

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

MTG Review Decision Document

Review of MTG6: Ambulight PDT for the treatment of non-melanoma skin cancer

This guidance was issued in July 2011.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Recommendation

It is recommended to defer the review until April 2017

2. Original objective of guidance

To evaluate the case for adoption of the Ambulight system for treating non-melanoma skin cancer.

3. Current guidance

- 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.

4. Rationale

There have been no significant changes to the technology or to the care pathway and updated cost modelling does not significantly reduce the uncertainty concerning adoption described in the original recommendation. Although there has been no new evidence published which is likely to materially affect the recommendations, deferring the review would allow an upcoming study to be included (see section 6.5 for details).

5. Implications for other guidance producing programmes

No conflicts or overlaps with ongoing or published appraisals or guidance, was identified.

6. New evidence

6.1 Technology availability and changes

The technology is still available to the NHS, through a UK distributor Spirit Healthcare. There has been a minor modification to the technology since the production of the guidance, in that the controller element can now be re-used whereas previously it was single-use. The company has confirmed that technical functions remain the same, and the new device is covered by the same CE mark. The device name has changed from Ambulight PDT to Ambulight Multi PDT. The cost of the device is £500, with an additional cost of £50 for consumables compared to a cost in the range of £180 to £250 quoted in the original guidance for the single-use device. However due to the increase in component lifespan, the per patient treatment cost is lower, £104 compared to £400 previously

6.2 Clinical practice

The current management section of MTG6 states that the care pathway for ‘the management of non-melanoma skin cancer in secondary care (specifically those lesions intended for treatment with Ambulight PDT) varies substantially.’ It cites a number of comparators including no treatment, standard hospital-based PDT, topical chemotherapy, topical immunomodulators, surgical excision, curettage, cryotherapy, and radiotherapy. There is no NICE guideline on the treatment of non-melanoma skin cancer

NICE's guideline on the recognition and referral of [suspected cancer](#) (2015) includes a 7-point checklist that helps clinicians decide whether a person should be urgently referred to a specialist for an appointment under the 2-week rule, (where urgent referrals to a specialist should be seen within 2 weeks). The guideline recommends that a person with suspected non-melanoma skin cancer presenting in primary care should be referred for specialist opinion either under the 2-week rule (squamous cell

carcinoma) or as a routine referral. All people who present in primary care with a possible cutaneous squamous cell carcinoma should be referred urgently under the 2-week rule to a skin specialist, as in the case of suspected melanoma. Basal cell carcinoma should be referred as a routine referral; however low-risk basal cell carcinoma can be managed in a community setting by a suitably qualified level 1 practitioner (GP).

Ambulight is currently cited within the NICE treatment pathway: [skin cancer overview](#) ([basal cell carcinoma](#) and [squamous cell carcinoma](#)). Responses from 2 experts have indicated that there have been no significant changes to the treatment pathway since the publication of the guidance.

6.4 New studies

One published paper and 3 conference abstracts were identified in searches for new evidence since the guidance was published.

Ibbotson (2012) is a observational study involving 53 patients with 61 lesions (30 superficial basal cell carcinoma, 30 Bowen's disease, 1 actinic keratosis). All patients received 1 cycle of Ambulight PDT treatment, 18 received an additional (second) cycle with Ambulight, and 23 received Ambulight and conventional PDT (Aktilite) on separate lesions. The principal endpoint was patient elicited pain scores using a 0 to 10 rating scale. The overall median pain score was 2 for the first treatment, and 4 for the second treatment. In the patients who received Ambulight and conventional PDT, the median pain score was 1 and 5 respectively. In the same patients, when asked to state their preferred treatment, 16 stated Ambulight, 2 conventional PDT, and 1 stated no preference. There were no adverse events in the study population.

Freeman (2012) is a short commentary on the benefits of home use Ambulight PDT compared to conventional PDT in terms of convenience, and comfort (lower fluence)

Ibbotson (2013) is a short commentary on developments in topical PDT treatment which makes a brief reference to encouraging early results from Ambulight, but provides no details on them.

Johnston (2015) reports on a study involving 4 patients which compares Ambulight to traditional photodynamic therapy (Aktilite PDT unit). The authors state that Ambulight demonstrates similar effectiveness as traditional PDT in the treatment of non-melanoma skin cancer and skin dysplasia, that it is better tolerated by the patient, more convenient and a cheaper treatment option. However they provide no results to substantiate these statements.

6.5 Ongoing studies

Unpublished study details	
Study details	NCT02872909 A randomised assessor-blinded comparison of low irradiance and conventional irradiance PDT for superficial non-melanoma skin cancer SH Ibbotson, J Ferguson, RS Dawe
Design	Randomised assessor blinded comparison between low irradiance and conventional irradiance PDT
Assigned interventions	Up to 4 treatments (2 cycles) of low irradiance (or comparator of conventional) PDT
Participants	50 patients with superficial basal cell carcinoma or Bowen's disease
Follow-up period	One year
Primary outcome	Pain of treatment
Secondary outcome(s)	Phototoxicity Patient evaluation Efficacy
Key results – efficacy	Pending
Key results – safety	Pending – no significant issues from trial to date and now in follow up
Information source	https://clinicaltrials.gov/ct2/show/NCT02872909
Any other comments	Last patient follow-up visit will be complete by end of 2016, data analysis will begin thereafter

7. Summary of new evidence and implications for review

The additional evidence is limited in terms of the number of studies, the methodology used and the outcomes reported. It is unlikely to lead to a change in the current recommendation.

8. Equality issues

No equality issues were raised in the original guidance

Contributors to this paper:

Technical Lead: Neil Hewitt

Technical Analyst (Evaluation): Paul Dimmock

Project Manager: Lee Dobson

Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequence	Selected – ‘Yes/No’
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE’s work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – ‘Yes/No’
Transfer the guidance to the ‘static guidance list’	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	No
Defer the decision to review the guidance to April 2017	NICE will reconsider whether a review is necessary at the specified date.	Yes
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

References

Freeman A, Freeman M (2012) Ambulight an organic led automated battery operated light source compared to the Actilight for Metvix PDT. *Australasian Journal of Dermatology* 53: 37-.

Ibbotson S (2013) Optimising the use of PDT in dermatology. *Lasers in Medical Science* 28 (5): 1219-1220.

Ibbotson SH, Ferguson J (2012) Ambulatory photodynamic therapy using low irradiance inorganic light-emitting diodes for the treatment of non-melanoma skin cancer: An open study. *Photodermatology Photoimmunology and Photomedicine* 28 (5): 235-239.

Johnston J, Lun K, Bond A et al. (2015) Ambulatory photodynamic therapy. *Australasian Journal of Dermatology* 56: 43-.