



**Australian Government**  
**Department of Health**

# **Application Form**

**(New and Amended Requests for Public Funding)**

(Version 2.5)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

The application form will be disseminated to professional bodies / organisations and consumer organisations that have will be identified in Part 5, and any additional groups that the Department deem should be consulted with. The application form, with relevant material can be redacted if requested by the Applicant.

Should you require any further assistance, departmental staff are available through the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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Email: [hta@health.gov.au](mailto:hta@health.gov.au)

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# PART 1 – APPLICANT DETAILS

## 1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: REDACTED

ABN:

Business trading name:

**Primary contact name:** REDACTED

Primary contact numbers

Business: REDACTED

Mobile:

Email: REDACTED

**Alternative contact name:** REDACTED

Alternative contact numbers

Business:

Mobile:

Email:

## 2. (a) Are you a consultant acting on behalf of an Applicant?

- Yes  
 No

**(b) If yes, what is the Applicant(s) name that you are acting on behalf of?**

Insert relevant Applicant(s) name here.

## 3. (a) Are you a lobbyist acting on behalf of an Applicant?

- Yes  
 No

**(b) If yes, are you listed on the Register of Lobbyists?**

- Yes  
 No

# PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

## 4. Application title

SENTINEL LYMPH NODE BIOPSY FOR INTERMEDIATE THICKNESS MELANOMA

## 5. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form).

Melanoma is a malignancy of skin pigment cells (melanocytes). The lifetime risk for melanoma in Australia is 1 in 24 for males and 1 in 35 for females. In 2011 there were 11,500 new cases diagnosed in Australia (Cancer Council Australia) and more than 1,500 die each year from the disease.

Fortunately, about 70% of cases are diagnosed at an early stage (<1.0mm thickness) where 5-year survival is >95%. With increasing depth, there is a stepwise decline in survival. Sentinel node status is the most significant prognostic indicator in patients with intermediate thickness melanoma. Patients with intermediate thickness melanoma (greater than 1.0mm depth) have an increased risk of lymph node involvement and hence poorer survival.

## 6. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Sentinel lymph node biopsy (SLNBx) is increasingly being performed in Australia for intermediate thickness melanoma. It provides important prognostic information for appropriately counselled patients.

Currently, this procedure is not coded in the MBS and alternative item numbers do not accurately reflect its use or procedural requirements.

SLNBx with excision of lymph node(s) identified by a combination of blue dye (lymphotropic dye injection) and lymphoscintigraphy/gamma probe, ideally performed at the time of the primary melanoma wide excision (although this is not always possible).

## 7. (a) Is this a request for MBS funding?

- Yes  
 No

## (b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)  
 New MBS item(s)

## (c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

Insert relevant MBS item numbers here

## (d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- i.  An amendment to the way the service is clinically delivered under the existing item(s)
- ii.  An amendment to the patient population under the existing item(s)
- iii.  An amendment to the schedule fee of the existing item(s)
- iv.  An amendment to the time and complexity of an existing item(s)
- v.  Access to an existing item(s) by a different health practitioner group
- vi.  Minor amendments to the item descriptor that does not affect how the service is delivered
- vii.  An amendment to an existing specific single consultation item
- viii.  An amendment to an existing global consultation item(s)
- ix.  Other (please describe below):

Insert description of 'other' amendment here

**(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?**

- i.  A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii.  A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii.  A new item for a specific single consultation item
- iv.  A new item for a global consultation item(s)

**(f) Is the proposed service seeking public funding other than the MBS?**

- Yes
- No

**(g) If yes, please advise:**

Insert description of other public funding mechanism here

**8. What is the type of service:**

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

**9. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):**

- i.  To be used as a screening tool in asymptomatic populations
- ii.  Assists in establishing a diagnosis in symptomatic patients
- iii.  Provides information about prognosis
- iv.  Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v.  Monitors a patient over time to assess treatment response and guide subsequent treatment decisions
- vi.  Is for genetic testing for heritable mutations in clinically affected individuals and, when also appropriate, in family members of those individuals who test positive for one or more relevant mutations (and thus for which the Clinical Utility Card proforma might apply)

**10. Does your service rely on another medical product to achieve or to enhance its intended effect?**

- Pharmaceutical / Biological
- Prosthesis or device
- No

**11. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?**

- Yes
- No

**(b) If yes, please list the relevant PBS item code(s):**

Insert PBS item code(s) here

**(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?**

- Yes (please provide PBAC submission item number below)
- No

Insert PBAC submission item number here

**(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?**

Trade name: Insert trade name here

Generic name: Insert generic name here

**12. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Protheses List?**

Yes

No

**(b) If yes, please provide the following information (where relevant):**

Billing code(s):

Trade name of prostheses:

Clinical name of prostheses:

Other device components delivered as part of the service:

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Protheses List Advisory Committee (PLAC)?**

Yes

No

**(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

Yes

No

**(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):**

Insert sponsor and/or manufacturer name(s) here

**13. Please identify any single and / or multi-use consumables delivered as part of the service?**

Single use consumables: Lymphoscintigraphy requires an injection of technetium antimony sulphur colloid prepared by a nuclear physician, injected into the site of the primary melanoma with a needle and syringe.

Patent Blue V 1ml is injected by the surgeon with a needle and syringe.

The reusable hand-held gamma probe (same as that used in breast cancer surgery) is required intraoperatively and is covered with a disposable sterile plastic sleeve for the procedure.

The wound for the SLNBx is closed with the same suture material as the primary melanoma site but generally would require an additional small dressing.

Multi-use consumables: Insert description of multi use consumables here

## PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

- 14. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:**

Type of therapeutic good: Lymphoscintigraphy (identical process to SLNBx for breast cancer (30299, 30300)). This is performed just prior to the operation in the nuclear medicine department and is not part of the operation itself, nor administered by the surgeon. Lymphoscintigraphy has its own MBS number (61469, 61712). The tracer activity is still detectable during the operation and is necessary for the conduct of the operation. It is detected by a hand-held gamma probe.

Manufacturer's name: Several manufacturers of gamma probes (e.g. Dilon Diagnostics), or Magnetic nanoparticle tracer (Endomagnetics Ltd)

Sponsor's name: Insert description of single use consumables here

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

- Class III  
 AIMD  
 N/A

- 15. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

- Yes (If yes, please provide supporting documentation as an attachment to this application form)  
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**

- Yes (if yes, please provide details below)  
 No

ARTG listing, registration or inclusion number: 224067 (*one example of a hand-held probe*)

TGA approved indication(s), if applicable: Insert approved indication(s) here

TGA approved purpose(s), if applicable: Insert approved purpose(s) here

- 16. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?**

- Yes (please provide details below)  
 No

Date of submission to TGA: Insert date of submission here

Estimated date by which TGA approval can be expected: Insert estimated date here

TGA Application ID: Insert TGA Application ID here

TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

- 17. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

- Yes (please provide details below)  
 No

Estimated date of submission to TGA: Insert date of submission here

Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)

Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

## PART 4 – SUMMARY OF EVIDENCE

**18. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.**

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication ***
1.	Randomised trial	Sentinel-node biopsy or nodal observation in melanoma.	1269 patients with an intermediate-thickness primary cutaneous melanoma were randomly assigned to wide excision and postoperative observation of regional lymph nodes with lymphadenectomy if nodal relapse occurred, or to wide excision and sentinel-node biopsy with immediate lymphadenectomy if nodal micrometastases were detected on biopsy.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/17005948">http://www.ncbi.nlm.nih.gov/pubmed/17005948</a>	2006
2.	Randomised	Final trial report of sentinel-node biopsy versus nodal observation in melanoma	Sentinel-node biopsy, a minimally invasive procedure for regional melanoma staging, was evaluated in a phase 3 trial in 2001 patients with primary cutaneous melanomas	<a href="https://www.ncbi.nlm.nih.gov/pubmed/24521106?dopt=Abstract">https://www.ncbi.nlm.nih.gov/pubmed/24521106?dopt=Abstract</a>	2014
3.	Review	Sentinel node biopsy in melanoma: Current controversies addressed.	Review of controversies in patient selection and follow-up treatment	<a href="http://www.ncbi.nlm.nih.gov/pubmed/27590685">http://www.ncbi.nlm.nih.gov/pubmed/27590685</a>	2016
4.	Meta-analysis	Sentinel lymph node biopsy plus wide local excision vs. wide local excision alone for primary cutaneous melanoma: a systematic review and meta-analysis.	Although no significant survival difference was observed in four of the six series, the pooling summary data from all the studies that deal with this issue suggested that SLNBx is associated with a significantly better outcome compared with WLEA for localized melanoma.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/27592851">http://www.ncbi.nlm.nih.gov/pubmed/27592851</a>	
5.	Retrospective analysis	Clinicopathologic Predictors of Sentinel Lymph Node Metastasis in Thin Melanoma	Retrospective review of 1240 patients in the multi-institutional Sentinel Lymph Node Working Group database from 1994 to 2012 to determine factors predictive of sentinel lymph node (SLN) metastasis in thin melanoma.	<a href="http://jco.ascopubs.org/content/early/2013/10/29/JCO.2013.50.1114.abstract">http://jco.ascopubs.org/content/early/2013/10/29/JCO.2013.50.1114.abstract</a>	2013

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
6.	Meta-analysis	Sentinel Lymph Node Biopsy in T4 Melanoma: An Important Risk-Stratification Tool.	A meta-analysis of 10 retrospective studies of patients with T4 melanoma demonstrating the role of sentinel lymph node biopsy as the most significant predictor of outcome for patients with T4 melanoma (HR=2.3)	<a href="http://link.springer.com/article/10.1245%2Fs10434-015-4894-4">http://link.springer.com/article/10.1245%2Fs10434-015-4894-4</a>	2015
7.	Randomised controlled trial	Complete lymph node dissection versus no dissection in patients with sentinel lymph node biopsy positive melanoma (DeCOG-SLT): a multicentre, randomised, phase 3 trial.	Randomised controlled trial of 483 patients with sentinel node positive melanoma randomised to nodal observation versus completion lymph node dissection.	<a href="http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(16)00141-8/abstract">http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(16)00141-8/abstract</a>	2016

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

\*\*\* If the publication is a follow-up to an initial publication, please advise.



19. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	Randomised controlled trial	Multicentre selective lymphadenectomy trial II	Randomised trial comparing nodal observation with completion lymph node dissection for patients with sentinel lymph node positive melanoma	Under review at N Engl J Med	Under review

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

\*\*\*Date of when results will be made available (to the best of your knowledge).

## PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

**20. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

- a. General Surgeons Australia REDACTED
- b. Australian Society of Plastic Surgeons
- c. The Australasian College of Dermatologists
- d. The Royal Australian College of General Practitioners
- e. Australasian Association of Nuclear Medicine Specialists (AANMS) may also be relevant if information is required on radioisotopes.

**21. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

N/A

**22. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

- a. Melanoma Patients Australia
- b. Melanoma Institute Australia

**23. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

N/A

**24. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1	Mr David Gyorki FRACS
Telephone number(s)	
Email address	
Justification of expertise	Surgical Oncologist, Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne

Name of expert 2	Dr Christopher Allan FRACS
Telephone number(s)	
Email address	
Justification of expertise	Surgical Oncologist, Mater Private Breast Cancer Centre and Princess Alexandra Hospital Melanoma Unit, Brisbane

*Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.*

## PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

### **PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION**

- 25. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:**

Melanoma is a malignancy of skin pigment cells (melanocytes). The lifetime risk for melanoma in Australia is 1 in 24 for males and 1 in 35 for females. There are more than 12,000 new cases diagnosed in Australia each year and more than 1,500 die each year from the disease. Fortunately, most cases are diagnosed at an early stage (<1.0mm thickness) where 5-year survival is >95%. With increasing depth, there is a stepwise decline in survival.

Sentinel node status is the most significant prognostic indicator in patients with intermediate thickness melanoma. Patients with intermediate thickness melanoma (greater than 1.0mm depth) have an increased risk of lymph node involvement and hence poorer survival.

- 26. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:**

The proposed patient population that would benefit from the use of this service is patients with malignant cutaneous melanoma depth greater than 1.0mm. The presence or absence of nodal disease impacts on long term survival. Lymph node positive patients may subsequently be offered a nodal clearance for local disease control. There are a number of medical treatments with survival benefits for stage IV patients (distant metastases) that are currently being trialled in stage III patients (lymph node positive). Thus sentinel lymph node positive patients may be eligible for adjuvant treatment in the future that could provide survival benefits.

- 27. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):**

Currently patients with intermediate thickness melanoma either have clinical surveillance of the regional lymph nodes or SLNBx depending on patient wishes, after an informed discussion with their general practitioner, dermatologist, or surgeon.

### **PART 6b – INFORMATION ABOUT THE INTERVENTION**

- 28. Describe the key components and clinical steps involved in delivering the proposed medical service:**

- Identify appropriate patients (melanoma greater than 1.0mm depth)
- Obtain informed consent for the proposed medical service
- Pre-operative lymphoscintigraphy to identify the nodal basin
- Subcutaneous injection Patent Blue V around site of the primary melanoma
- Appropriate clearance of the primary melanoma based on NHMRC Guidelines
- Identification of the sentinel lymph node(s) using a combination of hand-held gamma probe and visualisation of blue lymphatics
- Removal of sentinel lymph node(s) and refer for histopathology
- Wound closure in the usual fashion

- 29. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?**

No

**30. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

N/A

**31. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):**

Lymphoscintigraphy requires nuclear medicine services. It is possible to perform SLNBx with blue dye (lymphotropic dye injection) alone, although identification rates are lower.

The best results are achieved with combination of lymphoscintigraphy and blue dye (lymphotropic dye injection) (greater than 95% identification).

**32. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:**

N/A

**33. If applicable, advise which health professionals will primarily deliver the proposed service:**

The service can be performed by a surgeon trained in the technique (including General Surgeon, Plastic and Reconstructive Surgeon, ENT, procedural dermatologist).

**34. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:**

A significant proportion of cutaneous melanomas are treated in General Practice. For SLNBx to be performed, this would require referral to an appropriately trained proceduralist / specialist (this is already happening on a wide scale in the absence of an MBS number).

**35. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:**

A proceduralist / specialist who has undergone training in the technique of SLNBx.

**36. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:**

Similar to training in SLNBx in breast cancer, it is suggested that the first 20 cases be supervised.

Surgeons already performing SLNBx in the management of breast cancer will not need additional training.

**37. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):**

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

Specify further details here

**(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:**

The service can only be performed in a licenced operating theatre.

**38. Is the proposed medical service intended to be entirely rendered in Australia?**

Yes

No – please specify below

Specify further details here

**PART 6c – INFORMATION ABOUT THE COMPARATOR(S)**

- 39. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):**

Currently patients with intermediate thickness melanoma either have clinical surveillance of the regional lymph nodes or SLNBx depending on patient wishes, after an informed discussion with their general practitioner, dermatologist, or surgeon.

SLNBx for melanoma is already being performed within the MBS but cannot be identified from other indications for lymph node biopsy (30075, 30329, 30332, 31420, 31423).

If the observation only group develop clinical or radiological evidence of nodal disease during follow-up (about 20%) then a therapeutic lymph node dissection is offered to those patients provided there is no distant metastases.

- 40. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?**

- Yes (please provide all relevant MBS item numbers below)  
 No

30075, 30329, 30332, 31420, 31423

- 41. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):**

Currently patients with intermediate thickness melanoma either have clinical surveillance of the regional lymph nodes or SLNBx depending on patient wishes, after an informed discussion with their general practitioner, dermatologist, or surgeon.

- 42. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

- Yes  
 No

- (b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:**

A new MBS item number is proposed to replace existing non-specific item numbers, which encompass a broad range of indications of which SLNBx for melanoma is just one.

- 43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):**

The pathways are already in existence and utilised with MBS numbers mentioned above.

Potentially 30% of melanoma cases within Australia would be suitable for SLNBx.

**PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME**

**44. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):**

- Gives patients better prognostic information.
- Improved local disease control.
- Possible improved survival in lymph node positive subset who proceed on to have radical nodal clearance.
- Would usually be performed at the same occasion as wider excision of the primary site, so no additional admission. Likely admission duration would be day only or 23 hour stay.
- Minor morbidity from the node biopsy in 10% - seroma, infection, haematoma. Small risk of serious complications - nerve injury, lymphoedema.
- Trials of adjuvant molecular and immune therapies are currently underway (vemurafenib (BRIM-8 study); pembrolizumab) under the hypothesis that survival gains in stage IV (distant metastases) will translate into an overall survival benefit in patients with stage III disease (lymph node positive).

**45. Please advise if the overall clinical claim is for:**

- Superiority  
 Non-inferiority

**46. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

Both Safety and Clinical Effectiveness Outcomes have been very well documented in major published trials (see *Final Trial Report of Sentinel-Node Biopsy versus Nodal Observation in Melanoma (MSLT 1)* and other trials listed in question 18).

**Safety Outcomes:** List safety outcomes here

**Clinical Effectiveness Outcomes:** List clinical effectiveness outcomes here

## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

**47. Estimate the prevalence and/or incidence of the proposed population:**

30% of new cutaneous melanoma cases each year in Australia.

Actual use would be lower, due to patient decline, patient unsuitability, etc.

**48. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:**

Single use for each diagnosis of melanoma.

**49. How many years would the proposed medical service(s) be required for the patient?**

Single use for each diagnosis of melanoma.

**50. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:**

2,500 - 3,000. This would include patients treated within the public health sector.

**51. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:**

As mentioned in question 39, this procedure is already widely performed but is not quantifiable. The complexity of the procedure is not recognised in the current MBS, and may be a barrier to its further use.

A SLNBx specific item number would enable accurate documentation of the prevalence of this procedure and more of the population would potentially benefit from its use.



## PART 8 – COST INFORMATION

**52. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:**

As per 30299.

This procedure is already being performed within the MBS but cannot be identified from other indications for lymph node biopsy (30075, 30329, 30332, 31420, 31423).

The cost is commensurate with SLNBx for breast cancer (30299-30303). This is between the value of lymph node biopsy (30075) and lymph node clearance (30330, 30335, 30336, 31426, 31429, 31438, 35551).

Future costs could rise if effective adjuvant therapy were to become indicated for node positive patients.

**53. Specify how long the proposed medical service typically takes to perform:**

20-30 minutes

**54. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.**

Category 3 – Treatment of Malignant Melanoma and Locally Aggressive Skin Tumours
SENTINEL LYMPH NODE BIOPSY OR BIOPSIES for cutaneous melanoma, where the primary lesion is 1.0mm or greater in depth, and appropriate excision of the primary has occurred, using preoperative lymphoscintigraphy and lymphotropic dye injection (Anaes.) (Assist.)
Fee: \$637.45

## PART 9 – FEEDBACK

The Department is interested in your feedback.

**55. How long did it take to complete the Application Form?**

8 hours

**56. (a) Was the Application Form clear and easy to complete?**

- Yes  
 No

**(b) If no, provide areas of concern:**

There was limited flexibility in the questions for this particular application, which is for a procedure that is already occurring without a specific item number.

**57. (a) Are the associated Guidelines to the Application Form useful?**

- Yes  
 No

**(b) If no, what areas did you find not to be useful?**

Insert feedback here

**58. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?**

- Yes  
 No

**(b) If yes, please advise:**

Insert feedback here