NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

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. Review decision

Transfer the guidance to the static list.

2. Original objective of guidance

To assess the case for adoption of Ambulight PDT for the treatment of 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

The recommendation in the guidance did not support the adoption of this technology because there was not sufficient evidence and the cost consequences of adoption were not certain. A review of the guidance in October 2015 proposed to defer the

review until the publication of a new study (Ibbotson et al 2018). This study has now been published in abstract form and does not provide substantial new evidence that would result in an update to the recommendations. The company has not provided any additional information for the guidance review process, but stated that they are planning a new device for launch next year. No new information which would change the recommendations has been identified from published studies, expert advice or care pathway changes and so it is proposed to place the guidance on the static list.

5. New evidence

The search strategy from the original assessment report was re-run. References from July 2011 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The technology is still available to the NHS. 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 device name has changed from Ambulight PDT to Ambulight Multi PDT and is covered by the same CE mark. The company declined to complete the company information request form but indicated that there have been no material changes to the technology.

5.2 Clinical practice

The NICE pathway is https://pathways.nice.org.uk/pathways/skin-cancer. There have been no changes to the NICE pathway since the previous guidance review. One expert stated ideally Ambulight would be available for use at home for non-routine use in selected patients who would benefit from home use.

5.3 NICE facilitated research

None.

5.4 New studies

One abstract on this technology has been published since the last guidance review in October 2016. Ibbotson et al. (2018) reported the findings of a RCT (assessor blinded) comparing Ambulight with conventional photodynamic therapy for superficial non-melanoma skin cancer. The study, carried out in Scotland, included 50 patients who were randomised to receive Ambulight (n = 32) or conventional PDT (n = 18). There were no significant differences in tolerance or effectiveness of treatment with 1-year follow-up and patients were very satisfied with treatment. The authors concluded that the findings confirm that Ambulight is as effective as hospital-based treatment for patients with small lesions of superficial basal cell carcinoma and Bowen disease and is a convenient treatment option for selected patients, allowing care closer to home.

6. Summary of new information and implications for review

There has not been sufficient published clinical evidence to suggest that a review of the recommendations would be required. The cost modelling in the guidance has not been updated because there is still a lack of evidence for clinical effectiveness. The cost consequences associated with using Ambulight in the community are still uncertain.

7. Implications for other guidance producing programmes

No comments were received highlighting any implications for other guidance programmes. Two experts responded to the review process and neither use the technology routinely.

8. Implementation

NICE was unable to identify any uptake data for Ambulight and is not aware of other audit or activity data around photodynamic therapy for patients with small non-melanoma skin cancers in an ambulatory care setting. One expert used this technology within a research study, however they believe use of the technology outside of a research setting is limited.

9. Equality issues

No new equality issues were identified in the original guidance or the guidance review.

Contributors to this paper:

Technical analyst: Liesl Millar

Technical adviser: Bernice Dillon

Acting Programme Director:	Mark Campbell
Project Manager:	Sharon Wright

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	Consequences	Selected
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	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
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.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

References

Ibbotson, S.; Dawe, R.; Moseley, H.; Samuel, I.; Ferguson, J. (2018), A randomized, controlled trial of portable compared with conventional photodynamic therapy for superficial nonmelanoma skin cancer, British Journal of Dermatology vol. 179 supplement1 pp 100

National Institute for Health and Care Excellence
Medical Technologies Evaluation Programme

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Consultation Comments table

There were 3 consultation comments from 2 consultees (1 NHS professionals and 1 Organisation. The comments are reproduced in full, arranged in the following groups – (list groups used, for example, clinical use, cost considerations and miscellaneous).

Table 2

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	1 National Institute of Health Research Devices for Dignity MedTech Co-operative	General	Thank you for the invitation to feedback on this topic. This particular topic is outside the Devices for Dignity theme areas and so we will not be a stakeholder for this review but look forward to participating on any relating to long term health conditions	Thank you for your comment.
2	2 National Institute for Health and Care Excellence	General	Thank you for inviting us to comment. There were no adoption support resources for this guidance	Thank you for your comment.
3	2	General	No further comments	Thank you for your comment.

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
	National Institute for Health and Care Excellence			

"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."