Application for MBS eligible service or health technology

ID:
HPP200031

Application title:
Demo

Submitting organisation:
DEMONSTRATION ORGANISATION

Submitting organisation ABN:
56602226906

Application description

Succinct description of the medical condition/s:
Demo

Succinct description of the service or health technology:
Demo

Application contact details

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

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

Application contacts

Contact name	Email	Type

Application details

Have you lodged an MSAC application for this service or health technology previously?
No

Have you had a pre-application meeting with the Department?
No

Has the Department notified you that your application will bypass the PICO Advisory Sub-Committee (PASC)?
No

Please select the PASC meeting relevant to this application:

Will a full assessment report be required for your application?

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

Which list/schedule will the other health technologies be listed on?
Both

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

Please select any relevant MBS items.

MBS item number	Selected reason type

What is the type of service or health technology?
Investigative

Please select the type of investigative health technology:

Can you confirm that the application reflects their perspectives on the use of the proposed health technology or service?

Provide a summary of how you obtained and used this input in preparing this application:

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	PICO set 1

PICO set 1

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Supporting documentation

Document type	File name(s)
Application PICO set documents	
Reference list	

Population

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

Search and select the most applicable Medical condition terminology (SNOMED CT):

Intervention

Name of the proposed health technology:

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:

Outcomes

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

Proposed MBS items

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

Please provide a cost break down attachment:

Document type	File name(s)
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)?

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

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

Year 2 estimated uptake(%):

Year 3 estimated uptake(%):

Year 3 estimated uptake(%):

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

Optionally, provide details:

Will the technology be needed more than once per patient?

Provide references to support these calculations.

Document type	File name(s)
Estimated utilisation references	

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

ABN (if known):

Professional body name:
Demo

Rationale:
Demo

List all appropriate professional bodies / organisations representing the group(s) of health professionals who request the health technology/service:

ABN (if known):

Professional body name:
Demo

Rationale:
Demo

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

ABN (if known):

Professional body name:
Demo

Rationale:
Demo

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

Number of organisations listed: 1

ABN (if known):

Professional body name:
Demo

Rationale:
Demo

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Professional body name:
Demo

Rationale:
Demo

Nominate (at least) two experts who could be approached about the proposed service or health technology and the current clinical management of the service or health technology. Include justification of expertise for each expert:

Number of experts identified: 1

Expert 1

Name: Demo

Email address: Demo@demo.com

Phone: 12345

Rationale: Demo

Please upload an in principle statement of clinical relevance:

Document type	File name(s)
In principle statement of clinical relevance	

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?
Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?
No

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?
No

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?
No

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

Is the therapeutic good in the process of being considered for inclusion by the TGA?
Yes

Please provide the TGA Application ID:

Please provide the TGA submission date:
01/01/0001

Codependent details

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

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

Have you lodged a Prostheses List application for this proposed medical service or health technology?:

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

Please provide a rationale for the codependency:

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?

Are there any single and/or multi-use consumables delivered as part of the service or health technology?

Large files

Document type	File name(s)
Large files	