



Australian Government

Department of Health

Application xxxx:

Please include title of application

PICO Confirmation

(to guide a new application to MSAC)

(Version 1.0)

This PICO Confirmation Template is to be completed to guide a new request for public funding for new or amended medical service(s) (including, but not limited to the Medicare Benefits Schedule (MBS)). It is relevant to proposals for both therapeutic and investigative medical services.

Please complete all questions that are applicable to the proposed service, providing relevant information only.

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

Phone: +61 2 6289 7550

Email: hta@health.gov.au

Website: <http://www.msac.gov.au>

Version Control

Document History

Version Number	Date Changed	Author	Reason for Change
0.1	10 March 2016	MSAC Reforms	Final for Publication
0.2	19 May 2016	MSAC WEB	Accessibility compliance

Document Approval

Version Number	Date Changed	Author	Reason for Change
1.0	19 May 2016	MSAC Web	Document released for Online publication

This text is written in hidden text. The **hidden (red) text** provides instructions for completing the different components in the template. All hidden text has a dotted underline under it. When you have finished addressing the hidden text in this template, please remember to delete it and change the style to normal (non-hidden) text. If you do not do this, you will have large blank areas in your document.

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

(less than one page and to be completed per patient population)

Component	Description
Patients	<u>Please describe the characteristics of the patient population for whom the intervention is to be considered for use.</u>
Prior tests (for investigative medical services only)	<u>Please indicate any tests that would be done before the proposed investigative medical service is used.</u>
Intervention	<u>Please describe the proposed medical service.</u>
Comparator	<u>Please specify the current medical service(s) most likely to be replaced or supplemented by the proposed intervention.</u>
Outcomes	<p><u>Please advise the types of outcomes which may be changed by introducing the proposed service relating to:</u></p> <ul style="list-style-type: none"> • <u>Safety including any potential risk of harm to patient.</u> • <u>Efficacy / effectiveness including, but not limited to, patient-relevant outcomes.</u> • <u>Healthcare resources.</u> • <u>Cost-effectiveness.</u> • <u>Total Australian Government healthcare costs.</u>

PICO or PPICO rationale for therapeutic and investigative medical services only

Population

Describe the patient population for whom public funding of the proposed medical service is intended. This may include identifying the medical condition (or disease) relevant to the service, and any characteristics that identify a subgroup of the overall disease population.

Please summarise the frequency (prevalence and / or incidence of the population or disease in question).

Rationale

Where alternative patient populations could be suggested, provide a brief rationale for each component of the description proposed. This may include reference to the patient populations recruited into the studies expected to form the evidence base in the assessment to be considered by MSAC.

Describe the current approach to how a patient within this population is investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible (and/or not eligible) for the proposed medical service.

Prior test (investigative services only - if prior tests are to be included)

Indicate what tests would usually be undertaken prior to when the proposed investigative service is used that would inform which patients are included in or excluded from the proposed population.

Intervention

Describe the key features of the proposed medical service.

Please provide details of how the proposed medical service is expected to be used, including any proposed limitations for public funding, such as frequency of use, setting of use, and provider type.

Where there is more than one variation of the proposed medical service, indicate which existing options would be (a) included, and (b) excluded by this description.

Please indicate whether the proposed medical service is currently funded or reimbursed in the private or public setting in Australia for the same or another clinical indication.

Rationale

Where alternative ways of using the proposed medical service could be suggested, provide a brief rationale for each component of the description proposed.

Comparator

Indicate how the use of the proposed medical service is expected to change practice, for example, is it to replace or substitute a current practice, in addition to, or to augment current practice.

Nominate the main alternative to compare with the proposed medical service.

In the absence of a comparator, usual standard of care without the proposed medical service.

Rationale

Where alternative comparators could be nominated, provide a brief rationale for the nomination.

Please advise of any limitations on the provider or the setting in which the comparator can be provided.

Outcomes

Patient relevant

Identify the types of expected changes in patient-relevant health outcomes if the proposed medical service is publicly funded, including primary effectiveness (improvement in function, relief of pain) and secondary effectiveness (length of hospital stays, time to return to daily activities).

Describe the types of safety-relevant outcomes, including any potential risks of harm to patients.

Healthcare system

Please identify the types of likely broader consequences of the proposed medical service across the healthcare system if introduced including potential changes in patterns of healthcare resource provision and access issues.

Rationale

Where alternative outcomes could be suggested, provide a brief rationale for each outcome identified.

Current clinical management algorithm for identified population

Provide a clinical management algorithm (e.g.: flowchart) explaining the current approach (i.e. including the comparator) to management and any downstream services (aftercare) of the proposed eligible population/s in the absence of public funding for the proposed medical service, preferably with reference to existing clinical practice in Australia.

Proposed clinical management algorithm for identified population

Provide a clinical management algorithm (e.g.: flowchart) explaining the expected management and any downstream services (aftercare) of the eligible population/s if the proposed medical services is publicly funded.

Proposed economic evaluation

Advise whether the comparative clinical claim is likely to be non-inferior (similar) or a substantially different (superior or inferior) and advise the appropriate type of economic evaluation. This should be based on the preliminary supporting evidence advised within the Applicant’s Application Form. For more information on the types of economic evaluation, see the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee*.

It should be pointed out that the *Technical Guidelines* also outline how to put together the structure of the decision analytic model underpinning the proposed economic evaluation, which is informed by the final structure of the PICO agreed to by PASC, as well as the list of health care resources and health outcomes variables to be considered in the economic evaluation. In a previous iteration of the MSAC process, the fundamental structure of decision analytic model of the proposed economic evaluation including a list of health care resources was presented to PASC for consideration. However, this information now simply needs to be presented in Section D of the assessment report that is subsequently put together during the ESC stage of the process.

Proposed item descriptor

If public funding is sought through the MBS, draft an MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category (proposed category number) – (proposed category description)
Proposed item descriptor
Fee: \$(proposed fee)

If public funding is not sought through the MBS, please provide an explanation for the amount to be charged for any non-MBS service proposed to MSAC for public funding.