growth factor (VEGF). VEGF causes new blood vessels in the eye to grow; these are weak and leak fluid (oedema) into the macula. The macula is the area of the retina responsible for the clearest vision. Fluid leaking into the eye can cause scarring and cell loss and if left untreated may lead to significant loss in vision or permanent blindness. The Noctura wavelength is selected to target rod photoreceptors in the retina; this may prevent rod cells from adapting to the dark. This is designed to reduce the need for the additional oxygen, which would otherwise be needed by the dark-adapted eye. It also reduces the risk of nocturnal retinal hypoxia in the diabetic eye.

The moulded acrylic window in a Noctura 400 Sleep Mask keeps the OLEDs away from the eyelids. The OLEDs are powered by 2 coin-cell batteries attached to printed circuit boards, housed in a padded fabric mask held in place over the eyes with a fabric strap and fastener. The mask records data on use and compliance for 8 hours each night over a 12-week period. The data recorded are retrieved by placing the mask in a reader device containing PPX Works software. The reader is programmed to each person's normal sleep pattern and has a 14-hour operational window. Noctura 400 Sleep Mask is partially recyclable, and is replaced after each 12-week period. The data stored on the reader are

then analysed. As the sleep mask is designed to prevent DR, people using it would generally continue to have this treatment indefinitely.

Innovations

Noctura 400 Sleep Mask is a non-pharmacological, non-invasive treatment that delivers light to the back of both eyes while the person is sleeping. If used in the early stages of DR it may slow down or even stop the condition from worsening. At present, when early-stage DR is detected there are no treatment options available other than monitoring until the disease reaches a sight-threatening stage.

Current NHS pathway or current care pathway

People with diabetes should have an eye screening test at least once every year as part of the English national screening programme for DR (see NICE's guidelines on type 1 diabetes in adults: diagnosis and management and diabetes (type 1 and type 2) in children and young people: diagnosis and management, as well as the Royal College of Ophthalmologists guidelines on DR). The frequency of screening depends on the presence and severity of DR or DMO. At the first screening appointment, photographs are taken of the retina, and are graded. If there is no retinopathy, or very early changes, then the person is recalled for another photograph in 1 year. If pre-proliferative changes or non-sight-threatening maculopathy are detected, the person may be referred to hospital or clinic for more frequent review. If the condition progresses to a more advanced or proliferative stage, treatment is offered every 2 to 4 weeks.

Treatment consists of laser photocoagulation of the leaky blood vessels for DR and intravitreal injections of anti-VEGF (see NICE's technology appraisal guidance on ranibizumab and pegaptanib for age-related macular degeneration) or steroids (see NICE's technology appraisal guidance on dexamethasone intravitreal implant) for DMO. If DMO does not respond to non-corticosteroid treatment, intravitral implants of dexamethasone are an option for eyes with an intraocular lens.

Population, setting and intended user

Noctura 400 Sleep Mask is designed for use at home by people with diabetes at any stage. If adopted by the NHS, the Noctura 400 Sleep Mask could be used as part of a preventative strategy in primary care in people with no evidence of retinopathy or, more

likely, for people with late-stage DR and DMO. For people with late-stage DR or DMO, clinical ophthalmologists would prescribe Noctura 400 Sleep Mask in a secondary care, outpatient setting.

Costs

Technology costs

Table 1 Costs associated with Noctura 400 Sleep Mask

Description	Cost	Additional information
Noctura 400 Sleep Mask	**Unprogrammed masks:** £172 for 12 weeks (4 to 5 per year). Total annual cost, £688 to £860 per person. **Preprogrammed masks:** £197 for 12 weeks (4 to 5 per year). Total annual cost, £788 to £985 per person.	People will need up to 5 masks per year. Unprogrammed masks are supplied in batches of 20.
Computer, PPX Works software licence and 1 day of set-up and training	£600	One-off set-up cost for clinics using unprogrammed masks. Fee includes a lifetime software license; no renewal fees are charged.
Cost of an outpatient appointment (1 per year)	£53 per appointment; total annual cost £212 to £265 per patient (4 to 5 appointments per year).	–

All patients need a new mask every 12 weeks and the company recommend a face-to-face

review each change, although this is subject to clinical judgement. This equates to a patient getting up to 5 masks and outpatient appointments per year.

There are 2 purchasing options for the mask:

- Unprogrammed masks are slightly cheaper and need programming by NHS staff before use. They are subject to an additional one-off set-up cost for individual clinics; the cost per patient will be dependent on the size of the clinic. The total annual cost per patient for this approach is £900 to £1,125 (excluding the programming cost; dependent on number of masks needed per year).
- Preprogrammed masks are set-up by the company and sent directly to patients with no clinic set-up costs. The total annual cost per patient for this option is £1,000 to £1,250.

Costs of standard care

The total cost of intravitreal anti-VEGF injections for DMO in 1 eye is £6,536 per patient per year (based on £550 for cost of treatment; £267 per day-case appointment; and an average of 8 treatments per year). The corresponding total cost of treatment of both eyes is £10,936 (assuming both eyes are treated at the same appointment). The cost of laser photocoagulation is £138 per procedure and people would also need monitoring clinic visits, up to 4 per year for those with proliferative DR at a cost per visit of £84 (Royle et al. 2015). These costs were inflated from 2012/13 to 2016/17 prices using the hospital and community health services index (PSSRU 2017).

Resource consequences

Using Noctura 400 Sleep Mask would represent an additional cost to the NHS. If any treatment were shown to prevent or slow the progression of early-stage DR, then it may reduce interventions, such as intravitreal injections, which would lead to NHS savings. Similarly, if shown to be as effective as current interventions, Noctura Mask 400 could save money. However, there is currently no evidence to support these assumptions. In particular, there is no evidence of the effectiveness of the mask in people with late-stage DR or DMO and no formal cost-effectiveness analysis has been done comparing Noctura 400 Sleep Mask to current standard care.

Adopting Noctura 400 Sleep Mask is not expected to have a significant effect on NHS

facilities or infrastructure, aside from the need for one-off training for eye clinicians that the company estimates takes no more than 1 day. Additional staff training would be needed on using Noctura 400 Sleep Mask and, depending on the supply model that the hospitals selects, instruction in programming it. The company estimates that about 2 nurses per hospital would need training, which would last for either 1 to 2 hours or 1 day, depending on the level of training that was needed.

Regulatory information

Noctura 400 Sleep Mask is CE marked as a class IIa medical device.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

People who are registered as blind or partially sighted, as well those who are not registered but whose sight loss has a substantial and long-term effect on their ability to carry out day-to-day activities are considered disabled. Disability is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in line with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five observational studies are summarised in this briefing, including 166 patients. One study included patients with DMO and a cohort of healthy volunteers (Sahni et al. 2017). These participants used Noctura 400 Sleep Mask, which exposes both eyes to light. In a second study, patients with DMO with either advanced non-proliferative or early proliferative DR also used Noctura 400 Sleep Mask (Kuchynka et al. 2017). A third study, for which only an abstract was available, was a retrospective review of patients with diabetes (some of whom had no retinopathy) who used the mask over a period of 16 months (Ng et al. 2017).

An earlier version of the mask, known as the Arden mask, was used in 2 further studies with a total of 46 patients (Arden et al. 2010; Arden et al. 2011). Unlike Noctura 400 Sleep Mask, the Arden mask only exposed 1 eye to light, so patients in these studies acted as their own controls (that is, the eye exposed to the light through the mask was assessed against the other eye that was not exposed). Aside from this difference, the Arden mask appears to be functionally very similar to the Noctura 400 and so this evidence was judged to be relevant.

Table 2 summarises the clinical evidence, as well as its strengths and limitations. Two of the studies using Noctura 400 Sleep Mask reported some small improvements in retinal thickness (Sahni et al. 2017) and best corrected visual acuity (Kuchynka et al. 2017). These studies focused largely on safety and usability of the mask and no other changes in vision were observed. Some adverse events associated with the mask were reported, including eye soreness and eyelid swelling, itchy and dry eyes and general discomfort when wearing the mask. The third study reported limited data as it was an abstract only, but showed no progression of retinopathy (measured through retinopathy grading and best corrected visual acuity) over the course of follow-up.

The 2 studies using the Arden mask also reported small improvements in retinal function following mask use. One study showed a reduction in thickness of the zone of maximal oedema, a reduction in the number of intraretinal cysts and improvements in visual acuity in treated versus untreated eyes in patients with mild DR (Arden et al. 2011). The other study showed an improvement in colour vision (tritan thresholds) associated with the Arden mask (Arden et al. 2010). Neither study reported any adverse events or complications.

Overall assessment of the evidence

The evidence for Noctura 400 Sleep Mask comes from 5 studies, 2 of which used a predecessor of the mask. The evidence gives a limited indication that Noctura 400 Sleep Mask may provide beneficial effects to patients with mild, non-proliferative DR and DMO, or prevent progression of these conditions in patients with diabetes who do not currently have DR or DMO. No evidence has been presented for treating patients with diabetes with advanced (proliferative) DR or DMO.

However, the study populations were limited, both in the number of patients included and the severity of disease. Only 1 study compared outcomes in patients using the mask against a group of healthy controls, and none compared treatment with the mask against other available therapies. The outcomes in the study were mainly measures of safety and usability and intermediate or proxy outcomes for retinal function, such as retinal thickness. This meant that the reported results were largely limited to the technical success of the mask, rather than any more patient-centred outcomes.

A high-quality randomised control trial is needed to support the use of this technology. Studies are also needed on the cost effectiveness of the technology compared with standard care, particularly for laser photocoagulation.

Table 2 Summary of included studies

Arden et al. 2010	
Study design and population	A 2-centre observational study in Germany and Turkey, including 12 patients with mild to moderate non-proliferative DR.
Intervention(s) and follow-up	Arden mask (1 eye treated, 1 eye used as control), worn every night for 1 year in the German patients and 3 months in the Turkish patients (patient numbers in each country not reported).

Arden et al. 2010	
Results	**Retinal function** **Colour vision:** In 9/10 patients there was improvement in tritan thresholds in treated versus untreated eyes: Mean (SD) in micrometres at baseline, 6.7 (1.9) versus 8.8 (6.0); mean (SD) at study end, 6.5 (1.4) versus 10.0 (7.0); p=0.03. Protan thresholds remained unchanged throughout the study in treated versus untreated eyes: Mean (SD) at baseline, 2.9 (0.67) versus 3.19 (1.05); mean (SD) at study end, 2.95 (0.56) versus 3.17 (1.04); p=0.359. **Dark retinal anomalies (microaneurysms, dot haemorrhages):** Fundus photography showed that areas of dark anomalies (as a proportion of total retinal area), indicating microaneurysms and/or dot haemorrhages, decreased in treated eyes over the course of the trial: Mean (SE) at baseline, 1.31% (0.73%); at study end, 0.73% (0.45%); p=0.07 (n=11). Areas of dark anomalies increased in untreated eyes: Mean (SE) at baseline, 0.69% (0.41%); at study end, 0.92% (0.37%). The binomial probability that treatment was ineffectual and these differences were because of chance was calculated as 0.01. **Safety/patient experience** No patients reported any ocular or systemic complications during the study.
Strengths and limitations	**Strengths:** Use of statistical analysis. **Limitations:** Small number of patients; inconsistent follow-up, no true control group (non-treated eye used).
Arden et al. 2011	
Study design and population	A single-centre observational study in the UK, including 34 patients with mild non-proliferative DR and early untreated DMO.
Intervention(s) and follow-up	Arden mask (1 eye treated, 1 eye used as control), worn every night for 6 months. Follow-up after 3 and 6 months of wear.

Arden et al. 2010	
Results	**Retinal function** **Thickness:** Swelling increased in 8 and 16 treated and untreated eyes respectively, and decreased in 26 and 18 eyes respectively. Mean (SD) macular cube thickness for treated eyes and untreated eyes at baseline was 282 (51) micrometres and 278 (25) micrometres respectively, and changed insignificantly after 6 months of wear to 279±16 micrometres and 279±22 micrometres respectively. The authors attribute this to the fact that DMO was localised. There were significant changes in the thickness of the zone of maximal oedema over 6 months. Months 1 to 6: mean (SD), 12.0 (23.8) micrometres; p=0.01. Months 1 to 3: mean (SD), 9.1 (21.9) micrometres; p=0.01. Months 3 to 6: mean (SD), 7.6 (22.7) micrometres; p=0.04. The difference between mean change in the treated eye and mean change in the untreated eye was -13 (95% CI, -17.5 to -7.2) micrometres p=0.052, suggesting that thickness in the treated eyes reduced to a greater extent than in the untreated eyes. There were no significant changes in the thickness of the central subfield zone over 6 months. Months 1 to 6: mean (SD), 5.9 (34.2) micrometres; p=0.18. Months 1 to 3: mean (SD), 6.3 (28.9) micrometres; p=0.13. Months 3 to 6: mean (SD), 7.7 (47.8) micrometres; p=0.20. However, the difference between mean change in the treated eye and mean change in the untreated eye was significant: -11 (95% CI, -14.7 to -6.9) micrometres ; p=0.026). **Cysts:** 28 treated eyes and 9 untreated eyes had intraretinal cysts at baseline. After 6 months of wear, 9 of the cysts in treated eyes had disappeared or reduced considerably, while the number of untreated eyes with cysts increased to 20. **Visual acuity:** At baseline, there was no statistically significant difference in acuity (ETDRS letters) between treated eyes and untreated eyes: Mean (SD), 78.04 (7.80) and 76.52 (8.10) respectively; p=0.39. However, after 6 months there was a statistically significant difference in acuity, indicating improvements in the treated eyes: mean (SD), 80.18 (5.32) and 74.59 (8.52) respectively; p=0.001. This is just below the threshold for clinical significance (5 letters). **Contrast sensitivity:** At baseline, there was no statistically significant difference for CS (Pelli-Robson) between treated eyes and untreated

Arden et al. 2010	
	eyes: mean (SD), 31.71 (5.38) and 30.16 (4.71) respectively; p=0.214. However, after 6 months there was a non-statistically significant difference in CS, indicating improvements in the treated eyes: Mean (SD), 33.14 (4.57) and 30.50 (4.95) respectively; p=0.054. **BCVA:** 10/13 patients with BCVA <80 in the treated eyes at baseline improved by 5 letters or more. For untreated eyes, 3/9 patients with BCVA <80 at baseline improved, while 6 remained unchanged and 3 deteriorated by >3 letters. **Safety/patient experience** No patients reported any adverse events, mood alteration or difficulties with wearing the mask or sleeping.
Strengths and limitations	**Strengths:** Use of statistical analysis. **Limitations:** Low patient numbers; masks had a high failure rate (light not administered continuously); untreated eyes used as the control and were not equal in all respects at baseline to treated eyes (number of cysts and thickness of ETDRS zone 1).
Kuchynka et al. 2017	
Study design and population	A single-centre, prospective, open-label clinical trial conducted in the Czech Republic, including 45 patients with DMO.
Intervention(s) and follow-up	Noctura 400 Sleep Mask, worn every night for 6 months. Patients received new masks monthly. Patients had either advanced non-proliferative or early proliferative DR.

Arden et al. 2010	
Results	**Safety/patient experience** **Adverse events:** No major safety issues relating to using the mask were identified. However, a minority of patients reported mask discomfort, rubbing of straps and other design-related issues. Results from a patient questionnaire showed that 23% found the mask uncomfortable, 14% reported sleeping difficulties that were beyond what they had experienced before mask wear, 14% found the mask light intrusive, and 9% experienced new trouble falling asleep. Three (7%) patients left the trial early because of light intolerance or mask wear intolerance. An additional 3 patients left the trial because of severe adverse events that were judged not to be related to the mask (4 further patients left the trial for unknown reasons). **Treatment compliance:** Most patients wore the mask nightly, but mask wear generally fell short of the 8 hours available. Mean nightly mask use was 4.96 (SD=2.97) hours. Two patients wore the mask for mean periods of less than 2 hours per night. There was a downward trend in mask wear after 3 months of use, although this was not statistically significant. **Patient experience:** After 6 months of mask wear, 26% patients felt that they were not willing to continue wearing the mask and 23% were unsure whether they were willing to continue wearing the mask. **Retinal function** BCVA improved following 13% to 14% over 6 months of mask wear. The results of the OCT of CST over 6 months were mixed with 38.8% of eyes examined showing improvement, 29.9% remaining the same and 31.1% deteriorating. Overall there was thinning of the CST from before the trial by 12 micrometres and 27 micrometres for the left and right eye respectively.
Strengths and limitations	**Strengths: -** **Limitations:** One of the authors acts as a medical and scientific adviser to the company; patients received new masks monthly, but it is generally assumed that masks are changed every 12 weeks in clinical practice (in line with the company's instructions); no control group.
Ng et al. 2017	

Arden et al. 2010	
Study design and population	A retrospective review of clinical data conducted in the UK, including 15 patients with diabetes with at least 1 year of follow-up.
Intervention(s) and follow-up	Noctura 400 Sleep Mask, worn for an average of around 18 months. Patients self-funded use of the mask.
Results	**Retinal function** **BCVA:** 74±18 and 67±28 in the right and left eyes respectively, at baseline. After 8 months of using the mask, BCVA was 77±15 and at month 16 it was 72±19. **Retinopathy grading:** ranged from R0M0 (no retinopathy) to R3sM1P1 (stable treated retinopathy) at baseline, and remained stable throughout the study. **Safety/patient experience** No significant safety signal was detected. Mean nightly duration of mask use was 5 hours 11 minutes per night (65% of the 8-hour illumination provided by the mask).
Strengths and limitations	**Strengths:** Use of real-world data. **Limitations:** Low patient numbers; abstract only presented so more detailed results (for example, statistical analysis) are not available; possibility of response bias as patients in a self-funded pilot of the mask may be more motivated and, therefore, more likely to show compliance.
Sahni et al. 2017	
Study size, design and location	A single-centre, prospective, longitudinal safety study conducted in the UK, including 60 patients. 15 patients with DMO (group C) and 45 healthy controls (group A, 21 patients aged 18–30 years; group B, 24 patients aged 50–70 years).
Intervention and comparator(s)	OLED sleep mask (Noctura 400 Sleep Mask, Polyphotonix Medical Ltd), worn every night for 3 months.

Arden et al. 2010	
Key outcomes	**Retinal function** **Thickness:** In the DMO group, there were significant changes in mean thicknesses per 1 micrometre change in baseline thickness for CST and maxST at 3 and 4 months. CST: month 3, -0.77 micrometres, p<0.001; month 4, -0.79 micrometres p<0.001. MaxST: month 3, -0.44 micrometres ,p=0.05; month 4, -0.62 micrometres, p<0.01.**Cysts:** 10/15 (67%) patients in the DMO group showed a reduction/clearance of cysts in the maximum pathology subfield. **Other measures of vision:** No significant change was detected in DMO patients after 3 months of wear in CCT, BCVA, mfERG or EOG (change measured at 4 months). However, a small, but statistically significant change was observed for CS (letters), p=0.01. **Safety/patient experience** **Loss of concentration/alertness caused by sleep deprivation:** Performance in a psychomotor vigilance test (reaction time and number of lapses) deteriorated in the healthy control groups after 3 months. Patients in the DMO group had poorer performance at baseline, but showed no statistically significant change during the study. **Psychological wellbeing:** GHQ12 scores in all groups worsened in after 3 months (Group A -28.0%,p=0.01; group B -21.2%, p=0.03; group C -12.7%, p<0.05). **Adverse events:** 75% participants in the healthy control groups and 40% in the DMO group who wore the sleep mask for ≥1 month reported ≥1 adverse event. The most common were: eye soreness (n=5; 5 healthy controls, 0 DMO patients); eyelid swelling (n=4; 4 healthy controls, 0 DMO patients); itchy eyes (n=4; 3 healthy controls, 1 DMO patient); and dry eyes (n=3; 2 healthy controls, 1 DMO patient). Events were mostly attributed to the fabric mask. One serious adverse event occurred that was deemed unlikely to be related to the mask. **Sleep disturbance:** 6 patients in the healthy control groups withdrew before study completion because of light intolerance and sleep disturbance caused by the mask. No patients in the DMO group withdrew for this reason (although 2 did withdraw: 1 following an unrelated medical event, and 1 for no reason provided).

Arden et al. 2010	
Strengths and limitations	**Strengths:** Prospective study design; use of statistical analysis. **Limitations:** Relatively low patient numbers; no comparison with standard care for DMO, or with no mask wear; high number of study withdrawals (16/60).

Abbreviations: BCVA, best corrected visual acuity; CCT, Cambridge colour vision test; CS, contrast sensitivity; CST, central subfield thickness; DMO, diabetic macular oedema; DR, diabetic retinopathy; EDTRS, Early Treatment Diabetic Retinopathy Study; EOG, electrooculogram; GHQ12, General Health Questionnaire of psychological wellbeing; maxST, mean thickness of subfield with maximal pathology; mfERG, multifocal electroretinogram; OLED, organic light-emitting diode; SD, standard deviation; SE, standard error.

Recent and ongoing studies

A search on clinicaltrials.gov identified the following ongoing trial:

- Noctura400 treatment for diabetic retinopathy (CANDLE). Multicentre, interventional, randomised, parallel assignment, open-label trial (patients receiving ranibizumab only versus experimental: Noctura 400 with ranibizumab) ClinicalTrials.gov identifier: NCT02207712. Status: Ongoing. Device: Noctura 400.

One ongoing study was identified through citation searching during study selection:

- CLEOPATRA study: the clinical efficacy and safety of light-masks at preventing dark adaptation in the treatment of non-centre-involving diabetic macular oedema ISRCTN85596558. Status: Completed. Device: Noctura 400.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 of the specialist commentators who provided comments were familiar with or had used this technology before.

Level of innovation

All commentators thought that Noctura 400 Sleep Mask was a novel technology, and 1 highlighted that there was no other treatment available for DR that used this approach. One commentator emphasised that the mask would be used as an add-on therapy for DR, including macular oedema, but could also have a role in preventing the progression of DR. One commentator noted that the mask represented a potentially significant contribution to existing management of patients with pre-clinical or established DR and/or DMO but the precise levels of benefit and patient populations in which the mask should be used were yet to be established.

Potential patient impact

All 3 commentators remarked that the mask has the potential to generate significant benefits to non-proliferative DR to stop progression and the subsequent loss of vision. One commentator added that the mask may benefit patients with proliferative DR and/or DMO but more evidence of benefit is needed. Two commentators stated that the mask would be particularly beneficial for people under 65 as they may have mild, non-proliferative DR. One commentator highlighted that use of the mask should not replace good diabetic control as this is necessary to reduce the risk of complications.

One commentator noted that patients would need to be compliant in order to see the progression of the condition slowed. If that were to happen, fewer hospital visits and invasive treatments (for example, photocoagulation) would be needed. A second commentator added that if use of Noctura 400 led to a reduction in invasive treatments (for example anti-VEGF injections) this would significantly reduce the burden on patients and could lead to improved visual outcomes. The commentator agreed that using the mask could potentially significantly reduce the number of hospital visits needed.

Potential system impact

Two commentators stated that use of the mask would likely have a positive effect on NHS services by reducing the number of people referred to hospitals and the number of treatments for progressive DR.

The commentators thought that some changes to NHS facilities may be needed. Two commentators noted that a monitoring system would be necessary, and suggested that

this could be done through virtual clinics and digital surveillance services, which are already set-up in some centres. One commentator suggested that minor changes to process would be needed to provide patients with training on using the mask and discussing the importance of compliance. They added that a system for disposing of the mask and its batteries would also be needed. Another commentator thought that use of the mask could be integrated into present infrastructure very easily as the mask could either be incorporated into the current diabetic screening programme or could be managed by hospital services when patients were attending clinics. The specialist suggested that, depending on the numbers of prescriptions, extra staff may be needed to programme the masks, although they would expect this to be done by the company.

One commentator highlighted that the mask would lead to cost savings if it was effective, which they believed had not been shown yet. Another thought that it was difficult to evaluate the potential cost savings with no significant trials or cost-effectiveness information available.

General comments

Two of the specialists highlighted the potential of the Noctura 400 Sleep Mask, if it is proven to be effective, to transform current management of DR and DMO. The results of the ongoing CLEOPATRA and CANDLE studies are needed before further decisions on the potential use of the mask in clinical practice are made. They added that the concerns over potential sleep deprivation and effects on psychomotor vigilance tasks - such as the speed at which people respond to stimuli - and psychosocial wellbeing needed further investigation.

One commentator remarked that the mask hasn't been evaluated in late-stage proliferative DR so it may not be clinically effective in that group. One commentator noted positive feedback from a small number of people with DR who could self-fund the mask.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr David Steel, consultant ophthalmologist, Sunderland Eye Infirmary. Did not declare any interests.

- Miss Daniela Vaideanu-Collins, consultant ophthalmic surgeon, James Cook University Hospital Middlesborough. Miss Vaideanu-Collins is involved in a clinical evaluation of the mask, but has no financial benefit.
- Mr Ian Pearce, consultant ophthalmologist and director of the Clinical Eye Research Centre, Royal Liverpool University Hospital. Mr Pearce has conducted paid work for the commercial healthcare sector, none of which involved the mask under review.

Development of this briefing

This briefing was developed for NICE by Newcastle and York External Assessment Centre. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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