



Australian Government

Department of Health

Application Form

[Add Application Title Here]

(New and / or Amended

Request for Public Funding)

(Version 2.4)

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 to determine whether a proposed medical service is suitable.

Please use this template, along with the associated [Application Form Instructions](#) 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 separate [MSAC Guidelines](#) should be used to guide health technology assessment (HTA) content of the Application Form

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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): Insert corporation/partnership details here if relevant

Corporation name: Insert corporation name here

ABN: Insert ABN here

Business trading name: Insert business trading name here

Primary contact name: Insert name of primary contact here

Primary contact numbers

Business: Insert business number here

Mobile: Insert mobile number here

Email: Insert email address here

Alternative contact name: Insert name of alternative contact here

Alternative contact numbers

Business: Insert business number here

Mobile: Insert mobile number here

Email: Insert email address here

2. (a) Are you a consultant acting on behalf on an applicant?

Yes

No

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

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

(c) Have you engaged a consultant on your behalf?

Yes

No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

4. Application title

Insert application title here

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)

Insert succinct description of medical condition here

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)

Insert succinct description of proposed medical service here

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/technology:

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 medical service/technology?

- 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

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 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: Insert description of single use consumables here

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

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

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

Type of therapeutic good: Insert description of single use consumables here

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

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

- (b) Has it been listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? If the therapeutic good has been listed on the ARTG, please state the ARTG identification numbers, TGA-approved indication(s), and TGA-approved purpose(s).

ARTG ID: Insert ID number 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

- (c) If a medical device is involved, has the medical device been classified by TGA as a Class III OR Active Implantable Medical Device (AIMD) under the TGA regulatory scheme for devices?

- Class III
 AIMD
 N/A

- (d) Is the therapeutic good classified by TGA for Research Use Only (RUO)?

15. (a) If not listed on the ARTG, 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 the therapeutic good is not ARTG listed, is the therapeutic good in the process of being considered by TGA?

- Yes (if 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

- (c) If the therapeutic good is **NOT** in the process of being considered by TGA, is an application to 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

16. Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At ‘Application Form lodgement’, please do not attach full text articles; just provide 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.	For each key journal article or published research relating to your proposed service, insert the type of study design in this column and columns below	For each key journal article or published research relating to your proposed service, insert the title of article or research (including any trial identifier or study lead if relevant) in this column and columns below	For each key journal article or published research relating to your proposed service, insert a short description of research in this column and columns below	For each key journal article or published research relating to your proposed service, insert a website link to journal article or research (if available) in this column and columns below	For each key journal article or published research relating to your proposed service, insert the date of publication in this column and columns below
2.	Insert study design	Insert title	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title	Insert description	Insert website link	Insert date

* 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.

17. Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application). Do not attach full text articles; this is just 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.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

* 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

- 18. List all appropriate professional bodies/organisations representing the health professionals who provide the service. For MBS-related applications ONLY, please attach a brief ‘Statement of Clinical Relevance’ from the most relevant college/society.**

List all professional bodies / Organisations here

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

List professional bodies / Organisations here

- 20. List the consumer organisations relevant to the proposed medical service (noting there is NO NEED to attach a support letter at the ‘Application Lodgement’ stage of the MSAC process):**

List relevant consumer organisations here

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

List relevant sponsor/s and or manufacturer/s here

- 22. Nominate two experts that can be contacted about the proposed medical service, and current clinical management of the condition:**

Name of expert 1: Insert name here

Telephone number(s): Insert phone number/s here

Email address: Insert email address here

Justification of expertise: Insert a justification of expertise here

Name of expert 2: Insert name here

Telephone number(s): Insert phone number/s here

Email address: Insert email address here

Justification of expertise: Insert a justification of expertise here

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), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

- 23. 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):**

Insert definition of medical condition and additional information here

- 24. Specify the characteristics of patients with (or suspected of having) the medical condition, who would be eligible for the proposed medical service/technology (including details on how a patient would be investigated, managed and referred within the Australian health care system, in the lead up to being eligible for the service):**

Insert patient characteristics and details here

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Insert key components and clinical steps here

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

Insert description of registered trademark component here

- 27. 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?**

Insert description of approach here

- 28. 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)?**

If applicable, insert description of limitations here

- 29. 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:**

If applicable, insert description of resources or other medical services here

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

If applicable, insert description of professionals here

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

Insert key components and clinical steps here

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

If applicable, insert specification of limitations here

- 33. 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:**

If applicable, insert advice regarding training or qualifications

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

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- 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:

Describe rationale here

35. 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)

- 36. 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). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service):**

Specify comparator/s here

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

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

Specify item number/s here

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

- In addition to (i.e. it is an add-on service)
 Instead of (i.e. it is a replacement or alternative)

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

Outline service/comparator substitution here

PART 6c CONTINUED – INFORMATION ABOUT ALGORITHMS (CLINICAL MANAGEMENT PATHWAYS)s

39. Define and summarise the CURRENT clinical management pathway (algorithm) that patients follow when they receive the COMPARATOR service (i.e. the landscape before the proposed service is introduced). An easy-to-follow flowchart is preferred, depicting the current clinical management pathway, but dot-points would be acceptable. Please include health care resources used in the current landscape (e.g. pharmaceuticals, diagnostics and investigative services, etc.).

Define and summarise the current clinical management pathways here

40. Define and summarise the PROPOSED clinical management pathway (algorithm) that patients would follow after the proposed service/technology is introduced, including variation in health care resources.

PART 6d – INFORMATION ABOUT CLINICAL OUTCOMES

41. 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):

Summarise clinical claims here

42. Please state what the overall clinical claim is:

State overall clinical claim

43. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

List the key health outcomes here

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

44. Estimate the prevalence and/or incidence of the condition in the proposed population:

Insert prevalence and/or incidence here

45. Estimate the number of times the proposed medical service/technology would be delivered to a patient per year:

Insert estimate here

46. How many years would the proposed medical service/technology be required for the patient?

Insert number of years here

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

Insert estimate here

48. Estimate the anticipated uptake of the proposed medical service/technology 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.

Insert estimate here

PART 8 – COST INFORMATION

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

Insert likely cost here

50. Specify how long the proposed medical service/technology typically takes to perform:

Specify duration here

51. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and usage characteristics that defines eligibility for the medical service/technology.

Category (insert proposed category number here) – (insert proposed category description here)

Proposed item descriptor: insert proposed item descriptor here

Fee: \$(insert proposed fee here)

52. If public funding is sought through an alternative (non-MBS) funding arrangement, please draft a service description to define the population and usage characteristics that defines eligibility for the service/technology.

Proposed item descriptor: insert proposed item descriptor here

Fee: \$(insert proposed fee here)

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

Insert approximate duration here

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

- Yes
 No

(b) If no, provide areas of concern:

Describe areas of concern here

55. (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

56. (a) Is there any information the Department should consider in the future, relating to questions contained or not contained in this Application Form?

- Yes
 No

(b) If yes, please advise:

Insert feedback here