

Reimbursement of sunscreen

Medicines Management Programme

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List of abbreviations

AK	Actinic keratosis
ACBS	Advisory Committee on Borderline Substances
BCC	Basal cell carcinoma
DP	Drug Payment
EU	European Union
GMS	General Medical Services
HPV	Human papillomavirus
HPRA	Health Products Regulatory Authority
IARC	International Agency for Research on Cancer
ICS	Irish Cancer Society
ISF	Irish Skin Foundation
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NMSC	Non-melanoma skin cancer
PPD	Persistent pigment darkening
SCC	Squamous cell carcinomas
SPF	Sun protection factor
UPF	Ultraviolet protection factor
UV	Ultraviolet
UVA	Ultraviolet A
UVB	Ultraviolet B
WHO	World Health Organisation

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1. Purpose

Skin cancer is the most common cancer in Ireland, with just over 10,000 new cases diagnosed in 2013. Most cases of skin cancer are caused by ultraviolet (UV) radiation which comes from the sun.¹ The Primary Care Reimbursement Service (PCRS) historically reimbursed certain sunscreen products for particular patient groups (e.g. renal transplant patients), when prescribed by a consultant, under Discretionary Hardship Arrangements. The Medicines Management Programme was asked to review the recommendations for reimbursement of sunscreen products under the community drug schemes in Ireland.

2. Approaches to sun protection

There are two types of UV radiation, UVA and UVB. Small amounts of UV radiation are essential for the production of vitamin D in people but overexposure is harmful resulting in acute and chronic health effects on the skin, eye and immune system.² Both UVA and UVB can cause cancer.³ The UV index is a measure of the level of UV radiation which is expected at the earth's surface- the higher the level the less time it takes the skin to burn and the greater the risk of skin damage which can lead to skin cancer.

Spending time in the shade can reduce a person's exposure to the sun. Good shade can give up to 75% protection from UV rays. Covering up with clothes and wearing a wide brimmed hat which gives shade to the face, neck, head and ears can also protect the skin. Sunglasses should be worn to protect the eyes from sun damage as mild irritation and sunburn of the cornea can occur with short-term UV exposure while cataracts and cancer can develop with long-term exposure. The Irish Cancer Society (ICS) recommend wearing sunscreen from April to September in Ireland to reduce the risk of skin cancer.¹

The UV index is a measure of how strong UV radiation is on any given day. A UV index of 1-2 is low risk, 3-5 is medium risk, 6-7 is high risk, 8-10 is very high risk and 11+ is extreme risk. Hence when the UV index is 3 or more, there is a greater risk of skin damage that can lead to skin cancer. The ICS recommend following the 'Sunsmart Code' when the UV index is 3 or more.¹

2.1 The SunSmart Code

The ICS has developed a 'SunSmart Code' which gives advice on how to protect the skin from the sun in five steps: ¹

Step 1: Seek some shade

Step 2: Slip on clothes

Step 3: Wear sunglasses

Step 4: Use sunscreen

Step 5: Know the UV index

2.2 Clothing

The type and structure of clothing fabric, its colour and tightness and whether the garment is wet or dry will determine its effectiveness in protecting against UV radiation. Less UV radiation passes through tightly woven or knitted fabrics, darker colours while wet or worn fabrics may lose some of their UV protection properties.² The protection afforded by clothing fabrics is measured as the Ultraviolet Protection Factor (UPF). The European Standard for Sun-protective Clothing states that fabrics labelled as UV-protective must give an UPF greater than 40 as well as an average UVA transmission of less than 5% to provide sufficient protection from sun exposure.⁴

2.3 Sunscreen

Sunscreens are cosmetic products according to Council Directive 76/768/EEC. The efficacy of sunscreen products and the claims made relating to efficacy are addressed in Commission Recommendation 2006/647/EC. The regulation of cosmetics in Ireland falls under the remit of the Health Product Regulatory Authority (HPRA).

Sunscreens have an important protective function against UV radiation. Topical sunscreens are broadly divided into organic (chemical) and inorganic (physical) agents. Inorganic sunscreens (titanium dioxide and zinc oxide) reflect and scatter UVB, UVA and visible radiation by forming an opaque barrier of inert metal particles. They may also absorb UV radiation depending on the particle size. These are often cosmetically unacceptable due to their white appearance. Organic sunscreens act by absorbing UV and re-emitting chemical energy as heat or light. Several chemical filters exist that shield against UVB, UVA or both. Filters are specific for given wavelengths hence they are often combined in sunscreens to obtain broad-spectrum protection. Adverse events from organic sunscreens occur more often in patients suffering from photodermatoses and include allergic and irritant contact dermatitis, phototoxic and photoallergic reactions, contact urticaria, and in rare

cases anaphylactic reactions.⁴ Broad-spectrum sunscreens protect the skin from both UVA and UVB rays.

3. Measurements of sunscreen protection

3.1 UVB

UVB causes inflammation of the skin (sunburn). Sun protection factor (SPF) is a measure of a sunscreen's ability to prevent UVB radiation from damaging the skin. Many sunscreen labels contain a category of sun protection: 'low' (SPF 6 & 10), 'medium' (SPF 15, 20 & 25), 'high' (SPF 30 & 50) and 'very high' (SPF 50+).¹

In vitro tests have shown that SPF 15 sunscreens filter out 93% of UVB rays, while SPF 30 protects against 97% and SPF 50 protects against 98% of UVB rays. It is important for the sunscreen to include broad-spectrum protection that also shields adequately against UVA.⁵

3.2 UVA

UVA penetrates the skin further than UVB and hence causes skin aging. A sunscreen which claims UVA protection must provide a certain level of UVA protection as per European Union (EU) guidelines. The EU commission has recommended that the UVA protection factor for a sunscreen should be at least one third of the SPF.⁶ Products which achieve this requirement will have the letters 'UVA' in a circle logo on the label to show it meets minimum standards for UVA protection.

No standard method exists to measure the UVA protection of sunscreens. The star rating system was developed by Boots Company and is generally accepted. It is based on Diffey's UVA/UVB ratio. The star system ranges from 1 to 5 with a star value of 5 reflecting the highest protection.

Another method of measuring UVA protection is the persistent pigment darkening (PPD) method. It is similar to the SPF method of measuring UVB protection. Instead of measuring erythema or reddening of the skin, the PPD method uses UVA radiation to cause a persistent darkening or tanning of the skin. The PPD method was recommended by the European Commission in 2006. It is the preferred method of some manufacturers such as La Roche Posay®, Vichy® and L'Oreal®. A sunscreen with a PPD rating of 10 means it should take around 10 times longer for the skin to tan with this sunscreen compared to unprotected skin. Although there is no standardised numbering system for PPD, the higher the number, the greater the UVA protection provided.

4. Quantity of sunscreen to be applied

The International Agency for Research on Cancer (IARC) of the World Health Organisation (WHO) has emphasised the importance of the link between the correct application of sunscreen products and the efficacy of the SPF claimed. Applying the correct amount and frequent re-application of sunscreen products is important.⁷

4.1 European Commission

The efficacy of sunscreen products and the claims made relating to efficacy are addressed in the European Commission Recommendation (2006/647/EC). It recommends that in order to reach the protection level indicated by the SPF, sunscreen products need to be applied in quantities similar to those used for testing the products. This equates to six teaspoons of lotion (approximately 36 grams) for the body of one average adult person. Applying a smaller quantity of sunscreen product leads to a disproportionate reduction in protection. For example if the quantity applied is reduced by half, protection may fall by as much as two-thirds.⁶

4.2 Health Products Regulatory Authority

The HPRA recommends the average sized adult should be using at the very least six full teaspoons of sunscreen. The amount of sunscreen recommended to be applied for adults and children are detailed in Table 1 below. Amounts are calculated based on the surface area of an average adult's skin of 1.8m² and the average weight and height of children at these ages.³

Table 1: Recommended amount of sunscreen to be applied to children and adults*

Age	Amount per application
2 years	2 teaspoons (10 mls)
5 years	3 teaspoons (15 mls)
9 years	4 teaspoons (20 mls)
13 years	5 teaspoons (25 mls)
Adults	6 teaspoons (30 mls)

*These recommendations are guidance only. Adults and children should apply at least the guidance amount of sunscreen.

4.3 The Irish Cancer Society

The ICS recommends applying 35mls of sunscreen to cover the whole body of an adult.¹ Table 2 outlines the recommended amount to be applied to each body area of an adult.

Table 2: Recommended amount of sunscreen to be applied per area of body (adult)

Area of application	Amount of sun cream for each area
Each arm Face Neck and ears	½ teaspoon (2.5 mls)
Each leg Front of body Back of body	1 teaspoon (5 mls)

4.4 National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) guideline on 'Sunlight Exposure: Risks and Benefits' highlights that most people do not apply enough sunscreen. The guidelines states the amount needed for the body of an average adult to achieve the stated SPF is around 35mls, if it is applied too thinly, the amount of protection is reduced.⁸

NICE recommend making people aware that if they plan to be out in the sun long enough to risk burning, sunscreen needs to be applied twice to exposed areas of skin: half an hour before, and again around the time they go out in the sun.⁸

4.5 American Academy of Dermatology

The American Academy of Dermatology recommends applying one ounce (30mls) to cover the exposed areas of the body.⁹

5. At risk groups

The NICE guideline on 'Sunlight Exposure: Risks and Benefits' (2016) lists the following groups of people who should take extra care to avoid skin damage and skin cancer:⁸

- Children (particularly babies) and young people
- People who tend to burn rather than tan
- People with lighter skin, fair or red hair, blue or green eyes, or who have lots of freckles
- People with moles
- People who are immunosuppressed
- People with a personal or family history of skin cancer

People can be immunosuppressed and have less resistance to skin problems as a result of a disease or use of a particular drug for example transplant recipients.⁸

5.1 Transplant recipients

Transplant recipients of all major solid organs have a much higher risk of skin cancers than people in the general population due to their immunosuppressive medication.¹⁰ The incidence of skin cancer is proportional to the level of immunosuppression.¹¹ Liver transplant recipients, who often receive lower levels of immunosuppressive therapy than other transplant recipients have a lower risk of skin carcinoma.¹² UV is one of the major co-factors in the development of skin cancer in the immunosuppressed. UV induced non-melanoma skin cancer (NMSC) like invasive squamous cell carcinomas (SCC) and actinic keratosis (AK), and basal cell carcinoma (BCC) are the commonest forms of cancer in organ transplant recipients.¹³ SCC is the most frequent occurring, occurring 65-250 times more often in transplant patients.^{14,15} Furthermore transplant recipients with fair skin are at

much higher risk of development of skin cancer than those with dark skin¹⁶ and 36% of Irish renal transplant recipients develop a NMSC 20 years after transplantation.¹⁷ Skin examinations may detect pre-cancers such as AKs before they turn into cancers¹⁸ therefore prevention of skin cancer in this cohort should include regular dermatological monitoring for early detection.¹⁹

In a case controlled study assessing the preventative effects of regular sunscreen use on AK, SCC and BCC in chronically immunosuppressed organ transplant recipients, two of the main causes for non-compliance reported by patients were (1) sunscreens are cosmetically and socially unacceptable and (2) the cost of high quality sunscreens.¹³

Other risk factors for skin cancer include the length of time the patient has been immunosuppressed, advancing age, male sex, human papillomavirus (HPV), warts and predisposing genetic variations.¹⁸

6. Cost of sunscreens

The cost of sunscreens can vary substantially between different manufacturers and products. Premium pharmacy brands which have been reimbursed to date through the Discretionary Hardship Arrangements (underpinned by Hospital Prescriptions) include La Roche Posay®, Vichy® and Roc®. La Roche Posay® sunscreen had the highest expenditure of these brands in the period January to June 2015 through the Hardship Arrangements. Table 3 and 4 compares the cost and sun protection characteristics of a La Roche Posay® sunscreen and another popular brand, Boots Soltan® Protect and Moisturise. There is an eight fold price differential between Soltan® and La Roche Posay® SPF50+ lotions (see Table 3). Both products are SPF50+ and provide a high level of UVA protection however they use different methods to measure their UVA protection. La Roche Posay® Anthelios products have a high PPD while the Soltan® range has a maximum UVA 5 star rating.

Table 3: Comparison of cost and sun protection properties of La Roche Posay® and Soltan® sunscreen for the body

	La Roche Posay® Anthelios XL Comfort Lotion	Soltan® Protect and Moisturise Suncare Lotion
SPF	50+	50+
UVA protection	PPD 32	5 star rating
Cost	€19.99 (100mls)	€5.00 (200mls)
Cost per litre	€199.90	€25.00

Prices correct as of 8 May 2017 (www.boots.ie)

Table 4: Comparison of cost and sun protection properties of La Roche Posay® and Soltan® sunscreen for the face

	La Roche Posay® Anthelios comfort sun cream	Soltan® Protect and Moisture face cream
SPF	50+	50+
UVA rating	PPD 39	5 star rating
Cost	€20.00 (50ml)	€5.50 (50ml)
Cost per litre	€400	€110

Prices correct as of 8 May 2017 (www.boots.ie)

7. Reimbursement of sunscreens

7.1 In Ireland

Prior to this review, the PCRS reimbursed certain sunscreen products for particular patient groups (e.g. renal transplant patients), when prescribed by a consultant, under discretionary hardship arrangements. Currently these prescriptions must be:

- written by a consultant
- for a sunscreen product of SPF 50

There is currently no requirement for products prescribed to be evaluated for appropriate UVA protection rating and the cost of available alternatives is not taken into consideration.

7.2 In England

The Advisory Committee on Borderline Substances (ACBS) advises on specified conditions where certain substances may be regarded as drugs and may be prescribed on the National Health Service (NHS). The only approved indication for prescribing sunscreens on NHS prescriptions is for skin protection against UV radiation in abnormal cutaneous photosensitivity. This includes genetic disorders, photodermatoses, vitiligo from radiotherapy and chronic or recurrent herpes simplex labialis. Photodermatoses are a group of skin conditions caused by an abnormal reaction to UV radiation, particularly UVA. These conditions can be classed as either photosensitive or photoaggravated photodermatoses.²⁰

There are only five approved sunscreen products which meet ACBS criteria and can be prescribed on the NHS to treat abnormal cutaneous photosensitivity: Anthelios® XL SPF 50+ melt-in cream, Sensense® Ultra lotion SPF 50+, Uvistat® Lipscreen SPF 50, and Uvistat® cream SPF 30 and 50.²¹

The NHS Clinical Commissioners recently announced that they plan to review the reimbursement of sunscreen in the near future as it can be purchased at a low cost over the counter.

8. Summary

Excessive exposure to UV rays is an important and avoidable cause of skin cancer. There are many groups of 'at risk' people including the immunosuppressed, people with many moles and people with a personal or family history of skin cancer who should take extra care to avoid skin damage and skin cancer.⁸

Sunscreen is not an alternative to covering up with suitable clothing and shade but it does offer additional protection. Protective measures with clothes, hats and sun avoidance are first line measures to prevent sun exposure.

All transplant recipients not just renal transplant recipients, are at a higher risk of skin cancer. The risk is proportional to the level of immunosuppression therapy the patient is on. Prevention of skin cancer in transplant patients also requires education of patients about the importance of sun protection and prescribers must ensure patients are counselled on its appropriate application.

Historically sunscreens have been reimbursed for renal transplant recipients on the Hardship Scheme, however no standard products were recommended nor reimbursed price outlined. Higher cost products were historically applied for without clear guidance on recommended product standards or unit price agreement.

9. Conclusion

In Ireland the price of sunscreen has reduced in recent years such that cost should not be a barrier to utilisation. As we prioritise financial spend on new medicines, the Medicines Management Programme (MMP) conclude that sunscreen should not be reimbursed on the DP Scheme as high quality products can be purchased at a low cost in many pharmacies and supermarkets.

For patients with GMS eligibility and who are organ transplant recipients, sunscreen could be made available through Discretionary Hardship Arrangements due to the higher risk of skin cancer in this cohort. The sunscreens reimbursed through this process should be in line with the recommendation for product quality and cost as outlined below.

Sunscreens should only be reimbursed through Discretionary Hardship Arrangements when the prescription has been written by a consultant dermatologist or transplant specialist and products reimbursed should be at an appropriate price as outlined below.

Preparations to be considered for reimbursement should be as follows:

- ✓ **SPF 50+ only**
- ✓ **high UVA protection (appropriate information available on product packaging)**
- ✓ **cost-effective volume product (i.e. 200ml or 400ml preparations) only**
- ✓ **Cost of up to €9.99 per 200ml preparation (<€50 per litre)**

The MMP recommends reimbursement of selected 'Preferred' sunscreens of:

- **SPF 50+**
- **High UVA rating (5 Star rating or high PPD)**
- **Best value for money (based on volume and unit cost)**

For transplant recipients with GMS eligibility only

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