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Horizon Scanning Technology Prioritising Summary

Home ultraviolet B (UVB) phototherapy for the treatment of severe psoriasis

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AHTA

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PRIORITISING SUMMARY

REGISTER ID: **000438**

NAME OF TECHNOLOGY: **HOME ULTRAVIOLET B (UVB) PHOTOTHERAPY**

PURPOSE AND TARGET GROUP: **FOR THE TREATMENT OF SEVERE PSORIASIS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number
☐	No	
☐	Not applicable	

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Netherlands	✓		
United States	✓		
United Kingdom	✓		

IMPACT SUMMARY:

Several companies have ultraviolet units registered on the ARTG capable of treating dermatological conditions including psoriasis. Biosoft Pty Ltd (Sydney) distribute a unit (ARTG number 164976) manufactured by Herbert Waldmann GmbH & Co KG (Switzerland), Australian Ultra Violet Services (Operations) Pty Ltd (Victoria) distribute units (ARTG numbers 157535 and 151535) manufactured by the Daavlin Distributing Company (USA) and Emergo Asia Pacific Pty Ltd (Sydney) distribute a unit (ARTG number 155287) manufactured by Pharos Life Corp (Canada). Only the latter unit is stipulated for home therapy use, however the ARTG lists its therapeutic use for acne not psoriasis. This summary aims to examine the use of ultraviolet B (UVB) home phototherapy for the treatment of severe psoriasis under the supervision of a dermatologist.

BACKGROUND

Psoriasis is a T-cell mediated chronic inflammatory and hyper-proliferative disease of the skin characterised by erythematous plaques or patches of red skin covered with white scales. Psoriatic lesions are often associated with pain and itching (Levine & Gottlieb 2009). There are several variants of psoriasis including vulgaris or plaque[1], guttate[2], inverse[3], pustular[4] and erythrodermic[5] psoriasis (National Psoriasis Foundation 2010). Psoriasis presents in a bimodal age distribution with a peak in incidence between the ages of 15 and 30 years and a later peak in incidence between 50-60 years of age. More severe psoriasis is usually associated with an earlier age of onset (Levine & Gottlieb 2009). Genetic factors have been shown to predispose individuals to psoriasis and at least nine susceptibility loci have been identified (Edlich et al 2009). The risk of developing psoriasis is 41 per cent in children with both parents affected, 14 per cent if one parent is affected and six per cent if one sibling is affected (Levine & Gottlieb 2009). Environmental and lifestyle factors have also been demonstrated to exacerbate symptoms of psoriasis including smoking, alcohol consumption, emotional stress and obesity (Jankovic et al 2009).

Ultraviolet B (UVB) radiation is a common, well established treatment for psoriasis and has an estimated success rate approaching 80 per cent (Yelverton et al 2006). Psoriasis responds to treatment with UVB due to the inflammatory nature of the disease, with UVB capable of inhibiting immunity in a localised, rather than systemic manner. UVB can induce immunosuppression by affecting the action of skin-associated lymphoid tissue and can suppress contact or delayed-type hypersensitivity. Apoptosis of immune competent cells may be induced by high doses of UVB (Stein et al 2008).

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[1] Most common form of psoriasis with 80% of patients having this form. Characterised by raised, inflamed, red lesions covered by a silvery white scale typically found on the elbows, knees, scalp and lower back.

[2] Often develops in childhood. Appears as small, red, individual spots on the skin with lesions usually on the trunk and limbs. These spots are not usually as thick as plaque lesions. Guttate psoriasis often develops rapidly in response to stress or injury.

[3] Inverse psoriasis is found in the armpits, groin, under the breasts, and in other skin folds. Appears as bright-red lesions that are smooth and shiny. Inverse psoriasis is subject to irritation from rubbing and sweating because of its location in skin folds and tender areas.

[4] Primarily seen in adults, pustular psoriasis is characterised by white blisters of noninfectious pus surrounded by red skin. May be localised to the hands and feet, or covering most of the body. It begins with the reddening of the skin followed by formation of pustules and scaling. May be triggered by internal medications, irritating topical agents, overexposure to UV light, pregnancy, systemic steroids, infections, stress and sudden withdrawal of systemic medications or potent topical steroids.

[5] Erythrodermic psoriasis is a particularly inflammatory form of psoriasis that affects most of the body surface, characterised by periodic, widespread, fiery redness of the skin and the shedding of scales in sheets, rather than smaller flakes. The reddening and shedding of the skin are often accompanied by severe itching and pain, heart rate increase, and fluctuating body temperature. Erythrodermic psoriasis causes protein and fluid loss that can lead to severe illness including infection, pneumonia and congestive heart failure (National Psoriasis Foundation 2010).

Home UVB therapy units such as the one manufactured by Waldmann GmbH & Co KG, appear to be large and cumbersome but are light weight and have foldable sides which enable them to be stored in a small space (Figure 1). The dimensions of the unit closed are approximately 1880 (W) x 604 (H) x 135 mm (D) and open 1880 (W) x 882 (H) x 512 (D) mm. The unit weighs approximately 60 kg but is mobile on castors in all directions. The UVB-100 operates on a timer to ensure correct exposure time. Goggles should be used for protection of the eyes while undergoing treatment. Other smaller units are available but are specific in their use ie the UVB 236 unit may be used for the irradiation of the face, hands or soles of feet (Waldmann Group 2010).

Figure 1 The Waldmann UVB-100 home therapy unit (printed with permission Waldmann)

The UVB 100 unit delivers radiation to only one side of the body at a time, so separate treatment is required for the front, back and each side of the body. This is more limited compared to UVB treatment delivered in a hospital environment which is capable of providing all round body radiation (Cameron et al 2002).

CLINICAL NEED AND BURDEN OF DISEASE

There is a lack of prevalence data available in Australia for psoriasis. The AIHW report "Australia's Health 2004" reported an estimated 335,000 people, or 1.8 per cent, with psoriasis in the year 2001 (AIHW 2004). An early review of the epidemiology of psoriasis in Australia reported population prevalence estimates of psoriasis, based on cross-sectional studies which used clinical examinations as their criteria, to range from 0.3 to 2.5 per cent. One cohort study included in this review estimated psoriasis incidence to be 60.4 per 100,000 person years in one cohort study (Plunkett & Marks 1998). It has been estimated that 10-30 per cent of patients diagnosed with psoriasis will have a severe form of the disease covering more than 10 per cent of their body (Yelverton et al 2006).

Australia-wide, the total number of services for the MBS item numbers 14050 and 14053 (see comparator section) for the calendar year January 2008 to December 2008 was 440,343 and 26,930, respectively. This may represent multiple visits by the same patient but may also be treatment for other dermatological conditions.

The total number of Australian public hospital separations (L40) for psoriasis for the period 2007-08 was 3,288, representing a total number of patient days of 6,928. The majority of separations were for arthropathic psoriasis (n=1,105).

Prevalence data for New Zealand could not be obtained.

DIFFUSION

Home UVB therapy is not practised in Australia (personal communication Australasian College of Dermatologists). UVB therapy is conducted by specialist dermatologists.

COMPARATORS

Treatments currently available are topical agents used predominantly for mild disease and for recalcitrant lesions in more severe disease, phototherapy for moderate disease, and systemic agents, including photo-chemotherapy, oral agents, and injectable biological agents for more severe cases (Edlich et al 2009).

SAFETY AND EFFECTIVENESS ISSUES

The potential for uptake of home phototherapy was investigated in an early study conducted in the large health catchment area of Tayside, Scotland (Cameron et al 2002). Tayside is a large, mainly rural area covering 3,200 square miles with hospital UVB treatment only available in two main hospital centres, requiring many patients to travel long distances for treatment. A pilot questionnaire established that 75 per cent of psoriasis outpatients supported the introduction of a home treatment service, with 42 per cent citing difficulties with time off work and 24 per cent found travel expenses onerous. Forty per cent of patients questioned were willing to pay for the transportation of the equipment. Phase I of the study involved instructing and training patients (n=10, median age 33 years, range 19-65 years) in the use of the home therapy equipment within the hospital, while Phase II was the implementation of home therapy in the community (level IV intervention evidence). Radiation dose distributions were calculated for the home units to make them comparable to the larger, full body units used in hospital. From historical data, the median number of treatments required using hospital-based UVB to reach minimal residual activity (MRA) or clearance of psoriasis was 18 exposures with a median dose of 9.33 J[6] cm^2.

[6] J cm2 = joules (energy) per square centimetre

In Phase I of the study, 10 patients were trained in the use of the home therapy. Seven patients reached MRA or clearance of their psoriasis in a median of 18 exposures (range 15-22) and a median dose of 10.38 J cm^2. The psoriasis in three patients did not respond to the home treatment protocol as quickly and therapy was finalised using the larger hospital UVB equipment, achieving MRA or clearance in a median of 28 exposures. In Phase II of the study, 23 patients with chronic plaque psoriasis undertook home therapy, with 18 patients reaching MRA or clearance in a median of 22.5 exposures with a median dose comparable to hospital-based treatment of 9.84 J cm^2. Three patients had moderate improvement of their psoriasis in a median of 33 exposures and two patients were slow responders and switched treatment protocols. One patient with guttate psoriasis experienced clearance in 22 exposures. Self-assessed erythema was a common reported adverse event with 62 per cent of patients[7] reporting grade 1 erythema, 42 per cent grade 2 and 26 grade 3. No patients reported grade 4 erythema[8]. One patient experienced severe claustrophobia using the hospital-based equipment but was able to use home-based therapy successfully. In addition, one child was treated successfully at home by her mother. Basic costs for this study are provided below in the cost impact section.

A randomised controlled, multi-centre trial conducted in the Netherlands, randomly allocated patients with mild to severe forms of plaque or guttate psoriasis to home-based (n=98) or hospital-based (n=98) UVB therapy (level II intervention evidence). Although patients and the treating dermatologist could not be blinded to outcomes, an independent, blinded assessment of patients was conducted by a research nurse. Patients were recruited form 14 hospital outpatient departments. For home-based therapy patients, 30-60 minutes of training was provided by a nurse upon delivery of the UVB unit. Patients were followed-up over the course of treatment. The main effectiveness outcome measure was an improvement from baseline using the current gold standard, the psoriasis area and severity index (PASI) and the self-administered psoriasis area and severity index (SAPASI). Reported outcomes included the proportion of patients with a 50, 75 and 90 per cent improvement from baseline (PASI 50, 75, 90 and SAPASI 50, 75, 90), which are considered to be a clinically meaningful endpoint, an indication of successful treatment and almost complete clearance of disease, respectively (Koek et al 2009).

Of the 196 enrolled patients only 184 commenced treatment. Five patients violated protocol and switched treatment programs and seven patients did not commence treatment due to medical reasons including pregnancy and resolution of symptoms (Koek et al 2006). Effectiveness outcome measures are summaries in Table 1. The

[7] Including 8 patients treated for other dermatological conditions

[8] Erythema is a redness of the skin caused by congestion of the capillaries in the lower layers of the skin. It occurs with any skin injury, infection, or inflammation. Grade 1 = slight and painless, settling within 24 hours, grade 2 = obvious painless erythema, settling within 48 hours, grade 3 = symptomatic and marked erythema settling in 2-3 days, grade 4= severe burn with blisters, settling within 4-5 days.

median PASI score at baseline for home-based therapy patients was 8.4 which decreased 74 per cent to 2.2 post-treatment and compared favourably with a decrease of 70 per cent (from 7.0 to 2.1) for hospital-based patients. The median SAPASI score at baseline for home-based therapy patients was 6.7 which decreased 82 per cent to 1.2 post-treatment which was similar to the 79 per cent decrease (from 7.0 to 1.4) observed in the hospital treated patients. Treatment effect as defined by the mean decline in PASI and SAPASI scores (data not given) for both groups was significant ($p<0.001$) but not significant across the groups ($p>0.3$).

Four of the outcome measures indicated that home-based therapy was as effective or superior to hospital-based therapy, however the SAPSAI 75 and SAPASI 75 scores did have very wide confidence intervals. Although the PASI 50 and PASI 75 had point estimates that indicated equal effectiveness, the confidence intervals suggest that home-based therapy may be inferior to hospital-based therapy.

Table 1 Outcome measure of home-based vs hospital based UVB treatment

	Home UVB Numbers of patients (%)	Outpatient UVB Numbers of patients (%)	Difference [95% CI]
	n=94	n=91	
SAPASI 50 SAPASI 75 SAPSAI 90	81.9 (77) 69.1 (65) 43.6 (41)	79.1 (72) 59.3 (54) 29.7 (27)	2.8 [-8.6, 14.2] 9.8 [-4.0, 23.6] 13.9 [0.002, 27.8]
	n=91	n=84	
PASI 50 PASI 75 PSAI 90	70.3 (64) 40.7 (37) 19.8 (18)	72.6 (61) 41.7 (35) 19.0 (16)	-2.3 [-15.7, 11.1] -1.0 [-15.6, 13.6] 0.8 [-10.9, 12.5]

Home-based therapy patients had a higher number of irradiations compared to hospital-based patients (34.4 vs 28.6), however the mean cumulative dose at the end of therapy was only slightly higher for home-based patients (51.5 J cm^2 vs 46.1 J cm^2). There was no difference in adverse events reported by either group. Adverse events for home-based patients compared to hospital-based patients included mild erythema (28.8% vs 28.6%), severe erythema (5.5% vs 3.6%), blistering (0.3% vs 0.6%) and a burning sensation (7.1% vs 10.0%). Similar reductions in the psoriasis disability index were noted in both groups post-treatment and scores on the SF-36 were similar between the two groups. However, patients treated at home evaluated their therapy more favourably than those treated in hospital. Ninety and 60 per cent of the home-based and hospital-based patients, respectively, stated that they would prefer home treatment in the future.

Another recent small case series reported on the outcomes of psoriasis patients treated with home UVB in combination with acitretin. Results from this study have not been reported in this summary due to the small sample size (n=27), lack of comparative

data with hospital-based UVB and the inability to assess the effectiveness of home UVB therapy alone (Yarbrough et al 2009; Yelverton et al 2008; Yentzer et al 2008).

COST IMPACT

The Medicare Benefits Schedule has two items numbers pertaining to the use of UVB therapy for dermatological conditions either administered in a whole body cabinet (MBS item number 14053, fee $48.75) or to localised body areas in a hand or foot cabinet (MBS item number 14050, fee $48.75). There is no MBS item number for home UVB phototherapy.

The evaluators contacted Waldmann GmbH & Co KG on several occasions to obtain a basic price of the UVB-100 home therapy unit, however no response was forthcoming. SolArc System Inc (USA) offers similar units with prices ranging from US$1,795 to $2,895. It is likely that individuals would not be expected to purchase these units and that the units would be made available for hire for short treatment periods.

A cost-effectiveness study was conducted in the United States in 2006 (Yelverton et al 2006). Results from this study may not applicable to Australia or New Zealand due to differences in health systems. A model was developed from the perspective of a third-party payer (ie an insurance company) to compare the direct cost of home phototherapy and common systemic treatments over a 30-year treatment period. Direct costs of home UVB treatment included the purchase of the UVB unit, maintenance of the unit including bulb replacement (estimated to be every 5 years) and follow-up visits to a dermatologist every three months. Treatment was estimated to be thrice weekly over an average time of six minutes.

The 2006 values for various psoriasis treatments over 30-years were as follows (US$):

UVB	$7,085	Methotrexate	$19,102
UVA	$37,591	Acitretin	$75,113
Efalizumab	$171,912	Etanercept	$255,334
Alefacept	$319,356		

The break even analysis revealed that home UVB therapy was less costly within two years of initiation of treatment compared to all other treatments considered. Within one month treatment with etanercept was more costly than UVB therapy, by 11 months UVA therapy had exceeded costs of UVB and costs of methotrexate exceeded those of UVB within 23 months. It should be noted that treatment with biological agents may become cheaper over time. In addition, the long-term effect of the new biological therapies are unknown and it may be conceivable that patients may enter into remission with the use of these agents and no longer require treatment.

The small pilot study conducted by Cameron et al (2002) reported on the basic, direct costs of providing home-based UVB therapy compared to hospital-based treatment for both the patients and the hospital (Table 2). Although the costs to hospitals increased

with the implementation and administration of the home therapy program, patient costs decreased markedly.

A long-term cost-effectiveness study is required to establish the benefits of home UVB therapy.

Table 2 Basic, direct costs of home and hospital-based UVB treatment

Hospital-based UVB treatment		Home-based UVB treatment	
Patient costs	Hospital costs	Patient costs	Hospital costs
Travel/parking Loss of earnings Childcare	Staff time Equipment costs Running costs	Travel/parking Loss of earnings Childcare (during training) Courier costs	Staff time Equipment costs
Median estimated cost per course of therapy		Median estimated cost per course of therapy	
£189	£89	£128	£112

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

Home UVB therapy may be useful for patients in rural and remote areas who are unable to seek treatment at a specialist dermatologist. In addition, many patients cite time lost at work while undergoing hospital-based treatment as an important reason to seek home therapy.

SUMMARY OF FINDINGS

From the randomised controlled trial it would appear that home-based UVB therapy is as effective as that offered to outpatients in a hospital setting. In addition, there was no difference in the number of adverse events recorded between the two groups. A long-term cost-effectiveness study is required to ascertain if home-based UVB therapy is a viable financial option, however the benefits for patients in rural and remote locations may outweigh and slight increase in costs.

HEALTHPACT ACTION:

UVB therapy is a widely used and effective treatment for psoriasis. HealthPACT have recommended that this summary be disseminated to colleges of interest including the College of Dermatology and College of General Practitioners as well as to all the jurisdictions. No further review of this technology by HealthPACT is required.

NUMBER OF INCLUDED STUDIES

Total number of studies 2
Level II intervention evidence 1

Level IV intervention evidence 1

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SEARCH CRITERIA TO BE USED:

Home Care Services
Outpatient Clinics, Hospital

Psoriasis/*radiotherapy
Ultraviolet Therapy
Ambulatory Care
Home Care Services