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.

Phone: +61 2 6289 7550

Fax: +61 2 6289 5540

Email: hta@health.gov.au

Website: www.msac.gov.au

# PART 1 – APPLICANT DETAILS

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

| |
|---|
| Corporation / partnership details (where relevant): Merck Sharp & Dohme |
| Corporation name: **redacted** |
| ABN: **redacted** |
| Business trading name: **redacted** |

**Primary contact name: redacted**

| |
|---|
| Primary contact numbers |
| Business: **redacted** |
| Mobile: **redacted** |
| Email: **redacted** |

**Alternative contact name: redacted**

| |
|---|
| Alternative contact numbers |
| Business: **redacted** |
| Mobile: **redacted** |
| Email: **redacted** |

**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**

PD-L1 testing for access to pembrolizumab in patients with unresectable mesothelioma

**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)**

Unresectable mesothelioma

**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)**

ImmunoHistoChemistry (IHC) test for evaluation of Programmed Cell Death Ligand 1 (PD-L1) expression to determine eligibility for treatment with pembrolizumab

**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

A submission for use of Keytruda in unresectable mesothelioma is planned in February 2017.

Keytruda is also PBS listed for use in metastatic melanoma (10424P, 10436G, 10475H, 10493G)

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

Trade name: Keytruda

Generic name: Pembrolizumab

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

☐ Yes

☐ No

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

Billing code(s): Insert billing code(s) here

Trade name of prostheses: Insert trade name here

Clinical name of prostheses: Insert clinical name here

Other device components delivered as part of the service: Insert description of device components here

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses 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:

The PD-L1 test comes as part of a kit (PD-L1 22C3 PharmDx$^{TM}$ kit) The kit is designed for 50 single use tests.

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:

The PD-L1 test is a class III in vitro diagnostic test which uses IHC (CT1056 Immunohistology cell marker IVDs)

Manufacturer's name: Dako Pty Limited

Sponsor's name: Merck Sharp & Dohme (Australia) Pty Limited

**(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: Insert ARTG number here

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: March 2016

Estimated date by which TGA approval can be expected: October 2016

TGA Application ID: DV-2016-IVA-02469-1/DA-2016-01000-1

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. | Non-randomised trial | Alley et al, Cancer Research 2015 75:15 SUPPL. 1 Clinical safety and efficacy of pembrolizumab (MK-3475) in patients with malignant pleural mesothelioma: Preliminary results from KEYNOTE-028 | Keynote 028 was a nonrandomized, multicohort, phase Ib trial of pembrolizumab for PD-L1-positive advanced solid tumors (ClinicalTrials.gov, NCT02054806). Mesothelioma represented one cohort of this study.<br>Of 25 patients with malignant pleural mesothelioma whose tumours expressed PD-L1 (>=1%), the preliminary response rate when treated with pembrolizumab (10mg/kg Q2W) was 24% (n=6). | link to article | 1 August 2015 |

** 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. | Non randomised | Study of Pembrolizumab (MK-3475) in Participants With Advanced Solid Tumors (MK-3475-158/KEYNOTE-158) | Keynote 158 is a nonrandomized, single arm multicohort, phase Ib trial of pembrolizumab (200 mg Q3W) for patients with advanced solid tumors (ClinicalTrials.gov, NCT02628067).<br>One cohort is mesothelioma patients who have received 2L treatment or later.<br>**REDACTED** | link to research | Preliminary data available by Q1 2017 |

** 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):**

Medical Oncology Group of Australia

Royal College of Pathologists of Australasia

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

Not applicable

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

Asbestos Diseases Foundation of Australia Inc. (ADFA)

Bernie Banton Foundation

The Asbestosis and Mesothelioma Association of Australia (AMAA)

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

Not applicable

**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: **redacted**

Telephone number(s): **redacted**

Email address: **redacted**

Justification of expertise: **redacted**

Name of expert 2: **redacted**

Telephone number(s): **redacted**

Email address: **redacted**

Justification of expertise: **redacted**

*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:**

Mesothelioma is a cancer of the protective lining of the body cavities and internal organs, such as the lungs, heart and bowel. There are two main types: pleural (approximately 90%) and peritoneal (approximately 10%). Formerly a rare tumour, Australia currently has the 2nd highest rate of mesothelioma in the world due to the heavy nationwide use of asbestos from 1940 until the 1980s. There were 641 new diagnoses in 2014, with an incidence of 2.5 cases per 100 person-years. The incidence is expected to peak in Australia in the next decade, mirroring the long latency period between asbestos exposure and development of MM.

Unfortunately, symptoms of mesothelioma do not usually show up until it is in its late stages. Symptoms of pleural mesothelioma include shortness of breath, persistent dry cough and a dull aching pain in the upper body, whilst painful and swollen abdomen, nausea and vomiting and high temperature are signs of peritoneal mesothelioma.

As mesothelioma is most often diagnosed when it has already advanced beyond the option of surgical removal, the aim of treatment is to prolong life and keep the person as comfortable as possible. It has one of the lowest survival rates of all cancers, with approximately 6% of patients alive five years after their diagnosis. The mortality rate is comparable to the incidence rate and there were 607 deaths related to mesothelioma in 2014.

**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:**

It is proposed that PD-L1 testing be undertaken in patients diagnosed with unresectable mesothelioma. The majority (approximately 85%) of those diagnosed are men and the age range of those affected is 70-79.

As per their standard diagnostic workup, the patient would undergo a biopsy. The tissue removed as part of the biopsy and used for the mesothelioma diagnosis confirmation would be used for immunohistochemical testing with PD-L1. The testing would be done by a pathologist alongside other immunohistochemical tests which are done routinely, and it would be proposed that the test is a pathologist determinable test

**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):**

Patients diagnosed with mesothelioma are treated with cisplatin (or carboplatin) + pemetrexed in the first line setting.

After progression of on first line therapy, there is no “standard of care”. Various treatment option include vinorelbine, pemetrerxed monotherapy or reinitiation with platinum-based therapy + pemetrexed (provided there has been sufficient a relapse-free interval)

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

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

PD-L1 expression in cancer tumour biopsies can be assessed using immunohistochemical (IHC) testing with antibodies that bind specifically to the PD-L1 protein. It is proposed that the PD-L1 test is undertaken as part of the initial diagnostic workup of the patient, following the biopsy, alongside other IHC tests.

PD-L1 IHC should be undertaken in any NATA accredited laboratory and reported by a certified pathologist. It is proposed that PD-L1 testing should be a "pathologist determinable test", in line with all other IHC tests.

The PD-L1 assay used during the pembrolizumab mesothelioma clinical development program is known as the PD-L1 IHC 22C3 pharmDx Assay (developed by Dako). This assay was used to assess PD-L1 expression in the cancer tumour biopsies in the KEYNOTE 028 (KN028) and Keynote 158 (KN158) clinical studies. Detailed information of the PD-L1 22C3 pharmDx assay kit components as well as its performance studies will be presented for MSAC consideration in the co-dependent technology submission.

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

Currently there are no PD-L1 tests reimbursed by MSAC.

In terms of the PD-L1 test for this application, MSD has a commercial alliance with DAKO. DAKO will be developing the commercial test for PD-L1. The finalization of the commercial test, including any applicable registered trademark, is still pending.

**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?**

Not applicable

**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):**

**Access**

Whilst there are PD-L1 antibodies which are commercially available, PD-L1 testing is not done routinely in patients with mesothelioma, as there is no treatments which are reimbursed for mesotheliomapatients whose tumours express PD-L1.

**Frequency**

As per the protocols for the KN028 and KN0158 studies, only one PD-L1 test was required through the course of their disease. The test would be undertaken prior to commencement of pembrolizumab to enable identification of those patients most likely to benefit from treatment.

**Sample consideration**

There is currently no known role for PD-L1 testing in monitoring a patient's response to pembrolizumab treatment.

KN028/KN158 will include patients enrolled on the basis of archival or newly obtained biopsy tissue.

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

As immunohistochemistry is a well established technique in all major pathology labs, laboratories already have the platform infrastructure to perform testing on PDL-1 and the antibody is the only additional resource required.

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

As IHC testing is a common procedure and as PD-L1 expression is anticipated to be frequently identified (45% of cases for ≥1% PD-L1 expression: Alley et al. 2015), it is proposed that PD-L1 IHC testing be eligible to be carried out in any pathology laboratory holding the appropriate accreditation to claim pathology services through the MBS. In practice, it is anticipated that the majority of PD-L1 testing would occur in pathology laboratories associated with a public hospital.

A certified pathologist would be responsible for conducting the test and reporting the results.

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

Not applicable

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

A certified pathologist would be responsible for conducting the test and reporting the results. Specialists including respiratory physicians or oncologists may provide a referral for PD-L1 testing.

**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:**

Consistent with introduction of diagnostic tests associated with access to other targeted therapies, pathologist training and quality assurance programs would be expected to be developed with respect to delivery of diagnostic tests for access to treatments targeting the PD-1 pathway on the PBS.

**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

It is anticipated that the majority of PD-L1 testing would occur in pathology laboratories associated with a public hospital.

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

Not applicable

**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):**

The comparator is no PD-L1 testing and treatment with standard of care (1st line cisplatin + pemetrexed)

**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

Specify item number/s here

**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):**

Refer to attachment

**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:**

Outline service/comparator substitution here

**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):**

Refer to attachment

***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):**

The clinical claim is that PD-L1 testing followed by treatment with pembrolizumab in PD-L1 positive patients with unresectable mesothelioma is associated with improved health outcomes. It will be driven by two factors:

1. Acceptable safety and analytical performance of PD-L1 test. (To be assessed by MSAC.)

2. Superior effectiveness with acceptable safety of treating PD-L1 positive patients with pembrolizumab relative to standard of care without testing. (To be assessed by PBAC).

**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:**

| |
|---|
| **Safety Outcomes:** |
| Physical harms from testing |
| Adverse events related to a change in treatment |
| **Clinical Effectiveness Outcomes:** |
| Primary endpoint: Overall Response rate, Duration of Response |
| Secondary endpoints: Progression free survival, Overall survival, Quality of life |

# PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

641 new diagnoses[1]

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

Once in a lifetime (as per the KN028/KN158 protocols)

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

It is presumed only one PD-L1 test would be required for a patients through the course of the disease

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

Approximately 641 new diagnoses will utilise the PD-L1 test in year 1

**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:**

Currently patients with mesothelioma have very limited treatment options. If the results of KN028/158 indicate that pembrolizumab is of benefit to in patients with PD-L1 positive tumours, , it is expected that uptake of the PD-L1 test would be rapid and all patients diagnosed with unresectable mesothelioma would have a PD-L1 test, so that those who are PD-L1 positive may be treated with pembrolizumab.

The risk of leakage would be minimal as testing would be restricted to patients potentially eligible for pembrolizumab.

[1] https://www.mesothelioma-australia.com/media/12174/amr_4thannualdatareport_final.pdf

# PART 8 – COST INFORMATION

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

The expected fee is likely to be consistent with other immunohistochemical tests.

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

Typically IHC takes between 2.5-4 hours depending on instrumentation and protocol used.

**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 (insert proposed category number here) – (insert proposed category description here) |
| --- |
| Proposed item descriptor:<br><br>Immunohistochemical examination of biopsy material from a patient diagnosed with unresectable mesothelioma by immunoperoxidase or other labelled antibody techniques using the PD-L1 antibody to determine if the requirements relating to programmed cell death ligand 1 (PD-L1) status for access pembrolizumab under the Pharmaceutical Benefits Scheme (PBS) are fulfilled<br><br>Fee: To be determined |

# PART 9 – FEEDBACK

The Department is interested in your feedback.

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

Insert approximate duration here

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

☐ Yes

☐ No

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

Describe areas of concern here

**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