Application for MBS eligible service or health technology

Application ID:
HPPxxxxxx

Application title:
<title>

Submitting organisation:
<Applicant organisation>

Submitting organisation ABN:
<Organisation ABN>

Application description

Succinct description of the medical condition/s:
Content

Succinct description of the service or health technology:
Content

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?
<response>

Are you applying on behalf of an organisation, or as an individual?
<response>

Applicant organisation name: <response>

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prostheses List?
<Yes> / <No>

Which list/schedule will the other health technologies be listed on? *(if 'Yes' above)*
<response>

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?
<response>

What is the nature of the amendment? *(if an amendment)*
<response>

Other reason for amendment: *(if an amendment)*
<response>

Justification for amendment: *(if an amendment)*
<response>

Relevant MBS items

Please select any relevant MBS items:

MBS item number	Selected reason type
<MBS item>	<reason>
<MBS item>	<reason>
<MBS item>	<reason>

What is the type of service or health technology?
<response>

Please select the type of investigative health technology: *(if investigative)*
<response>

Please select the type of molecular diagnostics health technology: *(if molecular diagnostics)*
<response>

Specify the number of genes/biomarkers in the panel assay: *(if Multigene/biomarker panel assay)*
<response>

Is it possible to vary or select the genes/biomarkers requested within the panel? *(if Multigene/biomarker panel assay)*

<response>

PICO sets

Application PICO sets:

PICO set number	PICO set name

Application PICO set #: <PICO set name>

State the purpose(s) of the health technology for this PICO set and provide a rationale: *(if investigative)*
(repeat the following fields for each purpose entered by the applicant)

Purpose category:
<response>

Purpose description:
<response>

What additional purpose(s) could the health technology be used for, other than the purposes listed above for this PICO set? *(if investigative)*
(repeat the following fields for each purpose entered by the applicant)

Purpose category:
<response>

Purpose description:
<response>

Rationale:
<response>

Supporting documentation

Document type	Document file name
Application PICO set document	
Reference list	

Population

Describe the population in which the proposed health technology is intended to be used:
<response>

Select the most applicable Medical condition terminology (SNOMED CT):
<response>

Intervention

Name of the proposed health technology:
<response>

Comparator

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:
<response>

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
<response>

Proposed MBS items

Please provide at least one proposed item with their descriptor and associated costs, for each Population / Intervention: (repeat the fields highlighted below for each proposed item provided)

Proposed item	<system generated>
MBS item number (where used as a template for the proposed item)	<response>
Category number	<response>
Category description	<response>
Proposed item descriptor	<response>
Proposed MBS fee	<response>
Indicate the overall cost per patient of providing the proposed health technology	<response>
Please specify any anticipated out of pocket expenses	<response>
Provide any further details and	<response>

explain	

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
<response>

Please provide a cost break down attachment:

Document type	File name
Cost breakdown attachment	

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

<response>

Please state what the overall claim is, and provide a rationale:

<response>

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
<response>

Provide the percentage uptake of the proposed health technology by the proposed population:
Year 1 estimated uptake (%):
<response>

Year 2 estimated uptake (%):
<response>

Year 3 estimated uptake (%):
<response>

Year 4 estimated uptake (%):
<response>

Estimate the number of patients who will utilise the proposed technology for the first full year:

<response>

Optionally, provide details:
<response>

Will the technology be needed more than once per patient?
<response>

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):
<response>

Optionally, provide details:
<response>

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):
<response>

Optionally, provide details:
<response>

Provide references to support these calculations:

Document type	File name
Estimated utilisation references	

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service: (repeat the following fields for all items entered)

<Professional body name>
<Professional body name>

List all appropriate professional bodies / organisations representing the group(s) of health professionals who request the health technology/service: (repeat the following fields for all items entered)

<Professional body name>
<Professional body name>

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service: (repeat the following fields for all items entered)

<Professional body name>
<Professional body name>

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: # (repeat the following fields for all items entered)

<Professional body name>
<Professional body name>

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology: (repeat the following fields for all items entered)

<Professional body name>
<Professional body name>

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

<response>

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TPG)? *(if 'Yes' above)*

<response>

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

<response>

Please enter all relevant ARTG ID's:

ARTG ID	ARTG name

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

<response>

Provide details: *(if 'Yes' above)*

<response>

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?

<response>

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

<response>

Is the therapeutic good in the process of being considered by the TGA? *(if 'Yes' above)*

<response>

Please provide details of when you intend to lodge an ARTG inclusion application, or provide a rationale if you do not intend to lodge an ARTG inclusion application: *(if 'No' above)*

<response>

Please provide the TGA Application ID: *(if in the process of being considered by the TGA)*

<response>

Please provide the TGA submission date (DD/MM/YYYY):

<response>

Codependent details

Will a submission be made to the Pharmaceutical Benefits Advisory Committee (PBAC)?
<response>

Please provide a rationale for the codependency and indicate how the proposed PBS restriction would reference the intervention(s) proposed for MSAC consideration:
<response>

Will a submission be made to the Prostheses List Advisory Committee (PLAC)?
<response>

Please provide a rationale for the codependency:
<response>

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

Please provide the name(s) of the sponsor(s) and / or manufacturer(s): *(if 'Yes' above)*

Sponsor details

Sponsor name:
<response>

Manufacturer details

Manufacturer name:
<response>

Describe and explain the similarities:
<response>

Are there any single and/or multi-use consumables delivered as part of the service or health technology? *(if 'No' above)*
<response>

Provide details:
<response>