



Australian Government

Department of Health

Application 1356:

**Melanoma surveillance photography – total
body photography and digital dermoscopy**

PICO Confirmation

(to guide a new application to MSAC)

(Version 0.1)

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Component	Description
Patients	Adults (aged ≥ 18 years) with minimum of 15 naevi and at least one of the following: <ol style="list-style-type: none"> 1. Personal history of melanoma 2. Family history of two or more first degree relatives having had melanoma 3. Personal history of gene mutation CDKN2A and one first or second degree relative with melanoma 4. 100 or more common naevi 5. Six or more atypical/dysplastic naevi
Prior tests	None
Intervention	<ul style="list-style-type: none"> • Total Body Photography (once every 5 years) • Total body pigmented lesion digital dermoscopy (DD/SDD) (once a year) ('Long term FU SDD; all lesions') • Follow-up digital dermoscopy of a previously photographed (by digital dermoscopy) pigmented lesion within 8-16 weeks of digital dermoscopy but limited to once per year ('short term FU SDD')
Comparator	<ul style="list-style-type: none"> • Self-examination at home without the use of photography (monthly); • GP clinical examination/skin excisions without access to photography for real time comparison (once or twice per year); • Dermatologist clinical examination/skin excisions (including dermoscopy), without access to photography for real time comparison (once or twice per year)

Component	Description
Outcomes	<p><u>Safety:</u></p> <p><u>Efficacy/effectiveness:</u></p> <p>Average Breslow thickness of detected invasive melanoma</p> <p>Ratio of non-invasive to invasive melanoma</p> <p>Frequency distribution of Breslow thickness – in situ, <1mm, >1mm</p> <p>Ratio for benign:malignant excisions for melanoma diagnosis</p> <p>Time to diagnosis</p> <p>Quality of Life (QoL)</p> <p>Rate of non-melanoma skin cancer such as basal cell skin cancer and squamous cell skin cancer identified.</p> <p><u>Healthcare resources:</u></p> <p><u>GP and specialist consultations</u></p> <p>Skin surgery benign (diagnostic) excision</p> <p>Skin surgery benign (diagnostic) biopsy</p> <p>Skin surgery melanoma wide excision</p> <p>Skin surgery defect repair</p> <p>Histopathology</p> <p>Diagnostic surgical sentinel lymph node biopsy</p> <p>Therapeutic lymph node dissection</p> <p>Diagnostic radiology ultrasound</p> <p>Diagnostic radiology PET/CT scan</p> <p><u>Cost-effectiveness:</u></p> <p>Cost/QALY</p> <p>Cost/Life Year</p> <p><u>Total Australian Government healthcare costs.</u></p> <p>Cost to the PBS</p> <p>Cost to the MBS</p> <p>Cost to other Government Healthcare providers</p>

Population

The medical condition most relevant to the proposed service is melanoma.

Melanoma is a cancer of the pigment cells of the skin (melanocytes). Melanoma may grow out of an existing melanocytic naevus (“mole”) or from a single melanocyte on otherwise clear skin. Sun exposure is a major risk factor for melanoma and Australians have a high risk due to our geography/sun exposure. It is estimated that the risk of an individual dying from melanoma skin cancer by their 85th birthday will be 1 in 120 (1 in 78 males and 1 in 228 females) in 2016 (Australian Institute of Health and Welfare, 2016). The single most effective method of preventing metastasis is to surgically cut the melanoma out of the skin at the earliest point in its development. In the earliest phase of melanoma it is confined to the top layers of the skin, the epidermis, and is non-invasive. Melanoma in the non-invasive phase can be difficult to diagnose clinically. As melanoma becomes more advanced and penetrates the layers of the skin sequentially it is designated “invasive”. The melanoma is given a vertical thickness measurement in millimetres, the Breslow thickness, once it becomes invasive. The Breslow thickness of the melanoma at surgery correlates with risk of metastasis and mortality. Melanoma can also be measured using the Clark’s level of invasion and the American Joint Commission on Cancer (AJCC) classification of melanoma (see Appendices).

Although annual incidence of diagnosis is fairly well documented for a selected population by geography, age or sex it can be harder to determine how many patients have detectable melanoma at any given point in time and how that number might be altered by risk factors. One Australian study performed community screening with primary care doctors and found 33 melanomas in 16,383 clinical examinations (Aitken et al., 2006). For an unselected Australian population this gives a point prevalence of 1 in 498. Sensitivity however could not be assessed. In a screening and surveillance program performed by dermatologists 555 patients at very high risk of melanoma (familial melanomas and dysplastic naevus syndrome) at initial screening were seen to have 48 melanomas (Masri et al., 1990). This is a point prevalence of 1 in 12. With such a high point prevalence, screening and surveillance in very high risk groups by dermatologists will pick up many melanomas.

The proposed population would be Medicare eligible persons age 18 years or over and at high risk of developing melanoma. All patients would be referred by a general practitioner or specialist registered and practicing in Australia. Watts et al. (2015) summarised 34 melanoma practice guidelines from 20 countries and identified the following risk factors as placing individuals in the “very high risk group”. These factors are listed below:-

- More than 100 common naevi
- More than 5 atypical naevi
- Two or more first degree relatives affected by melanoma
- Immunosuppression
- Personal history of skin cancer and excessive sun exposure
- Personal history of melanoma
- More than 250 treatments of psoralen plus ultraviolet therapy

- History of radiation therapy as a child
- Familial atypical mole and melanoma syndrome
- Congenital naevi greater than 20cm in diameter
- CDKN2A gene mutation carriers

It is proposed the high risk eligible population for melanoma surveillance photography is as outlined below and this also forms part of the MBS item descriptor. The patient will be referred by a medical practitioner, be 18 years of age or older, and have a minimum of 15 or more pigmented lesions for photography. They must also satisfy at least one of the criteria outlined below:

- Personal history of melanoma OR
- Family history of 2 or more first degree relatives having had melanoma OR
- Personal history of CDKN2A genetic mutation and at least 1 first or second degree relative with melanoma OR
- 100 or more common naevi OR
- Six or more atypical/dysplastic naevi

Rationale

High melanoma risk populations worldwide are stratified to receive special surveillance and care. This is standard of practice (Watts et al., 2015). The following are features of high risk patients who can be prospectively identified for clinical surveillance.

In general terms, an individual's future risk of melanoma may depend upon:

- person's age and sex
- history of previous melanoma or non-melanoma skin cancer
- family history of melanoma
- number of naevi (common and atypical)
- skin and hair pigmentation
- response to sun exposure
- evidence of actinic skin damage
- immunosuppression
- solarium use
- Psoralen and ultraviolet therapy > 250 treatments
- personal or family history of pancreatic and breast cancer
- chemical/environmental/radiation exposures
- non-melanoma skin cancer and systemic cancer history
- genetic mutations predisposing to melanoma
- alcohol intake
- Parkinson's disease
- Medication history

Melanoma may develop from an existing naevus or alternatively from normal skin. Total body photography takes body shots from different body areas and is most useful as a reference point to

determine in the future if a pigmented lesion is “new” and therefore may be a melanoma. It is most useful to compare the total body photography to the patient directly. Digital dermoscopy is most useful to determine if a pigmented lesion is in fact a melanoma or on serial examination whether it has changed over time indicating a melanoma developing within an existing naevus. This can be performed by comparing digital dermoscopic images over time or directly comparing archived digital dermoscopic images with real time dermoscopy clinically during face to face consultation.

All patients at high risk can potentially benefit from total body photography, digital dermoscopy and serial digital dermoscopy regardless of the number of pigmented lesions they have under surveillance. In practice, most subjects who undergo melanoma surveillance photography have several pigmented lesions. The Australian experience with photography of all pigmented lesions on a subject show average naevus counts over 30. For the purposes of this application a minimum number of pigmented lesions of 15 will be required for a subject to be eligible to access a Medicare Benefit Schedule item number.

The specific benefits high risk patient groups receive from comprehensive melanoma surveillance photography are:

1. Melanoma detection at an earlier stage in its development
2. Less aggressive skin surgery as definitive treatment
3. Fewer benign lesion excisions
4. Reduced requirement for sentinel lymph node biopsy and investigation and treatment of metastatic disease
5. Diagnosis of non-melanoma skin cancer
6. Improved capacity for self-examination and early diagnosis at home
7. Increased sense of well-being following a comprehensive photography session and written report
8. Increased access to specialist dermatologist service
9. More timely access to specialist dermatology services

Currently, a patient at risk of melanoma is presented to a General Practitioner (MBS item 23 or 36). The patient may not seek further follow up with a GP or Dermatologist, continues with GP follow up only (1 or 2 visits per year) or the GP refers the patient to a Dermatologist for further examination (MBS item 104). The patient then may either continue with follow-up visits to the Dermatologist (1 or 2 per year; MBS item 105), continues with follow-up with the GP (1 or 2 visits per year; MBS item 23 or 36) or continues follow-up with both GP and Dermatologist (1 or 2 visits per year; MBS items 23, 36 and 105). Clinical assessment by either the GP or Dermatologist would result in 1 of 3 conclusions: that no pigmented lesions are suspicious for melanoma and no surgical excisions are needed, a lesion is suspicious for melanoma and is removed (histology assessment would show the lesion is benign), and lastly a lesion is suspicious, removed and is found to be malignant through histology assessment. If melanoma is found further assessment and surgery occurs. The more advanced the melanoma is in the skin at the time of diagnosis (measured by Breslow thickness in mm) the more extensive the surgery, further assessment, morbidity, mortality and cost. The incidence of melanoma increases by age, and the incidence of melanoma in patients aged under 18 is low. The number of new cases of melanoma in 15-19 year olds is 1.7 per 100,000 people and in 10-14 year olds the incidence is 0.4 per 100,000 people. This incidence rate increases by age, with 235.9

new cases per 100,000 people aged 85 and over (**Figure 1**). While rates in people aged under 18 is low, this patient population should be tested in a sensitivity analysis, at least in patients aged between 14 and 18.

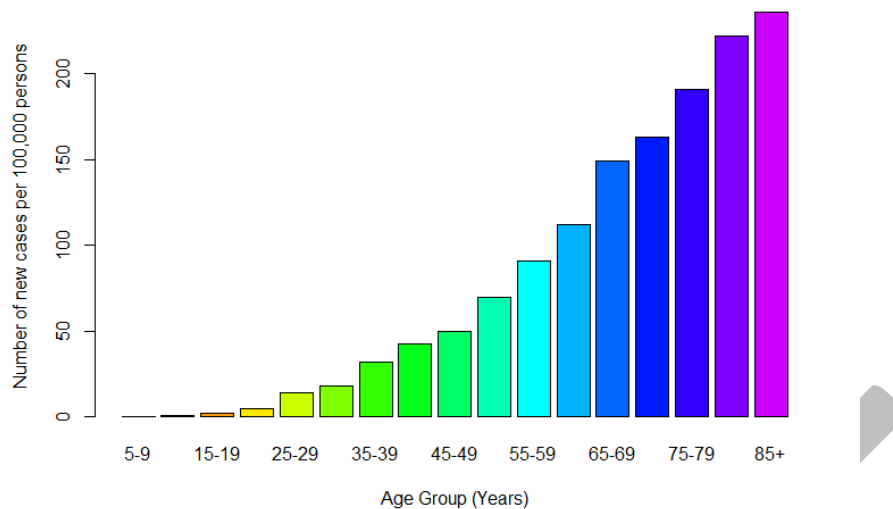


Figure 1: Estimated age-specific incidence rates for melanoma skin cancer, 2016 (Cancer Australia, 2016)

Prior test (investigative services only - if prior tests are to be included)

None

Intervention

There are three proposed medical services covered in this protocol:

- Total body photography (TBP; occurring once every five years) – Proposed Item A
- Total body pigmented lesion digital dermoscopy (DD/SDD; occurring a maximum of once every year, initial and long term follow up) –Proposed Item B
- Follow-up digital dermoscopy of a previously photographed (by digital dermoscopy) pigmented lesion within 8-16 weeks of digital dermoscopy (limited to once per year) –Proposed Item C

Melanoma surveillance photography (MSP) uses conventional photography as well as dermoscopic photography. Dermoscopy reveals features of the skin not visible through normal lighting and magnification. It does not however use any form of radiation or exposure other than polarised visible light.

Total body photography (TBP) is performed to photograph all the body regions. Different areas of the body are photographed in standard poses to give approximately 25 “long shot” photographs (19-36 depending on the system used and occasionally more) and all the existing naevi can be seen in those photographs (but not the very fine detail of each).

Once the body shots are performed individual melanocytic naevi are photographed up close (macro images) and then additionally through the dermatoscope i.e. digital dermoscopy. This includes all

pigmented lesions of any size that have any irregularity in them at all. It also includes all naevi and pigmented lesions on the body approximately $\geq 3\text{mm}$ in lateral diameter. In many cases there are more than 100 individual macro and dermoscopic photographs taken for a single individual.

Each individual close up and dermoscopic photograph is orientated and “tagged” to the body shots to show its exact anatomical location. That being the case TBP must be performed at baseline to allow correct anatomical position of each naevus photographed dermoscopically to be demonstrated.

The images are uploaded to a computer. The body shots and all individual naevus photographs are viewed by the reporting dermatologist and those that are melanoma or suspicious for melanoma are reported as requiring excision. Any other individual lesion/s that the referring doctor, the patient or the melanographer has a specific question about is also formally commented on in the report. The diagnoses are based on the appearance of each lesion specifically looked at by the reporting dermatologist and not via computer generated algorithm diagnosis.

A melanographer by definition for the purposes of this evaluation is a registered nurse with experience in both dermatology practice and photography. The melanographer works under instruction from the reporting dermatologist and the reporting dermatologist is responsible for the supervision and quality of the melanographer’s clinical work. Currently the only suggested requirement for a melanographer is that they be registered with AHPRA as a registered nurse and participates in self-directed continuing medical education. The Australasian College of Dermatologists in conjunction with the Australian Dermatology Nurses Association are in the process of currently co-ordinating a certification, ongoing education and audit process for melanographers in Australia.

At the time of the long term follow up study the previous whole body photographs are directly compared to the patient going through each body segment. This examination usually will be performed by the melanographer. This aspect requires time and a methodical approach. Any new lesion requires repeat photography of that specific body shot/segment (as well as the close up and dermoscopic photograph of the new lesion). Each individual naevus that was photographed at baseline is photographed as a close up shot and through the dermatoscope. All the images are reviewed by the dermatologist. Each individual lesion is compared to its previous photograph (or photographs if there has been more than 1 previous study). Any new changes are noted by the dermatologist and specifically if any changes suggestive of melanoma are noted then surgical excision is recommended. The subtle comparative changes seen over time can help diagnose “featureless” melanoma which cannot be diagnosed any other way. A report is produced similar in nature to the initial study (specific lesion comments, treatment recommendations and whether further photographic short term follow up is required). The images may be made available to the patient and/or their doctor to use for their own comparison over time at home or at the attending clinician’s surgery. The patient themselves can use the body shots and macro images for their own comparison at home. The patient’s attending doctor can do this too but additionally can use a dermatoscope to directly compare real time dermoscopy to the archival digital dermoscopic images. Various storage and transfer methods are available such as images on a data storage device such as a compact disc or via a password protected secure website. The over-riding principle is that any

report or images are only available to those with a bona fide interest and that they are secure. The applicant advocates for patient confidentiality and a robust security system around access to the patient's images. This is a major focus of the Australasian College of Dermatologists Teledermatology Guidelines which are in development.

Once the dermatologist has reviewed all the recorded referral and demographic data and all the photographs are reviewed a report is issued. The report is made available to the referring doctor and the patient. Although clinically trained, the melanographer makes no management decisions during the process regarding specific lesions or regarding interpretation of overall risk. If the melanographer feels that a lesion requires immediate action for some reason the melanographer directly informs the reporting dermatologist for their urgent determination.

Currently a private fee for comprehensive melanoma surveillance photography initial or long term follow up study in Australia is \$300-450. A current fee schedule for Molemap Australia quotes \$449 for an initial study (1 hour) and \$329 for follow up (www.molmap.net.au accessed 31/7/16) Currently the fee for a similar service in the USA is \$US400-450. The suggested cost for a short term follow up study of a few lesions has been costed at approximately \$70.

Total Body photography is expected to be performed at most once every 5 years per patient. Total body pigmented lesion digital dermoscopy (DD/SDD), initial and long term follow up, is expected to be used a maximum of once a year. Follow-up digital dermoscopy of a previously photographed pigmented lesion within 8-16 weeks of the digital dermoscopy (i.e. short term follow up) is limited to once per year.

Rationale

The reason all pigmented lesions are photographed dermoscopically at baseline and long term follow up is that:

1. In general approximately 50% of naevus derived melanomas arise from atypical naevi and 50% are derived from common naevi. Therefore if only atypical naevi are photographed the common naevi are not available for comparison in the future. Up to 30% of melanomas in high-risk patients may develop in unmonitored lesions if only clinically atypical lesions are photographed (Argenziano et al., 2013).
2. If only naevi which appear clinically atypical on inspection are looked at and photographed dermoscopically only 62% of dermoscopically abnormal naevi will be identified, i.e. many common naevi may have suspicious dermoscopic appearances which can only be identified if they are examined/photographed with a dermatoscope.
3. Commonly the photography will be performed by a trained Registered Nurse (melanographer) and photographing all pigmented lesions that could possibly be melanoma leaves the decision regarding differentiation between benign and malignant in the hands of the reporting dermatologist – not the nurse/melanographer taking the photographs.

A suggestion will also be made by the reporting dermatologist regarding the requirement for short term monitoring of one or more atypical lesions. It is common for the reporting dermatologist to also identify non-melanoma skin cancer and recommend its treatment. The rationale for follow up

photography is most important. There are a number of options regarding follow up photography after baseline photography has been performed:

1. A baseline study (total body photography, macro images and digital dermoscopy) may be performed and no follow up photography performed. The photographs however are used in follow up with the patient's self-examinations at home, with their GP clinical review and with their dermatologist if they are under specialist care. The photographs are used for comparison for real time clinical examination as a clinical aid. Baseline total body photography, macro images and digital dermoscopy is being proposed for an MBS item in this proposal i.e. proposed Items A + B
2. Short term follow up photography (macro images and digital dermoscopic images) may be suggested for just a few naevi only. These are naevi that do not have dermoscopic features of melanoma but have a patient reported history of change or an unusual dermoscopic appearance (but falling short of dermoscopic features of melanoma). This is called "short term follow up" and occurs at approximately 3 months from initial study. Another reason for short term follow up is for atypical lesions that for anatomical reasons would be difficult or disfiguring to biopsy or excise. Lesions on the palms, soles and the breasts in females are examples of such sites. A patient may undergo total body photography and digital dermoscopy of 100 naevi. Two naevi may be marked for short term follow up and only those two naevi are re-photographed at the 3 month mark. Short term follow up is an essential part of melanoma surveillance practice and the rationale and timing for its use is supported by the literature (Altamura et al., 2008; Beer et al., 2011; Moloney et al., 2014). Short term follow up MSP is being proposed for a MBS item in this proposal but only following an initial comprehensive MSP session (i.e. item B) and only within a window of 8-16 weeks after comprehensive photography as per the published literature. Short term dermoscopic follow up of a specific pigmented lesion generally only ever occurs once. If the lesion shows change at the short term follow up examination it is usually excised. If it does not show change it is likely to be benign and no further immediate action is required. Short term follow up photography is being proposed as an MBS item in this proposal i.e. proposed Item C. It is proposed this item may only be claimed a maximum of once per calendar year. The advice and suggestion to perform short term monitoring will usually be at the discretion of the reporting dermatologist. This advice would be contained in the report back to the managing clinician at the time of the baseline of long term follow up study (Item B).
3. Follow up photography may be performed for all of the naevi photographed at baseline and identification of any new pigmented lesions. It is uncertain in a high risk individual which naevi might be evolving into melanoma so all previous naevi are re-photographed and the new digital macro and dermoscopic images are compared to the previous ones. This is called "long term follow up". The whole process of long term follow up takes approximately the same resources as the initial photography. The interval between initial photography and long term follow up is variable but is usually not less than 1 year. One year is the period benchmarked by national and international publications and practice (Kittler et al., 2006). There is also a basis for this in published data about the rate of growth of melanoma and our ability to identify that change photographically (Altamura et al., 2008; Beer et al., 2011; Kittler et al., 2006; Lipsker, 2006; Liu et al., 2006; Moloney et al., 2014). Long term follow up photography is being proposed for a MBS item in this proposal (proposed item B). It is proposed long term follow up is only

- Dermatologist excision of skin lesions suspicious for melanoma

Rationale

Melanoma surveillance photography itself is time consuming. This is the reason the task of photography may be delegated to a melanographer under the instruction and supervision of the reporting dermatologist. The interpretation of the images and reporting is always performed by the dermatologist and a referring general practitioner can have a written report on the photography returned within 24 hours of the photography taking place. Access to dermatologist led melanoma surveillance photography is usually much quicker than access to face to face dermatologist consultation. This is because of the availability of the melanographer to do the time consuming photography and the fact the dermatologist can generate a report at any time of the day (not just restricted to daytime working hours). This being the case some general practitioners who have high risk patients refer them directly to a dermatologist for melanoma surveillance photography only (not clinical consultation) as they (the GP) will receive an opinion more quickly on a) whether the patient has a melanoma or not and b) which (if any) lesions require excision.

Home patient examination is more accurate in early diagnosis of melanoma when patients have undergone education in how to perform self-examination and it is also enhanced by patients using their own total body photography and clinical macroscopic photographs for home comparison. Patients also feel more satisfied that their surveillance for melanoma is indeed comprehensive if MSP is employed. Other potential clinical comparators therefore are the efficacy of home examination at finding melanoma and patient satisfaction with the surveillance process with and without melanoma surveillance photography

Outcomes

Patient relevant

MSP cannot in itself alter the true incidence of melanoma occurring in the skin as MSP is a diagnostic and clinical aid not a therapeutic intervention. MSP assists in diagnosing melanomas that may otherwise not become apparent on clinical examination for months or years. By assisting in the early diagnosis of melanoma it can find melanomas before they become invasive (in situ melanoma) or if invasive find melanomas before this local invasion in the skin becomes extensive. By doing so it reduces the risk and subsequent incidence of metastatic melanoma. Reduction in metastatic melanoma translates into improvements in mortality, morbidity and cost. . The primary outcomes proposed to measure these clinical claims would be a change in average Breslow thickness of detected invasive melanoma and a change in the in situ:invasive melanoma ratio. Additional outcomes would be the projected change in metastatic melanoma incidence and mortality as a result of early diagnosis (and surgical intervention). The economic claim is also made, that costs would be reduced due to earlier detection and removal of lesions. Earlier detection would result in a reduction in morbidity costs and treatment costs. In the economics of melanoma and skin cancer diagnosis and treatment a critical measure is the benign:malignant ratio. This notes how many benign lesions are excised for 1 melanoma to be diagnosed. A reduction in the benign:malignant ratio results in a reduction of cost incurred per melanoma diagnosed. The applicant claims MSP

based decisions on whether a lesion is excised or not results in a lower benign:malignant ratio and therefore a reduced cost per melanoma diagnosed. The benign:malignant ratio is also a primary outcome in this study. An additional outcome would be the change in time to assessment when referred by a general practitioner compared with a dermatologist for a clinical consultation, although this might increase utilisation, therefore increasing costs.

The additional procedure may decrease anxiety and lead to greater patient satisfaction. The primary outcomes to measure this claim would be the change in quality of life, using various specific instruments.

In the absence of historical or any future planned clinical trials comparing melanoma mortality with and without the use of MSP in high risk patients, early detection of melanoma is regarded as a valid clinical end point as it correlates with reduced morbidity and mortality (Geller et al., 2011). Early detection/diagnosis of melanoma is measurable. The early diagnosis of melanoma is best assessed by the depth of invasion of melanoma at the time of diagnosis. In-situ, non-invasive melanoma (Clark level 1) is the earliest point at which melanoma can be diagnosed and is almost universally curable. Invasive melanoma is measured by invasive thickness in millimetres which is the Breslow thickness. The greater the Breslow thickness the more likely metastasis and death will occur. Survival rates as they relate to Breslow thickness at diagnosis are readily available and one such graphical illustration is presented in section 4 of this proposal. Dermatologist led melanoma surveillance photography improves on early diagnosis as evidenced by higher in situ/invasive melanoma ratio and lower mean Breslow thickness of invasive melanoma. Early diagnosis of melanoma by the use of MSP compared to clinical consultation alone is demonstrated in the literature.

Healthcare system

The introduction of MSP is not expected to reduce the use of GP visits, and may reduce the use of Dermatologist visits. MSP is expected to augment current clinical practice and therefore assist in time to diagnosis. The identification of melanomas at an earlier stage is expected to reduce surgical costs and morbidity costs associated with more advanced melanomas. Translating this early detection into measurable human and resource costs precisely however is more difficult. The mortality, morbidity and cost in melanoma diagnosis and treatment often relates to the point in progression of melanoma at which it is diagnosed. Comparing the frequency distribution of diagnosis of melanoma between clinical examination alone and melanoma surveillance photography is one method to quantify costs. When melanomas are stratified into in situ, <1mm Breslow thickness and >1mm Breslow thickness the costs of these different arms can be quantified. This may be a more meaningful way to quantify the advantages of early diagnosis of melanoma rather than just in situ:invasive ratio and mean Breslow thickness of invasive melanoma.

Part of quantifying the potential benefit from early diagnosis of melanoma is to quantify the burden of disease as it relates to different stages of disease and from this modelling the benefit from early diagnosis can be extrapolated. One measure of this is disability adjusted life years. Disability adjusted life years (DALY) is a combination of years of life lost (YLL) and the burden of disability whilst living and enduring the disease (and its treatment) i.e. years of life with disability (YLD). Tromme et al, 2016, analysed a cohort of patients with 8016 melanomas and strongly supported the

idea that early diagnosis of melanoma improves outcome and quantified this by looking at DALY, YLL and YLD as they relate to different stages of melanoma.

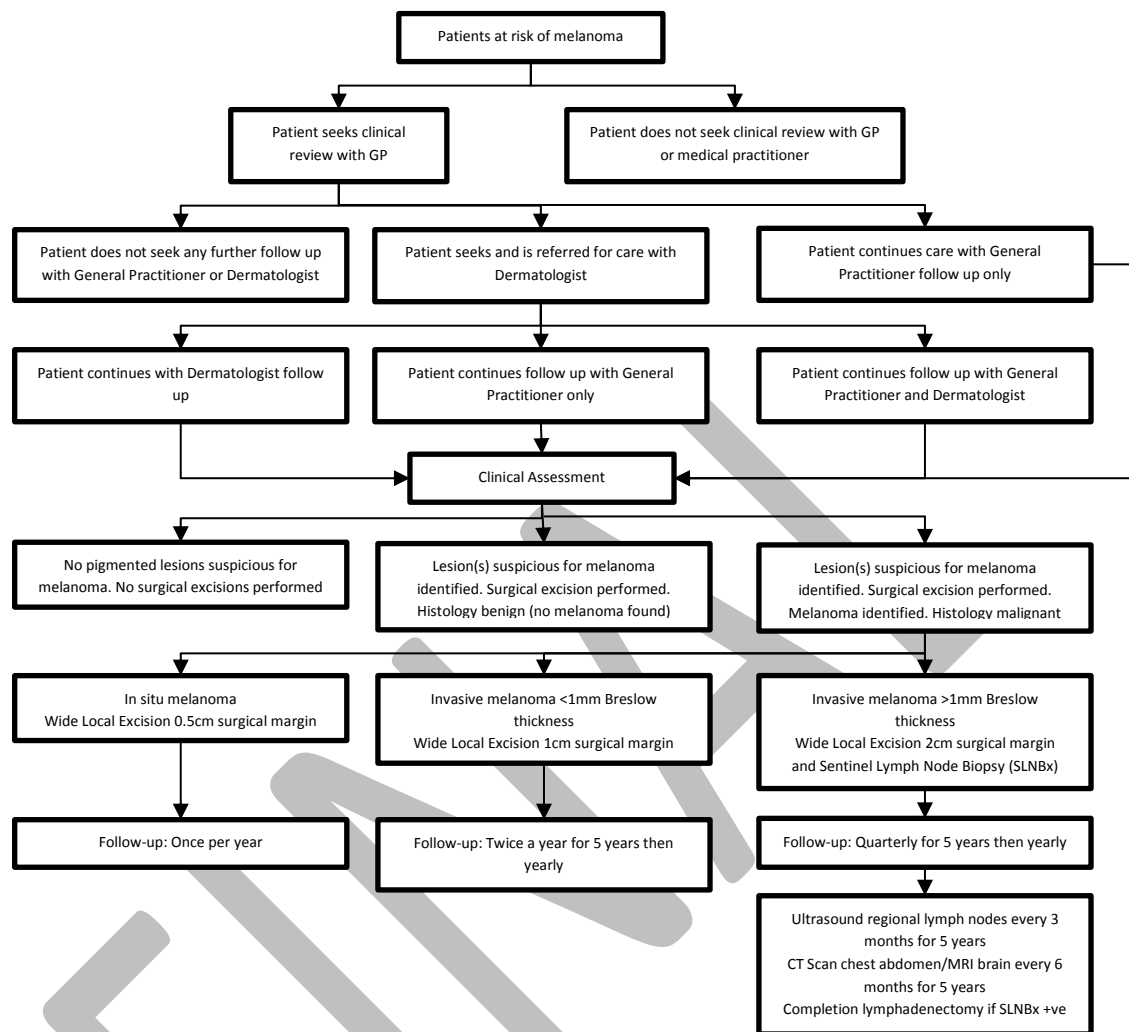
Early detection of melanoma reduces cost of treatment. There is a significant cost decrement when melanoma is diagnosed at an earlier stage, with a T4b lesion being approximately 2200 percent more expensive to diagnose and treat than an in situ melanoma (Alexandrescu D.T., 2009). The new and emerging medical therapies for metastatic melanoma are further increasing the monetary cost of treatment of advanced melanoma which also highlights the need for strategies for early detection of melanoma.

MSP is expected to reduce benign:malignant ratio of surgical excisions of pigmented lesions suspicious of being melanoma and therefore reduce costs during the diagnostic phase.

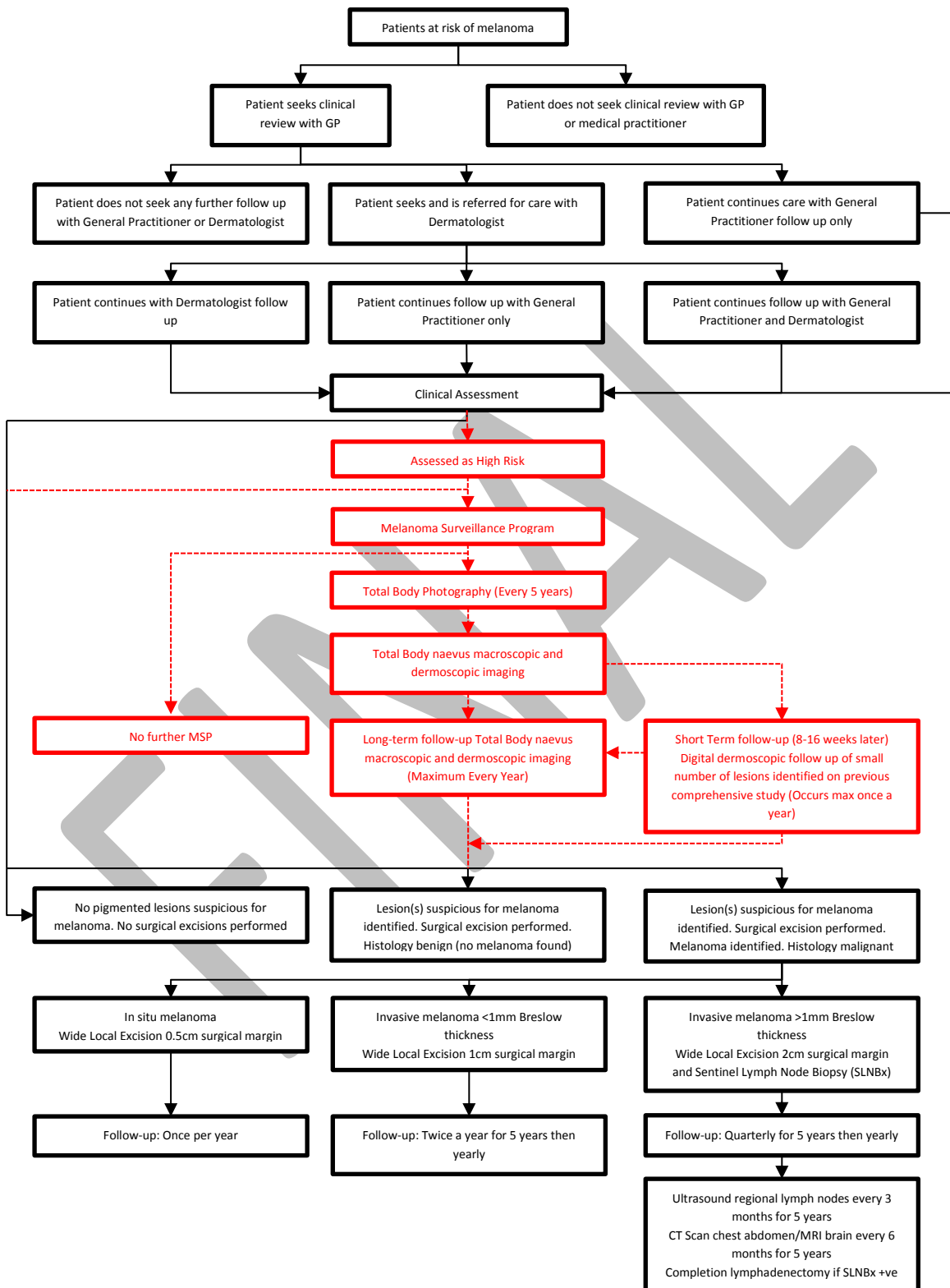
Rationale

The use of MSP is expected to decrease time to diagnosis, reduce the size of the average melanoma detected, , and increase the efficacy of self-examination. These outcomes would lead to less aggressive melanomas, and therefore less intensive therapies. The average cost of therapy would therefore decrease, costs associated with treatment morbidity would decrease, and the cost of more specialist services would decrease. There is the possibility that MSP increases the number of melanomas diagnosed, leading to increased treatment and more excisions. The utilisation of Dermatologist services may increase, as the speed of processing each referral would additionally increase, resulting in more patients processed.

Current clinical management algorithm for identified population



Proposed clinical management algorithm for identified population



Proposed economic evaluation

The clinical claim is that MSP is non-inferior in safety and superior in clinical effectiveness to current testing. According to the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee: Investigative* the required economic analysis is therefore a cost-utility analysis.

The economic evaluation may be complex given the various outcomes noted and should include a cost-effectiveness analysis. This economic evaluation could be quantified using a cost-utility analysis, where the measurement of the change in quality of life is included in the analysis. Some of the outcomes are qualitative in nature and may require an evidence linked modelling approach to demonstrate an advantage. It should be noted that several of the skin and melanoma excision item numbers have recently changed (November 2016). It may be appropriate to use the old item number system for this analysis given the long term data available.

Health outcomes to be considered in the economic evaluation could include:

- Fear of recurrent disease inventory (FRDI)
- Hornheide questionnaire of psychological well being
- Dermatology Life Quality Index Score (DLQI)
- POSAS scar severity score
- FACT-M melanoma life quality score
- Advanced melanoma treatment side effect cost quantification
- Sentinel lymph node biopsy complication rate

Health care resources to be considered in the economic evaluation could include:

- GP consultations (MBS 23, MBS 36)
- Specialist consultations (MBS 104, MBS 105)
- Skin surgery benign (diagnostic) excision (MBS 31205, MBS 31210, MBS 31215, MBS 31230, MBS 21235, MBS 31240, MBS 30071)
- Skin surgery benign (diagnostic) biopsy (MBS 30195)
- Skin surgery melanoma wide excision (MBS 31300, MBS 31305, MBS 31310, MBS 31315, MBS 31320, MBS 31325, MBS 31330, MBS 31335)
- Skin surgery defect repair (MBS 45200, MBS 45203, MBS 45206, MBS 45439, MBS 45442, MBS 45451)
- Histopathology (MBS 72816, MBS 72823, MBS 72830, MBS 72846, MBS 73049)
- Diagnostic surgical sentinel lymph node biopsy (MBS 30075, MBS 61469, MBS 61712)
- Therapeutic lymph node dissection (MBS 30329, MBS 30330, MBS 30332, MBS 30335, MBS 30336)
- Diagnostic radiology ultrasound (MBS 55816)
- Diagnostic radiology PET/CT scan (MBS 61553, MBS 61505, MBS 61719)
- Therapeutic radiotherapy for metastatic melanoma
- PBS/Day care unit/Hospital costs of advance medical treatments for metastatic melanoma, for example - Pembrolizumab, Nivolumab, Ipilimumab, Debrafenib, Vemurafenib, Trametinib

Proposed item descriptor

The following item descriptors have been proposed:

Category 2 – Diagnostic Procedures and Investigations
Group: D1 – Miscellaneous diagnostic procedures and investigations Subgroup 10–Other diagnostic procedures and investigations
[Item A] TOTAL BODY PHOTOGRAPHY performed by a specialist dermatologist, or on behalf of a specialist dermatologist by a registered nurse: <ul style="list-style-type: none">a) Only if performed in association with MBS Items Bi, Bii, Biii or Biv, andb) Only using image capture and processing equipment approved by the Therapeutic Goods Administrationc) Only claimable once in a 5 year periodd) Only if referred patient is 18 years of age or older and has a minimum of 15 lesions for photography
To be eligible: <ul style="list-style-type: none">a) the specialist dermatologist must hold current status on the Australasian College of Dermatologists register of Reporting Dermatologists andb) the reporting dermatologist must provide a diagnostic report* to the referring doctor andc) any registered nurse involved in the process must hold current status on the Joint Register of Registered Nurses Accredited in Melanoma Surveillance Photography held by the Australian Dermatology Nurses Association/Australasian College of Dermatologistsd) the item is only claimable once per calendar yeare) the service must be delivered at the reporting dermatologists practice site
(See para D1.10 of explanatory notes to this Category) Fee: REDACTED Benefit 75%= REDACTED, 85%= REDACTED

Category 2 – Diagnostic Procedures and Investigations

Group: D1 – Miscellaneous diagnostic procedures and investigations

Subgroup 10–Other diagnostic procedures and investigations

[Item Bi]

TOTAL BODY PIGMENTED LESION DIGITAL DERMOSCOPY performed by a specialist dermatologist or on behalf of a specialist dermatologist by a registered nurse using an image capture and processing device approved by the Therapeutic Goods Administration. To be eligible the subject must be 18 years of age or older, have 15 or more pigmented lesions for photography and be at high risk of melanoma as evidenced by:

- i. past personal history of melanoma or
- ii. family history of 2 first degree relatives with melanoma or
- iii. personal history of CDKN2A mutation and at least 1 first or second degree relative diagnosed with melanoma or
- iv. 6 or more atypical melanocytic naevi or
- v. 100 or more common melanocytic naevi or

Number of lesions photographed: 15-49

To be eligible:

- f) the specialist dermatologist must hold current status on the Australasian College of Dermatologists register of Reporting Dermatologists and
- g) the reporting dermatologist must provide a diagnostic report* to the referring doctor and
- h) any registered nurse involved in the process must hold current status on the Joint Register of Registered Nurses Accredited in Melanoma Surveillance Photography held by the Australian Dermatology Nurses Association/Australasian College of Dermatologists
- i) the item is only claimable once per calendar year
- j) the service must be delivered at the reporting dermatologists practice site

(See para D1.10 of explanatory notes to this Category)

Fee: REDACTED, Benefit 75%= REDACTED, 85%= REDACTED

Category 2 – Diagnostic Procedures and Investigations

Group: D1 – Miscellaneous diagnostic procedures and investigations

Subgroup 10–Other diagnostic procedures and investigations

[Item Bii]

TOTAL BODY PIGMENTED LESION DIGITAL DERMOSCOPY performed by a specialist dermatologist or on behalf of a specialist dermatologist by a registered nurse using an image capture and processing device approved by the Therapeutic Goods Administration. To be eligible the subject must be 18 years of age or older, have 15 or more pigmented lesions for photography and be at high risk of melanoma as evidenced by:

- i. past personal history of melanoma or
- ii. family history of 2 first degree relatives with melanoma or
- iii. personal history of CDKN2A mutation and at least 1 first or second degree relative diagnosed with melanoma or
- iv. 6 or more atypical melanocytic naevi or
- v. 100 or more common melanocytic naevi or

Number of lesions photographed: 50-99

To be eligible:

- a) the specialist dermatologist must hold current status on the Australasian College of Dermatologists register of Reporting Dermatologists and
- b) the reporting dermatologist must provide a diagnostic report* to the referring doctor and
- c) any registered nurse involved in the process must hold current status on the Joint Register of Registered Nurses Accredited in Melanoma Surveillance Photography held by the Australian Dermatology Nurses Association/Australasian College of Dermatologists
- d) the item is only claimable once per calendar year
- e) the service must be delivered at the reporting dermatologists practice site

(See para D1.10 of explanatory notes to this Category)

Fee: REDACTED, Benefit 75%= REDACTED, 85%= REDACTED

Category 2 – Diagnostic Procedures and Investigations

Group: D1 – Miscellaneous diagnostic procedures and investigations

Subgroup 10–Other diagnostic procedures and investigations

[Item Biii]

TOTAL BODY PIGMENTED LESION DIGITAL DERMOSCOPY performed by a specialist dermatologist or on behalf of a specialist dermatologist by a registered nurse using an image capture and processing device approved by the Therapeutic Goods Administration. To be eligible the subject must be 18 years of age or older, have 15 or more pigmented lesions for photography and be at high risk of melanoma as evidenced by:

- i. past personal history of melanoma or
- ii. family history of 2 first degree relatives with melanoma or
- iii. personal history of CDKN2A mutation and at least 1 first or second degree relative diagnosed with melanoma or
- iv. 6 or more atypical melanocytic naevi or
- v. 100 or more common melanocytic naevi or

Number of lesions photographed: 100-149

To be eligible:

- a) the specialist dermatologist must hold current status on the Australasian College of Dermatologists register of Reporting Dermatologists and
- b) the reporting dermatologist must provide a diagnostic report* to the referring doctor and
- c) any registered nurse involved in the process must hold current status on the Joint Register of Registered Nurses Accredited in Melanoma Surveillance Photography held by the Australian Dermatology Nurses Association/Australasian College of Dermatologists
- d) the item is only claimable once per calendar year
- e) the service must be delivered at the reporting dermatologists practice site*

(See para D1.10 of explanatory notes to this Category)

Fee: REDACTED, Benefit 75%= REDACTED, 85%= REDACTED

Category 2 – Diagnostic Procedures and Investigations

Group: D1 – Miscellaneous diagnostic procedures and investigations

Subgroup 10–Other diagnostic procedures and investigations

[Item Biv]

TOTAL BODY PIGMENTED LESION DIGITAL DERMOSCOPY performed by a specialist dermatologist or on behalf of a specialist dermatologist by a registered nurse using an image capture and processing device approved by the Therapeutic Goods Administration. To be eligible the subject must be 18 years of age or older, have 15 or more pigmented lesions for photography and be at high risk of melanoma as evidenced by:

- i. past personal history of melanoma or
- ii. family history of 2 first degree relatives with melanoma or
- iii. personal history of CDKN2A mutation and at least 1 first or second degree relative diagnosed with melanoma or
- iv. 6 or more atypical melanocytic naevi or
- v. 100 or more common melanocytic naevi or

Number of lesions photographed: ≥150

To be eligible:

- a) the specialist dermatologist must hold current status on the Australasian College of Dermatologists register of Reporting Dermatologists and
- b) the reporting dermatologist must provide a diagnostic report* to the referring doctor and
- c) any registered nurse involved in the process must hold current status on the Joint Register of Registered Nurses Accredited in Melanoma Surveillance Photography held by the Australian Dermatology Nurses Association/Australasian College of Dermatologists
- d) the item is only claimable once per calendar year
- e) the service must be delivered at the reporting dermatologists practice site*

(See para D1.10 of explanatory notes to this Category)

Fee: REDACTED, Benefit 75%= REDACTED, 85%= REDACTED

Category 2 – Diagnostic Procedures and Investigations

Group: D1 – Miscellaneous diagnostic procedures and investigations

Subgroup 10–Other diagnostic procedures and investigations

[Item C]

SHORT TERM FOLLOW UP DIGITAL DERMOSCOPY of selected pigmented lesions previously identified via digital dermoscopy and claimed under Items **Bi**, **Bii**, **Biii** or **Biv**, performed by a specialist dermatologist, or on behalf of a specialist dermatologist by a registered nurse.

To be eligible:

- a) the specialist dermatologist must hold current status on the Australasian College of Dermatologists Register of Reporting Dermatologists and
- b) the reporting dermatologist must provide a diagnostic report* to the referring doctor and
- c) any registered nurse involved in the process must hold current status on the Joint Register of Nurses Accredited in Melanoma Surveillance Photography held by the Australian Dermatology Nurses Association/Australasian College of Dermatologists
- d) the item is only claimable once per calendar year
- e) the service must have been expressly recommended by the reporting dermatologist in the preceding Total Body Pigmented Lesion Digital Dermoscopy (Item B) report
- f) the service must be performed in the time period 8-16 weeks from the date MBS service Item Bi, Bii, Biii, or Biv was performed
- g) the service must be delivered at the reporting dermatologists practice site

(See para D1.10 of explanatory notes to this Category)

Fee: REDACTED Benefit 75%=REDACTED 85%= REDACTED

Explanatory Notes

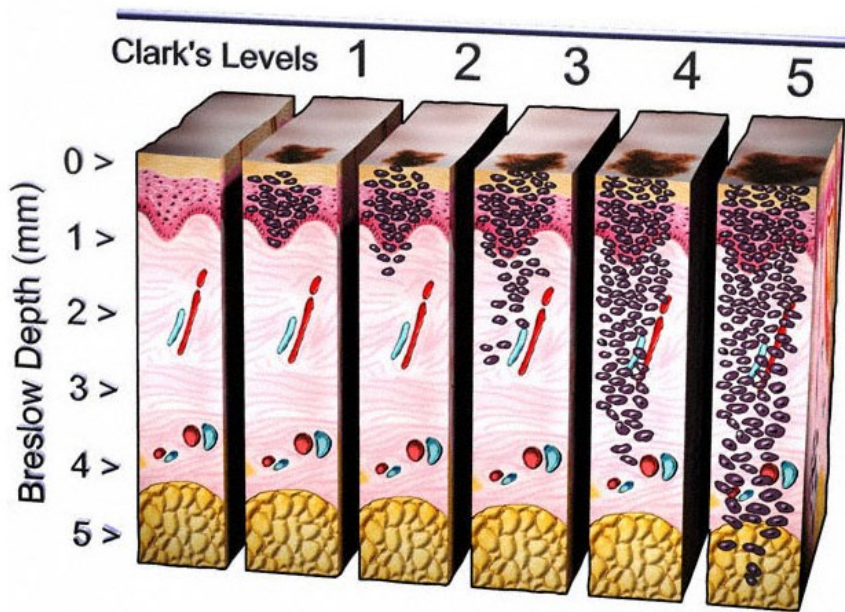
D1.10 Melanoma Surveillance Photography

Item A. Item A may only be claimed if performed in conjunction with Item B. Item A total body photographic findings do not require a report from the reporting dermatologist however if Item B is performed with Item A the report relating to Item B must note that item A has been performed. If Item A has been claimed previously the date of the last Item A procedure must appear on the patient's invoice/Medicare claim such as for example "previous Item A 1/1/2003"

Item B. The report to the referring doctor must document the Medicare eligible criteria, patient details, image capture technology used, time and date of image capture, name and qualifications of person performing the image capture, diagnosis and suggested management of specific lesions and whether short term follow up (Item C) is subsequently required. A referral is only valid for a single episode of Item B and any associated Item A or C that is required in association with that item B. The reporting dermatologist or their locum must be physically present at the practice site at the time of image capture.

Item C. The report to the referring doctor must document the Medicare eligible criteria, patient details, image capture technology used, time and date of image capture, name and qualifications of person performing the image capture, diagnosis and suggested management of specific lesions. A referral is only valid for a single episode of Item C. The reporting dermatologist or their locum must be physically present at the practice site at the time of image capture.

Appendix A: Clark's Levels and Breslow Depth



2001 Image by Med-Art ~ <http://www.med-ars.it>

Figure 2: Clark's levels and Breslow Depth of melanoma staging

Appendix B: American Joint Committee on Cancer: Melanoma skin staging

Table 1: AJCC staging - Primary Tumours

Classification	Thickness	Ulceration status/Mitoses
TX	Primary tumor cannot be assessed (for example, curettage or severely regressed melanoma)	-
T0	No evidence of primary tumour	-
Tis	Melanoma in situ	-
T1	Melanomas 1.0 mm or less in thickness	a: without ulceration and mitosis <math><1/mm^2</math> b: with ulceration or mitoses $\geq 1/mm^2$
T2	Melanomas 1.01–2.0 mm	a: without ulceration b: with ulceration
T3	Melanomas 2.01–4.0 mm	a: without ulceration b: with ulceration
T4	Melanomas more than 4.0 mm	a: without ulceration b: with ulceration

Table 2: AJCC staging - Regional Lymph Nodes

Classification	Number of Nodes	Nodal Metastatic Mass
NX	Patients in whom the regional nodes cannot be assessed (for example, previously removed for another reason)	-
N0	No regional metastases detected	-
N1	1 Node	a: micro-metastasis b: macro-metastasis
N2	2-3 nodes	a: micro-metastasis

Classification	Number of Nodes	Nodal Metastatic Mass
		b: macro-metastasis c: in transit met(s)/satellite(s) without metastatic nodes
N3	4 or more metastatic nodes, or matted nodes, or in transit met(s)/satellite(s) with metastatic node(s)	-

Table 3: AJCC staging - Distant Metastasis

Classification	Site	Serum LDM
M0	No detectable evidence of distant metastases	-
M1a	Metastases to skin, subcutaneous, or distant lymph nodes	Normal
M1b	Metastases to lung	Normal
M1c	Metastases to all other visceral sites Metastases to all other distant metastases to any site combined with an elevated serum LDH	Normal Elevated

PREVIEW

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