

Ambulight PDT for the treatment of non- melanoma skin cancer

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

- 1.1 Ambulight PDT offers a means of delivering photodynamic therapy (PDT) for patients with small non-melanoma skin cancers in an ambulatory care setting, including patients' homes, and its use may be associated with less pain than conventional PDT. However, the case for routine use of Ambulight PDT in achieving a more efficient service is not supported by the evidence submitted by the manufacturer. The quantity of clinical evidence on its use is limited and the cost consequences of adoption, when compared with conventional PDT, ranged from a saving (per patient) of £195 to a cost increase of £536. NHS organisations should take this into account, alongside other features of the technology, when considering whether to use Ambulight PDT.

2 The technology

Description of the technology

- 2.1 The purpose of the Ambulight PDT device (Ambicare Health Ltd) is to deliver PDT to treat non-melanoma skin cancer in an ambulatory setting, including patients' homes in selected cases.
- 2.2 Ambulight PDT comprises a small single-use light-emitting device (containing its own red light source generated by a diffuser and a series of light-emitting diodes), which is connected by a lead to a pocket-sized battery. This light-emitting device sticks to the skin using a disposable plaster, 3 cm in diameter, worn directly over the treatment site. The battery can be carried in a pocket, attached to a belt or worn around the neck. The device is designed to treat single lesions that are smaller than 2.4 cm in diameter.
- 2.3 Before delivering Ambulight PDT, a photosensitising pro-drug is applied as a topical cream to the treatment site, where it is absorbed and metabolised to the active photosensitiser over a 3-hour period. Photodynamic therapy is then delivered for 3 hours. The light source emits the same dose and wavelength of light as in conventional PDT but the intensity is reduced and the light is administered over a longer period of time.
- 2.4 Depending on the indication, 1 or 2 treatments with Ambulight PDT are needed to complete a course (with separate cream applications and light-emitting devices if 2 treatments are needed). Each treatment lasts 6 hours (3 hours for drug absorption and 3 hours for delivering PDT). As with conventional PDT, these 2 treatments are carried out between 1 week and 1 month apart.
- 2.5 The device is worn for the full 6 hours of treatment. It is programmed so that the light source does not turn itself on until 3 hours after the battery pack is switched on, to allow for the drug absorption. A flashing light indicates, after a further 3 hours, when treatment is complete. The device switches itself off and can be removed by the patient.

- 2.6 Ambulight PDT is designed to enable therapy to be delivered in an ambulatory care setting, which can include the patient's home. This can avoid the need for a hospital appointment to receive the PDT, reducing travel for some patients. It is claimed that in some cases the device may allow patients to continue with their normal daily activities. It is also claimed that using Ambulight PDT may reduce pain compared with conventional PDT.
- 2.7 The average selling price of Ambulight PDT, as stated in the manufacturer's submission, is £200 with a price range of £180 to £250. The cost of Ambulight PDT may vary because of differences in purchasing contracts.

Current management

- 2.8 Current practice in the management of non-melanoma skin cancer in secondary care (specifically those lesions intended for treatment with Ambulight PDT) varies substantially. For patients for whom treatment is considered suitable, options are standard hospital-based PDT, topical chemotherapy, topical immunomodulators, surgical excision, curettage, cryotherapy or radiotherapy, but the treatment of choice varies between hospitals. Some patients receive no treatment for their small low-risk skin lesions, based on clinical decisions that there is insufficient risk of progression or harm.
- 2.9 Conventional PDT is currently offered in some out-of-hospital settings; these may be in primary care, secondary care or in the community, but not in patients' homes.

3 Clinical evidence

Summary of clinical evidence

- 3.1 The main clinical outcomes for the treatment of non-melanoma skin cancer with Ambulight PDT are tumour response rate (including recurrence rates or need for additional treatment), pain during treatment and adverse events. Read more about the full details of all clinical outcomes considered by the committee in the [assessment report](#).
- 3.2 The committee saw data on a total of 28 patients who were treated with Ambulight PDT.
- 3.3 Attili et al. (2009) described a pilot study of 12 patients (8 patients with Bowen's disease and 4 patients with basal-cell carcinoma) with a median lesion diameter of 1.1 cm (range 0.6 to 1.9 cm) treated using a prototype of the Ambulight PDT device with 5-aminolevulinic acid as the photosensitiser. A complete response was reported in 75% (9/12) of patients at 6-month follow-up. At 12 months, 58% (7/12) of patients had complete tumour response (4 patients had peripheral margin failure; 1 had residual nodular component). In all patients for whom treatment was unsuccessful, the lesion size was greater than 1.5 cm in diameter.
- 3.4 Attili et al. (2009) reported pain immediately after treatment that was recorded using a numerical rating scale (1 to 10; higher score indicates worse pain). All 12 patients reported a pain score of 2 or less (range 0 to 2). No patients needed pain relief in the form of local anaesthesia or cool air treatment during therapy. One patient who reported excessive pain during previous PDT commented on the lack of discomfort with Ambulight PDT. These scores were compared retrospectively with those of 50 patients who had received conventional PDT using an inorganic light-emitting diode static lamp source (dose 75 J/cm²). The static lamp cohort had a median numerical rating scale score of 6 (range 1 to 10). Of the 50 patients, 11 needed local analgesia and all needed cool air treatment.
- 3.5 The manufacturer's submission presented data on the use of a light-emitting diode light source and methyl aminolevulinate cream (Metvix). These data

included five patients with single lesions treated using Ambulight PDT and 11 patients with multiple lesions whose lesions were treated with a range of PDT treatments (at least 1 lesion site was treated with Ambulight PDT; other sites were treated using conventional PDT or different light-emitting diode sources). Pain immediately after treatment was recorded on a visual analogue scale (1 to 10; higher score indicates worse pain). For single lesions treated using Ambulight PDT the pain score ranged from 1.5 to 7. For patients with multiple lesions treated using Ambulight PDT the pain scores ranged from 0 to 8. For multiple lesions treated with other PDT, pain scores ranged from 1.5 to 10. Insufficient data were available for analysing summary statistics (mean or median) for Ambulight PDT compared with conventional PDT.

3.6 No adverse events have been reported with Ambulight PDT.

Committee considerations

- 3.7 The committee considered that there was some evidence for efficacy of Ambulight PDT but that the quantity of evidence on its use was very limited. The committee considered that more clinical evidence is needed.
- 3.8 The committee noted that the manufacturer of this technology claims that it is equivalent to, but not more effective than, conventional PDT. The committee also noted that one of the claimed advantages over conventional PDT is that it can be used in ambulatory settings, including patients' homes in selected cases. The committee considered that the ambulatory nature of the device offers the potential to increase convenience of treatment for patients with impaired mobility. It also noted that patients could be treated with Ambulight PDT who might otherwise have difficulty accessing PDT.
- 3.9 The manufacturer's submission described various techniques that have been developed to reduce pain during PDT and presented studies demonstrating that reduced irradiance is associated with reduced pain. The committee considered that there was evidence to suggest that treatment with Ambulight PDT may cause less pain than conventional PDT in some patients.
- 3.10 The committee recognised that patient preference plays a significant part in the

decision to treat low-risk non-melanoma skin cancer.

- 3.11 Small non-melanoma skin cancers are common and most have a low risk of progression, but because of incomplete coverage of case reporting, the true incidence is unknown. The committee was advised that practice varies substantially when deciding on treatment for these lesions and that local service configuration influences the range of treatments that can be offered. Some patients are offered one of a range of treatments including topical chemotherapy, surgical excision, radiotherapy or standard hospital-based PDT, whereas others are not offered treatment. There are no good studies comparing the range of possible treatments.
- 3.12 The committee debated the usefulness of a device that treats only single lesions when many patients have multiple lesions needing treatment, and the fact that Ambulight PDT is suitable only for treating lesions of a small size. It also noted the differing views of expert advisers about the significance of pain as an issue with conventional PDT.
- 3.13 The committee recognised that Ambulight PDT is a new device at a relatively early stage of development with a consequently small evidence base but that the manufacturer is collecting more data. The committee considered the available clinical evidence and judged that it was insufficient to support the case for routinely adopting Ambulight PDT for treating non-melanoma skin cancers in the NHS in place of current management.
- 3.14 The committee recognised that Ambulight PDT is a current treatment option for carefully selected patients.

4 NHS considerations

System impact

- 4.1 Ambulight PDT allows PDT to be delivered in a community setting. This could reduce the demand on NHS transport services and hospital outpatient services as well as improving access to treatment and potentially reducing waiting times.
- 4.2 NICE's cancer service guideline on improving outcomes for people with skin tumours including melanoma states that the management of basal cell carcinomas imposes a significant workload on both primary- and secondary-care services. It recommends that treatment and care should take into account patients' needs and preferences, and recognises that there is a need to provide high-quality care close to a patient's home. A device that offers ambulatory PDT could be an attractive treatment option for some patients who express a strong desire to continue with their normal daily activities while receiving treatment.

Committee considerations

- 4.3 The committee recognised the potential for the system advantages on which the cost models described in section 5 were based.
- 4.4 The committee considered that the use of Ambulight PDT might make additional staff training necessary for accurate diagnosis and treatment delivery, and need additional infrastructure set up within ambulatory care settings. Although these would have initial outlay costs, there may be cost savings once a service is established.
- 4.5 The committee was advised that there is substantial variation in practice and that PDT is used much less in some hospitals than in others; this made consideration of any changes in service provision more complicated. Ambulight PDT is a current treatment option for non-melanoma skin cancer for carefully selected patients.

5 Cost considerations

Cost impact evidence

- 5.1 The manufacturer's cost analysis evaluated the costs of service configuration in which Ambulight PDT might be used, compared with conventional hospital-based PDT using a static lamp, for a complete treatment cycle, which consists of 2 treatments 1 week apart. In the cost analysis it was assumed that patients had already been diagnosed with non-melanoma skin cancer, so no costs associated with the diagnostic stage of management were included. The analysis did not include any costs associated with treatment efficacy or adverse events.
- 5.2 Four clinical scenarios were presented in which a GP with special interest in dermatology delivered PDT in the community with Ambulight PDT. These scenarios were presented for comparison against conventional hospital-based PDT using a static lamp:
- A GP operating in their own practice.
 - A GP operating in a specialist centre.
 - A GP operating in an outpatient clinic in secondary care.
 - A nurse hybrid service model (nurses delivering treatment in the patient's home after diagnosis by a GP with specialist interest in dermatology).
- 5.3 The costs of the first 3 of these clinical scenarios for service delivery were calculated using the analysis of the potential economic impact of the NICE cancer service guidance CSGSTIM (2006 and 2010) on skin cancer. The manufacturer did not include overheads or GP costs for the nurse hybrid service model.
- 5.4 The cost analysis did not include any impact on staff costs for additional training or for support for patients. Patients may need support and advice because Ambulight PDT has the potential to be used while they continue with daily activities, outside a clinical setting.

- 5.5 There was significant uncertainty in the costs presented in the submission so it was difficult to determine the likely cost difference in practice. The cost difference between PDT using Ambulight PDT and conventional PDT using a static lamp presented in the manufacturer's submission ranged from a cost saving of £195 to a cost increase of £536. The cost difference was dependent on the clinical scenario used for delivering PDT with Ambulight PDT and the method of calculating the cost of each scenario.
- 5.6 The cost analysis presented cost savings associated with Ambulight PDT in the form of removing the need for staff to administer illumination from a static machine, room hire for the illumination period, and anaesthesia, which could translate into resource savings.

Committee considerations

- 5.7 The committee considered that the cost models submitted by the manufacturer were complicated and difficult to interpret. The range of cost consequences was wide, with some showing an increase in cost to the service and others showing small savings. The committee was therefore unable to draw firm conclusions about the cost savings associated with using Ambulight PDT in the community.
- 5.8 The committee discussed the potential resource savings to the NHS from using Ambulight PDT in the community (see section 5.6). However, it is likely that the level of service provision for PDT already established in a community setting is a key factor in whether using Ambulight PDT might be associated with a cost saving or cost increase compared with conventional PDT with a static lamp. The committee was mindful of the additional costs involved in setting up the range of facilities to deliver PDT in the community, and was not convinced that the potential resource savings would confer sufficient advantage.

6 Conclusions

- 6.1 The committee concluded that the claimed clinical advantages of treating non-melanoma skin cancer using Ambulight PDT were not adequately supported by the limited evidence available, especially in light of the substantial variations in management of small, low-risk lesions. In addition, the pathways of care for using Ambulight PDT in ambulatory care settings are not yet established. The committee considered that the cost models did not present a robust case for benefits to the NHS.
- 6.2 The committee concluded that the case for adoption of Ambulight PDT as a routine treatment for selected patients in place of conventional PDT could not be supported at this stage. Ambulight PDT is one treatment option for people with non-melanoma skin cancer in the community. It is a novel development in the area of PDT that shows some promise, but further work is needed to support its case for adoption in the NHS.

7 Implementation

- 7.1 There are no implementation tools to accompany this guidance. A costing report was not prepared because the variation in practice and in service provision means that it is not possible to estimate the cost impact.

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