Australian Government

Department of Health

Application *xxxx:

[*Title of application]

PICO Confirmation

(To guide a new application to MSAC)

(Version 2.0)

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

Please complete all questions applicable to the proposed service/technology, providing relevant information only.

Should you require further assistance, Departmental staff are available via the Health Technology Assessment (HTA) Team:
Email: hta@health.gov.au
Website: www.msac.gov.au

[Instructional text]

Notes on the template

This document is the template for a PICO confirmation. A PICO confirmation is a document that contains the context for a proposed assessment of a health technology. It is used to establish the appropriate Population(s), Intervention, Comparator(s) and relevant Outcomes for a technology, and also inform the appropriate place for the technology in clinical practice. The PICO confirmation is considered by the PICO Advisory Sub-Committee (PASC), which ratifies the PICO confirmation.

The PICO confirmation has two purposes:

- It defines questions that must be answered in order for MSAC to make recommendations about public funding.
- It provides the basis of the research questions to be answered through a systematic review.

The PICO confirmation template is provided to encourage consistency between PICO confirmations. PICO confirmations may be straightforward, with a single population and comparator, or may be more complicated if multiple populations and/or uses of the proposed service/technology are to be assessed. If there are multiple distinct populations or indications, multiple PICO sets may be required to inform the context of the assessments.

Where possible, avoid duplication in PICO confirmations. If multiple PICO sets are required, it may be possible to state, for example, that the relevant outcomes are consistent across PICO sets, rather than repeating the same outcomes. However, providing separate PICO summary boxes for each PICO confirmation is preferable.

This page provides instructions on how the template should be interpreted. In addition to instructions below, please be mindful that web accessibility requirements must be met for all documents posted on Department of Health websites.

The template includes different coloured text:

- Text written in green represents instructional text, to be deleted prior to finalising the PICO confirmation. The beginning and end of instructional text is also indicated by the words 'Instructional text' and 'End instructional text', respectively.
- Text written in black represents proposed wording, and may contain highlighted and asterisked (*) text to indicate that an input is required.
- **Cross-references to Technical Guidance (TG) sections of the *Guidelines for preparing assessments for the Medical Services Advisory Committee* (MSAC Guidelines) are presented in blue and preceded by the words 'Refer to:'. These cross-references are to be deleted prior to finalising the assessment report.**

Technical guidance for completing the PICO confirmation template can be found in Section 1 of the MSAC Guidelines.

[End instructional text]

[Instructional text] For each PICO set, provide a PICO summary box (Table 1). Each box should be less than one page. [End instructional text]

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

Table 1 PICO for [*intervention] in [*patient population/indication]: PICO Set 1

Component	Description
Population	[Instructional text] Briefly describe characteristics of the patient population for whom the intervention is to be considered. [End instructional text]
Prior tests (for investigative technologies only)	[Instructional text] Briefly indicate tests that would be done before the proposed investigative technology is used. [End instructional text]
Intervention	[Instructional text] Briefly describe the proposed health technology. [End instructional text]
Comparator/s	[Instructional text] Briefly specify the current health technology (or technologies) most likely to be replaced or supplemented by the proposed intervention. [End instructional text]
Reference standard (for investigative technologies only)	[Instructional text] Describe the reference standard used to determine accuracy of the test. [End instructional text]
Clinical utility standard (for codependent tests only)	[Instructional text] Briefly describe the exact testing methodology used in the key trial that establishes clinical utility of the test–treatment combination. [End instructional text]
Outcomes	[Instructional text] Briefly advise the types of outcomes that may change by the introduction of the proposed service, relating to: • safety (including any potential risk of harm to the patient) • efficacy/effectiveness (including, but not limited to, patient-relevant outcomes) • health care resources • cost-effectiveness • total Australian Government health care costs. [End instructional text]
Assessment questions	What is the safety, effectiveness and cost-effectiveness of [*the intervention] versus [*the comparator] in [*the target population]?

Purpose of application

Refer to: MSAC Guidelines TG 1.1 (Request for public funding)

[Instructional text] Summarise the purpose of the application using the following format: [End instructional text]

An application requesting [*Medicare Benefits Schedule (MBS) listing OR public funding] of [*intervention name – e.g. repetitive transcranial magnetic stimulation (rTMS)] for [*indication – e.g. treatment of antidepressant medication-resistant major depressive disorder (MDD)] was received from the [*legal name of applicant] by the Department of Health.

OR

The codependent application requested:

- Medicare Benefits Schedule (MBS) listing of [*intervention name – e.g. optical coherence tomography (OCT) for the determination of patient eligibility and for efficacy assessment of a single treatment with ocriplasmin (JETREA®)]; and
- Pharmaceutical Benefits Scheme (PBS) Authority Required listing of [*medicine name – e.g. ocriplasmin for the treatment of vitreomacular traction (VMT) including those with full-thickness macular hole (FTMH)].

[Instructional text]

Outline the clinical claim made in the application form.

The clinical claim is typically phrased as one of the options below:

- The use of the proposed technology results in superior health outcomes compared to the comparator/standard practice.
- The use of the proposed technology results in noninferior health outcomes compared to the comparator/standard practice.
- The use of the proposed technology results in inferior health outcomes compared to the comparator/standard practice.

[End instructional text]

Refer to MSAC Guidelines TG 1.2 (Defining the clinical claim)

PICO criteria

Population

Refer to: MSAC Guidelines TG 2.1 (Population)

[Instructional text] Describe the target population for the proposed technology. [End instructional text]

Intervention

Refer to: MSAC Guidelines TG 2.2 (Intervention)

[Instructional text] Describe the proposed health technology. [End instructional text]

Comparator(s)

Refer to: MSAC Guidelines TG 2.3 (Comparator)

[Instructional text] Describe the comparator(s). [End instructional text]

Reference standard (for investigative technologies only)

Refer to: MSAC Guidelines TG 2.4 (Reference standard [relevant for investigative technologies only])

[Instructional text] If the assessment of test accuracy is required in a linked evidence approach, or as supplementary evidence in a direct from test to health outcomes approach, specify the reference standard to be used to determine accuracy of the test. [End instructional text]

Clinical utility standard (for codependent investigative technologies only)

Refer to: MSAC Guidelines TG 2.4 (Reference standard [relevant for investigative technologies only])

[Instructional text] Where a study reporting on health outcomes has used a test to categorise patients for treatment, the test and broader circumstances of testing is the clinical utility standard. Specify the exact testing methodology (including method of results interpretation) used in the key trial that establishes the clinical utility of the test–treatment combination. [End instructional text]

Outcomes

Refer to: MSAC Guidelines TG 2.5 (Outcomes)

[Instructional text] Describe the outcome measures most relevant to patients. These measures should be included in the assessment report to address the clinical claim. [End instructional text]

Refer to: MSAC Guidelines TG 28 (Value of knowing) and TG 29 (Other relevant considerations)

[Instructional text] Include any details of claims about the value of knowing if relevant (investigative technologies only), or about other relevant considerations that are unique to the proposed technology and have not been considered by MSAC previously or that may affect interpretation of the clinical or economic evidence is interpreted. [End instructional text]

Assessment framework (for investigative technologies)

Refer to: MSAC Guidelines TG 9 (Assessment framework)

[Instructional text]

Investigative technologies achieve their clinical claim (health outcomes) by affecting subsequent decisions and actions. Clinical claims of superiority usually need to show an improvement in health outcomes. As such, the information from the test would alter decision-making, treatments received and ultimately the health of the patient. In some cases, a single study incorporates all these components (direct from test to health outcomes evidence). Commonly, evidence is fragmented across steps, and connections between these steps must be explicitly discussed. There may be occasions where clinical claims of noninferiority will

require evidence through to health outcomes if there are differences that occur earlier in the evidentiary pathway that prevent a conclusion of equivalence.

An assessment framework is a graphical representation of each step (it is not a clinical management algorithm). Each step (denoted by a number) is an evidentiary requirement – applicable and transitive evidence for each step is required to ensure information or action from the previous step is translated to the next. Each number corresponds to one or more research questions. In some cases, a step may incorporate more than one population – for example, step 5 may involve test-positive and test-negative patients, and research questions may be required to establish the treatment effects in both of these populations.

Provide the assessment framework to show how the link between the test and relevant outcomes will be achieved. An example of a generic assessment framework is provided in Figure 1, but should ideally be adapted to be specific to the proposed test.

Provide the assessment questions related to the assessment framework.

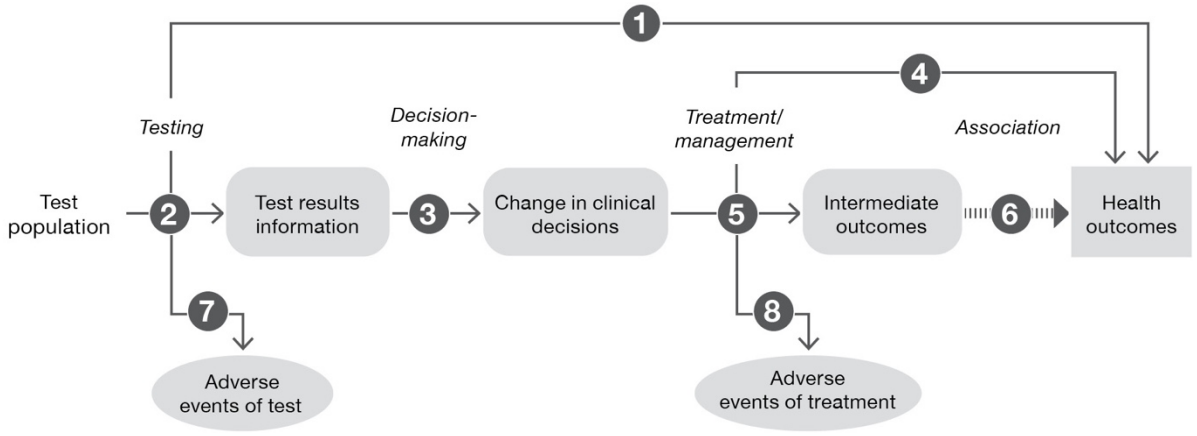

Figure 1 Generic assessment framework showing the links from the test population to health outcomes

Figure notes: 1: direct from test to health outcomes evidence; 2: test accuracy; 3: change in diagnosis/treatment/management; 4: influence of the change in management on health outcomes; 5: influence of the change in management on intermediate outcomes; 6: association of intermediate outcomes with health outcomes; 7: adverse events due to testing; 8: adverse events due to treatment

[End instructional text]

Clinical management algorithms

Refer to: MSAC Guidelines TG 2.6 (Clinical management algorithms)

[Instructional text] Provide the clinical management algorithm for the comparator(s).

Provide the clinical management algorithm for the intervention. Discuss differences between the two. [End instructional text]

Proposed economic evaluation

Refer to: MSAC Guidelines TG 17.5 (Type of economic evaluation)

[Instructional text] Describe the type of economic evaluation proposed, based on the clinical claim, and preliminary searches to check there is some evidence on which to examine the claim.

Table 2 provides a guide for determining which type of economic evaluation is appropriate. [End instructional text]

Table 2 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations

[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

Proposal for public funding

Refer to: MSAC Guidelines TG 3 (Proposed funding arrangements)

[Instructional text]

Describe the applicant's proposal for public funding (i.e. what is being proposed for funding, and whether it is under the MBS or another funding source).

State whether there are associated applications relating to the proposed health technology that are in progress (e.g. an application to the Therapeutic Goods Administration, Prostheses List Advisory Committee or Pharmaceutical Benefits Advisory Committee).

If public funding is sought through the MBS, draft an MBS item descriptor to define the population and medical use characteristics that would define eligibility for MBS funding, including a proposed MBS fee.

Category (*Insert proposed category no.) – *INSERT CATEGORY NAME)
MBS item *XXXX <*Insert intervention name> <*Specify any restrictions on use, e.g. patient characteristics to be satisfied, limits on frequency of use, limits on who can provide the item, or where it can be provided> <*Specify any relevant explanatory notes>
Fee: <*Insert proposed MBS fee>

Include justification for the proposed fee (and likely out-of-pocket costs).

If public funding is *not sought through the MBS*, remove the table above, and provide an explanation for the amount to be charged for the *non-MBS* service/technology.

[End instructional text]

Summary of public consultation input

[Instructional text] After the PASC meeting, insert a summary of de-identified consultation feedback received before the PASC meeting. [End instructional text]

Next steps

[Instructional text]

After the PASC meeting, insert the next steps.

For example:

PASC advised that, upon ratification of the post-PASC PICO, the application can proceed to the Evaluation Sub-Committee (ESC) stage of the MSAC process.

PASC noted the applicant has elected to progress its application as an ADAR (Applicant Developed Assessment Report).

[End instructional text]

References