NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

CENTRE FOR HEALTH TECHNOLOGY EVALUATION

EVALUATION PATHWAY PROGRAMME FOR MEDICAL TECHNOLOGIES

Medical technologies guidance

SCOPE

Ambulight PDT for the treatment of non melanoma skin cancer

1 Technology

1.1 Description of the technology

The purpose of the Ambulight device is to deliver ambulatory photodynamic therapy (PDT) to treat non melanoma skin cancer (NMSC).

Ambulight PDT comprises a small light emitting device (containing its own light source generated by a diffuser and a series of light emitting diodes), which is connected via a lead to a pocket-sized battery. This light emitting device adheres to the skin using a disposable plaster, 3 cm in diameter, worn by the patient directly over the target lesion. The battery can be carried in a patients pocket, attached to a belt or worn around the neck.

The light source generated by the device emits the same dose and wavelength of light as existing PDT light sources, but the intensity is reduced and administered over a longer period of time. The light source emits a peak wavelength of 640nm and a full width half maximum (FWHM) of 20nm. The irradiance of light emitted is 7mM/cm^2 and a total light dose of 75 J/cm^2 is delivered directly to the treatment site over a period of 3 hours.

Before delivery of the PDT treatment, a photosensitising pro-drug is topically applied to the target lesion site for 3 hours where it is absorbed and metabolised to the active photosensitiser.

Two Ambulight PDT treatments (with separate devices) are needed to complete a course; with each treatment lasting 6 hours (this includes 3 hours for drug absorption and 3 hours of controlled PDT delivery). These two treatments, as with conventional PDT, are carried out approximately 1 week to 1 month apart.

The device is worn for the full 6 hours. The device is programmed so that the light source does not turn itself on until 3 hours after the battery pack is switched on i.e. after 3 hours to allow drug absorption. A flashing light

indicates when treatment is complete; the device switches itself off and may be removed by the patient.

Due to the ambulatory nature of the Ambulight PDT device, and in contrast to the large static existing light sources, treatment may be administered in a local health care centre, GP practice or a patient's home, thereby avoiding the need for an outpatient or inpatient hospital appointment. This is more convenient for the patient, reduces the need for travel and in some cases allows the patient to continue with their normal daily activities while undergoing PDT.

1.2 Regulatory status

The Ambulight PDT device is CE marked.

Ambulight PDT is intended for use in combination with methyl aminolevulinate cream (trade name Metvix), since this is the only licensed photosensitising drug for the treatment of skin cancers. However, the device has been used with the unlicensed photosensitiser 5-Aminolaevulinic acid (5-ALA).

2 Reasons for developing guidance on Ambulight PDT

The Medical Technologies Advisory Committee (MTAC) recognised that Ambulight PDT may offer a potential benefit to patients with NMSC who cannot easily access hospital treatment or who require the use of hospital transport services. This may be particularly pertinent to elderly or disabled patients.

The Committee were advised that the incidence of NMSC is increasing and given this and our aging population, this technology has the potential to increase the convenience of PDT delivery for many patients.

The Committee were mindful of the small amount of data that were presented and strongly encourage that more data is included in the submission.

3 Relevant diseases and conditions

NMSCs are the most common cancers in the UK and are most common in older age groups. It is estimated that the actual number of new diagnoses in the UK is approximately 100,000 cases each year.

The target group for treatment with this technology are patients with pre-malignant and malignant NMSC tumours, with single lesions less than 2.4 cm in diameter. This includes patients with Basal Cell Carcinomas (BCC), Actinic Keratosis (AK) and Bowen's Disease (BD).

The target group does not include patients with Squamous Cell Carcinomas (SCC).

4 Patient benefit

4.1 Current management options (the comparator):

- Standard hospital-based PDT
- Topical chemotherapy
- Topical immunomodulators
- Surgical excision
- Curettage
- Cryotherapy
- Radiotherapy
- PDT using conventional LEDs, such as static lamps

4.2 Clinical outcomes relevant to the technology

The key outcomes relevant to this technology are tumour response rates (including recurrence rates or need for additional treatment), pain during treatment and quality of life parameters measured on the appropriate scales.

5 Care pathway and system impact outcomes

5.1 Care pathway impact

Ambulight PDT could enable PDT to be delivered in a new care setting away from hospitals. This could reduce the demand on hospital outpatient and

inpatient services as well as improve accessibility to treatment and thereby potentially reduce waiting times. However, there would be the need for additional staff training for accurate diagnosis and treatment delivery and for infrastructure to be set up within primary care settings.

5.2 System impact

Ambulight PDT may reduce the number of outpatient visits and / or hospitalisations for patients with NMSC requiring PDT as well as improve accessibility to treatment and reduce waiting times.

5.3 Other organisational factors

The relevant primary care staff will need training both for diagnosis and treatment delivery as accurate diagnosis is paramount and services will need to be set up to deliver Ambulight PDT.

6 Health inequalities and equality impact

The National Institute for Health and Clinical Excellence (NICE) is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:
• promote race and disability equality and equality of opportunity between men and women, and
• eliminate unlawful discrimination on grounds of race, disability, age, sex and gender, sexual orientation, and religion or belief in the way we carry out our functions and in our employment policies and practices.

6.1 Health inequalities

NMSC are most common in older age groups. This technology has no differential impact on inequalities in health within and between different population groups

6.2 Equality impact

There is no evidence to demonstrate variation in effectiveness of Ambulight PDT according to the age, gender, class or ethnicity of the target population. There appears to be no differential impact on inequalities in health within and between different population groups. A medical technology evaluation of Ambulight PDT is not likely to have an impact on the current burden of disease or to reduce inequalities in health.

7 Approach to cost measurement and health economic analysis

The cost analysis should begin after the patient has been diagnosed with NMSC or when treatment is indicated for NMSC. The cost analysis should take into account initial delivery costs including equipment, pharmaceuticals, and staff costs during set up and monitoring of the treatment. Costs of treating complications, repeat or additional treatments, and of longer-term clinical outcomes should be considered. Adverse events relating to use for the device and co-medication should be considered. Cost savings that result from reduced demand on outpatient and inpatient services should be included in the analysis.

The price of Ambulight PDT (device only) is currently £200 - £250 plus methyl aminolevulinate pharmaceutical costs of £240 per tube (up to 8 treatments). The list price of Ambulight PDT is not known.

8 External organisations

8.1 Professional organisations

8.1.1 Specialist societies contacted for Expert advice

The British Association of Dermatologists
The British Association of Aesthetic Plastic surgeons
The Royal College of General Practitioners

8.1.2 Societies or organisations for consultation

International Society for PDT

UK PDT Skin group

8.2 Patient organisations

NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary:

Skcin - Karen Clifford Skin Cancer Charity
British Skin Foundation
Cancer Equality
Cancer52
CANCERactive
CancerHelp UK

Helen Rollason Heal Cancer Charity
Macmillan Cancer Support
Rarer Cancers Forum
Skin Care Campaign
Tenovus The Cancer Charity

8.3 NHS trusts or other organisations with experience of the technology

At the time of briefing note completion, Ambulight PDT was understood by NICE to be being used at the following hospitals:

Ninewells Hospital, Dundee
Stirling Royal Infirmary
Leeds General Infirmary
Salford Royal
Belfast City Hospital
Harrogate & District Hospital

9 Other issues

Costs could vary significantly across regions because of commercial sensitivities and differences in purchasing contracts.

10 Related NICE guidance

10.1 Published

Improving outcomes for people with skin tumours including melanoma relating to the management of low risk basal cell carcinomas in the community. Cancer service guidance CSGSTIM. Issued Feb 2006.

Review in progress: Draft guidance currently available on NICE website for final fact check - See Improving Outcomes for People with Skin Tumours including Melanoma relating to the management of low risk basal cell carcinomas (BCCs) in the community.

Photodynamic therapy for non-melanoma skin tumours Interventional procedures guidance. Interventional procedures guidance IPG155. Issued Feb 2006.

Final recommendations:

1.1 Current evidence suggests that there are no major safety concerns associated with photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions).

1.2 Evidence of efficacy of this procedure for the treatment of basal cell carcinoma, Bowen's disease and actinic (solar) keratosis is adequate to support its use for these conditions, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.3 Evidence is limited on the efficacy of this procedure for the treatment of invasive squamous cell carcinoma. Recurrence rates are high and there is a risk of metastasis. Clinicians should ensure that patients understand these risks and that retreatment may be necessary. In addition, use of the Institute's Information for the public is recommended (available from www.nice.org.uk/IPGxxxpublicinfo).

10.2 Under development

Providing public information to prevent skin cancer. Public health guidance. Due Jan 2011

Resources and environmental changes to prevent skin cancer. Public health guidance. Due Jan 2011

10.3 Suspended or terminated

None identified

11 Statement of the decision problem

	Final scope issued by NICE
Population	Patients with NMSC or dysplasia (ie. Superficial basal cell carcinoma, actinic keratosis or Bowen's disease and excluding those with SCC), single lesion. Lesions should be < 2.4 cm in diameter
Intervention	Ambulight PDT with methyl aminolevulinate pharmaceutical Ambulight PDT with 5-ALA pharmaceutical
Comparator(s)	Conventional hospital based PDT PDT using a static lamp No treatment *Comparators should present data using methyl aminolevulinate cream and 5-ALA agents where possible.*
Outcomes	Tumour response rates to include recurrence rates or need for re-treatment or additional treatment), pain during treatment, quality of life parameters, device failure, other complications or adverse effects
Cost analysis	Comparative cost analysis of Ambulight PDT with methyl aminolevulinate and the relevant comparator for the treatment of NMSC: conventional hospital based methyl aminolevulinate cream with PDT. Cost analysis should account for initial delivery costs including equipment, pharmaceuticals and staff costs during set up and monitoring, hospital and clinic care, staff training, long-term disease management, adverse events including repeat or additional treatments and pharmaceutical costs. Cost savings from reduced demand on outpatient and inpatient services should also be included in the analysis. A sensitivity analysis for the use of 5-ALA would be useful.
Subgroups to be considered	For NMSC lesion types (BCC, AK and BD), consider whether there is any evidence of differential benefit between these types of lesion in comparison with other techniques. The role of Ambulight PDT in treating multiple lesions.

	Patients with smaller lesions: consider whether Ambulight PDT is more effective with reduced lesion size. Consider whether body size may affect effectiveness of Ambulight PDT.
Special considerations, including issues related to equity or equality	No special considerations were identified at scoping stage.