Melanoma surveillance photography – total body photography and digital dermoscopy

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Assessment report

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The technical information in this document is used by the Medical Services Advisory Committee (MSAC) to inform its deliberations. MSAC is an independent committee which has been established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

This report was prepared by the NHMRC Clinical Trials Centre. Clinical advice was provided by A/Prof Rob Miller. The report was commissioned by the Australian Government Department of Health.

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EXECUTIVE SUMMARY

Main issues for MSAC consideration

This assessment examines the evidence to support the listing of Melanoma Surveillance Photography (MSP), including total body photography (TBP) and digital dermoscopy (DD), on the Medicare Benefits Schedule (MBS). The service would be used in a dermatology setting for the target population at high and/or very risk of melanoma in addition to current clinical practice. The applicant has claimed that the successful listing of the technology in the target population and setting will lead to:

- Early detection of melanoma and subsequent improvement in prognosis
- Less aggressive skin surgery as definitive treatment, and fewer benign lesion excisions
- Reduced need for sentinel lymph node biopsy, and investigation and treatment of metastatic disease

Clinical evidence from three retrospective comparative studies in patients at high risk of melanoma suggests MSP conducted in a specialist dermatology setting might lead to earlier melanoma detection compared with standard care, but the quality of these studies was very low. There were no data regarding the number of excisions (Salerni, Lovatto et al. 2011, Salerni, Teran et al. 2014, Mintsoulis and Beecker 2016).

There was no comparative clinical evidence for the very high risk patient population.

A cost-effectiveness evaluation of MSP in patients at very high risk of melanoma was conducted, based on a previously published economic model (Watts, Cust et al. 2017). Results showed that MSP in this population was more effective and less costly than standard care. This analysis used real-world data from the Australian healthcare system and a single-arm prospective Australian study of very high risk patients receiving MSP. Therefore, it is directly relevant to the Australian setting. However, the transferability of these results to the high-risk population remains uncertain.

The total cost for the MBS per year (including a GP referral visit) given a moderate utilisation of the service may range from:

- High-risk population: $30,253,619.01 in 2018 to $130,630,860.53 in 2022
- Very high-risk population: $1,573,186.59 in 2018 to $6,538,092.15 in 2022

There is a high level of uncertainty regarding the approximate number of individuals at high risk and very high risk of melanoma in Australia. Access and utilisation of MSP may be lower than these projections indicate.

MELANOMA SURVEILLANCE PHOTOGRAPHY – TOTAL BODY PHOTOGRAPHY AND DIGITAL DERMOSCOPY

PURPOSE OF THE APPLICATION

This contracted assessment evaluates the effectiveness, safety, and cost-effectiveness of Melanoma Surveillance Photography (MSP) using digital dermoscopy (DD) and total body photography (TBP) for the follow-up of patients at high risk and/or very high risk of melanoma compared with standard care, in a dermatologist specialist setting.

MSP has three components:

1. TBP; occurring once every five years
2. Total body pigmented lesion DD; occurring once every year
3. Follow-up DD of a previously photographed (by DD) pigmented lesion within 8-16 weeks of digital dermoscopy; limited to once per year

The populations considered include Individuals aged 18 years or older and with a minimum of 15 or more pigmented lesions for photography. They must also satisfy at least one of the criteria outlined below:

High risk population	Very High risk population
1. Personal history of melanoma OR 2. Family history of two or more first-degree relatives having had melanoma OR 3. Personal history of CDKN2A genetic mutation and at least one first- or second- degree relative with melanoma OR 4. 100 or more common naevi OR 5. Six or more atypical/dysplastic naevi	1. Personal history of two or more primary melanomas OR 2. CDKN2A mutation OR 3. One past melanoma AND one of • 100 or more naevi OR • Six or more atypical naevi OR • Family history of three or more first- or second-degree relatives

PROPOSAL FOR PUBLIC FUNDING

There is currently no MBS item for MSP (and it is therefore self-funded). The proposed MBS item descriptors for the high-risk and very high-risk populations are summarised below in Table 1 and Table 2, respectively.

It is important to highlight that this assessment does not evaluate MSP as a population screening strategy, but the use of MSP for the monitoring of patients at high risk or very high risk of melanoma.

The proposed medical services would be implemented in addition to current clinical practice. Ideally patients at high and very high risk of melanoma perform their own self-examination at home, have a spouse or relative/friend look at inaccessible places such as the back regularly, see their general practioner (GP) regularly and are under the care of a dermatologist. Those who would benefit from MSP would have their TBP and DD images in addition to the above measures routinely done as a baseline, and repeated as per the attending dermatologist's recommendations.

A private fee for comprehensive MSP as part of an initial or long-term follow-up study in Australia is $300-450 per person per year. A current fee schedule for Molemap Australia quotes $449 for an initial study (1 hour) and $329 for follow up (Molemap 2017).

The proposed MBS fee for TBP is $100.00, and the fee for DD ranges from $117.65 to $205.90, depending on the number of lesions photographed. The suggested fee for short-term follow-up has been costed at $70 per visit. It is therefore important to note that the proposed MBS fee does not cover the total cost of MSP and patients would likely still incur out of pocket costs.

Table 1 Proposed MBS item descriptors for the high-risk population

MBS item Descriptors
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: a) Only if performed in association with MBS Items Bi, Bii, Biii or Biv, and b) Only using image capture and processing equipment approved by the Therapeutic Goods Administration c) Only claimable once in a 5 year period d) Only if referred patient is 18 years of age or older and has a minimum of 15 lesions for photography 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: $100.00 Benefit 75%= $75.00, 85%=$85.00

MBS item Descriptors

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: $117.65, Benefit 75%=$88.25, 85%=$100

MBS item Descriptors

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: $147.05, Benefit 75%=$110.30, 85%=$125

MBS item Descriptors

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

1. 6 or more atypical melanocytic naevi
2. Or 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: $176.45, Benefit 75%=$132.35, 85%=$150

MBS item Descriptors

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: $205.90, Benefit 75%=$154.40, 85%=$175

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: $70.00 Benefit 75%=52.50 85%=$59.50

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.

Table 2 Proposed MBS item descriptors for the very high-risk population

MBS item Descriptors
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: a) Only if performed in association with MBS Items Bi, Bii, Biii or Biv, and b) Only using image capture and processing equipment approved by the Therapeutic Goods Administration c) Only claimable once in a 5 year period d) Only if referred patient is 18 years of age or older and has a minimum of 15 lesions for photography 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: $100.00 Benefit 75%= $75.00, 85%=$85.00

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $117.65, Benefit 75%=$88.25, 85%=$100

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $147.05, Benefit 75%=$110.30, 85%=$125

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $176.45, Benefit 75%=$132.35, 85%=$150

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $205.90, Benefit 75%=$154.40, 85%=$175

MBS item Descriptors

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 performed by a specialist dermatologist, or on behalf of a specialist dermatologist by a registered nurse. Lesions selected may only be identified via:

a) Identification on total body pigmented lesion dermoscopy by the reporting Dermatologist and claimed under MBS items Bi-iv

b) Identification by the referring medical practitioner following physical examination used in conjunction with past total body photography (claimed under Item A) and past total body pigmented lesion dermoscopy (claimed under Items Bi-iv) as a clinical aid

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 twice per calendar year

e) if lesion/s identified at the time of total body pigmented lesion dermoscopic photography the service must be performed in the time period 8-16 weeks from the date of MBS service Item Bi,Bii, Biii, or Biv was performed

f) if lesion/s identified at physical examination using past photography (Items A, Bi-iv) as a clinical aid the lesion/s require photography at the time of referral for short term monitoring and this must be repeated in the time period 8-16 weeks to allow a comparative report to be produced

g) the service must be delivered at the reporting dermatologists practice site

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

Fee: $70.00 Benefit 75%=52.50 85%=$59.50

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.

COMPARATOR

The comparator is standard care without MSP conducted by a GP or dermatologist, or self-examination:

- Self-examination at home without use of comparative photographic images
- GP clinical examination without access to photography for real-time comparison (once or twice per year)
- Dermatologist clinical examination (including dermoscopy) without access to digital photography for real time comparison (once or twice a year)

BACKGROUND

Dermoscopy is a diagnostic technique that uses a hand-held magnifying device with cross-polarised light filters. It does not use any form of radiation or exposure of the skin to oil or alcohol, and reveals features of the skin not visible through normal lighting and magnification. The superior diagnostic accuracy of dermoscopy for melanoma detection compared with clinical naked-eye examination has been previously established (National Institute for Health and Care Excellence 2015), and therefore will not be investigated in this application.

Nevertheless, melanoma may be clinically and dermoscopically indistinguishable from melanocytic nevi, especially in early stages. In these cases, digital follow-up of melanocytic lesions may allow the identification of dermoscopic changes from baseline and early diagnosis of melanoma while minimising the excision of benign lesions (Salerni, Teran et al. 2013). Follow-up DD is used to monitor melanocytic lesions over a period of time, comparing new dermoscopic images to digitally-stored ones. The initial MSP consultation comprises TBP and DD. Follow-up involves repeat DD for comparison over time, which can be over a short-term or long-term period.

CLINICAL NEED

Melanoma is the fourth most prevalent cancer in Australia after prostate, breast and colorectal cancer. Early detection of melanoma is a key predictor of survival. In the earliest phase, melanoma is confined to the top layer of the skin, the epidermis, and is non-invasive. Five-year survival in patients with tumours thicker than 4 mm is only 55% compared with almost 100% survival for patients with tumours ≤1 mm thick (Australian Institute of Health and Welfare 2017).

In Australia, the Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand recommend surveillance for people at high-risk (National Health & Medical Research Council/Australian Cancer Network 2008), stating: “Individuals at high risk of melanoma and their partner or carer be educated to recognise and document lesions suspicious of melanoma, and to be

regularly checked by a clinician with six-monthly full body examination supported by total body photography and dermoscopy as required".

The applicant has claimed that the successful listing of MSP for the target population and specialist setting will lead to earlier detection of melanoma and subsequent improvement in prognosis, as well as reduced requirement for sentinel lymph node biopsy, treatment of metastatic disease, less aggressive skin surgery, and fewer benign lesion excisions.

CLINICAL EVALUATION

Three retrospective comparative studies of MSP versus standard care in patients at high risk of melanoma were identified in the systematic review and included in Section B (Salerni, Lovatto et al. 2011, Salerni, Teran et al. 2014, Mintsoulis and Beecker 2016). The addition of MSP resulted in a reduction in melanoma Breslow thickness, a measure of melanoma stage, (all studies $p < 0.05$) and an increase in situ: invasive ratio (in all three studies $p < 0.05$). This evidence suggests that MSP conducted in a specialist dermatology setting might lead to early melanoma detection in patients at high risk, but the quality of these studies was very low. There were no data regarding the number of excisions.

There was no comparative clinical evidence for the very high risk patient population.

Included studies did not present any data regarding the safety of the intervention. Both TBP and DD are non-invasive technologies. Hand-held dermoscopy is already in use as standard care in dermatology consultations to evaluate suspicious lesions. TBP is also widely available and consists of standard photography. TBP and DD are considered safe procedures.

ECONOMIC EVALUATION

One cost-effectiveness analysis comparing MSP in a specialist dermatology setting with standard care in the community was identified in the economic literature search (Watts, Cust et al. 2017). Results from this study indicate that MSP is both more effective and less costly than standard care in patients at very high risk of melanoma. The model by Watts et al. (2017) was replicated for this assessment. Three changes were made to the model:

1) MSP cost was amended to reflect our proposed MBS items fee,
2) the cost of new cancer treatments were added, and
3) the 2013 MBS items were updated to include 2017 costs.

The clinical inputs and model structure were unchanged (Section D). There is some uncertainty regarding the effectiveness inputs in the model, as the sources used to derive the utilities for melanoma by stage and probability of excisions are not published.

As per the published model, the replicated model showed that MSP in patients at very high risk of melanoma is more effective and less costly than standard care. The overall costs and effectiveness, and incremental costs and effectiveness as calculated for the intervention and comparator in the model are shown in Table 3.

Table 3 Base case cost-effectiveness results (10-year time horizon)

	MSP	***Standard care***	***Incremental***
Cost ($)	7,172.63	15,558.83	8,386.19
Effectiveness (QALY)	7.53	7.32	0.21

QALY: quality-adjusted life year; MSP: melanoma surveillance photography

Results from a one-way sensitivity analysis indicate that MSP is less costly and more effective than standard care up to a threshold of $1100 annual MSP cost per patient (Figure 1), which is a higher cost than the annual estimate per patient (based on the proposed MBS items fees) of $155 included in the model. Beyond this threshold, specialised surveillance (MSP) becomes more costly than standard care (given an annual cost of standard care of $70), but MSP remains cost-effective up to an annual cost of $2700 for a willingness to pay of $50,000 per quality adjusted life years (QALY) gained. It is important to note these results were obtained from a model of MSP in a population at very high risk of melanoma attending a highly specialised clinic within an urban centre, and these results might not be generalisable to the high-risk population across the country.

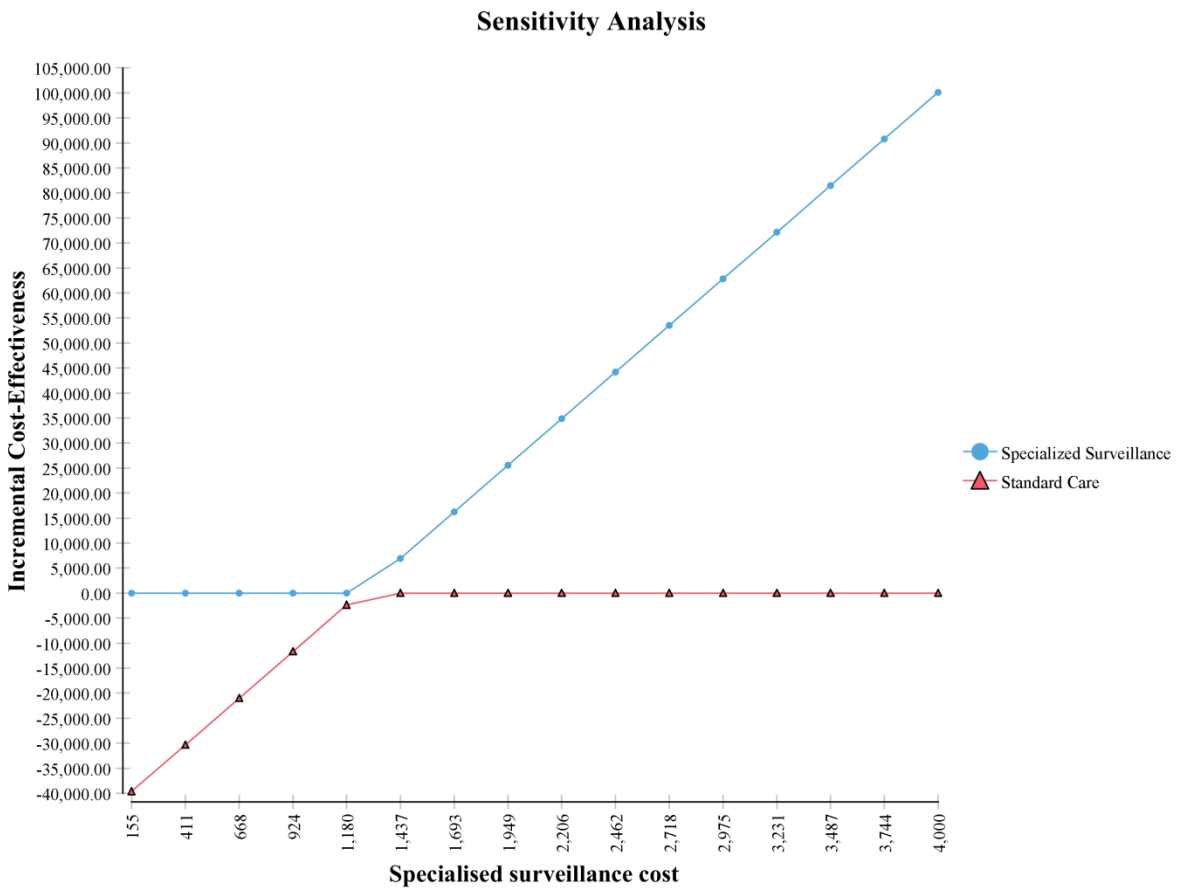

Figure 1 One way sensitivity analysis, incremental cost-effectiveness as cost of specialised surveillance (MSP) increases.

The model was most sensitive to variations in the probability of excisions in standard care, with a slight increase in the incremental cost-effectiveness ratio (ICER) as the probability of excision in standard care was changed from 0.8 to 0.1. However, none of the variables had a substantial impact on the ICER. A potential increase in the cost of MSP from $155 to $1000 did not significantly alter the cost-effectiveness of the intervention. Other key drivers of the economic model were the probability of early detection of melanoma (in-situ and stage I) by MSP, treatment costs for melanoma stage III and IV, and the probability of benign excisions in standard care (Figure 2).

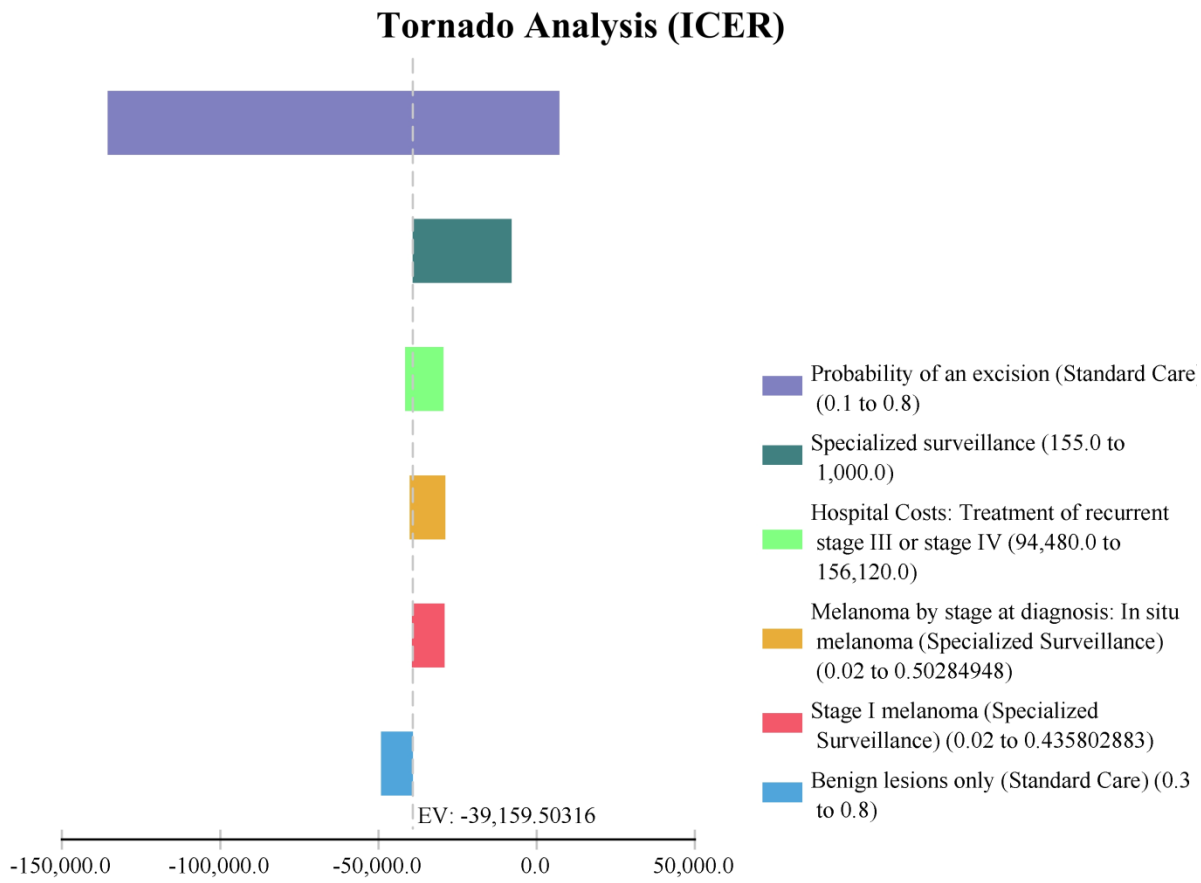

Figure 2 Tornado diagram: one-way sensitivity analysis of MSP versus standard care
ICER: incremental cost-effectiveness ratio, EV: expected value

A probabilistic sensitivity analysis (Figure 3) was conducted to evaluate the spread of results across the cost-effectiveness plane, which represents a measure of the ICER's degree of uncertainty. The incremental costs and QALY points were predominantly spread in the south-east quadrant, confirming that MSP is less costly and more effective than standard care.

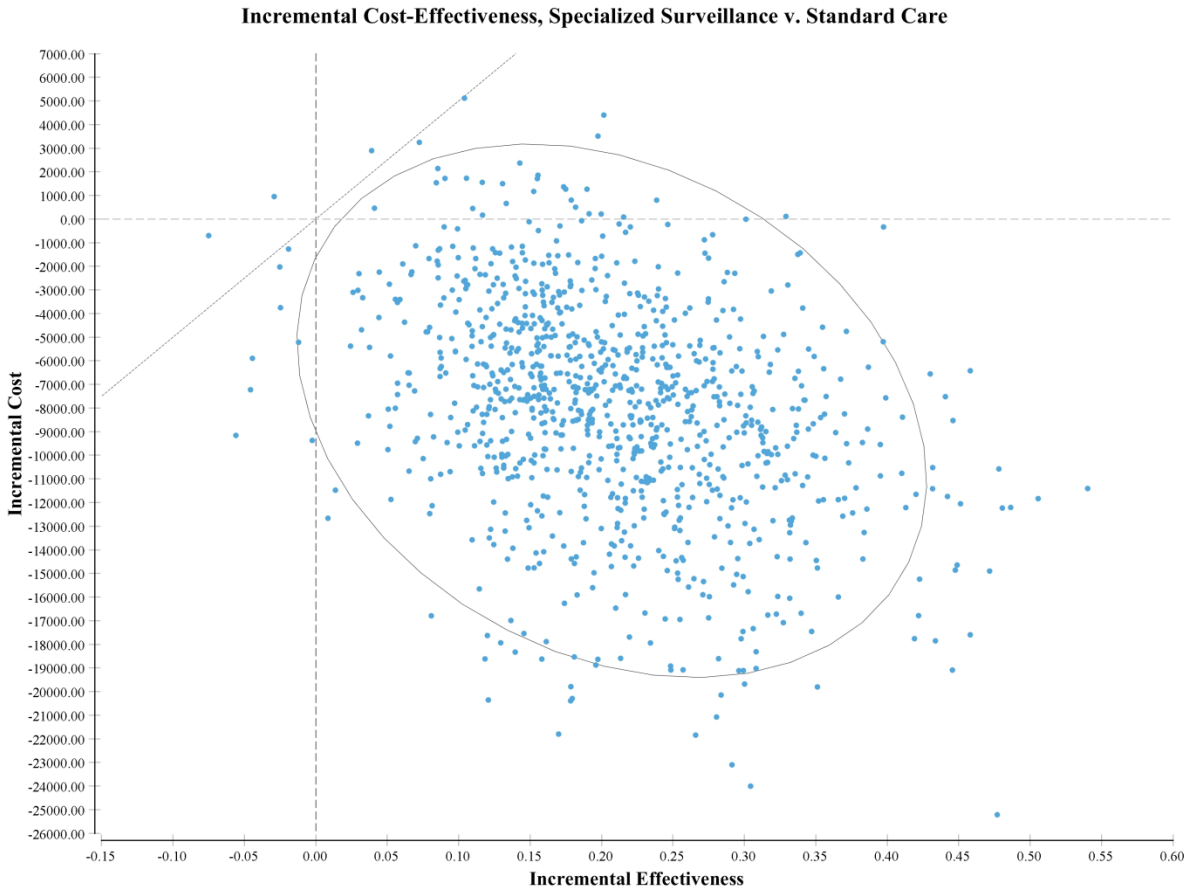

Figure 3 Monte Carlo simulation. Incremental cost-effectiveness of MSP versus standard care

FINANCIAL IMPLICATIONS

An epidemiological approach was used to estimate the financial implications of the introduction of MSP in high-risk and very high-risk patients. The calculation of the number of patients who would be eligible to receive MSP was based on data from the Australian Institute of Health and Welfare (AIHW) (Australian Institute of Health and Welfare 2017, Australian Institute of Health and Welfare 2017) and the Australian Bureau of Statistics (Australian Bureau of Statistics 2017).

Two scenarios were estimated to evaluate low and moderate utilisation of the proposed service in both populations, as 100% participation of the total eligible population in screening and monitoring services is not realistic. In the moderate utilisation scenario, we assumed an increase in MSP uptake from 20% to 60% over 5 years, and 90% compliance with follow-up MSP every year. Table 4 presents the estimated number or individuals at high risk and very high risk at 100% participation and moderate utilisation of MSP.

The total costs for the high-risk and very high-risk populations given a moderate utilisation, including an annual GP referral visit are presented below in Table 5.

Table 4 Number of eligible individuals at high-risk and very high-risk of melanoma in the Australian population; 100% and moderate utilisation of MSP

Population	*2018*	*2019*	*2020*	*2021*	*2022*
Total eligible (n); High risk	787,650	798,378	809,106	819,835	830,563
Total eligible (n), very high risk	40,958	41,068	41,179	41,289	41,399
Moderate utilisation (n); High risk	157,530	334,031	490,658	606,181	680,192
Moderate utilisation (n); Very high risk	8,192	17,235	25,089	30,680	34,044

Moderate utilisation: uptake 20% in 2018, increasing by 10% every year, and reaching 60% in 2022, 90% compliance;

Table 5 Total costs ($) to the MBS associated with MSP in high-risk and very high-risk patients; moderate utilisation

Population	*Cost per patient*	*2018*	*2019*	*2020*	*2021*	*2022*
High risk	GP ($37.05) + MSP ($155)	$30,253,619.01	$64,150,713.75	$94,230,898.45	$116,416,976.07	$130,630,860.53
Very high risk	GP ($37.05) + MSP ($155)	$1,573,186.59	$3,310,053.80	$4,818,365.30	$5,892,122.39	$6,538,092.15

Moderate utilisation: uptake 20% in 2018, increasing by 10% every year, and reaching 60% in 2022, 90% compliance
GP: general practitioner; MSP: melanoma surveillance photography3816

There is a high level of uncertainty regarding the approximate number of individuals at high risk and very high risk of melanoma in Australia; therefore, these estimates are only approximate. Access and utilisation of these medical services may be lower than these projections indicate, especially in rural areas.

ACRONYMS AND ABBREVIATIONS

Acronym/abbreviation	*Meaning*
ABS	Australian Bureau of statistics
AJCC	American Joint Commission on Cancer
APDC	Admitted Patient Data Collection
AIHW	Australian Institute of Health and Welfare
CTC	Clinical Trials Centre
DD	Digital dermoscopy
HESP	Health Expert Standing Panel
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
MSP	Melanoma surveillance photography
NHMRC	National Health and Medical Research Council
PASC	PICO Confirmation Advisory Sub-Committee of the MSAC
PBS	Pharmaceutical Benefits Scheme
QALY	Quality adjusted life year
TBP	Total Body Photography
TGA	Therapeutic Goods Administration

SECTION A CONTEXT

This contracted assessment of total body photography (TBP) and digital dermoscopy (DD) for the surveillance of melanoma is intended for the Medical Services Advisory Committee (MSAC). MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Schedule (MBS) in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

The NHMRC Clinical Trials Centre (CTC) has been commissioned by the Australian Government Department of Health to conduct a systematic literature review and economic evaluation of melanoma surveillance photography (MSP) using TBP and DD. This assessment has been undertaken in order to inform MSAC's decision-making regarding whether the proposed medical service should be publicly funded.

Appendix A provides a list of the people involved in the development of this assessment report.

The proposed use of MSP in Australian clinical practice was outlined in a PICO Confirmation that was presented to, and accepted by, the PICO Confirmation Advisory SubCommittee (PASC). The PICO Confirmation was released for public comment on 3 March 2014. The protocol was ratified by PASC in January 2017.

A.1. ITEMS IN THE AGREED PICO CONFIRMATION

The PICO for MSP was first submitted in 2014. Since this time, the PICO has changed a number of times and was ratified in an out-of-PASC session in 2017. The agreed population within the ratified PICO was a high risk population defined as:

Adults (aged ≥ 18 years) with minimum of 15 naevi and at least one of the following:

- Personal history of melanoma
- Family history of two or more first degree relatives having had melanoma
- Personal history of gene mutation CDKN2A and one first or second degree relative with melanoma
- 100 or more common naevi
- Six or more atypical/dysplastic naevi

Several interventions and comparators were listed within the PICO confirmation. The interventions listed were:

- Total Body Photography (TBP) once every 5 years
- Total body pigmented lesion digital dermoscopy (DD)/sequential DD once a year ('Long-term follow-up DD; all lesions')
- Follow-up DD of a previously photographed (by DD) pigmented lesion within 8-16 weeks of DD but limited to once per year ('short-term follow-up DD')

The comparators listed were:

- 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)

For the context of this assessment, it was imperative that these interventions be grouped as MSP and the comparator as standard practice. This was because the effectiveness of the MSP would be determined by the combination of all the individual elements described above rather than the incremental benefit of each element separately.

Limited comparative evidence was found using these criteria. An additional study was identified which assessed MSP in a very high risk Australian population (Watts, Cust et al. 2017). To include the evidence from this study, a more restrictive population was also included in this assessment. This very high risk population was defined as having:

1. A personal history of two or more primary melanomas OR
2. A CDKN2A mutation OR
3. One past melanoma AND one of
    - 100 or more naevi OR
    - Six or more atypical naevi OR
    - Family history of three or more first- or second-degree relatives

A.2. PROPOSED MEDICAL SERVICE

This application will focus on the assessment of Melanoma Surveillance Photography (MSP) – DD and TBP – in the follow-up of patients at high risk and very high risk of melanoma, and conducted in a dermatologist specialist setting.

MSP has three components:

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

Dermoscopy is a diagnostic technique that uses a hand-held magnifying device with cross-polarised light filters. It does not use any form of radiation or exposure of the skin to oil or alcohol, and reveals features of the skin not visible through normal lighting and magnification. The superior diagnostic accuracy of dermoscopy for melanoma detection compared with the naked eye examination has been previously established (National Institute for Health and Care Excellence 2015), and therefore will not be investigated in this application.

Nevertheless, melanoma may be clinically and dermoscopically indistinguishable from melanocytic nevi, especially in early stages. In these cases, DD follow-up of melanocytic lesions may allow the identification of dermoscopic changes from baseline and early diagnosis of melanoma while minimising the excision of benign lesions (Salerni, Teran et al. 2013). Follow-up DD is used to monitor melanocytic lesions over a period of time, comparing new dermoscopic images to digitally-stored ones. The initial MSP consultation comprises TBP and DD. Follow-up involves repeat DD for comparison over time, which can be short-term or long-term:

- Short-term follow-up DD: consists of only a few lesions re-examined photographically by DD at a set time (usually 3 months). It is usually only performed once on a specific lesion. If there is no change in a lesion within the specified 3 months period, there is no longer the need to continue short-term monitoring. If there is significant change in a lesion under short-term DD follow-up, it should be excised for histopathological examination for evidence of melanoma.
- Long-term follow-up DD: involves all the lesions under surveillance at routine yearly intervals. It may be recommended on a continued basis over many years.

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). All the existing naevi can be seen in those photographs (but not the very fine detail of each).

Once the TBP shots are performed, individual melanocytic naevi are photographed up close (macro images) and then additionally through DD. All pigmented lesions of any size that have any irregularity in them at all are photographed. It also includes all naevi and pigmented lesions on the body approximately ≥3mm in lateral diameter. In many cases, there are more than 100 macro and dermoscopic photographs taken for a single individual. Each individual close-up and dermoscopic

image is orientated and “tagged” to the TBP shots to show its exact anatomical location. That being the case, TBP must be performed at baseline to determine the correct anatomical position of each naevus photographed with DD.

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 suspicious for melanoma are reported as requiring excision. Any other individual lesion 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 the instruction of the dermatologist, who 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 an AHPRA (Australian Health Practitioner Regulation Agency)-registered nurse and participate in self-directed continuing medical education.

At the time of the follow-up consultation, the previous DD images are directly compared to the patient examination, going through each body segment. This examination will usually be performed by the melanographer. This 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 DD image of the new lesion. Each individual naevus that was photographed at baseline is photographed as a close-up shot and through DD. All the images are reviewed by the dermatologist. Each individual lesion is compared to its previous image (or images 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 observed then surgical excision is recommended. The subtle comparative changes seen over time can help diagnose “featureless” melanoma that 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 patients themselves can use the body shots and macro images for their own comparison at home. The patient’s GP can do this too, but additionally can use a hand-held dermatoscope to directly compare real-time dermoscopy to the stored DD 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 bone 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 (PICO confirmation).

MSP 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. Although clinically trained, the melanographer makes no management decisions during the process regarding specific lesions or the 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. The interpretation of the images and reporting is always performed by the dermatologist, and a report is issued once the dermatologist has reviewed the recorded referral, demographic data and all the images. A referring GP can have a written report returned within 24 hours of the photography taking place.

Access to dermatologist-led MSP 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). Therefore, GPs who have high-risk patients can refer them directly to a dermatologist for MSP only (not clinical consultations) and the GP will receive an opinion more quickly on whether their patients have a melanoma or not, and which (if any) lesions require excision. 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.

Follow-up examinations in subsequent years after initial studies require repeat full-body shots (TBP) after 5 years due to natural body, skin, hair, naevi and pigmentation changes over time. This has been factored in as part of the proposal, i.e. proposed item A.

TBP is expected to be used once every 5 years per patient, while total body pigmented lesion DD, initial and long-term follow-up, is expected to be used a maximum of once a year. Short-term DD follow-up of a previously photographed pigmented lesion within 8-16 weeks of DD is also limited to once per year.

A.3. PROPOSAL FOR PUBLIC FUNDING

There is currently no MBS item for MSP and it is therefore self-funded. The proposed MBS item descriptors for the high-risk and very high-risk populations are summarised in Table 1 and Table 2, respectively.

It is important to highlight that this assessment does not evaluate MSP as a population screening strategy, but the use of MSP for the monitoring of patients at high risk or very high risk of melanoma.

The proposed medical service would be implemented in addition to current clinical practice. Ideally patients at high and very high risk of melanoma perform their own self-examination at home, have a spouse or relative/friend look at inaccessible places such as the back regularly, see their GP regularly and are under the care of a dermatologist. Those who would benefit from MSP would have their TBP and DD images in addition to the above measures routinely done as a baseline, and repeated as per the attending dermatologist's recommendations.

A private fee for comprehensive MSP, initial or long-term follow-up study in Australia is $300-450 per person per year. A current fee schedule for Molemap Australia quotes $449 for an initial study (1 hour) and $329 for follow-up (Molemap 2017). The fee for a similar service in the USA is $US400-450.

The proposed MBS fee for TBP is $100.00, and the fee for DD ranges from $117.65 to $205.90, depending on the number of lesions photographed. The suggested fee for short-term follow-up has been costed at $70. It is therefore important to note that the proposed MBS fee does not cover the total cost of MSP and patients would likely still incur out of pocket costs.

Table 1 Proposed MBS item descriptors for the high risk population

MBS item Descriptors
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: a) Only if performed in association with MBS Items Bi, Bii, Biii or Biv, and b) Only using image capture and processing equipment approved by the Therapeutic Goods Administration c) Only claimable once in a 5 year period d) Only if referred patient is 18 years of age or older and has a minimum of 15 lesions for photography 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: $100.00 Benefit 75%= $75.00, 85%=$85.00

MBS item Descriptors

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: $117.65, Benefit 75%=$88.25, 85%=$100

MBS item Descriptors

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: $147.05, Benefit 75%=$110.30, 85%=$125

MBS item Descriptors

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

3. 6 or more atypical melanocytic naevi

4. Or 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: $176.45, Benefit 75%=$132.35, 85%=$150

MBS item Descriptors

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: $205.90, Benefit 75%=$154.40, 85%=$175

MBS item Descriptors

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: $70.00 Benefit 75%=52.50 85%=$59.50

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.

Table 2 Proposed MBS item descriptors for the very high risk population

MBS item Descriptors
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: a) Only if performed in association with MBS Items Bi, Bii, Biii or Biv, and b) Only using image capture and processing equipment approved by the Therapeutic Goods Administration c) Only claimable once in a 5 year period d) Only if referred patient is 18 years of age or older and has a minimum of 15 lesions for photography 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: $100.00 Benefit 75%= $75.00, 85%=$85.00

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $117.65, Benefit 75%=$88.25, 85%=$100

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $147.05, Benefit 75%=$110.30, 85%=$125

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $176.45, Benefit 75%=$132.35, 85%=$150

MBS item Descriptors

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 2 or more melanoma or

(ii) CDKN2A mutation carrier or

(iii) Past personal history of 1 melanoma AND

- a) Family history of melanoma in 3 first or second degree relatives OR
- b) 100 or more common naevi OR
- c) 6 or more atypical naevi

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: $205.90, Benefit 75%=$154.40, 85%=$175

MBS item Descriptors

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 performed by a specialist dermatologist, or on behalf of a specialist dermatologist by a registered nurse. Lesions selected may only be identified via:

a) Identification on total body pigmented lesion dermoscopy by the reporting Dermatologist and claimed under MBS items Bi-iv

b) Identification by the referring medical practitioner following physical examination used in conjunction with past total body photography (claimed under Item A) and past total body pigmented lesion dermoscopy (claimed under Items Bi-iv) as a clinical aid

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 twice per calendar year

e) if lesion/s identified at the time of total body pigmented lesion dermoscopic photography the service must be performed in the time period 8-16 weeks from the date of MBS service Item Bi,Bii, Biii, or Biv was performed

f) if lesion/s identified at physical examination using past photography (Items A, Bi-iv) as a clinical aid the lesion/s require photography at the time of referral for short term monitoring and this must be repeated in the time period 8-16 weeks to allow a comparative report to be produced

g) the service must be delivered at the reporting dermatologists practice site

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

Fee: $70.00 Benefit 75%=52.50 85%=$59.50

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.

A.4. PROPOSED POPULATION

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, melanoma is confined to the top layer 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 correlates with risk of metastasis and mortality (Figure 1). Five-year survival in patients with tumours thicker than 4 mm is only 55% compared with almost 100% survival for patients with tumours ≤1 mm thick. Melanoma can also be measured using the Clark's level of invasion and the American Joint Commission on Cancer (AJCC) classification of melanoma (Balch, Gershenwald et al. 2009).

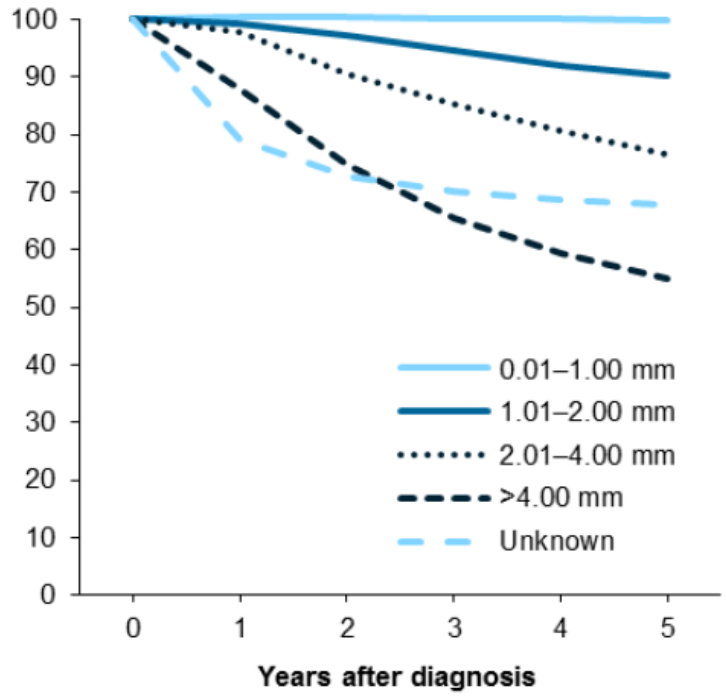

Figure 1 Relative survival (%) by tumour thickness
Source: (Australian Institute of Health and Welfare 2012)

The incidence of melanoma has increased over the past three decades, while mortality rates have not varied substantially during the same period (Figure 2). Men and older patients have higher incidence and mortality (Figure 3). In 2013, there were 12,744 new cases of melanoma diagnosed in Australia (7,513 males and 5,232 females). In 2017, this number is estimated to increase to 13,941 new cases of melanoma (8,392 males and 5,549 females). Five-year survival after diagnosis is estimated at 90.4% (88.3% in males and 93.3% in women), and after 10-years of diagnosis 98.6% of patients are expected to survive another 5 years (98.3% in males and 99.0% in females)(Australian Institute of Health and Welfare 2017). Despite high survival rates of melanoma overall, survival decreases considerably as tumour thickness increases (Figure 1).

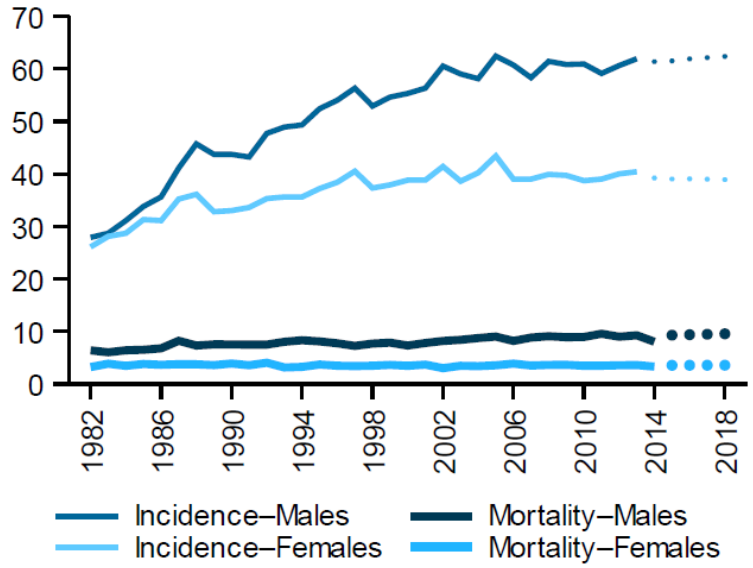

Figure 2 Melanoma incidence and mortality age-standardised rates (per 100,000) by sex, 1982-2018
Source: (Australian Institute of Health and Welfare 2017)

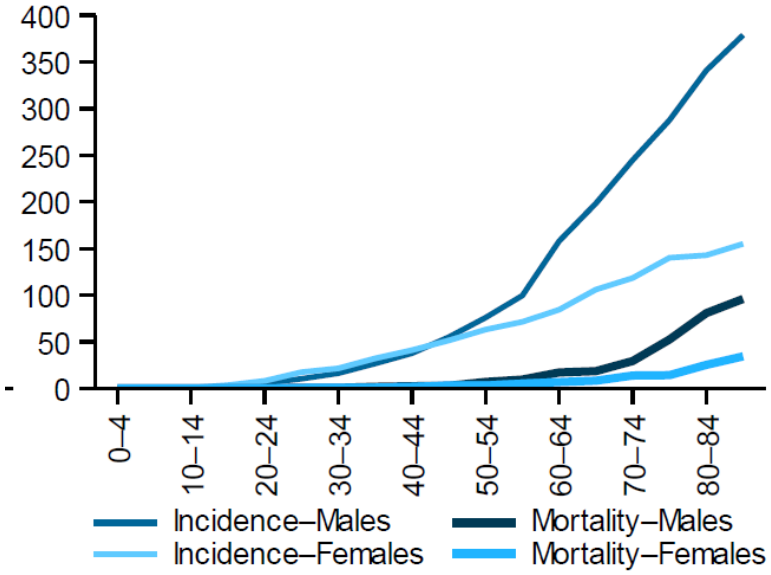

Figure 3 Incidence and mortality rates (per 100,000) for melanoma by age group and sex (2013-2014)
Source: (Australian Institute of Health and Welfare 2017)

Although annual incidence of melanoma is well documented, it can be harder to determine how many patients have melanoma at any given time (point prevalence), the number of people at high/very high risk or how individual risk factors contribute to the development of melanoma. Prevalence is a product of incidence and survival, defined as the number of people alive who have previously been diagnosed with cancer (Australian Institute of Health and Welfare 2017). It is important to consider prevalence data for health-care planning and service delivery, as it indicates the number of people receiving treatment or ongoing monitoring for their cancer. Melanoma is the fourth most prevalent cancer in Australia after prostate, breast and colorectal cancer. The 5-year prevalence by the end of 2012 was estimated at 51,697 persons (29,567 males and 22,130 females)(Australian Institute of Health and Welfare 2017).

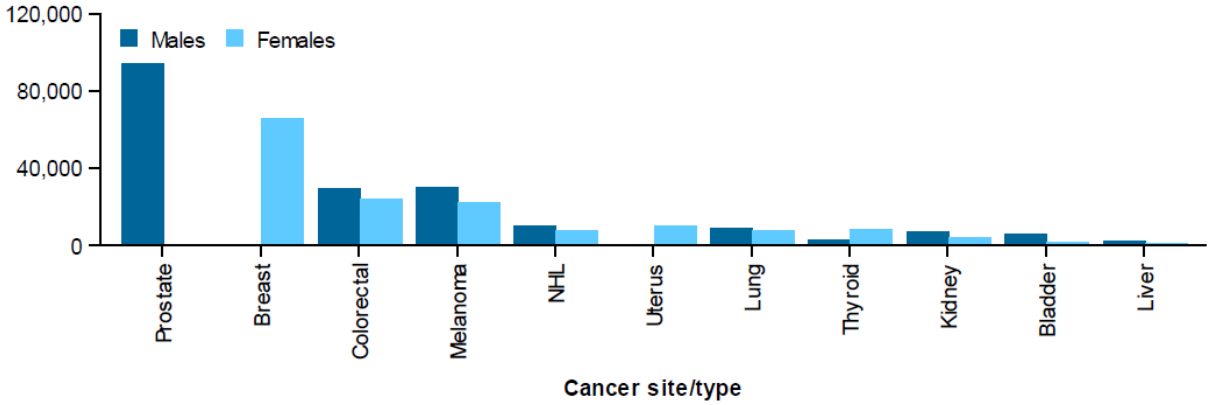

Figure 4 Five-year prevalence by cancer site/type (total number of cases) in 2012
Source: (Australian Institute of Health and Welfare 2017)
NHL: non-hodgkin lymphoma

POPULATION 1: HIGH RISK POPULATION

The proposed population as per the PICO confirmation is Medicare eligible individuals aged 18 years or over and at high risk of developing melanoma. The patient would have a minimum of 15 or more pigmented lesions for photography and would be referred by a medical practitioner to the dermatologist. They must also satisfy at least one of the criteria outlined below:

1. Personal history of melanoma OR
2. Family history of two or more first degree relatives having had melanoma OR
3. Personal history of CDKN2A genetic mutation and at least one first or second degree relative with melanoma OR
4. 100 or more common naevi OR
5. Six or more atypical/dysplastic naevi

POPULATION 2: VERY HIGH RISK POPULATION

Watts et al. (Watts, Cust et al. 2017) have recently conducted a cost-effectiveness analysis of MSP for patients at very high risk of melanoma. This cohort represents a more restricted proportion of the total Australian population compared to the high-risk population presented above, but given the relevance of these data (presented in detail in Section C and D) we are also considering this very high risk patient group in this assessment. The suggested definition of the very high risk population includes patients with:

1. A personal history of two or more primary melanomas OR
2. A CDKN2A mutation OR
3. One past melanoma AND one of
    - 100 or more naevi OR
    - Six or more atypical naevi OR
    - Family history of three or more first- or second-degree relatives

A.5. COMPARATOR DETAILS

The comparator is standard care without MSP conducted by a GP or dermatologist, or self-examination. This may include:

- Self-examination at home without the use of comparative photographic images
- GP clinical examination without access to photography (TBP, DD) for real time comparison
- Dermatologist clinical examination (including hand-held dermoscopy) without access to TBP/DD for real-time comparison

Many high-risk patients do not examine themselves and in fact do not visit their GP, let alone see a dermatologist. They might not be identified as high-risk by their GPs, or if they are identified as high-risk they might not offered a dermatologist consultation by the GP.

Table 3 describes the relevant MBS items for standard care in melanoma prevention.

Table 3 Relevant MBS item for standard care

MBS Item Descriptors
Category 1 - PROFESSIONAL ATTENDANCES 23 Group A1 - GENERAL PRACTITIONER ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Subheading 2 - LEVEL B Professional attendance by a general practitioner at consulting rooms (other than a service to which another item in the table applies), lasting less than 20 minutes and including any of the following that are clinically relevant: (a) taking a patient history; (b) performing a clinical examination; (c) arranging any necessary investigation; (d) implementing a management plan; (e) providing appropriate preventive health care; for one or more health-related issues, with appropriate documentation-each attendance Fee: $37.05 Benefit: 100% = $37.05 (See para A5 of explanatory notes to this Category) Extended Medicare Safety Net Cap: $111.15
Category 1 - PROFESSIONAL ATTENDANCES 36 Group A1 - GENERAL PRACTITIONER ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Subheading 3 - LEVEL C Professional attendance by a general practitioner at consulting rooms (other than a service to which another item in the table applies), lasting at least 20 minutes and including any of the following that are clinically relevant: (a) taking a detailed patient history; (b) performing a clinical examination; (c) arranging any necessary investigation; (d) implementing a management plan; (e) providing appropriate preventive health care; for one or more health-related issues, with appropriate documentation-each attendance Fee: $71.70 Benefit: 100% = $71.70 (See para A5 of explanatory notes to this Category) Extended Medicare Safety Net Cap: $215.10
Category 1 - PROFESSIONAL ATTENDANCES 104 Group A3 - SPECIALIST ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Professional attendance at consulting rooms or hospital by a specialist in the practice of his or her specialty after referral of the patient to him or her-each attendance, other than a second or subsequent attendance, in a single course of treatment, other than a service to which item 106, 109 or 16401 applies Fee: $85.55 Benefit: 75% = $64.20 85% = $72.75 Extended Medicare Safety Net Cap: $256.65
Category 1 - PROFESSIONAL ATTENDANCES 105 Group A3 - SPECIALIST ATTENDANCES TO WHICH NO OTHER ITEM APPLIES

MBS Item Descriptors
Professional attendance by a specialist in the practice of his or her specialty following referral of the patient to him or her- an attendance after the first in a single course of treatment, if that attendance is at consulting rooms or hospital Fee: $43.00 Benefit: 75% = $32.25 85% = $36.55 Extended Medicare Safety Net Cap: $129.00
Category 1 - PROFESSIONAL ATTENDANCES 110 Group A4 - CONSULTANT PHYSICIAN ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Professional attendance at consulting rooms or hospital, by a consultant physician in the practice of his or her specialty (other than psychiatry) following referral of the patient to him or her by a referring practitioner-initial attendance in a single course of treatment Fee: $150.90 Benefit: 75% = $113.20 85% = $128.30

A.6. CLINICAL MANAGEMENT ALGORITHM(S)

The proposed services are an addition to current clinical management of high-risk and very high risk patients for melanoma with the aim to diagnose melanoma at an early stage. The more advanced the melanoma is at the time of diagnosis (measured by Breslow thickness in mm) the more extensive the surgery, further assessment, treatment, morbidity, mortality and cost. Dermatologic consultation, skin excisions (including biopsy), and pathology costs are funded by the MBS, but surveillance including the use of digital dermoscopy is not funded under the MBS.

The proposed service is specifically for people at either:

- High risk or,
- Very high risk of melanoma

Currently, a patient at risk of melanoma is presented to a GP (MBS item 23 or 26). The patient may not seek further follow-up with a GP or dermatologist, or may continue with GP follow-up only (1 or 2 visits per year), or the GP may refer the patient to a dermatologist for further examination (MBS item 104). The patient may then either continue with follow-up visits with the dermatologist (1 or 2 per year; MBS item 105), continue with follow-up with the GP (1 or 2 visits per year; MBS item 23 or 26), or continue follow-up with both the 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), or a lesion is suspicious, removed and is found to be malignant through histology assessment. If melanoma is found further assessment and surgery occurs.

Clinical examination by a doctor may result in one or more lesions being identified as possible melanoma and being excised for diagnosis. On average, several suspected lesions will be excised for each melanoma identified. Benign lesions excised result in a cost to the health system and morbidity to the patient. Early diagnosis of melanoma leads to excisions with relatively narrow surgical margins (0.5 cm usually), and a less invasive intervention. More advanced melanoma often requires large amounts of tissue to be excised, sentinel lymph node biopsy, general anaesthetic and longer term investigative follow up – all involving significant cost, morbidity and mortality.

In the proposed clinical pathway, eligible patients would have been assessed as high or very high risk by either a GP or by both a GP and a dermatologist. Once a person has been assessed as high/very high-risk, he/she is photographed using TBP. Macro-imaging then occurs; individual melanocytic naevi are photographed at close range and these naevi are then examined through DD. TBP occurs every five years to refresh images. All naevi and pigmented lesions on the body approximately ≥ 3mm in lateral diameter are photographed. Short-term follow-up may occur within 8-16 weeks of total body DD, and only occur once in a year, at the discretion of the reporting dermatologist. Short-term DD follow-up may be requested for a select few naevi that do not have the dermoscopic features of melanoma, but have an unusual dermoscopic appearance or a patient-reported history of change. Short-term DD follow-up may also be requested for atypical lesions that for anatomical reasons would be difficult or disfiguring to biopsy or excise. Once a lesion has been identified through MSP, treatment and/or management is determined based on the size and histology of the melanoma. Surveillance continues after lesion identification.

The current clinical algorithm pathway is shown in black in Figure 5. The additional MSP program proposed in this assessment is shown in dotted red.

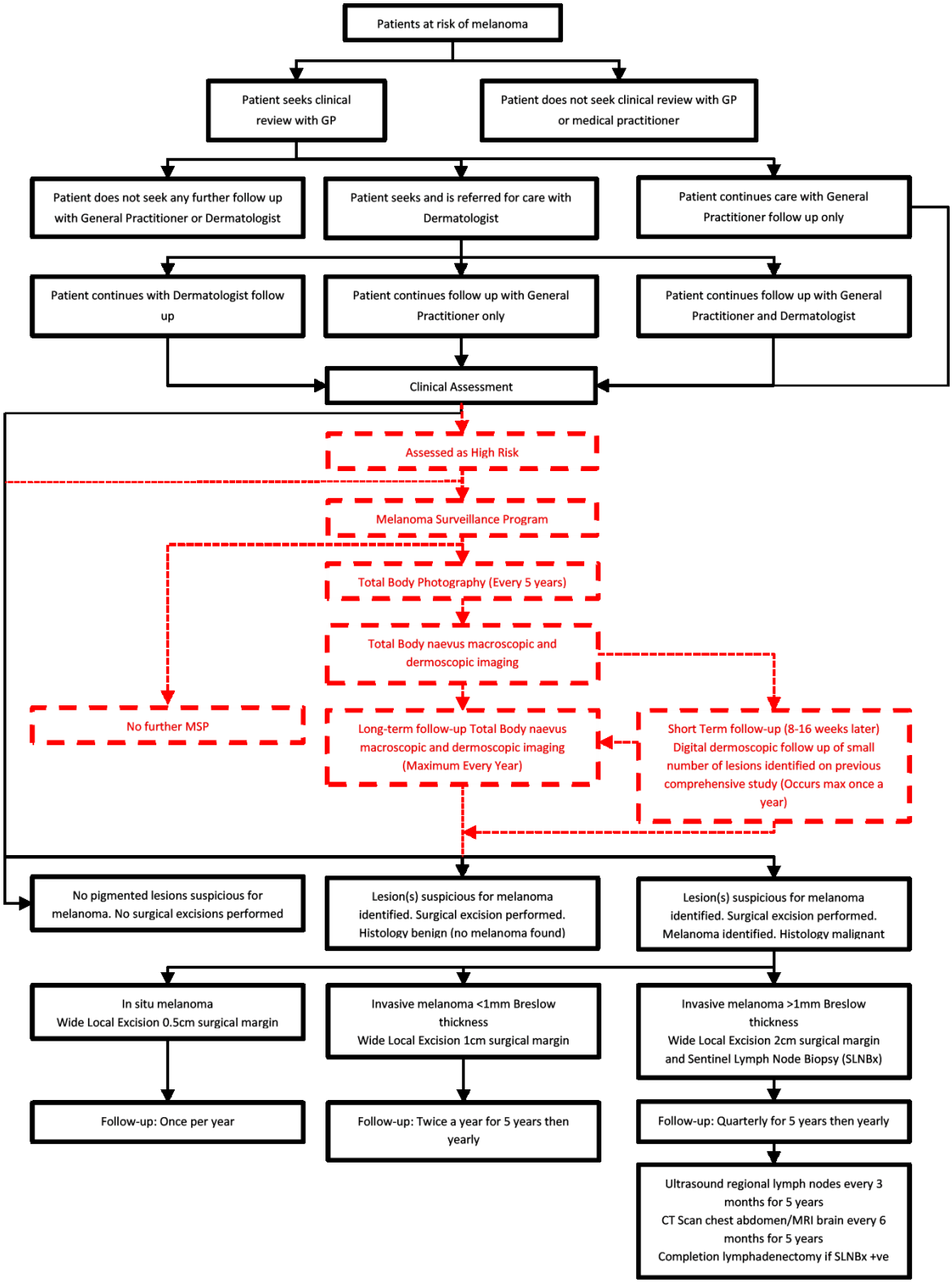

Figure 5 Clinical management algorithm for the proposed MSP relative to current clinical practice

A.7. KEY DIFFERENCES IN THE DELIVERY OF THE PROPOSED MEDICAL SERVICE AND THE MAIN COMPARATOR

MSP is conducted in addition to current practice to monitor high-risk and/or very high-risk patients, and is proposed to allow accurate comparison of melanocytic naevi over time. MSP may identify early histological changes and early-stages melanoma in the absence of specific criteria for malignancy, which could be missed by standard care alone.

Dermoscopy has been proved to be more sensitive and more specific at detecting melanoma than a naked eye clinical examination (National Institute for Health and Care Excellence 2015), but some melanocytic lesions remain indistinguishable from melanoma at early stages. MSP allows dermatologists to identify incipient changes over time and improve early diagnosis of melanoma (Salerni, Teran et al. 2013).

MSP has been previously described in Section A.2 and Section A.6.

The reasons all pigmented lesions are photographed with digital dermoscopy are:

1. Approximately 50% of naevus-derived melanomas arise from atypical naevi and 50% 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 (Salerni, Carrera et al. 2012).
2. If only naevi that appear clinically atypical are examined and photographed dermoscopically, only 62% of dermoscopically abnormal naevi would 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 (Seidenari, Longo et al. 2006).

A.8. CLINICAL CLAIM

Some international guidelines recommend that individuals at high risk of melanoma should receive surveillance as a standard of practice (Watts, Dieng et al. 2015). In Australia, the Clinical Practice Guidelines for the Management of Melanoma in Australia and New Zealand recommend surveillance for people at high-risk, stating: “Individuals at high risk of melanoma and their partner or carer be educated to recognise and document lesions suspicious of melanoma, and to be regularly checked by a clinician with six-monthly full body examination supported by total body photography and dermoscopy as required” (National Health & Medical Research Council/Australian Cancer Network 2008). However, MSP recommendations are largely based on consensus due to the lack of strong evidence.

The potential benefits of MSP for high-risk and very high-risk patient groups include:

- Melanoma detection at an earlier stage in its development;
- Less aggressive skin surgery as definitive treatment;
- Fewer benign lesion excisions;
- Reduced requirement for sentinel lymph node biopsy and investigation and treatment of metastatic disease;
- Improved diagnosis of non-melanoma skin cancer;
- Improved capacity for self-examination and early diagnosis at home; and
- Increased sense of well-being following a comprehensive photography session and written report

A.9. SUMMARY OF THE PICO

The guiding framework of a PICO Confirmation is recommended by MSAC for each assessment. The Population, Investigation/Index test, Comparator and Outcomes (PICO) Confirmation describes current clinical practice and reflects the likely future practice with the proposed medical service.

Two separate PICOs are presented in Box 1 and Box 2 to guide the systematic literature review for direct evidence and account for the high-risk and very high-risk populations.

Box 1 Criteria for identifying and selecting studies to determine the effectiveness and safety, and cost-effectiveness of MSP in patients with high risk of melanoma

Selection criteria	Description
Populations	High-risk – Adults (aged ≥ 18 years) with minimum of 15 naevi and at least one of the following: 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
Intervention	• Total Body Photography (once every 5 years) • Total body pigmented lesion digital dermoscopy (DD) (once a year) ('Long-term follow-up sequential DD; all lesions') • Follow-up digital dermoscopy of a previously photographed (by DD) pigmented lesion within 8-16 weeks of DD but limited to once per year ('short-term follow-up sequential DD')
Comparators	• 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)

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

Box 2 Criteria for identifying and selecting studies to determine the effectiveness and safety, and cost-effectiveness of MSP in patients with very high risk of melanoma

Selection criteria	Description
Populations	Very High-risk – Adults (aged ≥ 18 years) with minimum of 15 naevi and: 1. Personal history of two or more primary melanomas OR 2. CDKN2A mutation OR 3. One past melanoma AND one of • 100 or more naevi OR • Six or more atypical naevi OR • Family history of three or more first- or second-degree relatives
Intervention	• Total Body Photography (once every 5 years) • Total body pigmented lesion digital dermoscopy (DD) (once a year) ('Long-term follow-up sequential DD; all lesions') • Follow-up digital dermoscopy of a previously photographed (by DD) pigmented lesion within 8-16 weeks of DD but limited to once per year ('short-term follow-up sequential DD')

Selection criteria	Description
Comparators	• 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)
Outcomes	Safety: Efficacy/effectiveness: Average Breslow thickness of detected melanoma Frequency distribution of Breslow thickness – in situ, <1mm, >1mm Ratio for benign:malignant excisions for melanoma diagnosis Time to diagnosis Quality of Life (QoL) Rate of non-melanoma skin cancer such as basal cell skin cancer and squamous cell skin cancer identified. Healthcare resources: GP and specialist consultations Skin surgery benign (diagnostic) excision Skin surgery benign (diagnostic) biopsy Skin surgery melanoma wide excision Skin surgery defect repair Histopathology Diagnostic surgical sentinel lymph node biopsy Therapeutic lymph node dissection Diagnostic radiology ultrasound Diagnostic radiology PET/CT scan Cost-effectiveness: Cost/QALY Cost/Life Year Total Australian Government healthcare costs. Cost to the PBS Cost to the MBS Cost to other Government Healthcare providers
Systematic review question	What is the value of melanoma surveillance photography in addition to standard practice for the detection of melanoma in high risk patients?

A.10. CONSUMER IMPACT STATEMENT

No consumer responses were identified in the literature.

SECTION B CLINICAL EVALUATION

B.1. LITERATURE SOURCES AND SEARCH STRATEGIES

The medical literature was searched on 17 February 2017 to identify relevant studies and systematic reviews published with no date limits. Searches were conducted in the databases and sources described in Appendix 2 Search strategies. The search terms used are described below in Table 4.

Table 4 Search terms used in the systematic review (Ovid platform)

Element of clinical question	Search terms
Population	exp Melanoma/ exp Skin Neoplasms/ (pigmented adj2 (lesion$ or mole$ or nevus or nevi or naevus or naevi or skin)).mp. (melanom$ or melanocyt$).mp. cutaneous melanoma.tw. suspicious melanocyt$ lesion$.tw. melanoma$.tw. invasive melanoma.tw.
Intervention	exp Dermoscopy/ dermoscop$.mp. dermatoscop$.mp. photomicrograph$.mp. (epiluminescence adj2 microscopy).mp. total body photograph$.mp. screening.mp. or exp Mass Screening/ population surveillance.mp. or exp Population Surveillance/ exp "Early Detection of Cancer"/ surveillance.mp. diagnosis.mp. detection.mp.
Limits	None applied

B.2. RESULTS OF LITERATURE SEARCH

A PRISMA flowchart (Figure 6) provides a graphic depiction of the results of the literature search and the application of the study selection criteria (listed in Box 1 and Box 2) (Liberati, Altman et al. 2009).

Studies were selected independently by a single reviewer with a random sample receiving independent assessment by a second reviewer. Disagreements regarding study selection were resolved by discussion.

The selection process firstly included screening of titles and abstracts where the following exclusion criteria were used:

- Editorials; letters; research notes; case studies
- Conference abstracts/presentations with insufficient details
- Non-systematic reviews, non-comparative studies, diagnostic accuracy studies only
- Publications in languages other than English

Studies that could not be retrieved or that met the inclusion criteria but contained insufficient or inadequate data for inclusion are listed in Appendix 6 Excluded studies. All other studies that met the inclusion criteria are listed in Appendix 3 Studies included in the systematic review.

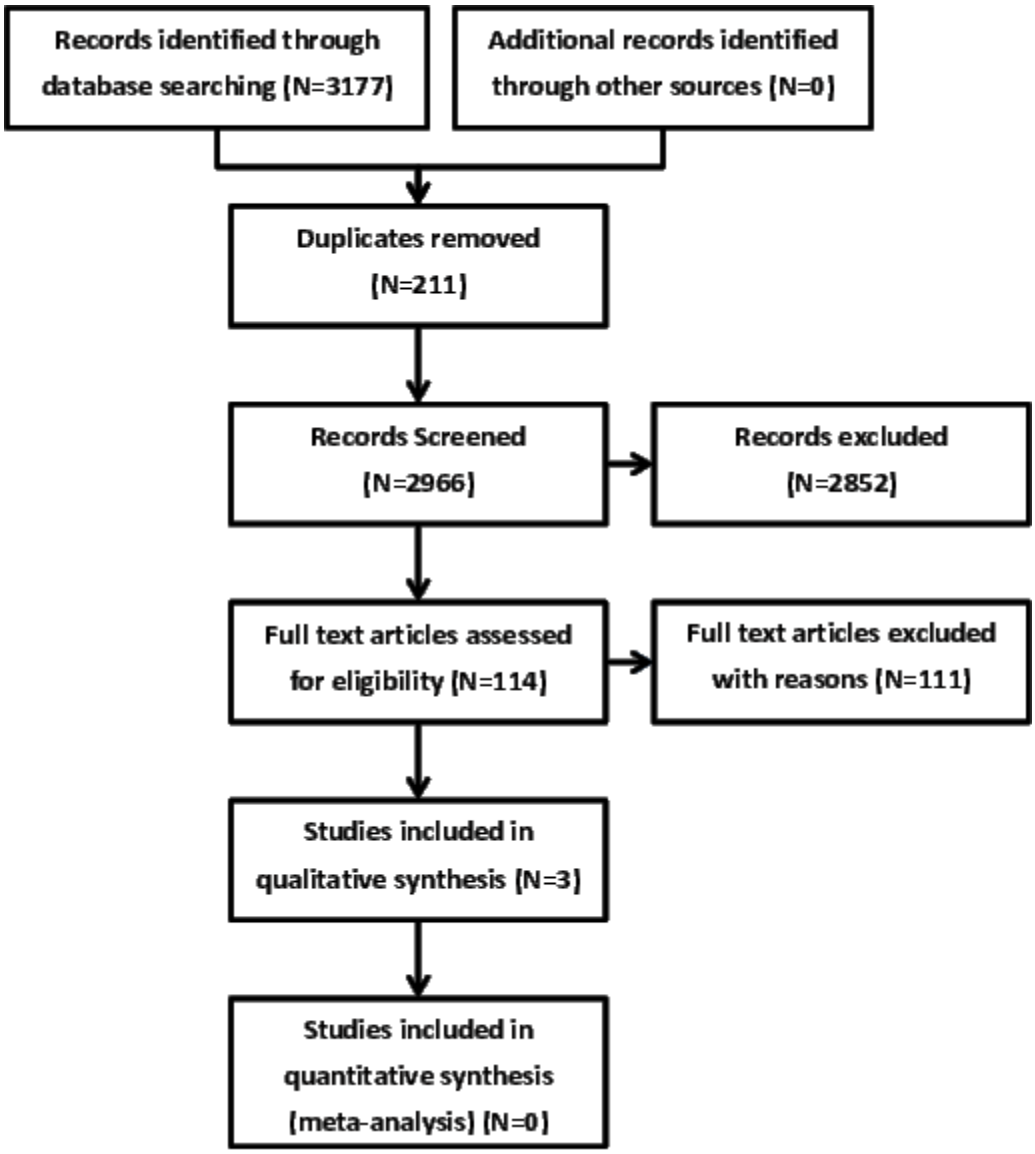

Figure 6 Summary of the process used to identify and select studies for the assessment

A profile of each included study is given in Appendix 3 Studies included in the systematic review. This study profile describes the authors, study ID, publication year, study design and quality (level of evidence and risk of bias), study location, setting, length of follow-up of patients, study population

characteristics, description of the intervention, description of the comparator and the relevant outcomes assessed. Study characteristics are also summarised in a shorter format in Section B.4.

The three included studies compared MSP with standard care using hand-held dermoscopy in patients at high risk of melanoma, were retrospective in design, and conducted in a dermatology specialist setting. Reported outcomes across the studies included Breslow index and percentage of in-situ/invasive melanoma. There were no data on the number of excisions or patient-follow-up.

APPRAISAL OF THE EVIDENCE

Appraisal of the evidence was conducted in 2 stages:

- Stage 1: Appraisal of the risk of bias within individual studies included in the review (Section B.3).
- Stage 2: Integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice (Sections B.6-B.8).

Following stage 1, the included studies were found to be at high risk of bias and the quality of the evidence too low to perform a meta-analysis of the reported outcomes. We were therefore unable to use GRADE to assess the estimate of effect per outcome across the studies.

B.3. RISK OF BIAS ASSESSMENT

We assessed the quality of the included studies using the NICE checklist for cohort studies (National Institute for Health and Care Excellence 2012), which examines the risk of bias and internal validity of cohort studies designed to answer questions about the relative effects of interventions. Each of the items was checked as 'yes', 'no' or 'unclear'. A summary of the quality assessment is presented in Table 5. This checklist was developed to critically appraise studies that include comparisons involving a test and subsequent management, and does not cover comparisons of diagnostic test accuracy. Therefore, this checklist is directly applicable to our review question, as we aim to evaluate key clinical outcomes following surveillance with TBP and digital dermoscopy over time compared to standard care, not the diagnostic accuracy of dermoscopy.

All of the included studies evaluated medical records from patients with melanoma, were retrospective in design and at high risk of bias (Salerni, Lovatto et al. 2011, Salerni, Teran et al. 2014, Mintsoulis and Beecker 2016). Two of the studies were conducted by the same lead author in two different countries, Spain and Argentina (Salerni, Lovatto et al. 2011, Salerni, Teran et al. 2014).

Selection bias was of concern across the studies and patient populations in the comparison groups differed significantly in some key baseline parameters, such as age. There were no studies which reported whether patients were consecutively selected into the surveillance programme. Patients in the surveillance groups for each of the three studies met the high-risk of melanoma criteria specified

in our protocol, but no inclusion criteria was provided for patients in the non-surveillance cohorts. The increased risk of melanoma in the control group can therefore not be established or compared with the population of interest.

The non-surveillance comparison group in Salerni, Lovatto et al. (2011) included patients referred to the dermatology department for evaluation of suspicious lesions. These patients were significantly older and less likely to have atypical mole syndrome (AMS) or previous melanoma than individuals in the surveillance programme (Salerni, Lovatto et al. 2011). Salerni, Teran et al. (2014) had two comparison groups – the first included patients who visited the dermatologist for a melanoma consultation, and the second included patients who attended routine control examinations using hand-held dermoscopy – but the baseline characteristics of these cohorts were not reported. Mintsoulis and Beecker (2016) evaluated medical records from two different dermatology clinics; patients in the control clinic had a previous history of melanoma and were older than patients in the MSP surveillance group, and most of them had received yearly skin checks in a general dermatology clinic with hand-held dermatoscopy. There may be systematic differences between the groups being compared that are not accounted for in the analysis and are likely to interfere with the effect of the intervention.

A further issue is the potential difference in care received by patients in the non-surveillance cohorts. Patients in the standard care group included in Mintsoulis and Beecker (2016) were monitored by a dermatologist at yearly intervals. Salerni et.al (2011) and (2014) did not report any details on the frequency of examinations or standard care details of patients in the non-surveillance groups (Salerni, Lovatto et al. 2011, Salerni, Teran et al. 2014).

The three studies clearly reported the outcomes of interest – Breslow thickness and frequency of in-situ melanomas – but none of them adjusted their analyses for potential prognostic/confounding factors (e.g. age).

None of the studies reported patient follow-up, attrition or compliance data. In summary, all three studies were at high risk of bias.

Table 5 Summary of quality assessment of included studies

Cohort Study Checklist	***Mintsoulis and Beecker (2016)***	***Salerni, Lovatto et al. (2011)***	***Salerni, Teran et al. (2014)***
Method of allocation to treatment groups was unrelated to potential confounding factors	*No*	*No*	*No*
Attempts were made within the design or analysis to balance the comparison groups for potential confounders	*No*	*No*	*No*
Groups were comparable at baseline	*No*	*No*	*Unclear*
Comparison groups received the same care apart from the intervention	*Unclear*	*Unclear*	*Unclear*
Blinding	*No*	*No*	*No*

Followed up for an equal length of time	*Unclear*	*Unclear*	*Unclear*
Comparable for treatment completion	*Unclear*	*Unclear*	*Unclear*
Comparable with respect to the availability of outcome data	*Unclear*	*Unclear*	*Unclear*
Appropriate length of follow-up	*Unclear*	*Unclear*	*Unclear*
Precise definition of outcome	*Yes*	*Yes*	*Yes*
Investigators were kept 'blind' to participants' exposure	*No*	*No*	*No*
Investigators were kept 'blind' to other important confounding and prognostic factors	*No*	*No*	*No*

B.4. CHARACTERISTICS OF THE EVIDENCE BASE

B.4.1. HIGH-RISK POPULATION

The literature search identified three retrospective comparative cohort studies assessing patient outcomes. These studies provided comparative data on Breslow thickness and tumour stages from melanoma biopsy samples of patients who had undergone MSP and those receiving standard care without MSP surveillance. The population undergoing MSP was comparable to the high risk population in our protocol (Salerni, Lovatto et al. 2011, Salerni, Teran et al. 2014, Mintsoulis and Beecker 2016).

See Appendix 3 Studies included in the systematic review for details on the individual studies included in the evidence base. A summary is provided below in Table 6.

Table 6 Key features of the included evidence comparing MSP with standard care

Trial/Study	N	Design/ duration	Risk of bias	Patient population	Key outcome(s)	Result used in economic model
Salerni, Lovatto et al. (2011)	Total: 201 MSP: 40 SC: 161	Retrospective cohort/ 2 years	High	High-risk of melanoma	• Breslow index • In situ melanoma •Invasive melanoma	Not used
Salerni, Teran et al. (2014)	Total: 89 MSP: NR SC: NR	Retrospective cohort/ 4 years	High	High-risk of melanoma	• Breslow index • In situ melanoma •Invasive melanoma	Not used
Mintsoulis and Beecker (2016)	Total: 224 MSP: 9 SC: 215	Retrospective cohort/ 10 years	High	High-risk of melanoma	• Breslow index • In situ melanoma •Invasive melanoma	Not used

MSP: melanoma surveillance photography, NR: not reported, SC: standard care

B.4.2. Very High-Risk population

No available evidence.

B.5. Outcome Measures and Analysis

B.5.1. High-Risk Population

All the included studies retrospectively assessed melanoma biopsies from patients who received MSP and compared these results to biopsies from high-risk patients who did not receive MSP.

Breslow index and frequency of in-situ: invasive melanoma were compared between the surveillance intervention and control groups.

T-tests were used in the statistical analysis for continuous variables in all three studies. No confidence intervals were reported for any of the studies. The small sample size in these studies suggests high variance. As this variance is not reported, reporting bias is assumed.

There is a high risk of selection bias that could have affected the results, as the comparability of the two populations is unclear and no attempt was made to adjust the analysis for potential confounders in the studies. Patient characteristics differed between the two comparison groups in two studies (Salerni, Lovatto et al. 2011, Mintsoulis and Beecker 2016), and the study by Salerni, Teran et al. (2014) did not provide any data on patient characteristics. Furthermore, strict inclusion criteria only applied to the intervention cohorts, and risk of melanoma might have been different between the comparison groups.

B.5.2. Very High-Risk Population

No available evidence.

B.6. RESULTS OF THE SYSTEMATIC LITERATURE REVIEW

IS IT SAFE?

Summary – MSP is a non-invasive surveillance technology.

There are no safety concerns with providing MSP using TBP and DD

Included studies did not present any data regarding the safety of the intervention. Both TBP and DD are non-invasive technologies. Hand-held dermoscopy is already in use as standard care in dermatology consultations to evaluate suspicious lesions. TBP is also widely available and consists of standard photography. TBP and DD are considered safe procedures.

IS IT EFFECTIVE?

Summary –

High risk population:

Mean breslow index was significantly reduced in three studies in the surveillance arm compared to the standard care arm (in all three studies p<0.05). The in-situ:invasive melanoma ratio was also significantly higher in the MSP arm than in standard care (in all three studies p<0.05).

All included studies are retrospective in design and at high risk of bias. These results should be interpreted with caution.

Very high-risk population:

No evidence was identified.

EFFECTIVENESS OUTCOMES

B.5.1. HIGH RISK POPULATION

In all the included studies, patients undergoing MSP had significantly higher numbers of melanomas in-situ and fewer invasive melanomas compared to those receiving usual care (Table 7).These differences in the number of in situ and invasive melanomas indicate that these lesions were detected at an earlier stage in the MSP surveillance cohorts. However, these studies had a retrospective design and high risk of bias, so the results should be interpreted with caution. It is important to note that standard care was not clearly defined in the studies and these populations might be potentially different regarding clinical and demographic characteristics as well as patterns of care (details discussed in Section B.8).

Table 7 Mean Breslow Index (mm)

Study	*MSP*	*Standard care*		*p*
Salerni, Lovatto et al. (2011)	0.54	1.71		<0.001
Salerni, Teran et al. (2014)	0.52	1.43[a]	0.77[b]	<0.05*
Mintsoulis and Beecker (2016)	0.03	0.34		0.02

MSP: melanoma surveillance photography
[a]Melanoma consultation; [b]Melanoma routine control
* Not specified which comparator this refers to

Breslow index was significantly lower in melanomas from patients in the MSP surveillance programme than in patients receiving standard care without MSP surveillance (Table 7). The ratio in-situ:invasive melanoma was higher in the MSP surveillance groups compared to standard care (Table 8).

No other outcomes specified in the protocol were reported.

Table 8 Frequency of in-situ and invasive melanoma, n (%)

Study	*Melanoma*	*MSP*	*Standard care*		*p*
Salerni, Lovatto et al. (2011)	In-situ	35 (70)	46 (27.8)		<0.001
	Invasive	15 (30)	119 (72.2)		<0.001
	Ratio in-situ:invasive	2.33:1	0.38:1		
Salerni, Teran et al. (2014)	In-situ	7 (58.3)	8 (22.9)[a]	26 (50.0)[b]	<0.05
	Invasive	5 (41.7)	27 (77.1)[a]	26 (50.0)[b]	<0.005*
	Ratio in-situ:invasive	1.40:1	0.29:1[a]	1:1[b]	
Mintsoulis and Beecker (2016)	In-situ	13 (92.8)	171 (61.7)		0.02
	Invasive	1 (7.14)	106 (38.3)		NR
	Ratio in-situ:invasive	13:1	1.61:1		

MSP: melanoma surveillance photography
[a]Melanoma consultation; [b]Melanoma routine control
*not specified which comparator this refers to

B.6.2. Very High-Risk Population

No available evidence.

B.7. Extended Assessment of Harms

B.7.1. High Risk Population

There was no comparative evidence on the number of nevi biopsies following MSP versus standard care. Clinical opinion estimates that MSP is associated with a reduced number of biopsies and benign:malignant excision ratio compared with standard care, which might help to reduce patient anxiety and morbidity associated with multiple procedures.

B.7.2. Very High Risk Population

No available evidence.

B.8. Interpretation of the Clinical Evidence

B.8.1. High-Risk Population

Evidence about the relative effectiveness of adding MSP to standard care is limited to three low-quality level III-3 studies reporting Breslow thickness and in-situ: invasive melanoma ratio. On the basis of the included evidence (Table 7 and Table 8), it is suggested that, relative to the comparator the intervention has non-inferior safety and uncertain effectiveness.

The decision not to conduct a meta-analysis was made due to the high risk of bias and the low number of included studies – three studies of poor quality, two of them by the same author. We were therefore unable to use GRADE to assess the estimate of effect per outcome across the studies. The effectiveness of the intervention can not be estimated due to the following features of the included studies:

1. Patient populations were heterogeneous. The demographic and clinical characteristics of the cohorts within and across studies might not be comparable.
2. Important risk factors such as age or previous melanoma were uncontrolled (Salerni, Lovatto et al. 2011, Mintsoulis and Beecker 2016) or unreported (Salerni, Teran et al. 2014). In the two studies that reported information on participant's age, patients in the control groups were significantly older than those undergoing MSP surveillance (Salerni, Lovatto et al. 2011, Mintsoulis and Beecker 2016). Salerni, Lovatto et al. (2011) reported a patient population within the MSP group who were significantly more likely to have atypical mole syndrome, a family history of melanoma or previous melanoma than the standard care group. These differences are likely to bias the results towards the intervention. None of the studies adjusted their statistical analysis for potential confounders. The definition of standard care was unclear and inconsistent across the studies. Mintsoulis and Beecker (2016) reported patients treated with standard care had a previous history of melanoma and underwent yearly dermoscopy surveillance (without digital photography) at a hospital dermatology clinic. This control population might differ from control patients in the other studies, where patients were referred to a dermatologist for melanoma evaluation but no information regarding their routine care were provided. Salerni, Teran et al. (2014) included two groups in standard care – one was identified as "melanoma consultation" and the second as "melanoma routine control", but no data was reported on frequency of examinations or baseline patient characteristics. Salerni, Lovatto et al. (2011) reported patients in the standard care group who were referred to the dermatology hospital department, but there was no discussion on prior patient care. Furthermore, none of the studies included any data on patient follow-up.
3. The patient population in the MSP groups across the studies was relatively small. The study by Mintsoulis and Beecker (2016) only evaluated medical records from nine patients (14 melanomas) in the surveillance arm during the time period from 2010 to 2014, compared to 215 patients (277 melanomas) in the standard care group over a 10-year period (2004-2014). Salerni et. al (2011) included data from 40 patients in the MSP group and 161 patients who had received standard care. Salerni, Teran et al. (2014) included 89 patients, but the exact number of patients in each comparison group was not reported, only the number of melanomas analysed (12 in MSP and 35 in standard care).

Mintsoulis and Beecker (2016) reported better outcomes – lower Breslow thickness and frequency of invasive melanoma in both MSP and standard care than the other two studies. Regular specialist

monitoring in the standard care group and the limited number of patients in the MSP group might have had an impact on these results. Salerni, Teran et al. (2014) reported patients in the non-MSP standard care group who received routine melanoma controls also had thinner Breslow index and a higher number of in-situ melanomas than those who were classified as having a melanoma consultation, suggesting a positive effect of melanoma monitoring without MSP.

None of the studies reported the number of excisions or ratio for benign:malignant excisions for melanoma diagnosis. These are important measures of effectiveness as the surveillance program is proposed to reduce the number of excisions leading to better quality of life for patients and reduced costs, however, increased excisions due to more intensive monitoring is also possible.

In summary, the addition of MSP resulted in a reduction in mean breslow thickness in all three studies (all $p<0.05$) and an increase in situ: invasive ratio (all $p<0.05$). A low Breslow index and higher frequency of in-situ lesions indicate early stage melanoma, which is a significant predictor of survival (Balch, Gershenwald et al. 2009, Australian Institute of Health and Welfare 2016, Wernli, Henrikson et al. 2016). Therefore, the findings are supportive of a benefit from MSP in the proposed population.

However, the quality of the evidence was very low and the applicability of the studies is limited. The findings should therefore be interpreted with caution and the true effect of the proposed intervention remains unclear. Further research in the form of randomised controlled trials is warranted to determine the impact of MSP on patient's outcomes.

B.8.2. Very High-Risk Population

No available evidence.

SECTION C TRANSLATION ISSUES

C.1. OVERVIEW

The clinical evaluation suggested that, relative to standard care, MSP has non-inferior safety and uncertain effectiveness based on the evidence profile given in Section B. Given the poor quality and limited data presented in Section B Clinical Evaluation, the clinical evidence was not considered sufficient to be used in the economic analysis.

The cost-effectiveness model is presented in Section D is based on a published economic evaluation (Watts, Cust et al. 2017). The study by Watts et al. (2017) is a cost-effectiveness analysis from the Australian healthcare system perspective, comparing the cost and benefits of MSP for very high-risk patients in a High-risk dermatology clinic at the Royal Prince Alfred Hospital in Sydney with standard care in the community.

The key translation issues for this model are:

1. Validity of the clinical evidence used in the model;
2. Applicability of the modelled population to the high risk population proposed for funding; and
3. Applicability of the model of care to those proposed for funding.

C.2. APPLICABILITY TRANSLATION ISSUES

All the studies presented in Section B include a patient population at high risk of melanoma, but no comparative evidence was found for patients at very high risk. In contrast, the study by Watts et al. (2017) focused on patients at very high risk, comparable to the very high-risk population in the agreed protocol, defined as individuals with at least one of the following characteristics:

- Confirmed family history of three or more first- or second-degree relatives with melanoma and a confirmed personal history of invasive melanoma;
- Dysplastic nevus syndrome and a confirmed personal history of invasive melanoma;
- Personal history of at least two confirmed invasive melanomas, one of which diagnosed in the past 10 years; and
- Confirmed high-penetrance mutation affecting melanoma risk.

The model by Watts (2017) is highly applicable to current clinical practice as it used data from the Australian healthcare system and a prospective Australian study of very high risk patients. Therefore, it is directly relevant for the Australian setting. However, the MSP intervention was conducted in a

cohort of very high risk individuals attending a highly specialised clinic in a tertiary hospital within an urban setting; therefore, the generalizability of the model's cost-effectiveness results to patients at high risk (for whom the evidence in Section B is relevant) is uncertain.

C.3. EXTRAPOLATION TRANSLATION ISSUES

Watts et al. (2017) developed a Markov model to simulate the management and progression of melanoma over a 10-year time horizon and six health states that would represent long-term follow-up (details of the model are described in Section D Economic Evaluation). The overall relative survival for melanoma has been reported to stabilise after 9 years (Criscione and Weinstock 2010). Therefore, the selected 10-year timeframe is appropriate for this analysis as it maximises the availability of data without increasing uncertainty about future projections.

The cost of treatment of late stage melanoma is highly variable and rapidly changing. New immunotherapy treatments were introduced in Australia after the study by Watts et al. (2017) was finalised. The model presented in Section D has included these new cancer immunotherapies, but these treatments and their utilisation rates may vary in the following years.

C.4. TRANSFORMATION ISSUES

Clinical effectiveness data used to derive the model probabilities of excisions or melanoma by stage inputs for the standard care group were obtained from linked data of patients participating in the "45 and Up" population-based study (Banks, Redman et al. 2008). These data were compared to that derived from a single-arm prospective study (Moloney, Guitera et al. 2014). However, the standard care data inputs have not been published, and not all the inputs used in the model were published in Moloney et al. (2014). Therefore, these clinical inputs can not be assessed with the same rigour as those considered in section B and their validity remains uncertain.

Breslow thickness was used as a surrogate to determine disease stage at diagnosis if spread of the disease was not documented (Table 9). The validation of this surrogate measure with AJCC stage was conducted in 77 primary melanomas with 92% agreement (weighted k statistic 0.93, 95% CI 0.87-0.89), indicating good concordance between the two staging methods.

Table 9 Melanoma stage according to Breslow thickness (mm)

Stage	*Breslow thickness (mm) or disease spread*
In-situ	No invasion
Stage I	0 to 1
Stage II	1.01 to ≤4
Stage III	≥4.01 or lymph node involvement
Stage IV	distant metastatic disease

Source: (Watts, Cust et al. 2017)

C.5. ANY OTHER TRANSLATION ISSUES

No other translation issues were identified.

SECTION D ECONOMIC EVALUATION

D.1. OVERVIEW

A cost-effectiveness analysis of MSP compared to standard care from the Australian health system perspective was identified in the economic literature search (Watts, Cust et al. 2017), and was considered to be key evidence for this application. This study used clinical data from a High-risk dermatology clinic within a tertiary hospital in Sydney and compared it to linked data from a population-based cohort of selected patients at very high risk of melanoma. The decision was, therefore, to conduct a cost-effectiveness analysis based on this model, keeping the model structure and updating the cost inputs with 2017 data.

D.2. POPULATIONS AND SETTINGS

The patient population in the economic evaluation includes individuals at very high risk of melanoma, as previously defined in the protocol:

1. Personal history of two or more primary melanomas OR
2. CDKN2A mutation OR
3. One past melanoma AND one of
    - 100 or more naevi OR
    - Six or more atypical naevi OR
    - Family history of three or more first- or second-degree relatives

The setting in the intervention group was a specialised surveillance clinic within a public hospital where patients at very high risk were seen by dermatologists or dermatology registrars. The standard care group included patients at very high risk who were monitored in the community by GPs or dermatologists. All patients had a previous melanoma.

There were insufficient data to assess the cost-effectiveness of this intervention in patients at high risk of melanoma.

D.3. STRUCTURE AND RATIONALE OF THE ECONOMIC EVALUATION

A summary of the key characteristics of the economic evaluation is given in Table 10 below.

Table 10 Summary of the economic evaluation

Perspective	Australian Health System
Comparator	Standard care in the community
Type of economic evaluation	Cost-effectiveness evaluation
Sources of evidence	Indirect comparison of a prospective single-arm study and population-based linked data
Time horizon	10 years in the model base case
Outcomes	QALYs
Methods used to generate results	Markov model
Health states	Patient presents for surveillance, dead from other causes, dead due to melanoma, recurrence of melanoma, stage III disease, stage IV disease
Cycle length	12 months
Discount rate	5%
Software packages used	TreeAgePro 2017

QALY: quality adjusted life year

LITERATURE REVIEW

Table 11Medline, Embase, and the Cochrane Database of Systematic Reviews (without time limits) were used to identify relevant studies, and this search was conducted on the 3rd April, 2017. HTA websites were also searched, but no relevant assessments were identified.

Table 11 Literature search for cost-effectiveness evaluation

#	*Search terms*	*Results*
1	exp Melanoma/	221459
2	exp Skin Neoplasms/	453738
3	(pigmented adj2 (lesion$ or mole$ or nevus or nevi or naevus or naevi or skin)).mp.	19075
4	(melanom$ or melanocyt$).mp.	309342
5	cutaneous melanoma.tw.	11891
6	suspicious melanocyt$ lesion$.tw.	40
7	melanoma$.tw.	221192
8	invasive melanoma.tw.	1331
9	or/1-8	688957
10	surveillance.ab.	417561
11	9 and 10	8753
12	"cost*".ab,ti.	1063476
13	exp "Costs and Cost Analysis"/	545328
14	"cost benefit analys*".ab,ti.	8656
15	Cost-Benefit Analysis/	165271
16	exp "health care costs"/	318520
17	12 or 13 or 14 or 15 or 16	1352849
18	11 and 17	372

One relevant cost-effectiveness analysis was identified in the literature review(Watts, Cust et al. 2017).

Watts et al (2017) reported that specialised surveillance was less expensive and more effective than standard care (Table 12) with mean savings of $6,828 per patient and mean gain in health-related quality of life of 0.31 quality-adjusted life years (QALY) over 10 years. The key drivers for these differences were earlier detection of melanoma with MSP, which resulted in lower treatment costs, and fewer excisions compared with standard care.

Table 12 Mean Total Costs ($) and QALYs per patient over 10 years

	Specialised surveillance	*Standard care*	*Difference (95% CI)*
Mean cost per patient	$13,468	$20,296	$6,828 ($5,564 to $8,092)
QALY	7.87	7.56	0.31 (0.27 to 0.35)

Source: (Watts, Cust et al. 2017)
QALY, quality-adjusted life years

STRUCTURE OF THE ECONOMIC EVALUATION

The Markov model developed by Watts et al. 2017 was replicated for this assessment (Table 10). In addition, the cost of MSP was amended to reflect the proposed MBS fee for this intervention, the cost of new cancer immunotherapies were added to the model, and 2013 MBS items were updated to include 2017 costs. The clinical inputs and model structure were unchanged. TreeAgePro 2017 R1.1 was used to conduct this economic evaluation.

The model compares the use of MSP for patients at very high risk of melanoma in a specialist dermatology setting with standard care in the community (

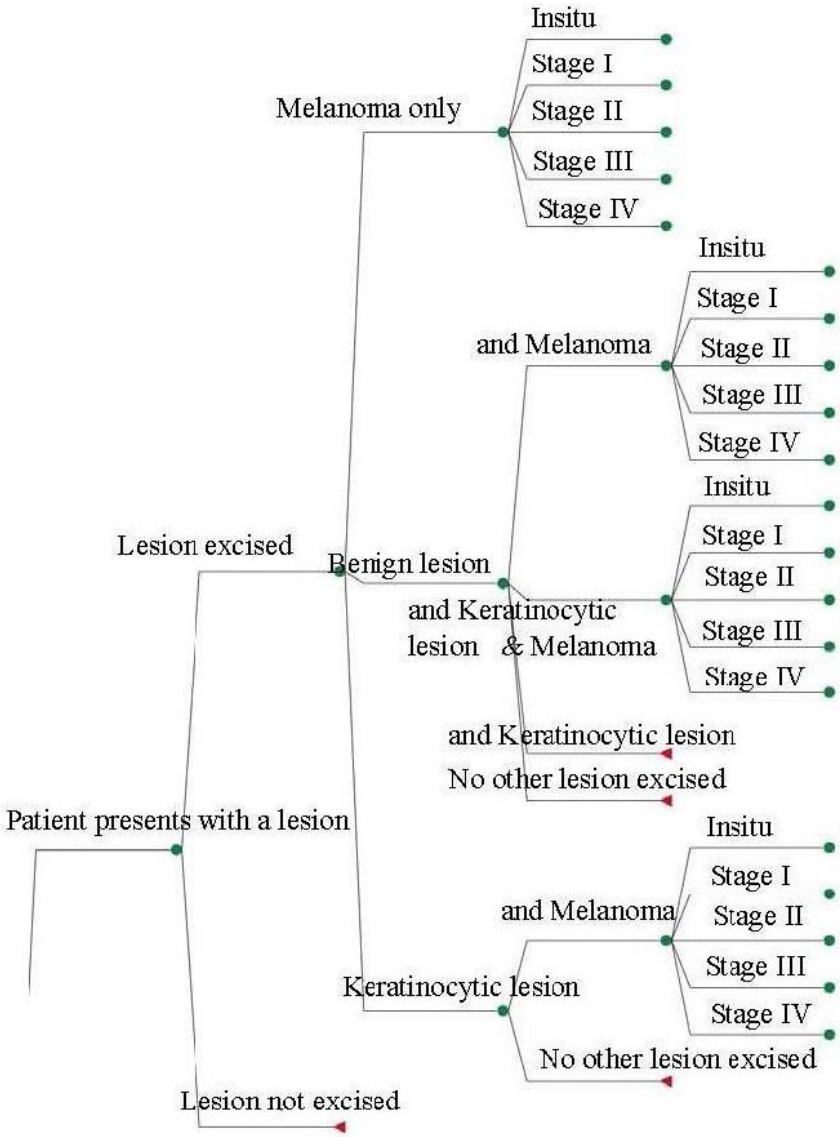

Figure 7). All patients start the model in the first year of surveillance and present with a lesion that is either excised or not, in which case the patient would return to surveillance at the specified interval. The excised lesions could be benign, keratinocytic or melanoma at different stages of development. A patient may have two types of lesions and several excisions within a year.

Patients in the MSP group had a skin examination every six months, and those in standard care once a year. In standard care, the model assumes all lesions identified for excision occur during the one skin surveillance appointment. Lesion thickness was used to determine melanoma stage (See section C. C.4. Transformation issues)

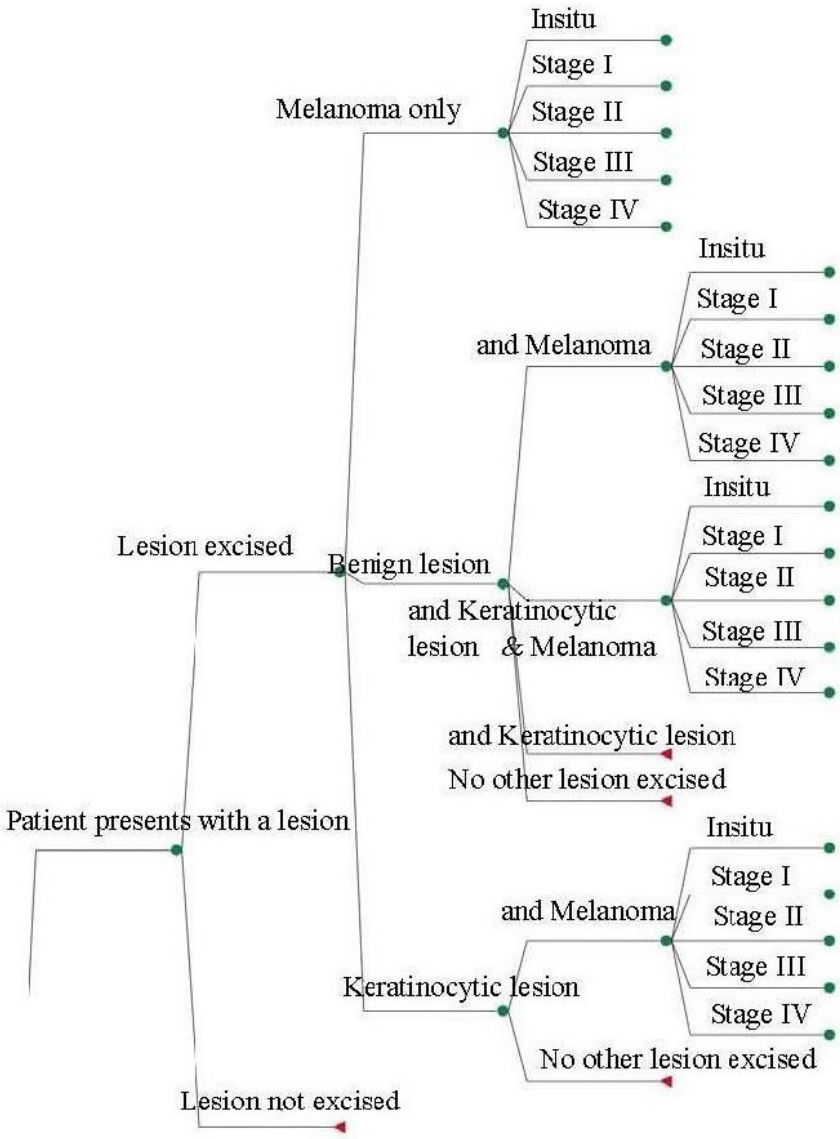

Figure 7 Decision analytic structure of the economic evaluation
Source: (Watts, Cust et al. 2017)

The primary outcome from the economic model is the cost per QALY gained over a 10-year time horizon. Six health states (

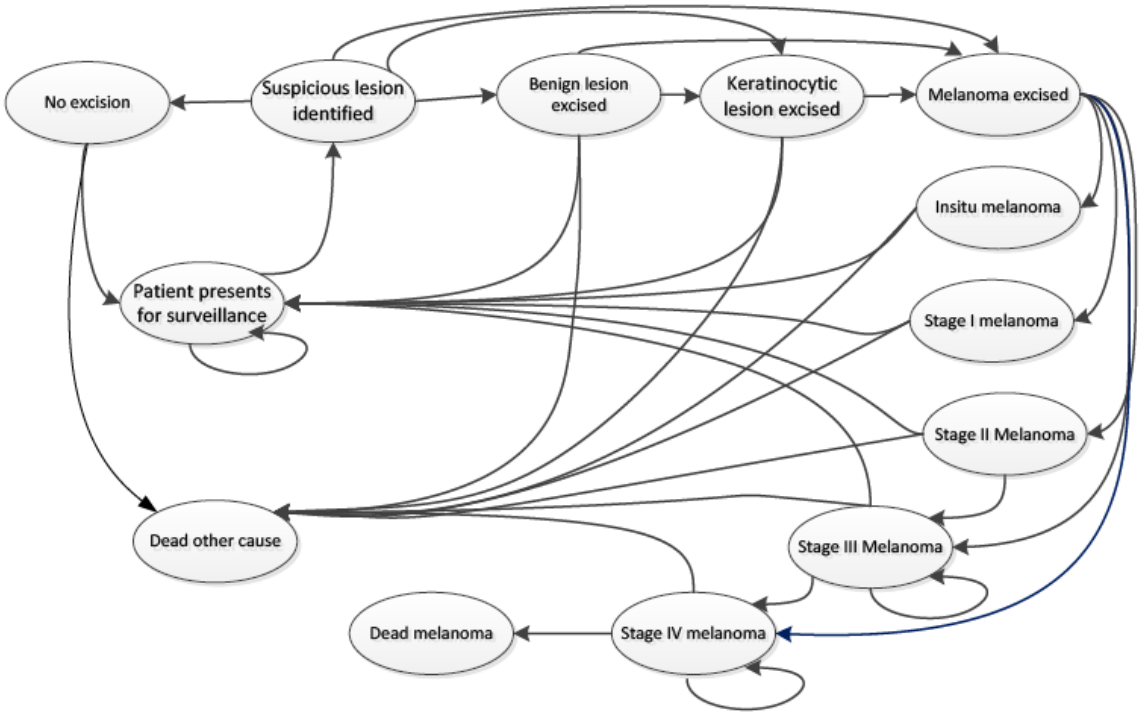

Figure 8) are presented in the model structure:

1) Patient presents for surveillance
2) Dead from other causes
3) Dead due to melanoma
4) Recurrence of melanoma
5) Stage III disease
6) Stage IV disease

Depending on the type of lesion excised, the patient may return for surveillance or move to another health state. If the lesion was a melanoma, the health state was determined by melanoma stage at diagnosis.

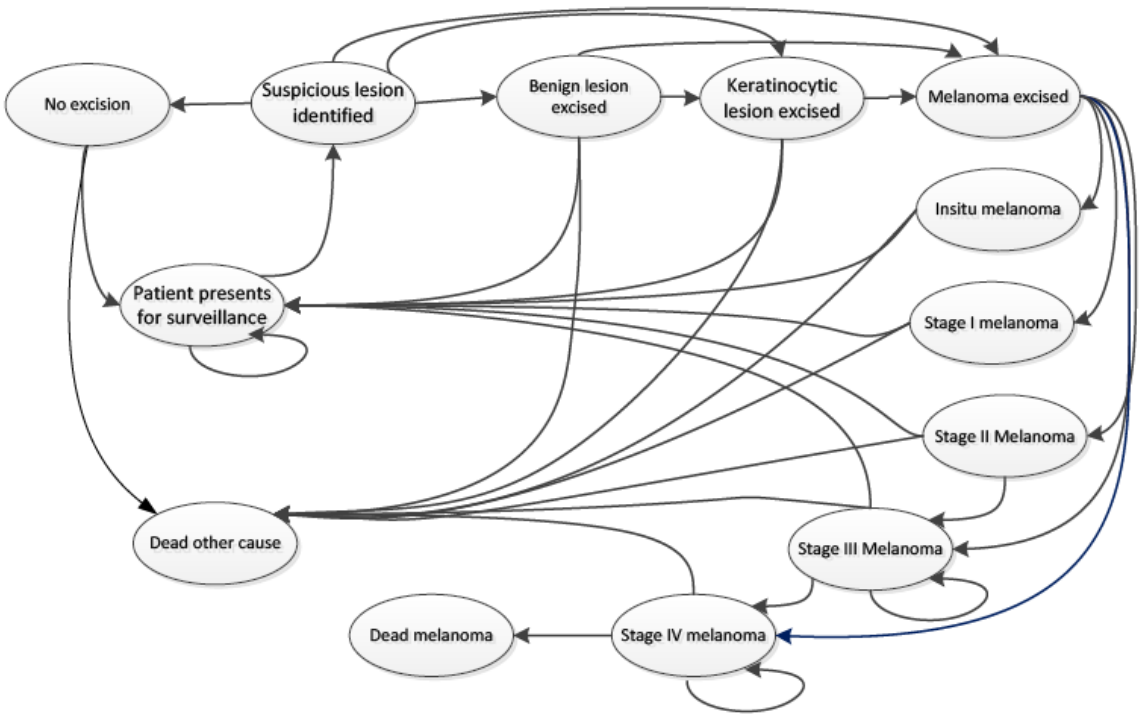

Figure 8 Markov model showing the transition between health states from patient presenting for MSP
Source: (Watts, Cust et al. 2017)

D.4. INPUTS TO THE ECONOMIC EVALUATION

The updated 2017 costs included in the economic evaluation are provided in Appendix 5 Updated costs.

Clinical data for the specialised surveillance group were obtained from a prospective 5-year (2006-2009) single-arm study conducted in the high-risk clinic (Moloney, Guitera et al. 2014). A total of 311 patients at very high risk of melanoma attended MSP examinations with a dermatologist or a dermatology registrar every 6-months, or returned for a 3-month short follow-up if a suspicious lesion was identified and not excised.

The standard care arm included data from 607 patients participating in the Sax Institute's "45 and Up" cohort study during the same period. The "45 and Up" is a population-based study that recruited 250,000 individuals aged 45 years and older from NSW from 2006 to 2009 with the aim of providing socio-demographic and health information on an ageing population in Australia (Banks, Redman et al. 2008). Patients at very high risk of melanoma, based on a personal history of melanoma and reported family history of two first-degree relatives with melanoma, were identified from this study. Only those with linked data to NSW Cancer Registry and Admitted Patient Data Collection (APDC) were included in the analysis.

Deterministic matching was conducted to minimise baseline differences between the two patient groups. However, some baseline characteristics remained unbalanced, such as higher proportion of men, older age and lower socioeconomic status in the standard care group compared to the MSP group (Table 13). Therefore, we are not able to rule out systematic differences between the two patient groups, which might have affected the results.

Table 13 Baseline characteristics of patients included in the cost-effectiveness analysis

Baseline characteristics	***MSP n=311***	***Standard care N=607***
Males, n (%)	*179 (58)*	*402 (66)*
Age in 2006, years		
Males, median (IQR)	*58 (50-67)*	*68 (60-76)*
Females, median (IQR)	*50 (41-58)*	*60 (50-68)*
Family and personal history, n (%)	*52 (16)*	*93 (15)*
Multiple primary melanomas, n (%)	*146 (47)*	*514 (85)*
Naevi and history of melanoma, n (%)	*219 (70)*	*NR*
CDKN2A mutation, n (%)	*17 (5)*	*NR*
Index of relative socio-economic disadvantage		
Ist quintile (most disadvantaged), n (%)	*24 (8)*	*95 (16)*
2nd quintile, n (%)	*43(14)*	*135 (22)*
3rd quintile, n (%)	*55 (18)*	*125 (21)*
4th quintile, n (%)	*46 (15)*	*89 (15)*
5th quintile (least disadvantaged), n (%)	*143 (46)*	*136 (22)*
Unrecorded, n (%)	*NA*	*27(4)*

IQR: interquartile range; MSP: melanoma surveillance photography
Source: (Watts, Cust et al. 2017)

The annual probabilities (Table 14) for melanoma by stage and excisions in the model were derived from the two sources described above. However, not all the included data used in the model to derive the probabilities for patients undergoing MSP were reported in Moloney et al. (2014). Excision probabilities were obtained from data collected in the first year of surveillance in the MSP arm, and 2008 linked data were used in the standard care group. The probabilities of melanoma by stage at diagnosis were calculated from Breslow thickness data from the high risk clinic and based on a weighted average over 5 years. In the standard care arm, linked MBS data with NSW Cancer Registry and APDC data were used to derive the probabilities. However, these data are not published and, therefore, it is not possible to adequately assess the validity of these inputs.

Life tables of the Australian Bureau of Statistics (ABS) were used to obtain overall mortality estimates, and AJCC staging data were used to estimate melanoma-specific mortality. Disease progression probabilities and utility scores reflecting the quality of life for each health state were obtained from the published literature.

Table 14 Annual probability inputs in specialised surveillance and standard care

	MSP			*Standard care*		
Melanoma by stage at diagnosis	**Base case**	**Low**	**High**	**Base Case**	**Low**	**High**
In situ melanoma	0.45	0.02	0.9	0.15	0.08	0.3
Stage I melanoma	0.42	0.02	0.84	0.59	0.29	0.9
Stage II melanoma	0.09	0.04	0.18	0.22	0.11	0.44
Stage III melanoma	0.03	0.02	0.06	0.05	0.02	0.09
Stage IV melanoma	0	NA	NA	0.005	0.003	0.01
Excisions under surveillance						
Probability of an excision	0.4	0.21	0.84	0.64	0.32	0.99
Melanoma only	0.12	0.06	0.24	0.05	0.02	0.09
Keratinocytic lesion only	0.18	0.09	0.36	0.13	0.07	0.26
Benign lesions only	0.5	0.25	0.99	0.28	0.14	0.55
Melanoma and keratinocytic lesion	0.02	0.01	0.04	0.03	0.01	0.06
Melanoma and benign lesion	0.07	0.03	0.14	0.08	0.04	0.17
Keratinocytic and benign lesion	0.09	0.04	0.18	0.33	0.15	0.66
Melanoma and keratinocytic and bening lesion	0.01	0.008	0.04	0.1	0.04	0.2

Source: (Watts, Cust et al. 2017)
MSP: melanoma surveillance photography
Low and high calculations for sensitivity analyses on the basis of multiplier equation (0.5 and 2) for excision probabilities and from published literature for other values.

Resource use, cost and clinical pathways for the surveillance arm were estimated from published data from the high-risk clinic (Watts, Cust et al. 2015). Clinical pathways for the standard care arm were obtained through telephone surveys of 10 GP clinics in NSW, and costs from MBS items. Patients in the standard care group were assumed to undergo an annual skin examination conducted by their GP or dermatologist, but only the MBS item for a GP consultation was used as the annual base care cost for standard care. A dermatologist consultation item was not considered. Additional follow-up costs were estimated for patients with disease progression.

MBS items for out-of-hospital costs in standard care were calculated at 100% of the scheduled fee, whereas a standard fee for service of 85% of the scheduled fee was applied for the high-risk clinic, as it was part of a public hospital. Costs of excisions were obtained from MBS item numbers and costs for ongoing surveillance were based on predicted frequency of consultation. Indirect costs (e.g. out-of-pocket costs for travel, productivity loss) were not included. Hospital costs were obtained from the APDC in NSW. Costs associated to death in hospital, palliative care and treatment of metastatic disease were obtained from published studies. All costs were adjusted to 2017 dollars and a standard discount rate of 5% was applied to all future costs and benefits.

The input costs for specialised surveillance included in the replicated model were calculated at 85% of the scheduled fee based on the proposed MBS items for this intervention (Table 15). The digital dermoscopy items (by number of naevi) were assumed to be evenly divided across the patient population (25% of patients accessing each of the 4 items). It was estimated that 10% of patients

may undergo short-term follow up every year. The total body photography item was divided by 5 to estimate an annual cost. The total annual cost per patient undergoing MSP was estimated to be $155. This is considerably less than the cost used in the published model of $884.

Table 15 Annual cost per patient of specialised surveillance, 85% of scheduled fee

Intervention	*Proposed MBS item cost ($)*	*Frequency of use*	*% Accessing*	*Annual Cost (2017 $) per patient*
Total Body Photography	85	1 every 5 years	100	17
Digital Dermoscopy (15-49 naevi)	100	annual	25	25
Digital Dermoscopy (50-99 naevi)	125	annual	25	31.25
Digital Dermoscopy (100-149 naevi)	150	annual	25	37.5
Digital Dermoscopy (150+ naevi)	175	annual	25	43.75
Short-Term Follow-up	59.5	annual	10	0.595
Total cost				155

*The following assumptions were applied: 25% usage of each digital dermoscopy item (i.e. of 100 patients using digital dermoscopy, 25 patients would be stratified to each dermoscopy item), and 10% of patients may undergo short-term follow-up every year

It should be highlighted that the proposed annual MBS fee of $155 does not cover the total cost of MSP and patients would likely still incur out of pocket costs. Indirect costs, such as patient out-of-pocket costs for travel, specialist visits or treatment, and productivity loss were not included in the model. In addition, adherence to the surveillance intervention was not taken into account.

The input for the annual cost for standard care was the same as that published in Watts et al. 2017, at $70 per patient (based on costs for a skin examination GP appointment, estimated from a telephone survey of skin cancer clinics and mixed practice clinics in NSW).

Treatment costs for stage III and IV were updated to include new immunotherapies that were not approved by PBS (Pharmaceutical Benefits Scheme) when the Watts et al. (2017) model was developed (Table 16). These costs are approximate, as there were no definite data on the percentage of patients receiving new immunotherapy treatments in Australia, and such treatment is likely to be highly individualised and rapidly changing.

Table 16 Annual cost per patient of unresectable stage III and stage IV melanoma

Treatment items, melanoma stage III and IV	***Annual cost (2017 $) per patient***
Staging	20,161.34
Follow-up	3,087.54
Unresectable Stage III/Stage IV	8,477.18
BRAF immunotherapy	59,118.76
NRAS immunotherapy	40,928.37
Chemotherapy	1,550.55
Adjuvant radiation	6,234.98
Palliative chemotherapy	694.47

Treatment items, melanoma stage III and IV	*Annual cost (2017 $) per patient*
Palliative radiotherapy	982.29
Supportive care	2,815.73
Complications	384.61
Total	144,435.83

ASSUMPTIONS INCORPORATED INTO THE MODEL STRUCTURE:

In the Watts (2017) model, the cost of MSP was based on the assumption that 36% of individuals undergoing MSP would be seen by a dermatologist and 64% would be examined by a GP. In the replicated model, the cost of MSP only accounts for the proposed MBS items and the assumption that all patients would go to a dermatologist.

It was assumed that patients at very high risk of melanoma were evenly distributed across the four digital dermoscopy MBS items according to number of naevi, and 10% of patients would need short-term follow-up (Table 15). This distribution might vary in a real-world setting.

The cost of standard care was estimated at $70, which might be an underestimate as it is likely that some patients at very high risk of melanoma would be already under surveillance by a dermatologist. Nevertheless, an increase in the baseline cost of standard care would favour the cost-effectiveness of the specialised surveillance intervention.

It was assumed that patients in standard care had one skin consultation per year, while those in the MSP group were monitored twice a year. However, the number of GP consultations in standard care might be higher given that patients in standard care had more excisions than those under specialised surveillance. In addition, there are uncertainties regarding the standard care intervention, such as details regarding frequency of follow-up or the proportion of patients who might be treated by GPs or dermatologists following their melanoma diagnosis.

No additional follow-up costs were applied for patients with in-situ, stage I and II melanoma. Costs for ongoing follow-up in patients with stage III and IV melanoma were based on the predicted frequency of specialist consultations: based on 3 monthly specialist consultation, 3-monthly ultrasound and 6-monthly positron emission tomography (PET) in the first and second year following diagnosis. Surveillance costs in the third and fourth year post-diagnosis included 6 monthly specialist consultation, 6-monthly ultrasound and annual PET. From year five, a cost for an annual specialist consultation and annual ultrasound was applied.

D.5. RESULTS OF THE ECONOMIC EVALUATION

INCREMENTAL COSTS AND EFFECTIVENESS

As per the published model, the replicated model showed that MSP in patients at very high risk of melanoma is more effective and less costly than standard care. The overall costs and effectiveness (QALY), and incremental costs and effectiveness as calculated for the intervention and comparator in the model, with the base case assumptions, are shown in Table 17. The mean cost per patient over 10 years in specialised surveillance and standard care was $7,172.63 and $15,558.83, respectively. The corresponding QALYs were 7.53 and 7.32. The mean saving associated with the use of MSP over 10 years was estimated at $8,386.19, and the mean QALY gain was 0.21.

Table 17 Cost-effectiveness results MSP compared with Standard care (10-year time horizon)

	MSP	*Standard care*	*Incremental*
Cost ($)	7,172.63	15,558.83	8,386.19
Effectiveness (QALY)	7.53	7.32	0.21

QALY: quality adjusted life year, MSP: melanoma surveillance photography

D.6. SENSITIVITY ANALYSES

Results from a one-way sensitivity analysis indicate that MSP is less costly and more effective than standard care up to a threshold of $1,100 for the annual cost of MSP, which is a higher cost than the

proposed estimate of $155 (

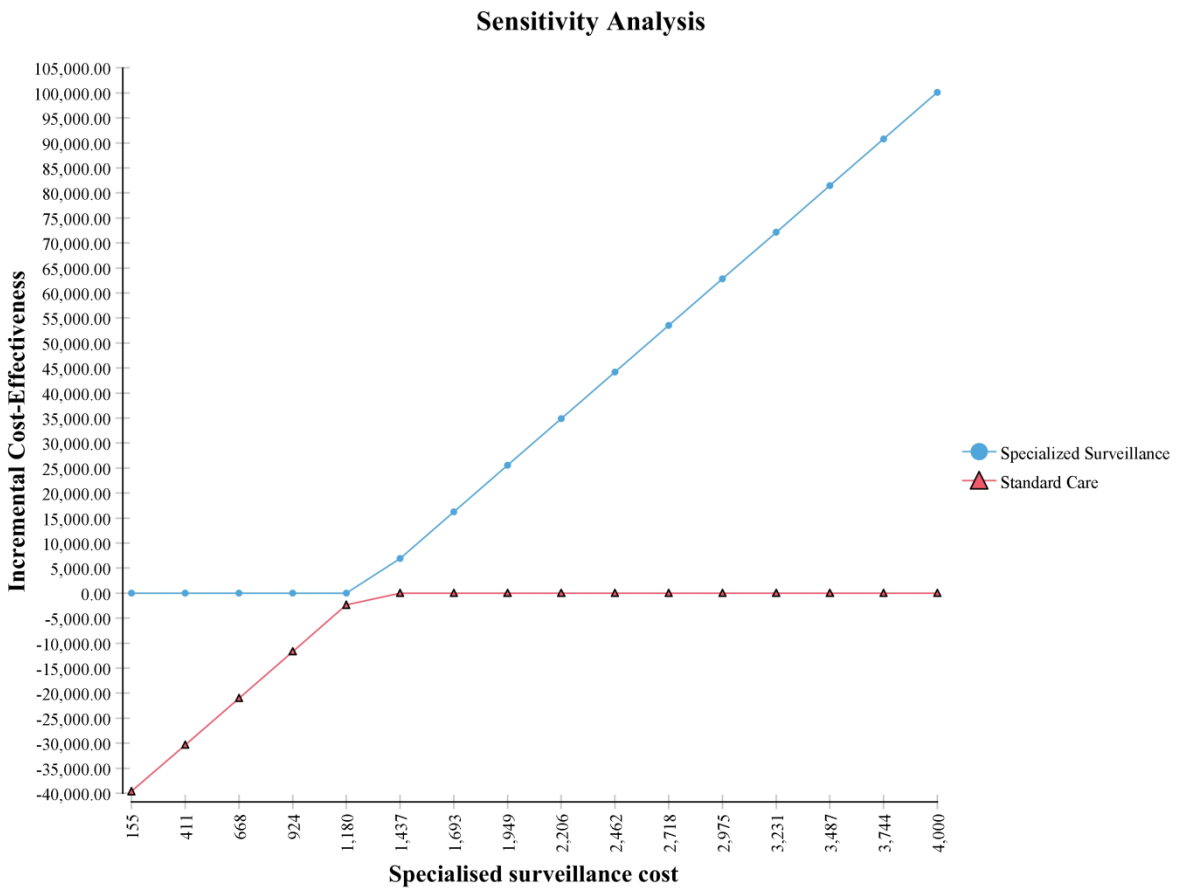

Figure 9). Beyond this threshold, specialised surveillance with MSP becomes more costly than standard care (given an annual cost of standard care of $70), but MSP remains cost-effective up to an annual cost of $2,700 for a willingness to pay of $50,000 per quality adjusted life years (QALY) gained.

It is important to note this threshold was obtained from a model of MSP in a population at very high risk of melanoma attending a highly specialised clinic within an urban centre, and these results might not be generalisable to the high-risk population in other areas of the country.

There is some uncertainty around the effectiveness inputs in the model. The key drivers for the cost-effectiveness of the model were earlier detection of melanoma and fewer excisions with MSP, but we could not validate the data used to derive these variables.

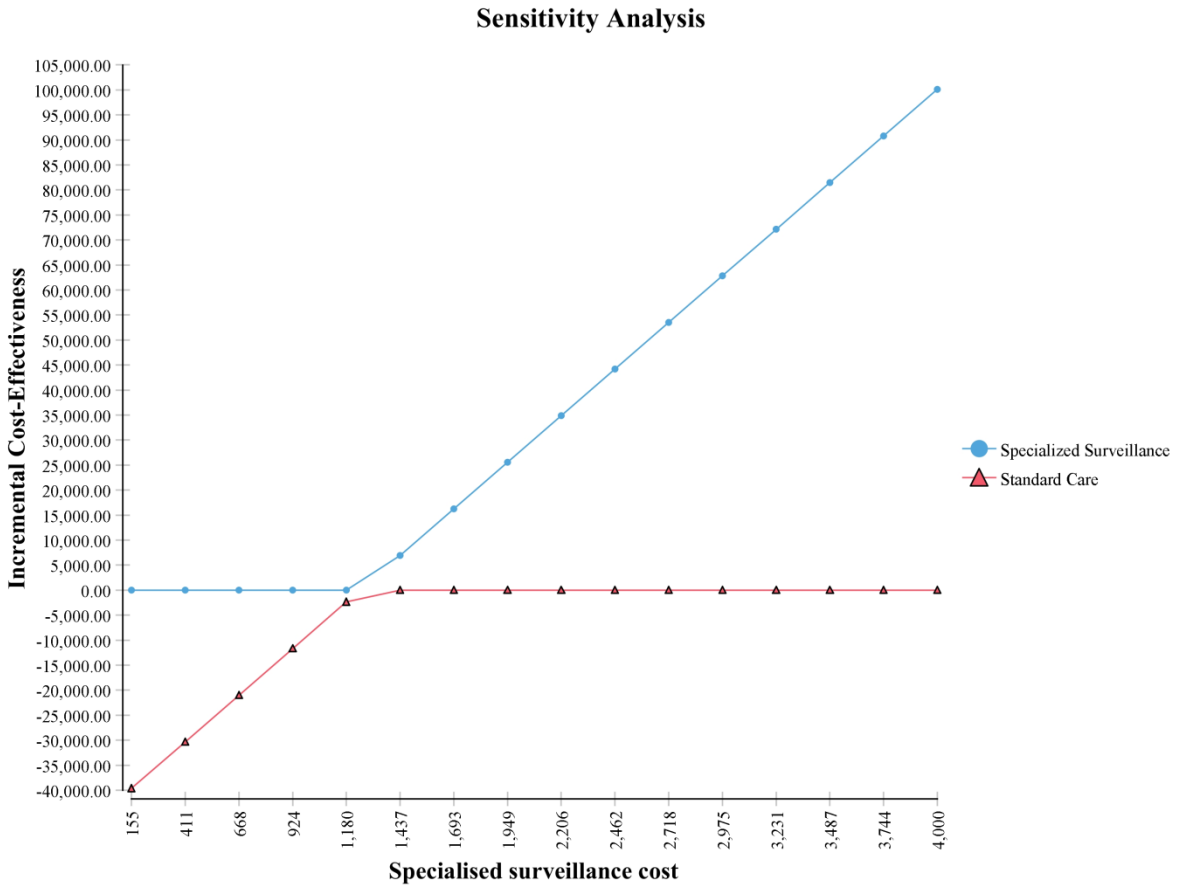

Figure 9 One way sensitivity analysis: incremental cost-effectiveness as cost of MSP increases

As a visual aid to determining which parameters have the greatest influence over the model's cost-effectiveness results, one-way sensitivity analysis scenarios are presented as a tornado diagram in Figure 10

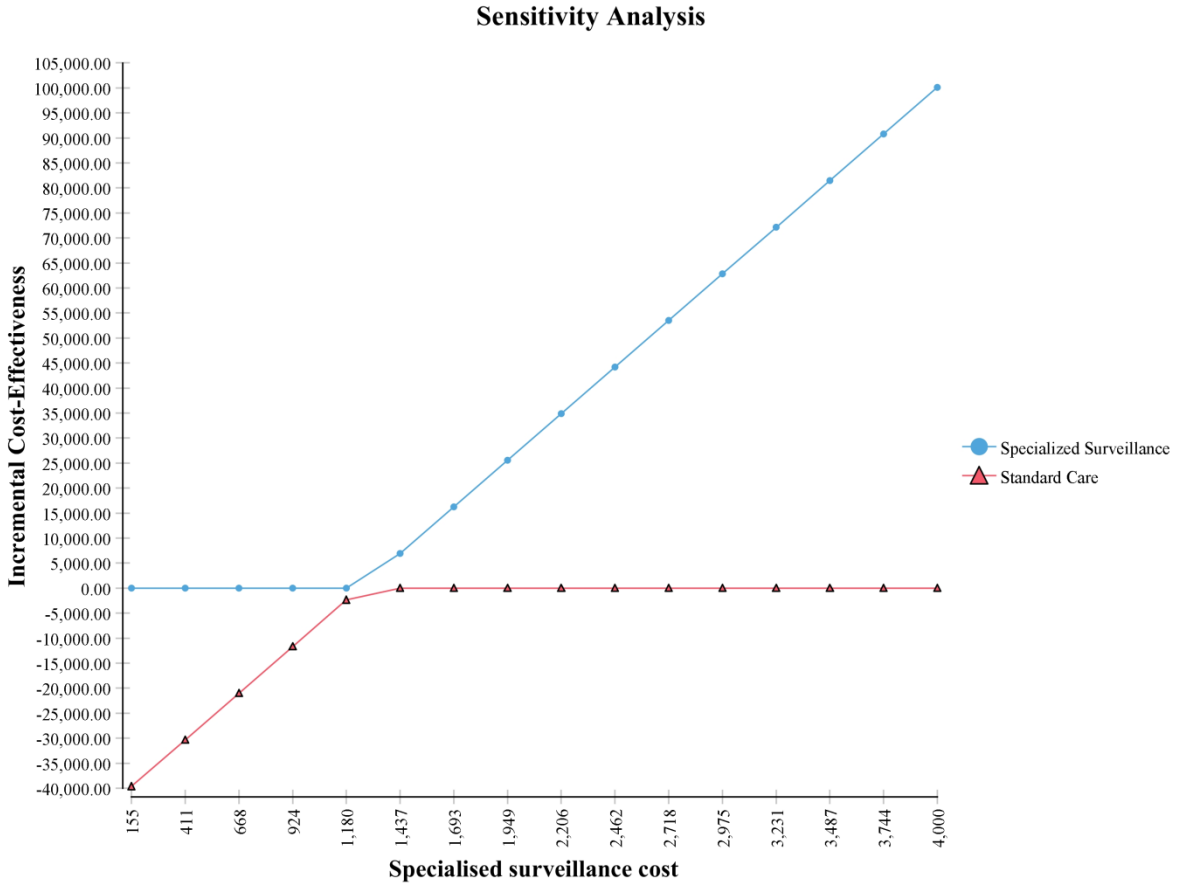

Figure 9. The model was most sensitive to variations in the probability of excisions in standard care, with a slight increase in the incremental cost-effectiveness ratio (ICER) as the probability of excision in standard care was changed from 0.8 to 0.1. However, none of the variables had a substantial impact on the ICER. A potential increase in the cost of MSP from $155 to $1,000 did not significantly alter the cost-effectiveness of the intervention. Other key drivers of the economic model were the probability of early detection of melanoma (in-situ and stage I) by MSP, treatment costs for melanoma stage III and IV, and the probability of benign excisions in standard care.

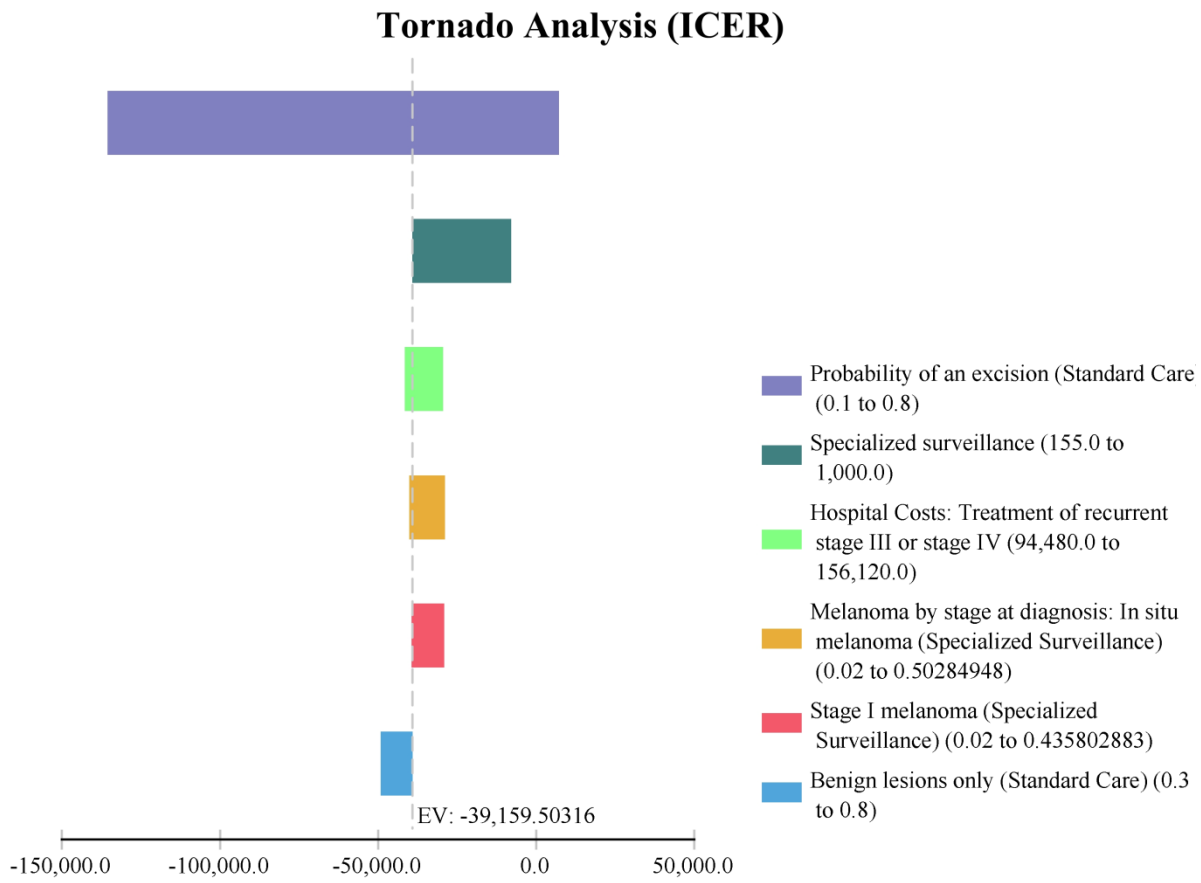

Figure 10 Tornado diagram: one-way sensitivity analysis of MSP versus standard care
ICER: incremental cost-effectiveness ratio, EV: expected value

A probabilistic sensitivity analysis (

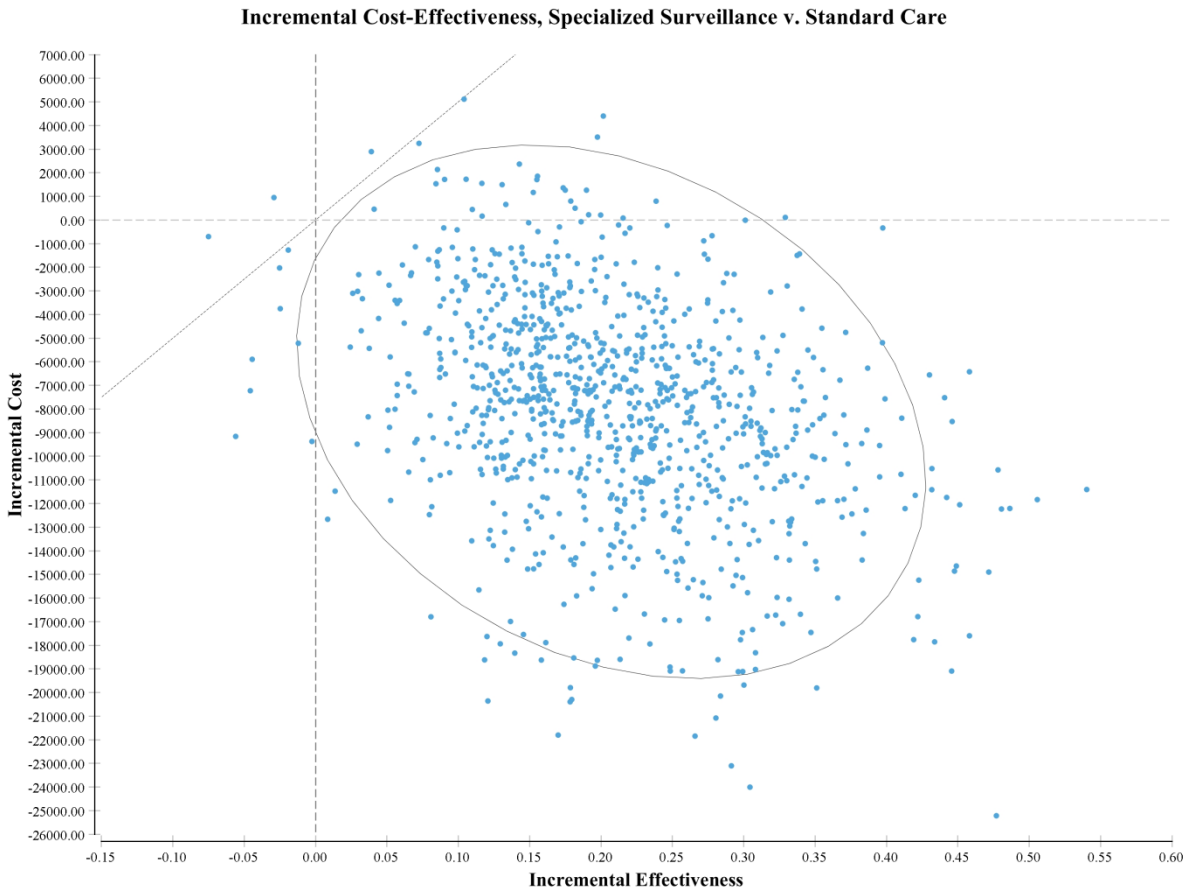

Figure 11) was conducted to evaluate the spread of results across the cost-effectiveness plane, which represents a measure of the ICER's degree of uncertainty. The incremental costs and QALY points were predominantly spread in the south-east quadrant, confirming that MSP is dominant, less costly and more effective than standard care.

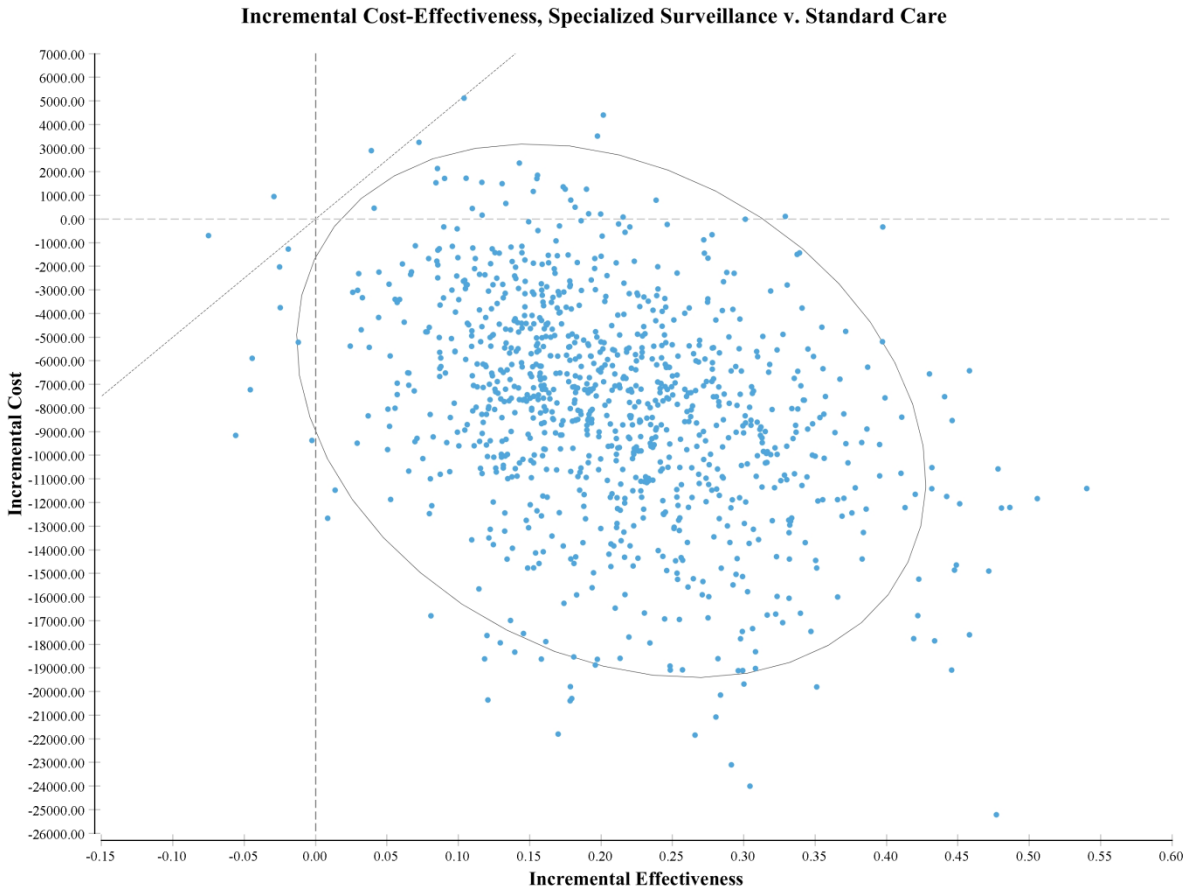

Figure 11 Monte Carlo simulation: Incremental cost-effectiveness of MSP versus standard care

SECTION E FINANCIAL IMPLICATIONS

E.1. JUSTIFICATION OF THE SELECTION OF SOURCES OF DATA

An epidemiological approach has been used to estimate the financial implications of the introduction of MSP in high risk and very high risk patients.

The calculation of the number of patients who would be eligible to receive MSP has been based on data from the Australian Institute of Health and Welfare (AIHW) (Australian Institute of Health and Welfare 2017, Australian Institute of Health and Welfare 2017) and the Australian Bureau of Statistics(Australian Bureau of Statistics 2017).

To estimate the size of the eligible populations, the AIHW projections have been combined with epidemiological parameters (Table 18) derived from published studies (Nordlund, Kirkwood et al. 1985, Newton, Bataille et al. 1993, Aitken, Welch et al. 1999, Vuong, Armstrong et al. 2016, Australian Institute of Health and Welfare 2017, Australian Institute of Health and Welfare 2017).

Table 18 Epidemiological parameters used in the calculation of the eligible populations

Parameter description	*Input*	*Source*
Population with previous melanoma	Annual incidence, survival	AIHW (2017)
Population with 100+ naevi	3%*	Newton (1993)
Population with 6 or more atypical naevi	4%*	Nordlund (1985)
Population with family history	7%*	Vuong (2016)
Population CDKN2A positive	0.2%Ψ	Aitken (1999)

*percentage of the population at risk, Ψpercentage of the population with previous melanoma

An estimation of the number of patients at high risk and very high risk of melanoma targeted by the proposed medical service is reported in Table 19. These calculations are an approximation given the lack of direct epidemiological data regarding the proportion of people at high risk and very high risk. The total number of individuals in the Australian population with the risk factors described in Table 18 was calculated with an overlap expectation for each risk factor of 50%, based on clinical advice from the applicant. As no prevalence data were found to establish the number of people at very high risk in the Australian population, clinical advice was sought, and it was suggested that individuals at very high risk would comprise approximately 40% of those with previous melanoma.

Table 19 Estimation of the number of people at high risk and very high risk of melanoma (2018–2022)

Description	*2018*	*2019*	*2020*	*2021*	*2022*
Population with previous melanoma (10 years)	102,394	102,670	102,946	103,223	103,499
Population with 100+ naevi	315,622	320,161	324,700	329,239	333,777
Population with 6 or more atypical naevi	420,830	426,882	432,933	438,985	445,036
Population with a family history	736,452	747,043	757,633	768,223	778,814

Description	*2018*	*2019*	*2020*	*2021*	*2022*
Population CDKN2A positive	205	205	206	206	207
Overlap expectation	50%	50%	50%	50%	50%
Total population at high risk	787,650	798,378	809,106	819,835	830,563
Total population at very high risk*	40,958	41,068	41,179	41,289	41,399

*Population at very high risk was estimated to be approximately 40% of that at high risk
ΨIt was assumed that individuals with CDKN2A would already be included within the population with previous melanoma and was not included in the overlap calculation

E.2. USE AND COSTS OF MELANOMA SURVEILLANCE

The annual cost of MSP is calculated by multiplying the number of patients in each population eligible for MSP by the proposed annual cost per patient. In our model, the annual cost per patient of the proposed MSP intervention at 85% of the scheduled fee was estimated to be $155 (Section D, Table 15). The total annual cost of MSP using this proposed MBS fee for the population at high risk was estimated at $122,085,678.70 in 2018, rising to $128,737,255.70 in 2022. The corresponding total annual costs for the high risk population were $6,348,448.88 to $6,416,910.47 (Table 20). These numbers, however, are estimates given a 100% utilisation rate of MSP and may not reflect the real world.

Table 20 Cost of MSP for individuals at high risk and very high risk of melanoma ($155 per patient, per year); 100% utilisation – 100% uptake and compliance

Population	*2018*	*2019*	*2020*	*2021*	*2022*
Number of individuals at high risk	787,650	798,378	809,106	819,835	830,563
Annual MSP cost, population at high risk	$122,085,679.41	$123,748,573.53	$125,411,467.64	$127,074,361.76	$128,737,255.87
Number of individuals at very high risk	40,958	41,068	41,179	41,289	41,399
Annual MSP cost, population at very high risk	$6,348,448.88	$6,365,564.28	$6,382,679.67	$6,399,795.07	$6,416,910.47

Note: rounding has been applied
MSP: melanoma surveillance photography

Uptake at a population level and compliance with MSP remain uncertain. Utilisation of MSP may be considerably lower than 100% if we take into account the relatively low participation observed in screening programmes (e.g. cervical screening 57.2%) (Australian Institute of Health and Welfare 2013) and low annual rates of compliance (22.2% to 26%) reported by some studies of individuals at high risk of melanoma attending annual digital dermoscopy follow-up examinations for melanocytic nevi (Schiffner, Schiffner-Rohe et al. 2003, Gadens 2014). Across studies, MSP compliance rates in patients at high risk of melanoma range from 22.2% to over 90% (Schiffner, Schiffner-Rohe et al. 2003, Salerni, Carrera et al. 2012, Gadens 2014).

Therefore, we conducted separate analyses to explore annual MSP costs in the scenarios of low and moderate utilisation. In the low-utilisation scenario (Table 21), we estimated that uptake would increase by 10% every year as more patients become aware of the service, thereby increasing from 20% in 2018 to 60% in 2022. Low compliance in the high-risk population was defined as 22.2%; that is the proportion of people who would return for follow-up. In the first year, we estimated that only 20% of the eligible population would undergo MSP; in the second year, 30% of the eligible population would uptake the service and 22.2% of those who had MSP the year before would return; in the third year, 40% new patients would uptake the service and 22.2% of those who received MSP the previous year would attend their follow-up; in the fourth and fifth year, uptake would go up to 50% and 60%, respectively, but compliance would stay low, at 22.2%.

No compliance data were found in the literature for the very high-risk population, so we did not include them in this analysis under the assumption these patients would be more compliant with the intervention given their elevated risk.

Table 21 Cost of MSP for individuals at high risk of melanoma ($155 per patient, per year); low utilisation (20% to 60% uptake, 22.2% compliance)

Population	*2018*	*2019*	*2020*	*2021*	*2022*
Number of individuals at high risk (low utilisation)	157,530	274,485	384,578	495,294	608,293
Annual MSP cost, population at high risk (low utilisation)	$24,417,135.88	$42,545,176.22	$59,609,616.18	$76,770,515.67	$94,285,408.00

Note: rounding has been applied
MSP: melanoma surveillance photography
Uptake was estimated as 20% in 2018, increasing by 10% every year, and reaching 60% in 2022

A scenario of moderate utilisation of services was estimated for both populations, assuming an increase on uptake from 20% to 60% over 5 years and 90% compliance. This was calculated as described above for the low utilisation scenario, but with 90% of patients returning for follow-up (Table 22).

Table 22 Cost of MSP for individuals at high risk and very high risk of melanoma ($155 per patient, per year); moderate utilisation – 20% to 60% uptake*, 90% compliance

Population	*2018*	*2019*	*2020*	*2021*	*2022*
Number of individuals at high risk (moderate utilisation)	157,530	334,031	490,658	606,181	680,192
Annual MSP cost, population at high risk (moderate utilisation)	$24,417,135.88	51,774,853.59	$76,052,013.85	93,957,986.42	$105,429,749.45
Number of individuals at very high risk (moderate utilisation)	8,192	17,235	25,089	30,680	34,044
Annual MSP cost ($), population at very high	$1,269,689.78	$2,671,483.15	$3,888,813.44	$4,755,422.91	$5,276,773.15

Population	*2018*	*2019*	*2020*	*2021*	*2022*
risk (moderate utilisation)					

Note: rounding has been applied
MSP: melanoma surveillance photography
*Uptake was estimated as 20% in 2018, increasing by 10% every year, and reaching 60% in 2022

E.3. CHANGES IN USE AND COST OF OTHER MEDICAL SERVICES

Early diagnosis of melanoma may reduce hospital costs and the need for immunotherapy treatment, which could be translated in savings for the State Government and PBS. It is assumed that GP visits and referrals to dermatologists may increase as a result of MSP uptake, which may increase Federal costs. The impact of MSP on excision rates remains unknown.

E.4. FINANCIAL IMPLICATIONS FOR THE MBS

It is estimated that patients may need an annual referral from their GP to a dermatologist and this cost has been added to the 5-year projections. The fee for a GP consultation ≤20 min (MBS00023) is $37.05 at a 100% rebate. Assuming the need for an annual referral to a dermatologist for MSP, the total cost for patients at high risk by 2022 would be estimated to be $82,115,548.69 if utilisation of services is moderate, and $20,255,168.68 if utilisation is low (Table 23). The corresponding costs for patients at very high risk assuming moderate utilisation are presented in Table 24.

Table 23 Total cost ($) to the MBS associated with MSP in high risk patients; moderate and low utilisation

	Cost per patient	**2018**	**2019**	**2020**	**2021**	**2022**
Intervention	-	-	-	-	-	-
Annual MSP cost; high risk (low utilisation)	$155	$24,417,135.88	$42,545,176.22	$59,609,616.18	$76,770,515.67	$94,285,408.00
Annual MSP cost; high risk (moderate utilisation)	$155	$24,417,135.88	$51,774,853.59	$76,052,013.85	$93,957,986.42	$105,429,749.45
Any co-administered services currently MBS listed	-	-	-	-	-	-
GP consultation ≤20 min (low utilisation)	$37.05	$5,836,483.13	$10,169,669.54	$14,248,621.16	$18,350,629.71	$22,537,253.98
GP consultation ≤20 min	$37.05	$5,836,483.13	$12,375,860.16	$18,178,884.60	$22,458,989.66	$25,201,111.08

	Cost per patient	2018	2019	2020	2021	2022
(moderate utilisation)						
Total services	-	-	-	-	-	-
Total cost: High risk (low utilisation)	GP + MSP	$30,253,619.01	$52,714,845.77	$73,858,237.34	$95,121,145.38	$116,822,661.98
Total cost: High risk (moderate utilisation)	GP + MSP	$30,253,619.01	$64,150,713.75	$94,230,898.45	$116,416,976.07	$130,630,860.53

Moderate utilisation: uptake 20% in 2018, increasing by 10% every year, and reaching 60% in 2022, 90% compliance;
Low utilisation: uptake 20% in 2018, increasing by 10% every year, and reaching 60% in 2022, 22.2% compliance
GP: general practitioner; MSP: melanoma surveillance photography

Table 24 Total costs ($) to the MBS associated with MSP in very high risk patients; moderate utilisation

	Cost per patient	2018	2019	2020	2021	2022
Intervention	-	-	-	-	-	-
Annual MSP cost; very high risk (Moderate utilisation)	$155	$1,269,689.78	$2,671,483.15	$3,888,813.44	$4,755,422.91	$5,276,773.15
Any co-administered services currently MBS listed	-	-	-	-	-	-
GP consultation ≤20 min (moderate utilisation)	$37.05	$303,496.81	$638,570.65	$929,551.86	$1,136,699.48	$1,261,319.00
Total services	-	-	-	-	-	-
Total cost: very high risk (moderate utilisation)	GP + MSP	$1,573,186.59	$3,310,053.80	$4,818,365.30	$5,892,122.39	$6,538,092.15

Moderate utilisation: uptake 20% in 2018, increasing by 10% every year, and reaching 60% in 2022, 90% compliance;
Low utilisation: uptake 20% in 2018, increasing by 10% every year, and reaching 60% in 2022, 22.2% compliance
GP: general practitioner; MSP: melanoma surveillance photography

E.5. FINANCIAL IMPLICATIONS FOR GOVERNMENT HEALTH BUDGETS

The model results indicate that MSP is less costly than standard care through early detection of melanoma and subsequent reduction in hospital costs and need for metastatic disease treatment. This would be translated into savings for the State Government.

THE BROADER IMPACT ON THE MBS

The model inputs (unpublished) indicate that the number of excisions was reduced with MSP in a specialised setting compared with standard care, but we found no comparative published studies that reported excisions rates. Therefore, we are unable to estimate the impact of this item on the budget.

OTHER GOVERNMENT IMPACTS

The overall cost of treatment for patients with melanoma stage III and IV was estimated in the economic model at a total cost of $144,436 per patient in 2017 dollars. High-cost targeted immunotherapies have appeared in the Australian market in the past 5 years, and treatment costs for advance melanoma might increase in the following years as new agents are approved and they are incorporated in clinical practice. A reduction in the number of people with late-stage melanoma would bring significant savings for the PBS, but the proportion of stage III and IV melanomas prevented in the eligible populations is difficult to estimate.

STATE AND TERRITORY GOVERNMENT HEALTH BUDGETS

Early detection of melanoma may result in fewer hospital admissions, fewer surgeries, and reduced need for monitoring of oncology patients with advanced disease. However, the specific impact of early detection on hospital savings remains uncertain.

E.6. IDENTIFICATION, ESTIMATION AND REDUCTION OF UNCERTAINTY

There is a high level of uncertainty regarding the approximate number of individuals at high risk and very high risk of melanoma in Australia. There were no studies that identified the proportion of people at high risk and very high risk, and we estimated these populations based on the prevalence of risk factors and clinical advice from the applicant.

There is significant variation in MSP compliance rates across studies. It is therefore not possible to estimate the proportion of individuals within the eligible population who may return for follow-up surveillance after the first consultation. The potential uptake of MSP in these populations is also uncertain, as many individuals may not identify themselves as high risk or seek medical attention. In addition, access to a dermatologist and out-of-pocket costs may be a barrier for widespread uptake of MSP and long-term compliance.

Watts et al. (2017) estimated in their model that 64% of patients at very high risk may visit a GP for skin examinations. Under this scenario, only 36% of eligible individuals at high or very high risk of melanoma may visit a dermatologist. This would significantly reduce our MSP-eligible population below the 57.2% estimated uptake in a dermatology setting. It is important to note that this

participation rate included about half of the eligible population for cervical screening, even though reminders were sent.

Uptake and compliance may be higher if health promotion programmes in melanoma prevention and automated patient recalls are implemented along with MSP in these populations.

The economic model identified that savings in hospital costs and PBS costs due to early detection of melanoma were driving the cost-effectiveness of MSP, along with the lower number of excisions in the surveillance group compared with standard care. However, we are not able to assess the impact of each individual factor on total savings.

SECTION F OTHER RELEVANT CONSIDERATIONS

Medical models of care are affected by the patient's geography, socioeconomic status, and patient's mobility and risk. Availability of health resources is variable throughout the country, and many patients who are at high risk do not access medical care (PICO confirmation).

Access to a dermatologist may be a barrier to long-term MSP given the low proportion of dermatologists in the Australian population (Table 25), especially in rural areas (The Australasian College of Dermatologists 2017).

Table 25 Registered dermatologists in Australia

State	*Total number of Dermatologists*	*Total Population (2016)*	*Number of dermatologists per 100,000 population*
Australian Capital Territory	5	396,294	1.26
New South Wales	250	7,726,924	3.24
Queensland	112	4,843,303	2.31
Northern Territory	1	245,191	0.41
Western Australia	60	2,617,074	2.29
South Australia	64	1,708,135	3.75
Victoria	203	6,069,636	3.34
Tasmania	6	519,063	1.16
Total	701	24,128,876	2.91

Source: (Australian bureau of Statistics 2017, The Australasian College of Dermatologists 2017)

Potential out-of-pocket costs raise the issue of equitable access to high-quality healthcare. The proposed MBS fee does not cover the total cost of MSP. A current fee schedule for Molemap Australia quotes $449 for an initial DD study (1 hour) and $329 for follow up (Molemap 2017), while the proposed MBS fee for DD ranges from $117.65 to $205.90, depending on the number of lesions photographed. The out-of-pocket costs to patients might be higher if they have to pay for GP or dermatologist visits, as the service would be implemented in addition to current clinical practice.

Travel costs may also have a substantial impact for patients who live far from main urban centres. In a cost analysis of 102 patients undergoing MSP in a High-Risk clinic in Sydney, Watts. et al. calculated that mean travel and accommodation costs (return trip) per patient per year were $407, and mean opportunity cost (time not at work or lost personal time) per visit was $502 (Watts, Cust et al. 2015). This population included patients at very high risk who may have required more frequent follow-up and surgical interventions than what we might expect in patients at high risk. Overall, individuals who live in rural areas could potentially incur out-of-pocket costs over $500, and people from a low socioeconomic status may not be able to afford MSP.

APPENDIX 1 CLINICAL EXPERTS AND ASSESSMENT GROUP

CLINICAL EXPERT

Name	Expertise
A/Prof Rob Miller	Australasian College of Dermatologists

ASSESSMENT GROUP

NHMRC Clinical Trials Centre

Name	Position
Sara Carrillo de Albornoz, MPH	Project Officer
Samara Lewis, PhD	Project Manager
Melina Wilson, PhD	Project Manager
Blaise Agresta, MPH	Project Manager

Noted conflicts of interest

There were no conflicts of interest.

APPENDIX 2 SEARCH STRATEGIES

Bibliographic databases

Electronic database	Time period searched
Embase	February 2017
Medline	February 2017
The Cochrane Library (CDSR, Central, DARE, HTA, HEED)	February 2017

Additional sources of literature (including websites)

Source	Location
Australian Institute of Health and Welfare (AIHW)	http://www.aihw.gov.au/
National Institute for Care and Care Excellence (NICE)	https://www.nice.org.uk/
Australian Bureau of Statistics	http://www.abs.gov.au/
Medicare Benefits Schedule	http://www.mbsonline.gov.au/
Cancer Council Australia	http://www.cancer.org.au/

APPENDIX 3 STUDIES INCLUDED IN THE SYSTEMATIC REVIEW

Table 26 Profiles of studies comparing MSP to standard care included in the systematic literature review

Authors Study ID Publication Year	Study design/ duration	Level of evidence[a] and risk of bias assessment[b]	Location Setting Length of follow-up	Study population characteristics	Description of Intervention	Description of Comparator	Relevant outcomes assessed (specified in PICO)	Measurement of outcomes and methods of analysis
Salerni 2011	Retrospective cohort 2 years	Level III-3 High risk of bias	Spain Single hospital Follow-up not reported	MSP: n=40 (50 melanomas) Male, n (%): 20 (50) Age, y (range): 49.9 (23-83) AMS, n (%):12 (30) Previous melanoma n (%): 24 (60) Family history of melanoma, n (%):10 (25) Control (referred patients): n=161 (165 melanomas) Male, n (%): 85 (52.8) Age, y (range): 61.7 (23-95) AMS, n (%): 22 (13.7) Previous melanoma n (%): 8 (5) Family history of melanoma, n (%): 15 (9.3)	Total body photography + digital dermoscopy with follow-up visits once or twice a year Duration of surveillance not reported	Handheld dermoscopy (GP referred)	Breslow Index In-situ melanoma Invasive melanoma	Biopsies of melanoma samples t-test for continuous variables
Salerni 2014	Retrospective cohort 4 years	Level III-3 High risk of bias	Argentina Single Hospital	MSP: n not reported (12 melanomas Control (melanoma	Total body photography + digital dermoscopy with follow-up visits	Handheld dermoscopy (melanoma consultation,	Breslow Index In-situ melanoma Invasive	Biopsies of melanoma samples t-test for continuous variables

Authors Study ID Publication Year	Study design/ duration	Level of evidence[a] and risk of bias assessment[b]	Location Setting Length of follow-up	Study population characteristics	Description of Intervention	Description of Comparator	Relevant outcomes assessed (specified in PICO)	Measurement of outcomes and methods of analysis
			Follow-up not reported	consultation): n not reported (35 melanomas) Patient characteristics not reported	once or twice a year Duration of surveillance not reported	melanoma routine control)	melanoma	
Mintsoulis and Beecker 2016	Retrospective cohort 10 years (4 years MSP and 10 years control)	Level III-3 High risk of bias	Canada Pigmented lesion clinics (MSP) General dermatology clinics (control) Follow-up not reported	MSP: n=9 (14 melanomas) Male, n (%): 5 (55.56) Age, mean (SD): 41.07 (12.62) Control: n= 215 (277 melanomas) Male, n (%): 128 (59.53) Age, mean (SD): 60.85 (14.52)	Total body photography + digital dermoscopy with follow-up visits once or twice a year Duration of surveillance not reported	Handheld dermoscopy (dermatology routine control once a year)	Breslow Index In-situ melanoma Invasive melanoma	Biopsies of melanoma samples t-test for continuous variables

MSP: melanoma surveillance photography
[a]source:(NHMRC 2009) [b]source:(National Institute for Health and Care Excellence 2012)

APPENDIX 4 MBS ITEM DESCRIPTORS

MBS Item Descriptors
Category 1 - PROFESSIONAL ATTENDANCES 23 Group A1 - GENERAL PRACTITIONER ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Subheading 2 - LEVEL B Professional attendance by a general practitioner at consulting rooms (other than a service to which another item in the table applies), lasting less than 20 minutes and including any of the following that are clinically relevant: (a) taking a patient history; (b) performing a clinical examination; (c) arranging any necessary investigation; (d) implementing a management plan; (e) providing appropriate preventive health care; for one or more health-related issues, with appropriate documentation-each attendance Fee: $37.05 Benefit: 100% = $37.05 (See para A5 of explanatory notes to this Category) Extended Medicare Safety Net Cap: $111.15
Category 1 - PROFESSIONAL ATTENDANCES 36 Group A1 - GENERAL PRACTITIONER ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Subheading 3 - LEVEL C Professional attendance by a general practitioner at consulting rooms (other than a service to which another item in the table applies), lasting at least 20 minutes and including any of the following that are clinically relevant: (a) taking a detailed patient history; (b) performing a clinical examination; (c) arranging any necessary investigation; (d) implementing a management plan; (e) providing appropriate preventive health care; for one or more health-related issues, with appropriate documentation-each attendance Fee: $71.70 Benefit: 100% = $71.70 (See para A5 of explanatory notes to this Category) Extended Medicare Safety Net Cap: $215.10
Category 1 - PROFESSIONAL ATTENDANCES 104 Group A3 - SPECIALIST ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Professional attendance at consulting rooms or hospital by a specialist in the practice of his or her specialty after referral of the patient to him or her-each attendance, other than a second or subsequent attendance, in a single course of treatment, other than a service to which item 106, 109 or 16401 applies Fee: $85.55 Benefit: 75% = $64.20 85% = $72.75 Extended Medicare Safety Net Cap: $256.65

MBS Item Descriptors
Category 1 - PROFESSIONAL ATTENDANCES 105 Group A3 - SPECIALIST ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Professional attendance by a specialist in the practice of his or her specialty following referral of the patient to him or her- an attendance after the first in a single course of treatment, if that attendance is at consulting rooms or hospital Fee: $43.00 Benefit: 75% = $32.25 85% = $36.55 Extended Medicare Safety Net Cap: $129.00
Category 1 - PROFESSIONAL ATTENDANCES 110 Group A4 - CONSULTANT PHYSICIAN ATTENDANCES TO WHICH NO OTHER ITEM APPLIES Professional attendance at consulting rooms or hospital, by a consultant physician in the practice of his or her specialty (other than psychiatry) following referral of the patient to him or her by a referring practitioner-initial attendance in a single course of treatment Fee: $150.90 Benefit: 75% = $113.20 85% = $128.30
Category 3 - THERAPEUTIC PROCEDURES 30071 Group T8 - SURGICAL OPERATIONS Subgroup 1 - GENERAL Diagnostic biopsy of skin, as an independent procedure, if the biopsy specimen is sent for pathological examination Multiple Services Rule (Anaes.) Fee: $52.20 Benefit: 75% = $39.15 85% = $44.40 (See para T8.7 of explanatory notes to this Category) Extended Medicare Safety Net Cap: $41.80
Category 3 – THERAPEUTIC PROCEDURES 45203 GroupT8 - SURGICAL OPERATIONS Subgroup 13 - PLASTIC AND RECONSTRUCTIVE SURGERY Subheading 2 - SKIN FLAP SURGERY 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 not in association with any of items 31356 to 31376 Multiple Services Rule (Anaes.) (Assist.) Fee: $406.05 Benefit: 75% = $304.55 85% = $345.15 (See para T8.95 of explanatory notes to this Category) Extended Medicare Safety Net Cap: $324.85

MBS Item Descriptors
Category 3 – THERAPEUTIC PROCEDURES 45669 Group T8 - SURGICAL OPERATIONS Subgroup 13 - PLASTIC AND RECONSTRUCTIVE SURGERY Subheading 4 - OTHER GRAFTS AND MISCELLANEOUS PROCEDURES VERMILIONECTOMY, using carbon dioxide laser or erbium laser excision-ablation Multiple Services Rule (Anaes.) Fee: $326.05 Benefit: 75% = $244.55 85% = $277.15 (See para T8.108 of explanatory notes to this Category)
Category 3 – THERAPEUTIC PROCEDURES 30075 Specialist Group T8 - SURGICAL OPERATIONS Subgroup 1 - GENERAL DIAGNOSTIC BIOPSY OF LYMPH GLAND, MUSCLE OR OTHER DEEP TISSUE OR ORGAN, as an independent procedure, where the biopsy specimen is sent for pathological examination Multiple Services Rule (Anaes.) Fee: $149.75 Benefit: 75% = $112.35 85% = $127.30

MBS Item Descriptors
Category 5 - DIAGNOSTIC IMAGING SERVICES 55808 GroupI1 - ULTRASOUND Subgroup6 - MUSCULOSKELETAL SHOULDER OR UPPER ARM, 1 or both sides, ultrasound scan of, where: (a) the service is not associated with a service to which an item in Subgroups 2 or 3 of this Group applies; and (b) the referring practitioner is not a member of a group of practitioners of which the providing practitioner is a member, and where the service is provided, for the assessment of one or more of the following conditions or suspected conditions: - evaluation of injury to tendon, muscle or muscle/tendon junction; or - rotator cuff tear/calcification/tendinosis (biceps, subscapular, suspraspinatus, infraspinatus); or - biceps subluxation; or - capsulitis and bursitis; or - evaluation of mass including ganglion; or - occult fracture; or - acromioclavicular joint pathology.(R) Bulk bill incentive Fee: $109.10 Benefit: 75% = $81.85 85% = $92.75
Category 5 – DIAGNOSTIC IMAGING SERVICES 55816 GroupI 1 - ULTRASOUND Subgroup 6 - MUSCULOSKELETAL HIP OR GROIN, 1 or both sides, ultrasound scan of, where: (a) the service is not associated with a service to which an item in Subgroups 2 or 3 of this Group applies; and (b) the referring practitioner is not a member of a group of practitioners of which the providing practitioner is a member (R) Bulk bill incentive Fee: $109.10 Benefit: 75% = $81.85 85% = $92.75 (See para DIQ of explanatory notes to this Category)

MBS Item Descriptors
Category 5 - DIAGNOSTIC IMAGING SERVICES 61553 GroupI4 - NUCLEAR MEDICINE IMAGING Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected metastatic or recurrent malignant melanoma in patients considered suitable for active therapy (R) Bulk bill incentive Fee: $999.00 Benefit: 75% = $749.25 85% = $918.80
Category 6 – PATHOLOGY SERVICES 72816 Group P5 - TISSUE PATHOLOGY Examination of complexity level 3 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 separately identified specimen (Item is subject to rule 13) Fee: $86.35 Benefit: 75% = $64.80 85% = $73.40
Category 6 – PATHOLOGY SERVICE 72817 GroupP5 - TISSUE PATHOLOGY Examination of complexity level 3 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 2 to 4 separately identified specimens (Item is subject to rule 13) Fee: $96.80 Benefit: 75% = $72.60 85% = $82.30
Category 6 – PATHOLOGY SERVICE 72818 GroupP5 - TISSUE PATHOLOGY Examination of complexity level 3 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 5 or more separately identified specimens (Item is subject to rule 13) Fee: $107.05 Benefit: 75% = $80.30 85% = $91.00

MBS Item Descriptors
Category 6 – PATHOLOGY SERVICES 72823 Group P5 - TISSUE PATHOLOGY Examination of complexity level 4 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 separately identified specimen (Item is subject to rule 13) Fee: $97.15 Benefit: 75% = $72.90 85% = $82.60
Category 6 – PATHOLOGY SERVICES 72830 GroupP5 - TISSUE PATHOLOGY Examination of complexity level 5 biopsy material with 1 or more tissue blocks, including specimen dissection, all tissue processing, staining, light microscopy and professional opinion or opinions - 1 or more separately identified specimens (Item is subject to rule 13) Fee: $274.15 Benefit: 75% = $205.65 85% = $233.05
Category 6 – PATHOLOGY SERVICES 72846 GroupP5 - TISSUE PATHOLOGY Immunohistochemical examination of biopsy material by immunofluorescence, immunoperoxidase or other labelled antibody techniques with multiple antigenic specificities per specimen - 1 to 3 antibodies except those listed in 72848 (Item is subject to rule 13) Fee: $59.60 Benefit: 75% = $44.70 85% = $50.70
Category 6 – PATHOLOGY SERVICES 73049 GroupP6 - CYTOLOGY Cytology of material obtained directly from a patient by fine needle aspiration of solid tissue or tissues - 1 identified site Fee: $68.15 Benefit: 75% = $51.15 85% = $57.95
Category 6 - PATHOLOGY SERVICES 73924 Group P10 - PATIENT EPISODE INITIATION Initiation of a patient episode that consists of 1 or more services described in items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72827, 72828, 72830, 72836 and 72838 (in circumstances other than those described in item 73925) from a person who is an in-patient of a hospital. Fee: $14.65 Benefit: 75% = $11.00 85% = $12.50

MBS Item Descriptors
Category 6 - PATHOLOGY SERVICES 73927 Group P10 - PATIENT EPISODE INITIATION Initiation of a patient episode by a prescribed laboratory that consists of 1 or more services described in items, 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72827, 72828, 72830, 72836 and 72838 from a person who is not a patient of a hospital. Fee: $2.40 Benefit: 75% = $1.80 85% = $2.05

APPENDIX 5 UPDATED COSTS

Table 27 Updated Annual health system costs in the economic model, 2017

Description	*Procedure Code*	*Cost per Item, $*	*No. in 12 months*	*Annual cost $*
Medical Consultation Type				
Standard-length consultation ≤20 min (level B)	*MBS 00023*	*37.05*	*95*	*3520*
Extended-length consultation >20 min (level C)	*MBS 00036*	*71.70*	*176*	*12619*
Dermatologic or surgical specialist				
Initial consultation	*MBS 00104*	*72.75*	*6*	*437*
Subsequent consultation	*MBS 00105*	*36.55*	*10*	*366*
Total consultation				*16,941*
Procedures for Excisions of Skin				
Diagnostic biopsy of skin	*MBS 30071*	*44.40*	*7.00*	*314.00*
Diagnostic excision of skin				
<10 mm	*MBS 31206*	*81.15*	*39.00*	*2930.00*
10 to <20 mm	*MBS 31211*	*104.65*	*2.00*	*209.30*
<6mm and nose, eyelid, eyebrow, lip, ear, digit or genitalia, or from a contiguous area	*MBS 31356*	*188.20*	*1.00*	*188.20*
<14mm and face, neck, scalp, nipple-areola complex, distal lower limb or distal upper limb	*MBS 31361*	*158.70*	*2.00*	*215.00*
<6mm and nose, eyelid, eyebrow, lip, ear, digit or genitalia, or from a contiguous area	*MBS 31356*	*188.20*	*1.00*	*188.20*
<14mm and face, neck, scalp, nipple-areola complex, distal lower limb or distal upper limb	*MBS 31361*	*158.70*	*1.00*	*158.70*
<14mm and face, neck, scalp, nipple-areola complex, distal lower limb or distal upper limb	*MBS 31361*	*158.70*	*1.00*	*158.70*
<14mm and face, neck, scalp, nipple-areola complex, distal lower limb or distal upper limb	*MBS 31361*	*158.70*	*4.00*	*634.80*
<14mm and face, neck, scalp, nipple-areola complex, distal lower limb or distal upper limb	*MBS 31361*	*158.70*	*1.00*	*158.70*
<14mm and face, neck, scalp, nipple-areola complex, distal lower limb or distal upper limb	*MBS 31372*	*262.40*	*2.00*	*524.80*
<15mm and other areas	*MBS 31374*	*239.65*	*1.00*	*239.65*
Total skin excisions				*5920*
Surveillance				
Sequential digital dermoscopy imaging				
1-3 Lesions		*70.49*	*43.00*	*3031.08*
>3 Lesions		*81.33*	*3.00*	*244.00*
Total monitoring				*3275.09*
Other Procedures[f]				
Single-stage local flap repair	*MBS 45203*	*345.15*	*1.00*	*345.15*
Vermilionectomy	*MBS 45669*	*277.15*	*1.00*	*277.15*

Diagnostic biopsy of lymph gland (by specialist)	*MBS 30075*	*127.30*	*1.00*	*127.30*
Ultrasonography of the groin	*MBS 55816*	*92.75*	*1.00*	*92.75*
Inpatient stay in standard ward (mean length of stay, 1.23 days)	*DRG 11Z*	*NA*	*NA*	*2215.56*
Pathological examination				
Level 3	*MBS 72816*	*73.40*	*22.00*	*1614.80*
Level 4	*MBS 72823*	*82.60*	*39.00*	*3221.40*
Level 5	*MBS 72830*	*233.05*	*3.00*	*699.15*
Immunohistochemistry	*MBS 72846*	*50.70*	*1.00*	*50.70*
Cytology fine-needle aspiration	*MBS 73049*	*57.95*	*1.00*	*57.95*
Total other procedures				*8701.91*
Total medical procedures (consultations, excisions, monitoring, and other)	*NA*	*NA*	*NA*	*34,838.00*
Mean Cost per Patient per Year (n patients=87)				*400.44*
Estimated total medical procedure costs per patient (MSP)	*Proposed MBS item*			*155*
Estimated total health system costs per patient				*556*

MSP: melanoma surveillance photography
Adapted from (Watts, Cust et al. 2015)

Table 28 Updated Treatment costs, 2017

Cost item	***MBS/DRG Item***	***Unit costs, $***	***No. in 12 months***	***Annual costs, $***
Diagnostic imaging techniques				
PET scan	n.a.			
Bone scan	61425	$510.60	1	$510.60
Gallium scan	61442	$639.50	1	$639.50
Surgery for lymph node recurrence with curative intent (lymphadenectomy)				
Other neoplastic disorders w major or procedures w/o catastrophic or severe complications	DRG R02B	$20,989	1	$20,988.79
Surgery for lymph node recurrence with curative intent (lymphadenectomy) with complications				
Other neoplastic disorders w major or procedures w catastrophic or severe complications	DRG R02A	$38,832	1	$38,831.77
Radiotherapy adjuvant				
Planning episode of 3-dimensional conformal radiotherapy				
Dosimetry for three dimensional conformal radiotherapy of level 3 complexity	MBS 15562	$952.65	1	$953
Simulation for three dimensional conformal radiotherapy (w/o iv contrast)	MBS 15550	$559.85	1	$560
Treatment				
Radiation oncology treatment, 10 rounds (1 field)	MBS 15254	$50.75	10	$508
Radiation oncology treatment, 10 rounds (subsequent 2 fields) (at $37.95 per field)	MBS 15269	$37.95	20	$759
Total cost for radiotherapy treatment				*$2,779*

Cost item	*MBS/DRG Item*	*Unit costs, $*	*No. in 12 months*	*Annual costs, $*
Immunotherapy adjuvant (for 3 months)				
induction therapy: Interferon alfa-2b (IV injection 5d/week for 4 weeks)	PBS 6246R	$1,861.68	20	$37,234
maintenance therapy: Interferon alfa-2b(IV injection 3d/week for 8 weeks)	PBS 6246R	$930.84	24	$22,340
Initial specialist consultation	MBS 104	$72.75	1	$73
Follow-up special consultation	MBS 105	$36.55	1	$37
Total cost for immunotherapy treatment				*$168,646*
Palliative Chemotherapy				
Dacarbazine 2 cycles (5 day-cycle (250 mg/m^2/day), 1 cycle every 3 weeks)		$48.94	10	$489
Anti-emetic: IV dexamethasone (8mg) single bolus per cycle (1 pack of 5 vials)	PBS 1291Y	$4.03	2	$8
Administration of chemotherapy				
Injection <1hr (once per cycle)	MBS 13915	$55.30	2	$111
Total cost for palliative chemotherapy				$608
Radiotherapy palliative				
Planning episode of 3-dimensional conformal radiotherapy				
Dosimetry for three dimensional conformal radiotherapy of level 3 complexity	MBS 15562	$952.65	1	$953
Simulation for three dimensional conformal radiotherapy (w/o iv contrast)	MBS 15550	$559.85	1	$560
Treatment				
Radiation oncology treatment, 10 rounds (1 field)	MBS 15254	$50.75	10	$508
Radiation oncology treatment, 10 rounds (subsequent 1 field) (at $37.95)	MBS 15269	$37.95	10	$380
Total cost for radiotherapy treatment				*$2,400*
Observation/ Follow-up at 3 months (in all patients)				
Follow-up specialist consultation	MBS 104	$72.75	1	$73
Full blood count	MBS 65070	$14.45	1	$14
Liver function tests	MBS 66512	$15.05	1	$15
CT scan (chest, abdomen, pelvis) with IV contrast	MBS 56807/56847	$358.65	1	$359
CT scan (head) with IV contrast	MBS 56007/56047	$159.85	1	$160
Total cost per follow-up				*$621*
Observation/ Follow-up at 3 months (in patients with incurable disease having undergone resection)				
Follow-up specialist consultation	MBS 104	$72.75	1	$73
Full blood count	MBS 65070	$14.45	1	$14
Liver function tests	MBS 66512	$15.05	1	$15
CT scan (chest, abdomen, pelvis) with IV contrast	MBS 56807/56847	$358.65	1	$359
CT scan (head) with IV contrast	MBS	$159.85		$160

Cost item	*MBS/DRG Item*	*Unit costs, $*	*No. in 12 months*	*Annual costs, $*
	56007/56047			
Brain MRI performed by a consultant physician scan of head for tumour of the brain or meninges (Contrast) (Anaesthesia)	MBS 63001	$342.75		$343
Total cost per follow-up				*$964*

CT: computerised tomography; IV: intravenous; PET: positron emission tomography;
Adapted from (Watts, Cust et al. 2015)

APPENDIX 6 EXCLUDED STUDIES

Reason for exclusion: Abstracts
(2011) "Abstracts Presented at the Australasian College of Dermatologists Biennial Spring Conference 2011." Australasian journal of dermatology 52.
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APPENDIX 7 REFERENCES

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