Application or referral for other medical 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 applying on behalf of an organisation, or as an individual?
<response>

Is the applicant organisation the organisation you are representing in the HPP today?
<response>

Applicant organisation name: <response>

Application details

Please select the program through which the health technology would be funded:
<Funding source type>

Specify the funding program: *(if 'Other' selected above)*
<response>

Please provide justification for selecting the above program:
<response>

Is the application for a new listing or a change to an existing listing?
<Change to existing listing> / <New listing> / <Not sure>

Provide a rationale for the change to an existing listing:
<response>

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

PICO sets

PICO sets:

PICO set number	PICO set name

Application PICO set #: <PICO set name>

Supporting documentation

Document type	Document file name
PICO set documents	
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>

Specified restrictions for funding

Please add one or more items, with specified restrictions for funding, for each Population / Intervention: (repeat the fields highlighted below for each proposed item provided)

Proposed item: <AAAAA>

Is the proposed item restricted?
<Yes - restricted> / <No - unrestricted>

Provide a short description of the restriction:
<response>

Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:
<response>

Proposed price of supply:
<response>

Indicate the overall cost per patient of providing the proposed health technology:
<response>

Provide details and explain:
<response>

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	

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>

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>

Please attach evidence to support the exemption: *(if 'Yes' above)*

Document type	File name(s)

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>