MSAC Application

Application Title

(Please insert the title of your application above)

PICO Set (number)

(If you are lodging multiple PICO Sets, please indicate the number of the PICO Set as required)

Population

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

Provide your response here

Specify any characteristics of patients with, or suspected of having, the medical condition, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible for the technology:

Provide your response here

Provide a rationale for the specifics of the eligible population:

Provide your response here

Are there any prerequisite tests?

Yes/No

Are the prerequisite tests MBS funded?

Yes/No

Provide details to fund the prerequisite tests:

Provide a response if you answered 'No' to the question above

Intervention

Name of the proposed health technology:

Provide your response here

Describe the key components and clinical steps involved in delivering the proposed health technology:

Provide your response here

Identify how the proposed technology achieves the intended patient outcomes:

Provide your response here

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?

Yes/No

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:

Provide a response if you answered 'Yes' to the question above

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):

Yes/No

Provide details and explain:

Provide a response if you answered 'No' to the question above

If applicable, advise which health professionals will be needed to provide the proposed health technology:

If applicable, provide a description of any related health professionals here

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:

If applicable, provide a description of any related health professionals here

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:

If applicable, provide a description of any related health professionals here

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?

Yes/No

Provide details and explain:

Provide a response if you answered 'Yes' to the question above

Indicate the proposed setting(s) in which the proposed health technology will be delivered:

(Select all relevant settings)

- ☐ Consulting rooms
- ☐ Day surgery centre
- ☐ Emergency Department
- ☐ Inpatient private hospital
- ☐ Inpatient public hospital
- ☐ Laboratory
- ☐ Outpatient clinic
- ☐ Patient's home
- ☐ Point of care testing
- ☐ Residential aged care facility
- ☐ Other (please specify)

Specify further details here

Is the proposed health technology intended to be entirely rendered inside Australia?

Yes/No

Provide additional details on the proposed health technology to be rendered outside of Australia:

Provide a response if you answered 'No' to the question above

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 healthcare system). This includes identifying healthcare resources that are needed to be delivered at the same time as the comparator service:

Specify your comparator(s) here

List any existing MBS item numbers that are relevant for the nominated comparators:

Specify MBS item numbers here

Provide a rationale for why this is a comparator:

Provide your response here

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?

(Please select your response)

☐ None (used with the comparator)
☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☐ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:

Provide your response here

Outcomes

(Please copy the below questions and complete for each outcome)

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):

(Please select your response)

☐ Health benefits
☐ Health harms
☐ Resources
☐ Value of knowing

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

Provide your response here

Proposed MBS items

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

Provide your response here

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

(Please copy the below questions and complete for each proposed item)

MBS item number (where used as a template for the proposed item)	Specify MBS item number here
Category number	Insert category number here
Category description	Insert category description here
Proposed item descriptor	Specify the proposed descriptor here
Proposed MBS fee	Insert proposed fee here
Indicate the overall cost per patient of providing the proposed health technology	Insert overall cost per patient amount here
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here
Provide any further details and explain	Provide further details here

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:

Provide your response here

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology?

Yes/No

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:

Please provide a response if you answered 'Yes' to the question above

USE OF THE HEALTH TECHNOLOGY

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:

Provide your response here

Explain what other healthcare resources are used in conjunction with the comparator health technology:

Provide your response here

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:

Provide your response here

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the proposed health technology:

Provide your response here

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, after the use of the comparator health technology:

Provide your response here

Describe and explain any differences in the healthcare resources used after the proposed health technology vs. the comparator health technology:

Provide your response here

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:

(Please ensure that the diagrams provided do not contain information under copyright)

Insert diagram/s here

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 select your response)

- ☐ Superior
- ☐ Non-inferior
- ☐ Inferior

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

Provide your response here

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?

Provide your response here

Identify how the proposed technology achieves the intended patient outcomes:

Provide your response here

For some people, compared with the comparator(s), does the test information result in:

(Please answer either Yes or No, deleting text as required)

A change in clinical management? Yes/No

A change in health outcome? Yes/No

Other benefits? Yes/No

Please provide a rationale, and information on other benefits if relevant:

Provide your response here

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?

(Please select your response)

☐ More costly
☐ Same cost
☐ Less costly

Provide a brief rationale for the claim:

Provide your response here

If your application is in relation to a specific radiopharmaceutical(s) or a set of radiopharmaceuticals, identify whether your clinical claim is dependent on the evidence base of the radiopharmaceutical(s) for which MBS funding is being requested. If your clinical claim is dependent on the evidence base of another radiopharmaceutical product(s), a claim of clinical noninferiority between the radiopharmaceutical products is also required.

Provide your response here

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement',

Do not attach full text articles; just provide a summary (repeat columns as required).

	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.					
3.					

** 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. For yet to be published research, provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

**** If the publication is a follow-up to an initial publication, please advise. For yet to be published research, include the date of when results will be made available (to the best of your knowledge).*

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 (repeat columns as required).

	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.					
3.					

** 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. For yet to be published research, provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

**** If the publication is a follow-up to an initial publication, please advise. For yet to be published research, include the date of when results will be made available (to the best of your knowledge).*