Australian Government

Department of Health

# House of Representatives

# STANDING COMMITTEE ON HEALTH

# INQUIRY INTO SKIN CANCER IN AUSTRALIA

# SUBMISSION FROM THE DEPARTMENT OF HEALTH

# MARCH 2014

# Contents

**EXECUTIVE SUMMARY** **3**

**1. INTRODUCTION** **4**

**2. SKIN CANCER IN AUSTRALIA – STATISTICS** **5**

*2.1 Current Statistics* *5*

*2.2 Future Trends* *6*

*2.3 Expenditure* *7*

**3. TREATMENT AND MANAGEMENT** **7**

*3.1 The Medicare Benefits Schedule – funding for the treatment of benign and malignant skin lesions* *8*

*3.2 Pharmaceutical treatments for skin cancer through the Pharmaceutical Benefits Scheme* *9*

*3.3 Funding for skin cancer treatment delivered in public hospitals* *10*

*3.4 Treatment centres* *11*

**4. EARLY DIAGNOSIS** **11**

*4.1 Primary care* *11*

*4.2 The Therapeutics Goods Act* *11*

*4.3 Health Workforce Supply, and Distribution* *12*

**5. PREVENTION** **12**

*5.1 Protection from UV radiation* *12*

*5.2 Sunscreens* *13*

**6. AWARENESS** **13**

*6.1 The National Skin Cancer Awareness Campaign* *14*

*6.2 National Sun Protection Survey* *14*

*6.3 Vitamin D* *14*

**7. CONCLUSION** **15**

*Attachment A – MBS items under review* *16*

*Attachment B - MBS Expenditure and Services Data* *27*

*Attachment C - Medicines currently listed on PBS for the treatment of skin cancer* *29*

*Attachment D - Medications for the treatment of skin cancer approved by the TGA* *30*

## EXECUTIVE SUMMARY

While the incidence of skin cancer is very high in Australia, our efforts to control it include well developed, long term, highly successful national strategies that involve a wide range of players, not only in the health field but across many sectors of the community.

Australia has been actively working to control all cancers, including skin cancer, with strong and consistent investments over the last 30 years. There have been public health prevention campaigns across the nation to raise awareness of skin cancers as well as policies and programmes focused on effective treatment and management. This sustained effort includes more than 30 years of systematic data collection on cancer incidence, mortality and survival statistics involving the Commonwealth as well as all state and territory governments.

Australia has made great progress in cancer control and skin cancer survival rates despite the high burden of disease. This is due partly to specific action related to skin cancer control and partly to our health system that allows universal access to affordable cancer care. While there are areas that could be improved, the primary health care system, specialist oncologists and hospitals are managing well the early detection and treatment of skin cancer. Outcomes are likely to further improve in the future as cost-effective and proven targeted therapies based on the genomic signature of a skin cancer become more widely available.

Although our rapidly ageing population will mean an overall increase in many cancers in the foreseeable future, there is now emerging evidence that the last 30 years of public health preventive measures are beginning to somewhat reduce the incidence of melanoma (the more serious and sometimes fatal type of skin cancer) and possibly non melanoma skin cancers (more prevalent but not as lethal) in younger age groups.

The Department of Health, through this submission, provides a summary overview of the many activities it undertakes in this field. These are set out according to the terms of reference set by the Standing Committee on Health for this Inquiry.

Other Agencies across the Health Portfolio also have specific roles in skin cancer control and these will be outlined in separate submissions from: Cancer Australia; the National Health and Medical Research Council; the Australian Institute of Health and Welfare; and the Australian Radiation Protection and Nuclear Safety Agency.

## 1. INTRODUCTION

Australia has among the highest incidence of skin cancer in the world, but we also detect, treat and manage this cancer well, such that we have among the best five year relative survival rates in the world.

Australia has been successful in controlling this cancer largely because of our universal health care system with affordable access to public hospitals, subsidised treatments and targeted therapies via the Medicare Benefits Scheme (MBS) and the Pharmaceutical Benefits Scheme (PBS). Access to general practitioners through primary care has assisted early detection. Together, general practitioners, dermatologists, plastic surgeons and oncology specialists, working with multidisciplinary care teams, provide much of the treatment related to the more serious skin cancer, melanoma.

We know that most skin cancer in Australia is preventable. All levels of government have worked co-operatively to implement a range of effective measures over the past 30 years from public health prevention and awareness campaigns to structural protection from the sun in childcare centres, and schools, through to sun protection policies in work places and community facilities. These efforts continue and are well supported by the work of the non-government sector, especially through the Cancer Councils across Australia. The impact of these activities is starting to show in the reduced incidence of melanoma in younger age groups. However, like public health campaigns to reduce smoking, there are multiple causes and effects as well as long lead times in cancer control, so it is often decades before the impact of these activities appear in health statistics. It is also difficult to attribute statistical trends to any one campaign, policy or change in clinical practice and management.

The future for Australia is that we are likely to see an overall increase in incidence as cancer is primarily a disease of the aged and we have a growing ageing population. However, based on current trends, overall mortality is likely to decrease as the impact of prevention activities show in longer time trends with younger generations and as more effective treatments become available.

Advances in research are likely to lead to improvements in survival. Australia has a strong record in research. The National Health and Medical Research Council (NHMRC) is the largest funder of cancer research in Australia. There is now a rapidly emerging area of research using genomics to develop tumour specific treatments based on the profile of the cancer. Many new treatments are proving to be more effective for a range of advanced cancers including promising findings for patients with melanoma.

Cancer Australia, the Australian Government's flagship cancer agency, has a number of programmes and initiatives aimed at all cancers including skin cancer. Cancer Australia works with a range of stakeholders, including clinicians, consumers and researchers to improve the implementation of evidence based best practice care which we know impacts positively on cancer outcomes.

The Australian Institute of Health and Welfare (AIHW) works with state and territory registries to compile national data contributing to our understanding of cancer. All state and territory governments have cancer registries which assist with the national monitoring of cancer incidence, mortality, prevalence and survival. Melanoma has been a notifiable disease

since 1982, so through the cancer registries, we have very good data available on this type of skin cancer. Non melanoma skin cancers (NMSC) are not notifiable diseases and hence, we are dependent on survey data and medical records to provide estimates of this highly prevalent form of skin cancer.

## 2. SKIN CANCER IN AUSTRALIA – STATISTICS

Skin cancer is usually grouped into NMSC and melanoma, with melanoma being the more serious as it can metastasise and lead to the spread of secondary cancers.

The two main types of NMSC are basal cell carcinomas and squamous cell carcinomas. These cancers do not usually metastasise (spread beyond the site of the original tumour), but nonetheless, they are the most commonly diagnosed type of skin cancers in Australia and the rest of the world. Although not invasive cancers, a third group of skin lesions called keratinocyte dysplasias may develop into non-melanoma skin cancers and include solar keratosis, Bowenoid keratosis and squamous cell carcinoma in-situ (Bowen's disease).

### *2.1 Current Statistics*

According to our national statistics, in 2002, Australia had the world's highest incidence rate in skin cancer, and it was estimated that approximately two in three Australians would be diagnosed with NMSC by the time they have reached the age of 70[1]. The overall incidence of skin cancer in Australia is two to three times the rates found in Canada, the US and the UK[2].

NMSC is the most common skin cancer in Australia with about 417,000 new cases predicted to have been diagnosed in 2010[1]. NMSC is not a statutory reportable cancer, therefore the true incidence rates are not known. However, despite the apparent very high incidence rate of NMSC, the mortality rate is relatively low with 543 deaths being reported in 2011 (355 males and 188 females)[3].

According to the latest statistics in 2010, melanoma was found to be the fifth most common cancer in Australia (when including NMSC), with 11,405 new cases (6,700 males and 4,705 females)[4].

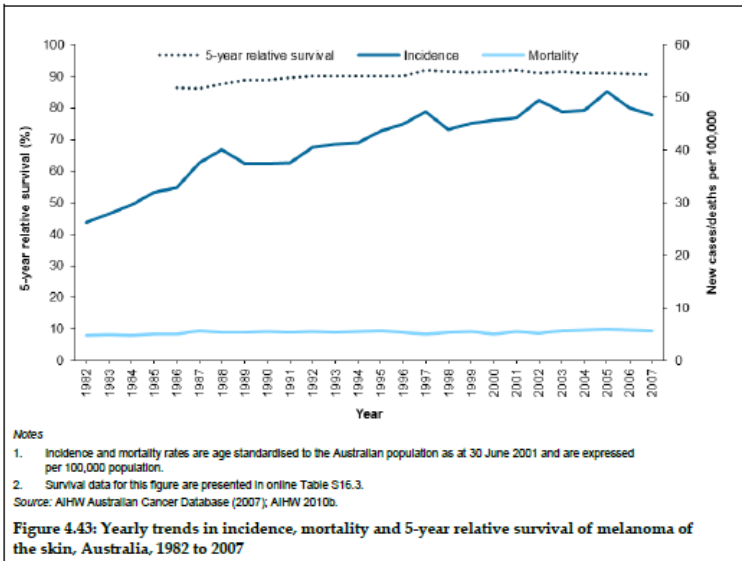
1 Staples MP, Elwood M, Burton RC, William JL, Marks R & Giles GG 2006. Non-melanoma skin cancer in Australia: the 2002 national survey and trends since 1985. Medical Journal of Australia 184(1): 6–10.

[2] Cancer Council Australia website, accessed 12 March 2014, <http://www.cancer.org.au/>

[3] AIHW 2014. Australian Cancer Incidence and Mortality (ACIM) books for 2014. Canberra: AIHW <http://www.aihw.gov.au/acim-books/>.

[4] AIHW 2014. Australian Cancer Incidence and Mortality (ACIM) books for 2014. Canberra: AIHW<http://www.aihw.ov.au/acim-books/>

Relative five-year survival rates in the period between 2006-2010 for all cancers in Australia is currently 66 per cent[5]. For melanoma of the skin, Australia has one of the highest five-year relative survival rates at over 91 per cent for the same period (89 per cent for males and 94 per cent for females)[6]. The five-year relative survival rate since 1982 can be seen in the top broken line of the graph below. The dark line in the middle of the graph shows the increasing incidence rate of melanoma age standardised from 1982 to 2007. The bottom lighter line shows the age standardised mortality rate for the same period, this indicates mortality is remaining low despite incidence rates increasing.




*Notes*

1. Incidence and mortality rates are age standardised to the Australian population as at 30 June 2001 and are expressed per 100,000 population.
2. Survival data for this figure are presented in online Table S16.3.

*Source:* AIHW Australian Cancer Database (2007); AIHW 2010b.

**Figure 4.43: Yearly trends in incidence, mortality and 5-year relative survival of melanoma of the skin, Australia, 1982 to 2007**

While melanoma is much less common than NMSC, it results in approximately three times as many deaths, with 1,544 deaths in 2011 (1,071 males and 473 females) [3].

At the end of 2007, there were 45,753 living Australians who had been diagnosed with melanoma sometime in the previous five years (5-year prevalence), and 136,016 living Australians who had been diagnosed with melanoma sometime in the previous 26 years when national records began[7].

### *2.2 Future Trends*

The incidence rate of melanoma has been rising since national records began in 1982. It is projected that there will be 17,570 new cases of melanoma diagnosed in 2020, an increase of 54% over the 2010 figure[8]. This is an expected trend for cancer in an ageing population.

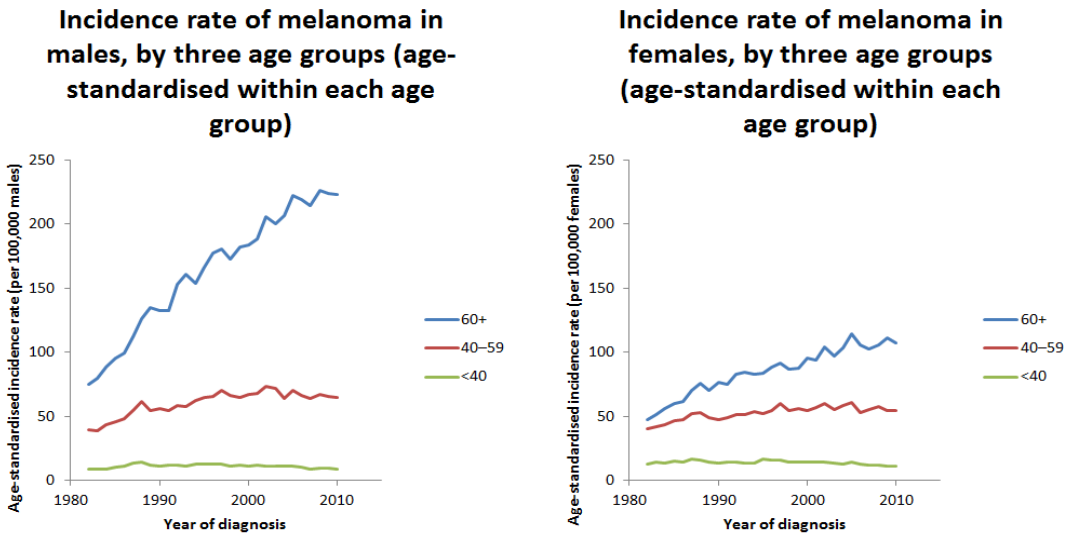
[5] AIHW 2012. Cancer in Australia: An Overview 2012.

[6] AIHW 2012b. Cancer survival and prevalence in Australia: period estimates from 1982 to 2010. Cancer series no. 69. Cat. no. CAN 65. Canberra: AIHW. [p. 87]

[7] AIHW 2012b. Cancer survival and prevalence in Australia: period estimates from 1982 to 2010. Cancer series no. 69. Cat. no. CAN 65. Canberra: AIHW. [p. 87]

[8] AIHW 2012a. Cancer incidence projections, Australia 2011 to 2020. Cancer series no. 66. Cat. no. CAN 62. Canberra: AIHW. [p. ix]

Encouragingly, a recent analysis of AIHW data shows that for younger age groups (40 years or younger), the incidence of melanoma is reducing[3].




Source: AIHW, ACIM Books

### *2.3 Expenditure*

In 2008–09, the cost to the Australian community of treatment for skin cancers was estimated to be $416.8 million ($367.4 million for NMSC and $49.5 million for melanoma)[9]. It was also estimated that total expenditure on all cancers was $4,526 million in 2008-09[10].

## 3. TREATMENT AND MANAGEMENT

The most effective treatment for skin cancer depends on the type of skin cancer, the stage of the disease, the severity of symptoms, and the person's overall health status. Australian Guidelines recommend complete surgical excision, including the removal of an appropriate margin of normal tissue, as the most appropriate treatment modality for both melanoma and non-melanoma skin cancers which provides the highest chance of curing the patient.

The *Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand* stipulate that the standard treatment for primary melanoma should be wide local excision (WLE) of the skin and subcutaneous tissues around the melanoma based on the maximum Breslow thickness of the primary melanoma (i.e. thickness/depth of the melanoma measured from the top layer of skin to the base of the tumour). While non-surgical techniques have been used in recent years for the treatment of melanoma, including imiquimod cream, cryotherapy and radiotherapy, their efficacy has not been established.

The *Basal cell carcinoma, squamous cell carcinoma (and related lesions) – a guide to clinical management in Australia* also recommends complete surgical excision of with appropriate margins of normal tissue. NMSCs may also be removed by micrographically

[9] (AIHW 2013 and unpublished data from AIHW Disease Expenditure Database).

[10] AIHW 2013 Health system expenditure on cancer and other neoplasms in Australia, 2008-09 cancer series no.81

controlled serial excision (or Mohs surgery), a highly specialised surgical technique by which individual layers of cancerous tissue are removed one at a time and examined under a microscope, by the same medical practitioner, until all cancerous tissue has been removed.

There are also a number of non-surgical techniques available for the treatment of NMSCs (including solar keratosis) supported by Australian guidelines including cryotherapy (direct application of liquid nitrogen to cause the destruction of cancerous tissue); curettage and diathermy/electrodesiccation (electrosurgery); topical agents or creams; photodynamic therapy; and radiotherapy.

All these procedures are provided by registered medical practitioners, including general practitioners, plastic surgeons and dermatologists.

### *3.1 The Medicare Benefits Schedule – funding for the treatment of benign and malignant skin lesions*

Medicare benefits subsidise the costs of fee-for-service medical care and some dental, nursing and allied health services. The level of Medicare benefits paid for services is a proportion of the Medicare 'Schedule fee'. The Medicare benefit, or 'rebate', is: 100 per cent of the Schedule fee for general practitioner services; 85 per cent of the Schedule fee for other services provided outside hospital; and 75 per cent of the Schedule fee for medical services in hospital and privately insured 'hospital substitute' services. The Medicare safety nets pay additional benefits when certain out-of-pocket cost thresholds are reached.

Prior to medical services being included on the MBS, an application needs to be made to the Medical Services Advisory Committee (MSAC). MSAC is an independent scientific committee comprising individuals with expertise in clinical medicine, health economics and consumer matters. It advises the Minister for Health on whether a new or existing medical service should be publicly funded based on an assessment of its comparative safety, effectiveness, cost-effectiveness and total cost, using the best available evidence. In providing this advice, MSAC may also take other relevant factors into account. This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for the Australian healthcare system.

The Medicare Benefits Schedule (MBS) contains over 5,800 items and represents annual Australian Government funding of more than $18 billion a year. The MBS includes a large number of items for the diagnosis and treatment of patients with skin cancer treated in the private sector. The Medical Benefits Division (MBD) within the Department, supported by the MSAC, is currently conducting a review of skin lesion excision and repair items listed on the MBS. In 2012, the MSAC established the Skin Services Review Consultation Committee, to review and amend the 79 MBS items (listed at Attachment A) related to the excision of skin lesions and skin flap repairs, to ensure that best clinical practice and guidelines for the excision of benign or malignant skin lesions is supported by the MBS and to ensure that the schedule is simplified.

In the 2012-13 financial year, over 2.21 million MBS services were claimed with $215 million in Medicare benefits paid for the 79 skin lesion excision and repair items identified for the review. Note that this figure does not include GP or specialist consultations, ablative treatment, pathology, imaging and oncology services that may be related to the

diagnosis of skin lesions. MBS expenditure and services data for the five years between 2008-09 to 2012-13 is outlined in **Attachment B**.

It is anticipated that the outcomes of the review will be available in late 2014 and that subject to Australian Government approval, the implementation of the new schedule will take place in 2015.

### *3.2 Pharmaceutical treatments for skin cancer through the Pharmaceutical Benefits Scheme*

If the cancer spreads beyond the skin and sentinel lymph nodes, chemotherapy may be used to kill the cancer cells. These are all prescription-only medicines and are accessible through the Pharmaceutical Benefits Scheme (PBS).

The purpose of the PBS is to provide reliable, timely and affordable access to a wide range of medicines for all Australian residents. Many of these medicines subsidised by the PBS cost a great deal more than the PBS co-payment amount.

Before a prescription medicine can be marketed in Australia, it must be included in the Australian Register of Therapeutic Goods (ARTG). In order to register a new medicine in Australia, a sponsor must submit an application together with supporting data to the Therapeutic Goods Administration (TGA). The TGA evaluates the data to establish the quality, safety and effectiveness of the product when used as intended.

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body comprising doctors, other health professionals and a consumer representative, makes recommendations to the Australian Government about PBS listings. The Government cannot list a medicine on the PBS unless the PBAC makes a recommendation in favour of its listing. The PBAC considers each PBS listing submission having regard to the safety, clinical effectiveness and cost-effectiveness (value-for-money) of the medicine for the intended use, in comparison with other available treatments. It is usually an industry sponsor of a product which holds the clinical and other data required for a PBS listing submission.

Over 4,700 branded products are currently subsidised by the Australian Government through the PBS. Many of them assist people with cancer including skin cancer. A list of the medicines currently listed on PBS for the treatment of skin cancer is included at **Attachment C**.

In recent years, advances in research have led to two new medicines being listed on the PBS for the treatment of advanced melanoma: ipilimumab (Yervoy®) and dabrafenib (Tafinlar®).

On 28 October 2013, the Minister for Health announced the Australian Government's approval to list 50 new and amended medicines and technologies, including Tafinlar, a new ground-breaking treatment for advanced melanoma. The required related genetic testing to determine appropriate eligibility of patients for this treatment was also listed on the MBS. This medicine was subsequently listed on the PBS on 1 December 2013.

This listing follows the 1 August 2013, Yervoy was listed on the PBS for the treatment of unresectable Stage III or Stage IV malignant (advanced) melanoma. This made the

treatment now accessible to many patients, whereas before listing on the PBS, the cost was prohibitive for many patients.

Without Australian Government subsidy these drugs would cost up to $94,000 and $110,000 respectively per patient per year for treatment, with a further cost of up to $230 for diagnostic testing.

There are further submissions to be considered by the PBAC for the treatment of melanomas (refer to **Attachment C**). However, the Australian Government does not interfere with the decision making process of the PBAC. Further, the Australian Government cannot compel a sponsor to make a submission for PBS listing to the PBAC.

Access to new and old cancer medicines is greatly assisted by the PBS where PBS co-payment and safety net arrangements help ensure that the most help goes to those in greatest need. Concession card holders such as pensioners can still purchase PBS-listed medicines that can cost up to $100,000 a year for just $6.00 per prescription, while general patients only pay up to $36.90.

Under the National Health Reform Agreement, state and territory governments manage the public hospital systems. As such, state and territory governments make decisions regarding the availability of public hospital services. Public hospitals are required to provide necessary medicines to in-patients free of charge but may not always provide medicines to outpatients. Some states may have state-based hospital formularies, while in other states and territories, decisions about formularies are made by individual hospitals. As the states and territories manage their own public hospital services individually, the extent to which medicines are provided to outpatients may vary between different jurisdictions.

Alternatively, treating medical practitioners may be able to contact the sponsors of the medicine in question about less expensive purchase options or whether the medicine can be supplied on a compassionate basis.

### *3.3 Funding for skin cancer treatment delivered in public hospitals*

The National Health Reform Agreement, agreed by the Coalition of Australian Governments in August 2011, introduced a nationally consistent system of Activity Based Funding for public hospitals services.

Under the national Activity Based Funding arrangements, the Commonwealth's contribution to public hospital services is now made on the basis of a National Efficient Price as determined by the Independent Hospital Pricing Authority.

Under the national Activity Based Funding arrangements, the Commonwealth provides Activity Based Funding payments for a variety of intensive procedures and treatments provided to admitted patients in public hospitals (e.g. for the excision of a skin cancer lesion). The Commonwealth also provides Activity Based Funding payments for outpatient (non-admitted) services delivered by dermatology or plastic and reconstructive clinics in public hospitals.

### *3.4 Treatment centres*

The Australian Government has invested $685 million in the establishment of 26 Regional Cancer Centres and patient accommodation facilities across Australia and a further $666.6 million in centres of excellence located in Sydney and Melbourne. These regional centres will improve access to surgical and radiation therapy for people living in regional Australia with melanoma.

## 4. EARLY DIAGNOSIS

Early diagnosis and treatment of skin cancer reduces the requirement for invasive surgery and improves outcomes and survival rates[11].

Early diagnosis is facilitated when the general public knows and understands about the importance of detecting changes in their skin early, followed by action to see a registered health professional.

### *4.1 Primary care*

In Australia, general practitioners are most often the first point of call for clinical early detection. The diagnosis and management of skin cancer is a core competency of general practitioners. General practitioners may treat the skin cancer themselves or make an appropriate referral for treatment. Referral services are provided by specialists such as dermatologists, plastic surgeons and oncologists.

The most common test to diagnose cancer, including skin cancer, is a biopsy. A skin biopsy involves medical removal of a tissue sample to determine the presence or extent of disease. This assessment is generally performed under a microscope by a pathologist.

Australia's good outcomes for skin cancers reflect that access to effective primary care services for early detection and evidence based treatment for skin cancers is working well.

### *4.2 The Therapeutics Goods Act*

The Therapeutic Goods Administration (TGA) supports the supply of safe and high quality medicines, medical devices and other therapeutic goods to the Australian population. It regulates medical devices marketed in Australia to ensure they meet the requirements which are set out in the *Therapeutic Goods Act 1989*, and in the *Therapeutic Goods (Medical Devices) Regulations 2002*. This includes for example, dermatoscopes which provide a polarised light to better examine skin lesions.

The TGA also requires medicines to be entered on the ARTG before being lawfully supplied in Australia. A list of approved skin cancer medicines, treatments and detection devices is provided at **Attachment D**.

[11] Cancer Council NSW website, accessed 13 March 2014,< http://www.cancercouncil.com.au/>

### *4.3 Health Workforce Supply, and Distribution*

Detection and treatment of skin cancer is considered a core competency of general practitioners. The high survival rates of skin cancer in Australia suggest that early detection and treatment is effective.

The Australian Government provides funding to the Australian College of Rural and Remote Medicine to provide a remote dermatology support programme, where general practitioners are able to email photos of skin lesions to dermatologists for advice.

The Commonwealth's Specialist Training Programme (STP) is making a significant contribution to increasing specialist training capacity. The intake of the programme has increased from 360 places in 2010 to 900 places in 2014. The STP is a targeted investment which extends vocational training for specialist registrars into settings outside traditional metropolitan teaching hospitals.

Under the National Cancer Work Plan, Cancer Australia is leading work on shared follow-up care for cancer. The project supports innovative use of the cancer workforce including service efficiencies, scope of practice, and new models of shared care between different specialists and general practitioners for follow-up care. The project optimises the use of the specialist workforce.

## 5. PREVENTION

Skin cancer is largely a preventable disease, although it is known that certain people with a specific genetic inheritance are more likely to succumb to this disease. Overall, it is estimated that between 95 per cent and 99 per cent of skin cancers are caused by exposure to the sun[12]. Prevention activities therefore focus on reducing sun exposure of the population through increasing awareness and the appropriate use of sunscreen and sun protection clothing. These measures are further supported through institutions and community facilities, especially where sun protection policies and/or measures are in place such as shade cloth areas in children's play areas and at public pools.

There has been a number of public health programmes aimed at preventing excessive exposure to UV radiation implemented across Australia by non-government cancer organisations and government health services over the past 30 years. The 'Slip! Slop! Slap!' and SunSmart slogans, developed in 1980 and 1987 by Cancer Council Victoria, have been the themes of many campaigns and are well recognised by Australians in relation to sun protection[13].

### *5.1 Protection from UV radiation*

Other sun protection measures in place to reduce the exposure of ultraviolet (UV) radiation include the assessment by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) on the safety of sun-protective clothing, sunglasses, shade cloth, sunscreen, solaria and providing guidance on their suitability.

[12] Cancer Council Australia, accessed 12 March 2014, <http://www.cancer.org.au/about-cancer/types-of-cancer/skin-cancer.html>
[13] Cancer Council Australia, National Cancer prevention Policy: Ultraviolet Radiation, 2011.

In addition, ARPANSA develops standards and guidance material, underpinned by evidence based scientific research. They also undertake scientific measurements of UV exposure for public and occupational safety to provide the evidence base for advice to the Australian Government and the community. Further details on ARPANSA's role in skin protection will be outlined in ARPANSA's submission to the Inquiry.

### *5.2 Sunscreens*

Sunscreens fall into two categories:

- *Primary sunscreens*, which are primarily for protection of the skin from UV radiation; and
- *Secondary sunscreens*, which are primarily for a cosmetic purpose (eg. moisturising) but also contain sunscreening agents to provide some protection from UV radiation.

In Australia, all primary and some secondary sunscreens are regulated as "Listed" medicines on the ARTG and must comply with the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1991*, and other legislated requirements and codes for Good Manufacturing Practice (GMP), quality control of ingredients, labelling, and advertising. This contrasts with international approaches to sunscreen regulation, which treats these products as cosmetics.

UV radiation levels in Australia are higher than other parts of the world. When combined with clearer atmospheric conditions and differences in ozone level, Australia is exposed to some of the strongest UV radiation levels in the world. It has thus been a long-standing situation that sunscreens are regulated in Australia to ensure safety, quality and efficacy.

Primary and secondary sunscreen marketed in Australia must comply with the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012). The Sunscreen Standard was recently updated to raise the Sun Protection Factor (SPF) limit from 30+ to 50+. The implementation of changes to adopt the new Sunscreen Standard came into force from 10 November 2012 via amendments to the *Therapeutic Goods Regulations 1991*. These sunscreens are significantly more protective than those previously available.

Some secondary sunscreens (such as moisturisers with SPF up to 15, make-up products, and lip balms) are classified as cosmetics and are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Competition and Consumer Commission rather than by the TGA.

## 6. AWARENESS

Evidence based communication campaigns, developed in collaboration with key stakeholders, have been shown to be effective in raising awareness and changing behaviour in health-related settings.

Improving awareness about skin cancer is carried out in a wide variety of settings and by a range of agencies in the community, including governments at all levels and the non-government sector.

### *6.1 The National Skin Cancer Awareness Campaign*

The Australian Government developed, implemented and evaluated three phases of the National Skin Cancer Awareness Campaign (NSCAC) beginning in 2006-07. This included mass media advertising and was the first Australian Government funded national skin cancer campaign.

For NSCAC, the Department worked with a campaign reference group comprising cancer prevention experts. Total funding for the campaign was $21 million from 2006-07 to 2009-10.

The campaign targeted teenagers (13-17 years) and young adults (18-24 years), as these groups have the worst sun protection behaviours and the highest frequency of sunburn. The theme of NSCAC was 'Protect yourself in five ways from skin cancer' and the campaign strategy was designed to increase the acceptability of multiple sun protection behaviours and the perception that this is normal, socially endorsed behaviour.

The pre- and post-campaign surveys showed significant increases in the target audience's adoption of sun protection behaviours, a strong positive effect on sun protection knowledge and perceived efficacy of sun protection methods, and increased knowledge of personal susceptibility to skin cancer.

The final evaluation of this campaign found "reduced year on year impact and limited uptake of protective behaviours across a range of situations" and that "there was significant scope for more changes in sun protection behaviours, attitudes and knowledge…"[14]. This finding shows that targeted campaigns to specific age groups can be effective in increasing awareness and changing behaviour but they may need to be updated to maintain their effectiveness.

All states and territories have their own sun protection awareness activities. These are conducted either through the state Cancer Councils or state governments and include the provision of website-based prevention and detection messages, and at different times have included media campaigns.

### *6.2 National Sun Protection Survey*

The Australian Government Department of Health has provided funding of $225,000 to support a National Sun Protection Survey, to be conducted under the auspices of the Cancer Council Australia in the summer of 2013-14. The National Sun Protection Survey will provide comprehensive information about the population's response to skin cancer prevention campaigns and programme activities across Australia. The study will also build knowledge on the demographic and other factors associated with specific sun-related attitudes and behaviours, and sunburn on summer weekends.

### *6.3 Vitamin D*

There has been recent debate that skin protection awareness activities could be contributing to Vitamin D deficiency in the Australian population.

[14] Ipsos-Eureka 2010 EVALUATION OF NATIONAL SKIN CANCER AWARENESS CAMPAIGN – THIRD PHASE (2009-2010).

Vitamin D is required by the body to maintain good health, in particular to keep bones and muscles strong and healthy[15].

Vitamin D is available through exposure of the skin to UV radiation, some foods (such as oily fish, eggs, and meat) and supplements which are readily available without medical prescription. The amount of sunlight each individual needs to make Vitamin D is also variable depending on factors such as skin type and lifestyle. Sun exposure is the major contributor to Australia's high incidence of skin cancer. A balance is therefore required between the risk of skin cancer from too much sun exposure and maintaining adequate Vitamin D levels.

The Cancer Council in conjunction with others has issued a statement providing guidance on getting the right balance of sun protection and exposure for vitamin D levels[15].

## 7. CONCLUSION

The incidence of skin cancer in Australia is very high and will continue to grow in the foreseeable future, given Australia's high exposure to intense sunshine and our rapidly ageing population. We do, however, have very high survival rates for skin cancer and overall, our control of this disease is well advanced.

Australia has developed a long-term, sophisticated and multi-dimensional response to its high incidence of skin cancer. Effort has been evident from all governments across the nation with collaborative support and initiatives from the non-government sector, especially the Cancer Councils. A range of settings have been targeted for prevention, including educational venues, work areas and leisure activities.

A robust health care system served by well skilled health practitioners and access to affordable tests, treatments and care has served well all those Australians affected by skin cancer. This combined set of strategies has improved outcomes for people with cancer. Improvements in survival are likely to increase as emerging research in genomics gives rise to new specific targeted therapies which may improve outcomes for those with advanced melanoma.

[15] The Australian and New Zealand Bone and Mineral Society, Osteoporosis Australia, the Australasian College of Dermatologists and the Cancer Council Australia- *Risks and Benefits of Sun Exposure-Position Statement (2007)*

## Attachment A – MBS items under review

| MBS item number | Item descriptor (GMST July 2013) | Total service numbers (2012-13) | Benefits paid (2012-13) |
|---|---|---|---|
| **Total** | | **2,210,743** | **$ 214,972,676** |
| 30071 | Diagnostic biopsy of skin or mucous membrane, as an independent procedure, if the biopsy specimen is sent for pathological examination | 843,645 | $31,079,608 |
| 31000 | Micrographically controlled serial excision of skin tumour utilising horizontal frozen sections with mapping of all excised tissue, and histological examination of all excised tissue by the specialist performing the procedure—6 or fewer sections | 7,818 | $ 3,296,168 |
| 31001 | Micrographically controlled serial excision of skin tumour utilising horizontal frozen sections with mapping of all excised tissue, and histological examination of all excised tissue by the specialist performing the procedure—7 to 12 sections (inclusive) | 2,441 | $1,333,924 |
| 31002 | Micrographically controlled serial excision of skin tumour utilising horizontal frozen sections with mapping of all excised tissue, and histological examination of all excised tissue by the specialist performing the procedure—13 or more sections | 513 | $336,931 |
| 31200 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal by surgical excision (other than by shave excision) and suture from cutaneous or subcutaneous tissue or from mucous membrane, other than a service:<br>(a) associated with a service to which item 45200, 45203 or 45206 applies; or<br>(b) to which another item in this Group applies<br>*Extended Medicare Safety Net Cap: $27.20* | 9,734 | $251,395 |
| 31205 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal of and suture, if:<br>(a) the lesion size is not more than 10 mm in diameter; and<br>(b) the removal is from cutaneous tissue, subcutaneous tissue or mucous membrane by surgical excision (other than by shave excision); and<br>(c) the specimen excised is sent for histological examination including the excision of a specimen to confirm a malignant tumour covered by any of items 31300 to 31335 (other than a service to which item 30195 applies)<br>*Extended Medicare Safety Net Cap: $76.35* | 291,946 | $21,098,821 |
| 31210 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal of and suture, if:<br>(a) the lesion size is more than 10 mm but not more than 20 mm in diameter; and<br>(b) the removal is from cutaneous tissue, subcutaneous tissue or mucous membrane by surgical excision (other than by shave excision); and<br>(c) the specimen excised is sent for histological examination; including the excision of a specimen to confirm a malignant tumour covered by any of items 31300 to 31335 (other than a service to which item 30195 applies) | 76,334 | $7,233,133 |

| | | | |
|---|---|---|---|
| 31215 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal of and suture, if:<br>(a) the lesion size is more than 20 mm in diameter; and<br>(b) the removal is from cutaneous tissue, subcutaneous tissue or mucous membrane by surgical excision (other than by shave excision); and<br>(c) the specimen excised is sent for histological examination;<br>including the excision of a specimen to confirm a malignant tumour covered by any of items 31300 to 31335 (other than a service to which item 30195 applies) | 25,465 | $2,783,357 |
| 31220 | Tumours (other than viral verrucae (common warts) and seborrheic keratoses), cysts, ulcers or scars (other than scars removed during the surgical approach at an operation), removal of 4 up to 10 lesions and suture, if:<br>(a) the size of each lesion is not more 10 mm in diameter; and<br>(b) each removal is from cutaneous tissue, subcutaneous tissue or mucous membrane by surgical excision (other than by shave excision); and<br>(c) all of the specimens excised are sent for histological examination;<br>including excisions to confirm a malignant tumour covered by any of items 31300 to 31335 (other than a service to which item 30195 applies) | 3,828 | $659,943 |
| 31225 | Tumours (other than viral verrucae (common warts) and seborrheic keratoses), cysts, ulcers or scars (other than scars removed during the surgical approach at an operation), removal of more than 10 lesions and suture, if:<br>(a) the size of each lesion is not more than 10 mm in diameter; and<br>(b) each removal is from cutaneous tissue, subcutaneous tissue or mucous membrane by surgical excision (other than by shave excision); and<br>(c) all of the specimens excised are sent for histological examination;<br>including excisions to confirm a malignant tumour covered by any of items 31300 to 31335 (other than a service to which item 30195 applies) | 789 | $227,034 |
| 31230 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal by surgical excision (other than by shave excision) and suture from nose, eyelid, lip, ear, digit or genitalia, including excision to establish the diagnosis of tumours covered by items 31300 to 31335—if the specimen excised is sent for histological examination (other than a service to which item 30195 applies) | 57,395 | $6,901,181 |
| 31235 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal of and suture, if:<br>(a) the lesion size is not more than 10 mm in diameter; and<br>(b) the removal is from the face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle) by surgical excision (other than by shave excision); and<br>(c) the specimen excised is sent for histological examination;<br>including the excision of a specimen to confirm a malignant tumour covered by any of items 31300 to 31335 (other than a service to which item 30195 applies) | 88,226 | $9,103,499 |

| | | | |
|---|---|---|---|
| 31240 | Tumour (other than viral verrucae (common warts) and seborrheic keratoses), cyst, ulcer or scar (other than a scar removed during the surgical approach at an operation), removal by surgical excision (other than by shave excision) and suture from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), including excision to establish the diagnosis of tumours covered by items 31300 to 31335, lesion size more than 10 mm in diameter—<br>if the specimen excised is sent for histological examination (other than a service to which item 30195 applies) | 23,327 | $2,884,089 |
| 31250 | Giant hairy or compound naevus, excision of an area at least 1% of body surface—if the specimen excised is sent for histological confirmation of diagnosis | 507 | $128,708 |
| 31255 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from nose, eyelid, lip, ear, digit or genitalia, if:<br>(a) the carcinoma is not more than 10 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 67,078 | $9,714,207 |
| 31256 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from nose, eyelid, lip, ear, digit or genitalia, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was not more than 10 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 2,646 | $415,754 |
| 31257 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from nose, eyelid, lip, ear, digit or genitalia, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was not more than 10 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 626 | $86,473 |
| 31258 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from nose, eyelid, lip, ear, digit or genitalia, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is not more than 10 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed;<br>other than a service to which item 31295 applies | 473 | $69,539 |

| | | | |
|---|---|---|---|
| 31260 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from nose, eyelid, lip, ear, digit or genitalia, if:<br>(a) the carcinoma is more than 10 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 28,159 | $4,679,766 |
| 31261 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from nose, eyelid, lip, ear, digit or genitalia, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 10 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 1,120 | $217,085 |
| 31262 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from nose, eyelid, lip, ear, digit or genitalia, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 10 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 500 | $82,603 |
| 31263 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from nose, eyelid, lip, ear, digit or genitalia, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is more than 10 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed;<br>other than a service to which item 31295 applies | 342 | $56,560 |
| 31265 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from the face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), if:<br>(a) the carcinoma is not more than 10 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 124,977 | $17,164,277 |
| 31266 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was not more than 10 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 3,235 | $466,664 |

| | | | |
|---|---|---|---|
| 31267 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was not more than 10 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 685 | $93,430 |
| 31268 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is not more than 10 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed;<br>other than a service to which item 31295 applies | 661 | $89,337 |
| 31270 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), if:<br>(a) the carcinoma is more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 76,951 | $13,841,064 |
| 31271 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 1,675 | $321,109 |
| 31272 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 570 | $97,475 |

| | | | |
|---|---|---|---|
| 31273 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed;<br>other than a service to which item 31295 applies | 367 | $63,837 |
| 31275 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), if:<br>(a) the carcinoma is more than 20 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 16,131 | $2,823,404 |
| 31276 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 20 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 462 | $97,040 |
| 31277 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 20 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 183 | $31,459 |
| 31278 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from face, neck (anterior to the sternomastoid muscles) or lower leg (mid calf to ankle), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is more than 20 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed;<br>other than a service to which item 31295 applies | 220 | $38,860 |
| 31280 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from an area of the body not covered by item 31255 or 31265, if:<br>(a) the carcinoma is not more than 10 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination | 167,953 | $19,406,997 |

| | | | |
|---|---|---|---|
| | and malignancy is confirmed | | |
| 31281 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from an area of the body not covered by item 31255 or 31265, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was not more than 10 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 2,894 | $362,047 |
| 31282 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from an area of the body not covered by item 31255 or 31265, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was not more than 10 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 642 | $76,969 |
| 31283 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from an area of the body not covered by item 31255 or 31265, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is not more than 10 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 469 | $56,053 |
| 31285 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from an area of the body not covered by item 31260 or 31270, if:<br>(a) the carcinoma is more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than by shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 103,669 | $16,492,235 |
| 31286 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from an area of the body not covered by item 31260 or 31270, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 1,795 | $299,684 |

| | | | |
|---|---|---|---|
| 31287 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from an area of the body not covered by item 31260 or 31270, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 410 | $ 63,552 |
| 31288 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from an area of the body not covered by item 31260 or 31270, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is more than 10 mm and not more than 20 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 401 | $63,044 |
| 31290 | Basal cell carcinoma or squamous cell carcinoma (including keratocanthoma), removal of, from an area of the body not covered by item 31260 or 31275, if:<br>(a) the carcinoma is more than 20 mm in diameter; and<br>(b) the removal is by therapeutic surgical excision (other than shave excision) and suture; and<br>(c) the initial specimen removed is sent for histological examination and malignancy is confirmed | 19,419 | $3,088,889 |
| 31291 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from an area of the body not covered by item 31260 or 31275, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 20 mm in diameter; and<br>(b) the removal is performed by the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 466 | $85,275 |
| 31292 | Basal cell carcinoma or squamous cell carcinoma, residual, removal of, from an area of the body not covered by item 31260 or 31275, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was more than 20 mm in diameter; and<br>(b) the removal is performed by a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision (other than shave excision) and suture; and<br>(d) the specimen excised is sent for histological examination | 194 | $29,370 |
| 31293 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from an area of the body not covered by item 31260 or 31275, following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the carcinoma is more than 20 mm in diameter; and<br>(b) the removal is by surgical excision (other than shave excision) and suture; and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 122 | $17,871 |

| | | | |
|---|---|---|---|
| 31295 | Basal cell carcinoma or squamous cell carcinoma, recurrent, removal of, from the head or neck (anterior to the sternomastoid muscles), following the removal of a previous basal cell carcinoma or squamous cell carcinoma at that site, if:<br>(a) the previous carcinoma was treated by previous surgery, serial cautery and curettage, radiotherapy or 2 prolonged freeze and thaw cycles of liquid nitrogen therapy; and<br>(b) the removal is performed by:<br>(i) a specialist in the practice of his or her specialty; or<br>(ii) a practitioner other than the practitioner who removed the previous carcinoma; and<br>(c) the removal is by surgical excision and suture; and<br>(d) the specimen excised is sent for histological examination and malignancy is confirmed | 3,814 | $708,654 |
| 31300 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of kin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle, removal of, from nose, eyelid, lip, ear, digit or genitalia, and suture, if:<br>(a) the tumour size is not more than 10 mm in diameter; and<br>(b) the removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 917 | $194,025 |
| 31305 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle-removal from nose, eyelid, lip, ear, digit or genitalia, tumour size more than 10 mm in diameter, and suture, if:<br>(a) removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(b) the specimen excised is sent for histological examination and confirmation of malignancy has been obtained | 1,020 | $246,064 |
| 31310 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle, removal of, from face, neck (anterior to sternomastoid muscles) or lower leg (mid calf to ankle), and suture, if:<br>(a) the tumour size is not more than 10 mm in diameter; and<br>(b) the removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 3,544 | $725,255 |
| 31315 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle, removal of, from face, neck (anterior to sternomastoid muscles) or lower leg (mid calf to ankle), and suture, if:<br>(a) the tumour size is more than 10 mm but not more than 20 mm in diameter; and<br>(b) the removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 3,164 | $779,113 |

| | | | |
|---|---|---|---|
| 31320 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle, removal of, from face, neck (anterior to sternomastoid muscles) or lower leg (mid calf to ankle), and suture, if:<br>(a) the tumour size is more than 20 mm in diameter; and<br>(b) the removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 1,685 | $382,585 |
| 31325 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle, removal of, from an area of the body not covered by items 31300 and 31310, and suture, if:<br>(a) the tumour size is not more than 10 mm in diameter; and<br>(b) the removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 12,242 | $2,637,013 |
| 31330 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle, removal of, from an area of the body not covered by items 31305 and 31310, and suture, if:<br>(a) the tumour size is more than 10 mm but not more than 20 mm in diameter; and<br>(b) the removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and malignancy is confirmed | 9,338 | $2,353,475 |
| 31335 | Malignant melanoma, appendageal carcinoma, malignant fibrous tumour of skin, merkel cell carcinoma of skin or Hutchinson's melanotic freckle-removal from areas of the body not covered by items 31305 and 31320, and suture, if:<br>(a) the tumour size more than 20 mm in diameter; and<br>(b) removal is by definitive surgical excision (with an adequate margin and as a result, no further surgery is indicated at the site of excision); and<br>(c) the specimen excised is sent for histological examination and confirmation of malignancy has been obtained | 3,491 | $863,147 |
| 45000 | Single stage local muscle flap repair, on eyelid, nose, lip, neck, hand, thumb, finger or genitals | 1,036 | $331,815 |
| 45003 | Single stage local myocutaneous flap repair to one defect, simple and small | 5,725 | $2,229,369 |
| 45006 | Single stage large myocutaneous flap repair to one defect (pectoralis major, latissimus dorsi, or similar large muscle) (H) | 467 | $284,089 |
| 45009 | Single stage local muscle flap repair to one defect, simple and small (H) | 378 | $58,340 |
| 45012 | Single stage large muscle flap repair to one defect (pectoralis major, gastrocnemius, gracilis or similar large muscle) (H) | 444 | $112,976 |
| 45015 | Muscle or myocutaneous flap, delay of (H) | 22 | $3,595 |
| 45039 | Arteriovenous malformation (3 cm or less) of superficial tissue, excision of | 86 | $14,274 |

| | | | |
|---|---|---|---|
| 45042 | Arteriovenous malformation, (greater than 3 cm), excision of | 26 | $5,581 |
| 45045 | Arteriovenous malformation on eyelid, nose, lip, ear, neck, hand, thumb, finger or genitals, excision of | 133 | $27,418 |
| 45200 | Single stage local flap, if indicated to repair one defect, simple and small, excluding flap for male pattern baldness and excluding H-flap or double advancement flap | 34,457 | $7,019,164 |
| 45203 | Single stage local flap, if indicated to repair one defect, complicated or large, excluding flap for male pattern baldness and excluding H-flap or double advancement flap | 27,846 | $7,804,045 |
| 45206 | Single stage local flap if indicated to repair one defect, on eyelid, nose, lip, ear, neck, hand, thumb, finger or genitals and excluding H-flap or double advancement flap | 30,131 | $8,341,119 |
| 45207 | H-flap or double advancement flap if indicated to repair one defect, on eyelid, eyebrow or forehead | 4,205 | $1,298,981 |
| 45209 | Direct flap repair (cross arm, abdominal or similar), first stage | 144 | $40,651 |
| 45212 | Direct flap repair (cross arm, abdominal or similar), second stage | 129 | $22,535 |
| 45215 | Direct flap repair, cross leg, first stage (H) | 5 | $ 3,416 |
| 45218 | Direct flap repair, cross leg, second stage (H) | 2 | $ 420 |
| 45221 | Direct flap repair, small (cross finger or similar), first stage | 57 | $7,102 |
| 45224 | Direct flap repair, small (cross finger or similar), second stage | 63 | $4,772 |
| 45227 | Indirect flap or tubed pedicle, formation of | 73 | $ 17,966 |
| 45230 | Direct or indirect flap or tubed pedicle, delay of | 48 | $5,754 |
| 45233 | Indirect flap or tubed pedicle, preparation of intermediate or final site and attachment to the site | 98 | $28,772 |
| 45236 | Indirect flap or tubed pedicle, spreading of pedicle, as a separate procedure (H) | 21 | $4,204 |
| 45239 | Direct, indirect or local flap, revision of, by incision and suture, other than a service to which item 45240 applies | 820 | $124,290 |
| **Total** | | **2,210,743** | **$ 214,972,676** |

## Attachment B - MBS Expenditure and Services Data

### Total MBS expenditure

**2012-13**

In the 2012-13 financial year, over 2.21 million MBS services were claimed with $215 million in Medicare benefits paid for the 79 skin lesion excision and repair items identified for review (this does not include GP or specialist consultations).

- GPs performed 1.16 million services ($108 million in benefits); and
- specialists performed 1.05 million services ($107 million in benefits).

**Growth in MBS expenditure**

Over the past five years (2008-09 to 2012-13), there has been a steady increase in the use of MBS items for skin lesion excision and repair of melanoma and non-melanoma (i.e. the 79 items under review including biopsy and flap repairs). The following table provides an outline of the annual growth in MBS item usage and benefits paid for the surgical excision and repair of melanoma and non-melanoma skin lesions (for the purpose of these statistics non-melanoma skin lesions refers to benign and malignant lesions).

| Financial year | Service numbers | Percentage increase of service numbers | Benefits paid |
|---|---|---|---|
| 2008/2009 | 1,865,879 | n/a | $169,245,428 |
| 2009/2010 | 1,921,742 | 3% | $178,258,188 |
| 2010/2011 | 1,984,305 | 3% | $188,457,022 |
| 2011/2012 | 2,103,674 | 6% | $202,273,688 |
| 2012/2013 | 2,210,743 | 5% | $214,972,676 |
| **5 YEAR TOTAL** | **10,086,343** | **18%** | **$953,207,002** |

**Total healthcare expenditure (2008-09)** [1]

In 2008-09, expenditure on skin cancers (melanoma and non-melanoma) in Australia was estimated to be $416.83 million (AIHW data December 2013).

### Melanoma

**MBS expenditure**

In the 2012-13 financial year, 35,401 services with $8.2 million in benefits paid (2012-13) for the surgical excision of melanoma skin lesions (i.e. this does not include biopsy or flap repairs):

- GPs performed 11,970 services ($2.96 million in benefits); and
- specialists performed 23,431 services ($5.22 million in benefits).

**Growth in MBS expenditure**
The following table provides an outline of the annual growth in MBS item usage and benefits paid for the surgical excision of melanoma over the past 5 years.

| Financial year | Service numbers | Percentage increase of service numbers | Benefits paid |
|---|---|---|---|
| 2008/2009 | 28,215 | n/a | $5,969,786 |
| 2009/2010 | 29,027 | 3% | $6,310,857 |
| 2010/2011 | 31,322 | 8% | $6,962,063 |
| 2011/2012 | 33,204 | 6% | $7,553,276 |
| 2012/2013 | 35,401 | 7% | $8,180,677 |
| **5 YEAR TOTAL** | **157,169** | **25%** | **$34,976,660** |

**Total healthcare expenditure (2008-09)**[1]
In 2008-09, expenditure on melanoma in Australia was estimated to be $49.5 million (AIHW data December 2013).

**Non-melanoma**
**MBS expenditure**
In the 2012-13 financial year, 1,217,632 services with $147.5 million in benefits paid (2012-13) for the surgical excision of non-melanoma skin lesions (i.e. this does not include biopsy or flap repairs):

- GPs performed 689,536 services ($82.25 million in benefits); and
- specialists performed 528,095 services ($65.19 million in benefits).

**Growth in MBS expenditure**
The following table provides an outline of the annual growth in MBS item usage and benefits paid for the surgical excision of non-melanoma skin lesions over the past 5 years..

| Financial year | Service numbers | Percentage increase of service numbers | Benefits paid |
|---|---|---|---|
| 2008/2009 | 1,091,703 | n/a | $119,185,075 |
| 2009/2010 | 1,117,025 | 2% | $125,315,615 |
| 2010/2011 | 1,133,622 | 1% | $131,757,925 |
| 2011/2012 | 1,177,501 | 4% | $139,827,327 |
| 2012/2013 | 1,217,632 | 3% | $147,438,766 |
| **5 YEAR TOTAL** | **5,737,483** | **12%** | **$663,524,710** |

**Total healthcare expenditure (2008-09)**[1]
In 2008-09, expenditure on non-melanoma skin cancer was estimated to be $367 million (AIHW data December 2013).

* Note: The MBS data provided only covers services specific to the surgical excision of skin lesions (including benign and cancerous lesions) and in addition there are MBS items available for GP and specialist consultations, ablative treatment, pathology, imaging and oncology services.

[1] ***AIHW 2013 and unpublished data from AIHW Disease Expenditure Database).***

**Attachment C - Medicines currently listed on PBS for the treatment of skin cancer**

The most recent additions to the PBS include the listings of ipilimumab (Yervoy) for the treatment of unresectable Stage III or Stage IV malignant melanoma and dabrafenib (Tafinlar) for the treatment of unresectable Stage III or Stage IV malignant melanoma for patients who are positive with a BRAF V600 mutation. The combined cost to the Australian Government for these two PBS listings is over $350 million over the forward estimates period.

Other established PBS listed medicines

| **Drug** | **Indication** | **2012-13 Expenditure** |
|---|---|---|
| Inteferon-alfa 2B | Malignant melanoma and several other cancers, and chronic Hepatitis B | $1.1 million |
| Fotemustine | Metastatic malignant melanoma | $1.1 million |
| Imiquimod | Basal cell carcinoma | $3.1 million |
| Carboplatin | Unrestricted listing | Figure cannot be obtained as PBS medicine can be used for other cancer conditions |
| Temozolomide | Treatment of glioblastoma multiforme | $20.0 million |

New medicines in the pipeline continue to be considered by the PBAC. For example, at its March 2014 meeting, the PBAC considered a new medicine, trametinib (Mekinist), to be used in combination with dabrafenib (Tafinlar), for the treatment of unresectable stage III or metastatic stage IV melanoma for patients who are positive with a BRAF V600 mutation. The outcomes of the March 2014 PBAC meeting will be published on the PBS website on 24 April 2014 at www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes.

The Australian Government provides funds to each state and territory government to assist with the cost of providing public hospital services. It may be possible for a patient's treating doctor to make an application to a local public hospital for assistance with the cost of a non-PBS listed medicine.

Alternately, treating doctors may be able to contact the sponsors of the medicine in questions about less expensive purchase options or whether the medicine can be supplied on a compassionate basis.

## Attachment D - Medications for the treatment of skin cancer approved by the TGA

### Melanoma medications

***Ipilimunab***

Ipilimunab (marketed under the trade names Yervoy and Winglore) is a monoclonal antibody that works by activating the immune system.[16] Cytotoxic T lymphocytes (CTLs) can recognise and destroy cancer cells; however, there is also an inhibitory mechanism that interrupts this destruction. Ipilimumab turns off this inhibitory mechanism through targeting Cytotoxic T-Lymphocyte Antigen 4 (CTLA-4) and allows CTLs to continue to destroy cancer cells. Ipilimunab is administered by intravenous (IV) infusion.
Ipilimunab was included on the ARTG on 4 July 2011 (ARTG IDs: 174319, 174322). The approved therapeutic use by the TGA is:
*Yervoy, as monotherapy, is indicated for the treatment of patients with unresectable or metastatic melanoma who have failed or are intolerant to prior therapy.*

***Vemurafenib***

Vemurafenib (trade name Zelboraf) inhibits proliferation and survival of cells with BRAF kinase mutations by suppressing signals in the mitogen-activated protein kinase (MAPK) pathway.[17] Mutations in BRAF kinase occur in about half of patients with metastatic melanoma; typically the mutation is "V600E", which increases BRAF activity by many orders of magnitude. The name "vemurafenib" comes from V600E mutated BRAF inhibition. Vemurafenib tablets are taken orally.
Vemurafenib was included on the ARTG on 10 May 2012 (ARTG ID: 183674). The approved therapeutic use by the TGA is:
*For the treatment of unresectable stage IIIC or stage IV metastatic melanoma positive for a BRAF V600 mutation.*

***Dabrafenib***

Dabrafenib (trade name Tafinlar) is a drug of the same class as vemurafenib: an inhibitor of BRAF kinase activity, and for the treatment of patients with BRAF V600 mutation positive melanoma.[18] Dabrafenib capsules are taken orally.
Dabrafenib was included on the ARTG on 27 August 2013 (ARTG IDs: 200922, 200936). The approved therapeutic use by the TGA is:
*For the treatment of patients with BRAF V600 mutation positive unresectable Stage III or metastatic (Stage IV) melanoma.*

***Trametinib***

Trametinib (trade name Mekinist) binds to and inhibits the MAPK enzymes MEK1 and MEK2, resulting in an inhibition of growth factor-mediated cell signalling and cellular proliferation in cancer.[19] The name "Mekinist" comes from MEK inhibitor. Trametinib tablets are taken orally.

[16] Kudchadkar RR, Gonzalez R, Lewis K. (2013) New targeted therapies in melanoma. *Cancer Control* 20: 282-288.
[17] Kudchadkar RR, Gonzalez R, Lewis K. (2013) New targeted therapies in melanoma. *Cancer Control* 20: 282-288.
[18] Gibney GT, Zager JS. (2013) Clinical development of dabrafenib in BRAF mutant melanoma and other malignancies. *Expert Opin Drug Metab Toxicol.* 9: 893-899.
[19] Grimaldi AM, Simeone E, Ascierto PA. (2014) The role of MEK inhibitors in the treatment of metastatic melanoma. *Curr Opin Oncol.* 26: 196-203.

Trametinib was included on the ARTG on 14 February 2014 (ARTG IDs: 205917, 205918, 205919). The approved therapeutic use by the TGA is:
*Mekinist in combination with dabrafenib is indicated for the treatment of patients with BRAFV600 mutation positive unresectable Stage III or metastatic (Stage IV) melanoma. Mekinist as a monotherapy is indicated for the treatment of patients with BRAFV600 mutation positive unresectable Stage III or metastatic (Stage IV) melanoma and in whom either there is intolerance to BRAF inhibitors or BRAF inhibitors cannot be used. Mekinist as monotherapy has not demonstrated clinical activity in patients who have progressed on BRAF inhibitor therapy (see CLINICAL TRIALS).*

***Dacarbazine***
Dacarbazine is an antineoplastic chemotherapy drug used in the treatment of various cancers including malignant melanoma, Hodgkin lymphoma, sarcoma, and islet cell carcinoma of the pancreas. Dacarbazine is a member of the class of alkylating agents, which destroy cancer cells by adding an alkyl group to its DNA. Dacarbazine is administered by IV infusion.
Dacarbazine was first included on the ARTG in 1992 (ARTG ID: 39954) and is marketed under several trade names. The approved therapeutic use by the TGA is:
*Chemotherapy of metastatic malignant melanoma and various sarcomas. In other cancers, the available evidence shows dacarbazine to be ineffective or less effective than established regimens. Note: The use of dacarbazine is restricted to hospitals with an oncology service.*

***Fotemustine***
Fotemustine (trade name Muphoran) is a drug of the same class as dacarbazine: an alkylating antineoplastic agent used in the treatment of malignant melanoma. Fotemustine is administered by IV infusion.
Fotemustine was included on the ARTG on 30 April 1993 (ARTG ID: 44019). The approved therapeutic use by the TGA is:
*Disseminated malignant melanoma, including cerebral metastases, administered alone or in combination with other cancer agents.*

***Temozolomide***
Temozolomide (trade name Temodal) is a drug of the same class as dacarbazine and fotemustine: an alkylating antineoplastic agent used in the treatment of various cancers including malignant melanoma and Grade IV astrocytoma (glioblastoma multiforme). Temozolomide capsules are taken orally.
Temozolomide was included on the ARTG on 30 June 1999 (ARTG IDs: 68720, 68721, 68722, 68723). The approved therapeutic use by the TGA is:
*As a first-line treatment for patients with advanced metastatic malignant melanoma.*

***Interferon alfa-2b***
Interferon alfa-2b (trade name Intron-A) is a specific interferon protein. Interferons are usually released by the body in response to a viral infection. Interferon alfa-2b works by stimulating the immune system to fight against the cancer cells. It also helps to regulate the reproduction of cancerous cells. Interferon alfa-2b is used to treat a broad spectrum of cancers including malignant melanoma, hairy cell leukaemia, Kaposi's sarcoma, chronic myelogenous leukaemia, and multiple myeloma. Interferon alfa-2b is administered by subcutaneous infusion.

Interferon alfa-2b was included on the ARTG on 29 May 1997 (ARTG IDs: 60021, 60024). The approved therapeutic use by the TGA is:
*Malignant melanoma: as an adjuvant therapy of malignant melanoma following surgery in patients who are at high risk of recurrence. The potential benefit to the patient should be assessed carefully. Although toxicity of the treatment may be substantial, for most patients, the benefit of therapy outweighed the risk.*

**Basal cell carcinoma (BCC) medications**

***Imiquimod***

Imiquimod is a topical medication, ie. it is a form of chemotherapy applied directly to the skin. When applied to the skin, imiquimod activates the adaptive immune system.[20]
Imiquimod was first included on the ARTG in 1998 (ARTG ID: 64798) and is marketed under several trade names. The approved therapeutic use by the TGA is:
*For treatment of solar (actinic) keratosis on the face and the scalp (see Precautions), and primary treatment of confirmed superficial basal cell carcinoma where surgery is considered inappropriate, and the treatment of external genital and peri-anal warts (Condyloma acuminata) in adults (see Precautions).*

***Methyl aminolevulinate***

Methyl aminolevulinate (trade name Metvix) is photosensitive topical medication used in photodynamic therapy.[21] After being applied to the skin cancer, the skin is illuminated with a proprietary red light (630 nm) source to activate the photosensitiser. The drug then becomes toxic to targeted malignant and other diseased cells.
Methyl aminolevulinate was included on the ARTG on 4 April 2003 (ARTG ID: 93838). The approved therapeutic use by the TGA is:
*Treatment of thin or non-hyperkeratotic and non-pigmented actinic keratoses on the face and scalp when other registered therapies are unacceptable. Primary treatment of superficial and/or nodular basal cell carcinoma where surgery is considered inappropriate. Treatment of biopsy-proven squamous cell carcinoma in situ (Bowen's disease), where surgery is considered inappropriate.*

***Vismodegib***

Vismodegib (trade name Erivedge) is a drug that specifically targets the Hedgehog signalling pathway; diseases associated with the malfunction of this cellular pathway include BCC.[22]
Unlike other topical treatments for BCC, vismodegib is supplied as capsules taken orally.
Vismodegib was included on the ARTG on 9 May 2013 (ARTG IDs: 196234, 214475). The approved therapeutic use by the TGA is:
*For the treatment of adult patients with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma where surgery and/or radiation therapy are not appropriate.*

[20] Love WE, Bernhard JD, Bordeaux JS. (2009) Topical imiquimod or fluorouracil therapy for basal and squamous cell carcinoma: a systematic review. *Arch Dermatol.* 145: 1431-1438.
[21] Lee Y, Baron ED. (2011) Photodynamic therapy: current evidence and applications in dermatology. *Semin Cutan Med Surg.* 30: 199-209.
[22] Kunstfeld R. (2014) Smoothened inhibitors in the treatment of advanced basal cell carcinomas. *Curr Opin Oncol.* 26: 184-195.

**Squamous cell carcinoma (SCC) medications**

***5-fluorouracil***

5-fluorouracil (trade name Efudix) is an antimetabolite that halts cell growth and cell division, destroying the damaged cells when applied to the skin as a topical medication.[23] When the skin heals, new skin appears. In the case of metastatic melanoma and other advanced cancers of the breast and pancreas, 5-fluorouracil can also be administered by IV infusion.

In Australia, Efudix was included on the ARTG on 23 August 1991 (ARTG ID: 13721) as a fluorouracil 5% w/w cream tube. The approved therapeutic use by the TGA is:
*Solar and senile keratoses, Bowen's disease.*

***Methyl aminolevulinate***

Methyl aminolevulinate (trade name Metvix) has been discussed above for treating BCC and is also used for SCC.

**Skin Cancer Treatment and Detection Devices**

*Dermatoscopy*

A dermatoscope uses polarised light to allow inspection of skin lesions unobstructed by skin surface reflections. It can then be determined whether any skin is to be removed and sent for biopsy. The vast majority of dermatoscopes currently in use in Australia fall under Class I medical devices: these are not assessed by the TGA prior to inclusion on the ARTG.

*Electrical impedance tomography*

Research has found that the electrical properties differ between benign and malignant skin lesions, setting the stage for cancer detection through determination of electrical properties.[24]

An electrical impedance scanner uses electrical impedance tomography (EIT) to produce an image of the conductivity of part of the body as inferred from surface electrical measurements. Conducting electrodes are attached to the skin and small alternating currents are applied to the electrodes.

The resulting electrical potentials are measured and an image produced. The electrical impedance scanner is a non-invasive Class IIa device that uses a disposable electrode. EIT is used as an aid when considering skin excision; it is not used to confirm a clinical diagnosis of melanoma. EIT is also used to detect breast cancer and monitor lung function.

*Nuclear medicine*

If melanoma is detected before it spreads to the sentinel lymph nodes, there is a 99 per cent survival rate.[25] Nuclear medicine, which involves the application of radioactive substances in the diagnosis and treatment of disease, is particularly useful in determining whether there has been metastasis to a regional lymph node. This is the most important prognostic factor in early-stage melanoma. The TGA has approved a hand-held nuclear medicine device to detect

[23] Love WE, Bernhard JD, Bordeaux JS. (2009) Topical imiquimod or fluorouracil therapy for basal and squamous cell carcinoma: a systematic review. *Arch Dermatol.* 145: 1431-1438.
[24] Glickman YA, Filo O, David M, et al. (2003) Electrical impedance scanning: a new approach to skin cancer diagnosis. *Skin Res Technol.* 9: 262-268.
[25] Intenzo CM, Truluck CA, Kushen MC, et al. (2009) Lymphoscintigraphy in cutaneous melanoma: an updated total body atlas of sentinel node mapping. *Radiographics* 29: 1125-1135.

differences in concentration of radioisotopes in tissue and thereby assist in demarcating tissue for excision during surgery.

*Brachytherapy*

Brachytherapy is a form of radiotherapy where a radiation source is placed inside or directly next to the area requiring treatment; the radiation kills cancer cells. Brachytherapy is commonly used as an effective treatment for skin, cervical, prostate and breast cancer.[26] The TGA has approved a low-power X-ray device for the treatment of surface lesions such as BCC and SCC.

*In vitro diagnostic medical devices*

In vitro diagnostic medical devices (IVDs) are, in general, pathology tests and related instrumentation used to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management. IVDs are typically used in diagnostic laboratories, at the point of care, and in the home.

Recent advances in melanoma research have led to the development of specific diagnostic tests to detect genetic mutations, such as BRAF mutations, that can be used to determine a patient's tumour mutation status prior to the commencement of treatment. This allows for targeted drug therapy and in some instances is now a requirement before certain drugs can be prescribed. These genetic tests are regulated by the TGA as Class III IVDs and are required to be included in the ARTG.

[26] Alam M, Nanda S, Mittal BB, et al. (2011) The use of brachytherapy in the treatment of nonmelanoma skin cancer: a review. *J Am Acad Dermatol.* 65: 377-388.