Australian Government

Department of Health

Application Form Guidelines

(New and Amended

Requests for Public Funding)

(Version 1.4)

These guidelines correspond to the Application Form for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). These guidelines will continue to evolve over time to reflect changes to the Medical Services Advisory Committee (MSAC) process and feedback from stakeholders.

These guidelines describe the detailed information that the Department requires in order for the MSAC to determine whether the proposed service is suitable for MSAC assessment, including identifying the pathway and the resource effort required in progressing the application through the MSAC process. They are intended to provide guidance to answer the questions with the Application Form, with the numbering used throughout corresponding to those on the Application Form.

When suitability has been determined, the Department will provide the completed Application Form and consult with professional bodies / organisations representing the group(s) of health professionals who provide the service.

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

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1. INTRODUCTION

1.1 Purpose and Role of the Medical Services Advisory Committee

The Medical Services Advisory Committee (MSAC) is a non-statutory committee established by the Australian Government Minister for Health in 1998. MSAC appraises new medical services proposed for public funding, and provides advice to Government on whether a new medical service should be publicly funded based on an assessment of its comparative safety, effectiveness, cost-effectiveness and total cost, using the best available evidence. Amendments and reviews of existing services funded by the MBS or other programs (for example, blood products or screening programs) are also considered by MSAC.

The MSAC advises the Minister for Health on medical services in relation to:

- the strength of evidence about the comparative safety, effectiveness, cost-effectiveness and total cost of the medical service;
- whether public funding should be supported for the medical service and, if so, the circumstances under which public funding should be supported;
- the proposed MBS item descriptor and fee for the service where funding through the MBS is supported; and
- other matters related to the public funding of health services referred by the Minister for Health.

MSAC also advises the Australian Health Ministers' Advisory Council (AHMAC) on health technology assessments referred under AHMAC arrangements.

There is no obligation on Government to accept or implement the advice MSAC provides.

1.2 Medicare

Medicare was established under the *Health Insurance Act* 1973 and is administered by the Department of Health. It provides Government assistance to people who incur medical expenses in respect of clinically relevant professional services provided by allied health, general practice and specialist medical practitioners. The key objective of Medicare is to ensure the quality, accessibility and affordability of health care services.

1.3 The Medicare Benefits Schedule (MBS)

The Medicare Benefits Schedule (MBS) provides rebates to patients for private medical (professional) services provided on a fee-for-service basis, and facilitates universal access to certain allied health, general practice and specialist medical services.

The MBS lists and describes the professional services for which a Medicare benefit is payable, the amount of that benefit, and any conditions applying to the use of that service. The MBS changes from time-to-time to reflect, for example, the availability of new medical services, changing medical practice, and the Government's current policy parameters for determining which professional services are suitable or not suitable for Medicare benefits. It should be noted that the MSAC does not evaluate specific devices but evaluates the proposed medical service where the delivery of the service may use a device.

The process for applying for MBS listing is done by submitting an Application Form to the Department of Health to determine the appropriate assessment pathway.

1.4 MBS Reviews

In April 2015, the Australian Minister for Health, the Hon Sussan Ley MP, announced the formation of the Medicare Benefits Schedule Review Taskforce, with the Taskforce providing expert guidance to Government on reshaping the MBS to better support the quality of Australians' health care and the sustainability of Medicare.

The Taskforce will review the MBS in its entirety, considering individual items as well as the rules and legislation governing their application.

The Department is currently considering how the reviews will expand on the MSAC process and the potential impact of changes to the MBS.

2. APPLICANT MATERIAL / DOCUMENTS

2.1 Commercial-in-Confidence material

Documents in the possession of the Department of Health are subject to the requirements of the *Freedom of Information Act 1982* which means that the Department may be required to grant access to documents in its possession.

Even if a document is considered commercial-in-confidence, this does not mean that access under this Act can be denied. The Department is required to consult with the author of the document when that document appears to have commercial-in-confidence material, and take the author's views into account when deciding to grant / not grant access to documents.

2.2 Confidential material

It is accepted that documents submitted throughout the MSAC process may contain information the Applicant believes is confidential.

However, these claims will be agreed to by the Department on a case-by-case basis, in line with current Government policies (these include, but are not limited to, statistical data and positions of trust classifications).

In any claim for confidentiality, the Applicant will be asked to state the basis on which the claim for confidentiality is being made. Further information on the relevant Government policies is available at Australian Governments Solicitors - Legal Briefing - number 64 - "Identifying and Protecting Confidential Information" webpage, located at http://www.ags.gov.au/publications/legal-briefing/br64.htm.

2.3 Dissemination of Application Form

The Application Form will be disseminated to professional bodies / organisations and consumer organisations that have been identified in Part 5 of the Application Form, and any additional groups that the Department has deemed should be consulted with. This will occur after suitability of the proposed medical service has been determined. The Application Form, with relevant material can be redacted if requested by the Applicant.

Further, the Application Form will also be placed on the application's individual webpage on the MSAC website for interested stakeholders to provide comment at any stage of the MSAC process after suitability has been determined. This webpage is a public webpage and can be viewed by all interested stakeholders.

3. HOW TO APPLY FOR PUBLIC FUNDING OF A MEDICAL SERVICE

3.1 Suitability for consideration

Before completing the Application Form, it is important to ensure that the proposed service is suitable for consideration by the MSAC, that is:

- the proposed medical service would be regarded by the relevant profession as a 'professional service' as generally defined by the *Health Insurance Act 1973*. Professional services that are covered include diagnostic and imaging services, and surgical and medical procedures. Not all services related to health care are eligible for funding under Medicare and some services are specifically excluded, such as cosmetic surgery and screening services; and
- the proposed medical service is likely to meet the Government's current policy parameters for funding professional services under Medicare.

If you are uncertain about whether a proposed service is suitable to be considered for public funding, please contact the HTA Team, in the Department of Health on (02) 6289 7550. Alternatively, you could seek guidance from the relevant college or speciality society.

3.2 Who can apply to MSAC?

Applications can be made by the medical profession, medical industry and others seeking Australian Government funding for a new medical service or a change to an existing service. Please note that the MSAC process is for Medicare funding for a new or an amendment to a medical service and it is not a process for seeking reimbursement of a service that has been provided and billed. Further, a medical service that is not defined by the *Health Insurance Act 1973* will not be assessed by MSAC.

3.3 When to lodge an application to MSAC

The PICO Advisory Sub-committee (PASC), the Evaluation Sub-committee (ESC) and the MSAC meet three times per year. The MSAC website provides a list of future meeting dates including timeframes for each meeting.

3.4 How long will it take MSAC to consider an application?

The HTA Team processes applications as soon as they are received. The time taken for an application to be determined suitable will depend on the completeness of the Application Form, the quality of the evidence, the complexity of the service and the complexities of policy considerations

To assist Applicants in tracking the progress of their applications, an Application Manager will be assigned to each application to support them through the process and to work with them to assist with making decisions about their application. Further, the status of an application is also uploaded on an application's individual webpage on the MSAC website.

4. APPLICANT WITHDRAWAL FROM THE PROCESS

An applicant may request that their application to MSAC be withdrawn at any time.

Applicants should note the following if MSAC has completed its considerations of an application and they then seek to withdraw that application:

a) following consultation with the applicant, the outcomes, recommendations and/or advice of MSAC will either be withheld or published in whole or in part; and
b) the advice of MSAC pertaining to the application may be provided to Government.

5. REGULATORY REQUIREMENTS

All therapeutic goods used in the provision of medical services must be assessed by the Therapeutic Goods Administration (TGA) and included on the Australian Register of Therapeutic Goods (ARTG) before they can be marketed in Australia.

As a general rule, MSAC does not support public funding for a service that uses a therapeutic good for indications beyond those for which it was included on the ARTG.

An application to MSAC can be lodged before relevant therapeutic goods are included on the ARTG provided that the Applicant has evidence that the relevant sponsor has commenced the TGA process. Confirmation of inclusion on the ARTG is required before MSAC can finalise its own appraisal of the corresponding medical service.

For further information on how therapeutic goods are defined, please refer to www.tga.gov.au.

6. ADVICE TO THE MINISTER

Following MSAC's consideration, the Department of Health is required to consider the financial impact to Government, consult with relevant stakeholders, seek Cabinet agreement and draft and implement legislative change(s) to amend or add an item to the MBS. It should be noted that there is no obligation on Government to accept or implement the advice MSAC provides.

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Applications can be made by the medical profession, medical industry and others seeking Australian Government funding for a new medical service or a change to an existing service.

Where the Applicant is a medical professional body or organisation, please ensure that the person who is nominated as a contact can assist with any queries the Department may have regarding the application.

These details will also be used by the Department to contact the Applicant regarding the status of their application. The Department should be notified of any changes to these details as soon as they occur as the Department will not communicate to any person who is not registered as the primary contact, noting that should the primary contact not be available, the Department will only communicate with the alternative contact.

2 (a) Are you a consultant acting on behalf on an applicant?

A consultant may be an individual or organisation acting as a third party on behalf of the medical profession, medical industry or others seeking Australian Government funding for a new medical service or a change to an existing service.

(b) If yes what is the Applicant(s) name that you are acting on behalf of?

Please identify the individual or organisation you are acting on behalf of.

3 (a) Are you a lobbyist acting on behalf of an Applicant?

In 2008, the Australian Government introduced a Lobbying Code of Conduct and established a Register of Lobbyists to ensure that contact between lobbyists and Commonwealth Government representatives is conducted in accordance with public expectations of transparency, integrity and honesty.

Any lobbyist who acts on behalf of third-party clients for the purposes of lobbying Government representatives must be registered on the Register of Lobbyists and must comply with the requirements of the Lobbying Code of Conduct.

(b) If yes, are you listed on the Register of Lobbyists?

A lobbyist wishing to conduct lobbying activities with a Government representative must be registered on the Register. The Lobbyists' Register is maintained by the Australian Government Department of the Prime Minister and Cabinet, with further information being available at http://lobbyists.pmc.gov.au/.

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

4 Application title

The title of the application should describe the proposed medical service and include the intervention and indications where applicable. No trade names should be included in the title of the application. Examples of application titles can be found on individual webpages on the MSAC website.

When suitability has been determined, the title will be published on the MSAC website, however, the Department retains the right to alter the wording provided but will do so after consulting with the Applicant. Further, the Department retains the right to refuse to publish information from the Applicant that the Department considers to be inaccurate or misleading.

5 Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words *(further information will be requested at Part 6 of the Application Form)*

Please limit the description of the medical condition to no more than 150 words and ensure that it is clear to a person without a scientific or clinical background. Examples of descriptions of medical conditions can be found on individual webpages on the MSAC website.

When suitability has been determined, the description of the medical condition will be published on the MSAC website, however, the Department retains the right to alter the wording provided but will do so after consulting with the Applicant. Further, the Department retains the right to refuse to publish information from the Applicant that the Department considers to be inaccurate or misleading.

6 Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested in Part 6 of the Application Form)

Please limit the description of the proposed medical service to no more than 150 words and ensure that it is clear to a person without a scientific or clinical background. Claims of therapeutic or diagnostic performance, cost effectiveness or the strength of evidence should not be included in this description. Examples of succinct descriptions of medical services can be found on individual webpages on the MSAC website.

When suitability has been determined, the description of the proposed medical service will be published on the MSAC website, however, the Department retains the right to alter the wording provided but will do so after consulting with the Applicant. Further, the Department retains the right to refuse to publish information from the Applicant that the Department considers to be inaccurate or misleading.

7 (a) Is this a request for MBS funding?

The MBS is a listing of Medicare services subsidised by the Australian Government. The *Health Insurance Act 1973* stipulates that Medicare benefits are payable for professional services. A professional service is a clinically relevant service which is listed on the MBS. A medical service is clinically relevant if it is generally accepted in the medical profession as necessary for the appropriate treatment of the patient.

Please advise if this is a request for funding on the MBS. If the proposed medical service is seeking public funding from other sources or if it is seeking public funding other than the MBS, please advise at Question 6(f).

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

Please advise if this proposal is to amend an existing MBS item number(s), that is, any change to an existing MBS item. Further information on an amendment to an existing MBS item number(s) is requested at 6(c) and 6(d).

Please advise if a new MBS item number(s) is being sought. Further information is requested at Part F (e).

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

Please identify the relevant MBS item number(s) that you are seeking to amend. Further information is requested at Question 6(d).

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

The sub-questions under Question 7 assist in determining the nature of the amendment and how they will be segmented (or classified) to determine the most appropriate MSAC pathway or to provide guidance on alternative options if MSAC is not appropriate. Depending on the degree of the amendment, some amendments will not require a full health technology assessment (HTA) and if suitable, may require an alternate, non health technology assessment pathway. The nature of the amendment also influences the intensity of the process required through PASC if a HTA is to be conducted.

i. An amendment to the way the service is clinically delivered under the existing item(s) where the intended use of an existing service has been expanded to include a new medical condition that is different altogether to the medical condition currently eligible under the existing item(s).

ii. An amendment to the patient population under the existing item(s) that broadens the intended use of an existing item *within* a medical condition to a new subgroup of patients in addition to the subgroup of patients already covered by the item. For example expanding the eligibility of the service as to when the service is used (i.e. in addition to the service being used as a 'third line' treatment in the management of a particular medical condition, the amendment is seeking use of the service also as 'second line').

iii. An amendment to the schedule fee of an existing MBS item where there is nothing to compare clinically as the clinical service is essentially remaining the same.

iv. An amendment to the time and complexity of an existing item(s) where there is nothing to compare clinically as the clinical service is essentially remaining the same, for example, time-tiered initial and subsequent attendance MBS item numbers.

v. Access to an existing item(s) by a different health practitioner group where the amendment is solely based on a request to provide the same clinical service already provided by other types of health professionals.

vi. Minor amendments to the item descriptor that does not affect or change how the service is delivered. Examples of this type of amendment include:

- administrative amendments, such as clarification of the wording of an existing item descriptor without altering its intended use, or changing a service description addressing terminology that is not technically correct or ambiguous;
- a change that addresses a typographical error or to align an item descriptor with the regulations (e.g. inclusion of a missing word as a result of error); and
- a change that proposes to remove reference to brand names in an existing item descriptor and make the wording of the descriptor generic.

vii. An amendment to an existing specific single consultation item where a single model of care is proposed to be the only clinical encounter covered by the service, for example, one item is included in the item descriptor.

viii. An amendment to an existing global consultation item (which are professional attendance items on the MBS that accommodate a range of clinical encounters to be covered under the one item), for example, health practitioner groups requesting increased funding for their existing general professional attendance items.

ix. Please describe (specify) any option that is not outlined above.

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

Question e assists in determining the nature of the new item being sought and how they will be segmented (or classified) to determine the most appropriate MSAC pathway or to provide guidance on alternative options if MSAC is not appropriate. Depending on the request for a new item(s), some will not require a HTA and if suitable, may require an alternate, non-health technology assessment pathway. The nature of the new service also influences the intensity of the process required through PASC if a HTA is to be conducted.

i. A new item(s) which also seeks to allow access to the MBS for a specific health practitioner group to provide the same clinical service already provided by another type of health professional(s).

ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population) and includes:

- services that may include a new surgical procedure and approach to treat particular medical conditions;
- specific consultative services where a single model of care is proposed to be the sole clinical encounter covered by the service;
- global consultation attendance items that cover multiple clinical encounters;
- co-dependent applications to subsidise an investigative / therapeutic medical service that depends on each other; and
- co-dependent applications to cover the time and complexity of administering the delivery of a drug.

iii. A new item that is proposing a specific single consultation item where a single model of care is proposed to be the only clinical encounter covered by the service, for example, one item is included in the item descriptor.

vi. A new item that is proposing a global consultation item where a proposal covers a range of clinical encounters, for example, a health practitioner group requesting new general professional attendance items.

(f) Is the proposed service seeking public funding other than the MBS?

Please advise if the proposed service is seeking public funding where it is not intended for inclusion on the MBS. This can include blood and blood products and screening programmes.

Advice provided by MSAC in relation to blood and blood products will have no implications regarding the responsibilities of State or Territory Governments. State and Territory Governments will continue to make their own decisions in relation to the 37% of the funding in the blood sector, as defined under the *National Blood Agreement*.

It should be noted that unless the Minister provides direction, Medicare benefits are generally not payable for health screening services, that is a medical examination or a test that is not reasonably required for the management of the medical condition of the patient, such as mammography screening entrance to schools and other educational facilities multiphasic screening etc. However, the Minister has directed that Medicare benefits be paid for some categories of health screening, such as a medical examination or test on a symptomless patient by that patient's own medical practitioner in the course of normal medical practice, to ensure the patient receives any medical advice or treatment necessary to maintain their state of health. Benefits would be payable for the attendance and tests which are considered reasonably necessary according to patients individual circumstances such as a pathology service requested by the National Health Foundation, a medical examination being a condition of child adoption or fostering, etc.

(g) If yes, please advise.

Please provide further advice if the proposed service you are seeking is for public funding other than the MBS.

8 What is the type of service?

Please identify the type of service you are seeking.

A ***therapeutic medical service*** is a service that impacts on health outcomes *directly*, that is, no other intermediate medical service needs to be provided to achieve the improvement in health outcomes. Examples of this type of service include novel surgical techniques, the insertion of a stent or other therapeutic device(s), and most blood products. Identifying whether a medical service is therapeutic has implications on the nature of the evidence that needs to be presented to the committee for consideration. This is expanded upon in a document titled the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Therapeutic* that is available on the MSAC website.

An ***investigative medical service*** is a service that generates clinically relevant information about the individual to whom the service is rendered. To achieve an impact in health outcomes, the investigative information must result in a change in the management of an intermediate therapeutic service i.e. it can only *indirectly* impact on health outcomes. Identifying whether a medical service is investigative has implications on the nature of the evidence that needs to be presented to the committee for consideration. This is expanded upon in document titled the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Investigative.*

Consultation medical services are services that tend to combine an investigative component (clinical history, examination and ordering of investigations) and a therapeutic component (the execution of a management plan) for the patient. Taking a history and examination of a patient is essential for a medical consultation and information clarified through a clinical assessment assists the health practitioner in determining what should happen next with a patient in terms of investigation and management.

- A ***single consultation medical service*** is where the service stipulated in the item descriptor is the only clinical encounter covered by the service.
- A ***global consultation medical service*** is where a service covers a range of clinical encounters.

Identifying whether a medical service is consultative has implications on the how the proposed service is handled by the Department and the Committee. This is expanded upon further in the Process Framework that is available on the MSAC website.

An ***allied health service*** is a service not undertaken by an eligible medical, nursing, midwifery or dental health professional, for example, audiology, physiotherapy, podiatry, psychology, etc.

A ***co-dependent technology*** occurs where the use of one health technology to directly improve health outcomes (e.g. a medicine or medical device or procedure) is improved by the use of another health technology (e.g. a pathology or an imaging technology) and where both technologies require consideration for public funding.

A ***hybrid health technology*** combines the characteristics of different health technologies (eg. a medicine or a medical device or a biological) in one intervention (e.g. drug eluting stents for treating cardiovascular disease or photodynamic therapy for treating skin disease).

9 For investigative services, advise the specific purpose of performing the service *(which could be one or more of the following)*:

If you are seeking an investigative service, please advise the purpose of performing the service(s):

i Detection of a disease, abnormality or associated risk factor in asymptomatic people, for example, using pap smears or mammography as an investigative medical service to elucidate information that explains or assists.

ii. A service that is applied to symptomatic individuals to elucidate information that explains and / or assists in managing their current clinical presentation.

iii. A service rendered to individuals in whom the underlying reason of their clinical presentation is not yet clear and the purpose of testing is to confirm a diagnosis that might explain and or add value in managing that individual's clinical presentation.

vi. A service that identifies a patient as suitable for a therapeutic medical service by predicating a variation in the effect of the medical service.

v. A service that monitors a patient over time after an initial investigation to guide subsequent treatment decisions if the treatment requires to be repeated.

vi. A service that tests for heritable mutations in clinically affected individuals to make a genetic diagnosis and thus estimate their variation in (predisposition for) future risk of further disease and, when also appropriate, cascade testing of family members of those individuals who test positive for one or more relevant mutations, to make a genetic diagnosis and thus estimate each family member's variation in (predisposition for) future risk of developing the clinical disease.

The purpose of performing an investigative medical service has implications on the nature of the evidence that needs to be presented to the committee for consideration and each purpose has differing aspects of evidence that needs to be considered. This is expanded upon in a document titled the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Investigative* that is available on the MSAC website. For tests of heritable mutations (see vi. above), the Clinical Utility Card proforma and process might apply.

10 Does your service rely on another medical product to achieve or to enhance its intended effect?

Please advise if the proposed medical service relies on a pharmaceutical / biological, or a prosthesis or device.

A prosthesis, in the context of listing a product on the Prostheses List, is a surgically implanted product. Examples include cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements and intraocular lenses, as well as human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue. For further information on a definition of a prosthesis and a detailed explanation of whether a device associated with a proposed service is relevant to the Prosthesis List can be found on the Department's website: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm

Further explanation on pharmaceutical or biological products can be found on the Pharmaceutical Benefits Scheme's website: www.pbs.gov.au.

11 (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

Please advise if the proposed medical service has a pharmaceutical component and has a PBS listing.

(b) If yes, please list the relevant PBS item code(s)?

If the proposed medical service has a pharmaceutical component to it, please advise of the PBS item code(s).

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

If an application (submission) is being considered by PBAC, please advise of the PBAC submission item number.

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Please advise what the trade and generic name of the pharmaceutical is.

If Question 10 is relevant to an application, the HTA Team will verify the above information with the PBAC Secretariat.

12 (a) If the proposed service is dependent on the use of a prosthesis is it already included on the Prostheses List?

If the proposed medical service is dependent on the use of a prosthesis, please advise.

(b) If yes, please provide the following information (where relevant):

If the proposed medical service is dependent on the use of a prosthesis, please advise the billing code(s) on the Prostheses List, the trade and clinical name of the Prostheses and any other device components that are delivered as part of the service.

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

If an application is in the process of being considered by a Clinical Advisory Group or PLAC, please advise of the PLAC application number.

If Questions 11a to 11c are relevant to this application, the HTA Team will verify the above information with the Prosthesis Section who manage the Prostheses List and Secretariat for PLAC.

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

Please advise if there are any other sponsor(s) and / or manufacturers that have a similar prostheses or device component which this application is relevant to.

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s).

If Question 11 (d) is relevant to an application, please provide the names of all commercial suppliers with similar prostheses or devices (technologies). It should be noted that the Government funds professional services rather than individual technologies. Any subsequent MBS item descriptor will generally describe the professional service and will not specify a particular device so that other equivalent technologies do not require a separate MSAC assessment. However, MSAC reserves the right to restrict funding of a medical service in order to accommodate the use of a particular brand and not others. On a case-by-case basis, the Committee will provide a rationale for this if it were to recommend this. MSAC will also observe procedural fairness and commercial-in-confidence issues in the assessment process where it is opened up to a broader generic assessment.

On receipt of applications the HTA team with the assistance of Departmental Medical Advisers and the Secretariat for PLAC will assess the broader clinical landscape to ensure that any other relevant sponsor(s) and / or manufacturer(s) that have a similar prostheses or device component in the Australian market place have been identified.

13 Please identify any single and / or multi-use consumables delivered as part of the service?

Please advise of any single and / or multi-use consumables delivered as part of the proposed medical service. Some examples of medical consumables are catheters and electrodes, syringes and needles, bandages and dressings etc. Consumable products generally tend to be non-durable and/or disposable in nature, and are often limited in terms of repeated use by more than one individual. In some instances these consumables in isolation can be of high cost.

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

14 (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide details.

This information will reiterate the answers that have been provided in the Application Form for Questions 9, 10 and 11 but are also required to be briefly summarised here. This summary will enable the HTA Team to identify whether the TGA needs to contacted to verify the regulatory status of a particular therapeutic good(s) associated with the application.

If applicable, please advise of the type of therapeutic good, manufacturer's name and sponsor's name.

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

Medical devices, diagnostic kits or pharmaceutical products may require TGA approval before they can be used in Australia.

If the medical device, diagnostic kit or pharmaceutical product is not listed, registered, included on the ARTG, or in the process of being listed, registered or included by the TGA, an assessment will not be eligible for considered by MSAC.

Where TGA approval is necessary, this will need to be completed before the MSAC can provide advice to Government on the proposed medical service.

If applicable, please advise if it is a Class III or AIMD. For more information on these classifications please see the TGA's website https://www.tga.gov.au/sites/default/files/devices-argmd-p1-01.pdf .

15 (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

Approval may be based on a full evaluation with an Australian Registration (Aust R) number being provide or a detailed evaluation of efficacy with no safety having been reviewed and an Australian Listing (Aust L) being provided. Please provide supporting documentation as an attachment if there is an exemption.

16 (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Please provide details of ARTG listing, registration or inclusion numbers, the TGA approved indication(s) and TGA approved purpose(s) if the therapeutic good has been listed or included on the ARTG.

17 If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

If the therapeutic good is in the process of being considered by TGA, please advise of date of submission to TGA, the estimate date of approval, the TGA Application ID, the TGA approved indication(s) and approved purpose(s) if applicable.

18 If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

If the therapeutic good is not in the process of being considered for listing, registration or inclusion by TGA, please advise if an application is being prepared, the estimated date of submission, proposed indication(s) and purpose(s) if applicable.

If Questions 14 to 16 are relevant to this application, the HTA Team will verify the above information with the TGA.

PART 4 – SUMMARY OF EVIDENCE

19 Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

A summary of the key journal articles or research projects that are most likely to be relevant to assessing the merits of a proposed medical service through MSAC should be provided here. Providing this summary ahead of time enables an Applicant to signal the likely evidence base that is going to be

relevant for inclusion in the Assessment Report that will need to be subsequently developed (provided this evidence remains relevant following the development of the PICO.

Two of the most frequently used databases to undertake a search is Medline and Embase. Please advise of the specific type of study design, the title of the identified study, a short summary of the study, the website link to the study and the date that the study was published. A table has been provided in the Application Form to capture this information.

The provision of information on evidence here is simply to provide a snapshot of the evidentiary landscape that will enable the HTA Team, with the assistance of Departmental Medical Advisers, to assess the broad availability and status of the body of evidence / trials underpinning an application. This has implications on the timing of the assessment through the MSAC process. Applicants are not expected to provide a detailed analysis of the body of evidence in question (what it is saying, or likely to say) in the Application Form. For further information, please refer to the *Process Framework*.

Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

If published studies are unavailable, the Application Form should include sufficient information to advise of any yet to be published articles or research that may have results in the future as MSAC needs to be confident that there are not trials or studies currently underway that are likely to influence their advice.

As requested in Question 17, please advise of the specific type of study design, the title of the identified study, a short summary of the study, the website link advising of information on the future of the study and the date that the study is anticipated to be published. This information will assist both the Applicant and the Department to determine the likely future timing of evidence publication and whether this is aligned with the ESC and MSAC meeting dates for the application (if these dates have already been proposed).

For both Questions 17 and 18, the HTA Team with the assistance of a Departmental Medical Adviser will verify via a general search of key clinical trial databases and registries (such as www.clinicaltrials.gov) when key studies are likely to have results approximately available. Applicants are welcome to submit unpublished evidence relevant to the MSAC consideration as part of the subsequent Assessment Report provided this evidence has been accepted for peer review publication and the proposed publication date falls relatively close to the date of the MSAC meeting. Applicants should also flag in this section of the application form whether they are aware of any grey literature (for example individual patient data) that may be pertinent to the consideration of their application.

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

20 List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated).

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the proposed medical service.

Please obtain a statement of clinical relevance from these bodies on the proposed medical service addressing their support of the clinical relevance of the service and commenting on the proposed fee.

The statement of clinical relevance confirms that the relevant professional bodies support the commencement of a process towards MSAC/government consideration of a particular application. Specifically, is the proposed service regarded by the relevant part of the Australian medical profession as 'clinically relevant' i.e. is the proposed service (be it a test or treatment) regarded by the profession as being 'necessary' in the management of the medical condition under consideration. This is a key requirement for eventual MBS listing.

The Department strongly recommends that the Applicant provide a complete list of the appropriate professional bodies / organisations and attach a statement of clinical relevance from each group nominated to assist with progressing the application in a more timely and efficient manner. The Department will provide this Application Form to identified stakeholders for feedback along with those the Department identifies that have not been listed by the Applicant.

21 List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service).

Identify any impact to different professional bodies within the MBS or organisations of the proposed medical service.

Professional bodies / organisations affected will be contacted by the Department to participate during consultation. It is recommended that the Applicant provide a thorough list of all impacted professional bodies / organisations that may be impacted by this medical service.

22 List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated).

Identify any relevant consumer organisations relevant to the proposed medical service. Although the MSAC assessment is based on evidence, the MSAC and the Department consider the views of consumers and their experiences with the proposed service as important.

23 List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service.

Identify any relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service.

24 Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

Please provide contact details of two clinical experts who can be contacted by the Department, HTA Groups contracted by the Department, and the MSAC and its sub-committees to provide clinical advice during the MSAC assessment process. Further, as Applicants are provided the opportunity to attend and participate in the PICO Advisory Sub-Committee where their PICO Confirmation will be discussed, Applicants are encouraged to have appropriate expertise attend with them as well.

It should be noted that the Department, HTA Groups, and the MSAC and its sub-committees may seek further advice from clinical experts who have not been nominated by the Applicant.

PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

25 Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality.

Define the medical condition (disease) that specifies the patient population that would benefit from the use of the proposed intervention.

26 Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service.

Clearly describe the characteristics of the patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed service. Please consider age ranges, the severity of the medical condition, the presence of co-morbidities, and how the patient will be investigated, managed and referred to be eligible for the service.

Please also specify any other patients who would also use the proposed medical service that may need to be evaluated.

27 Define and summarise the current clinical management pathway before patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point).

Explain the current clinical management pathway up to the point(s) where the proposed intervention would be appropriate.

PART 6b – INFORMATION ABOUT THE INTERVENTION

28 Describe the key components and clinical steps involved in delivering proposed medical service.

Explain the central components pertinent to delivering the service.

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

If the proposed medical service includes a registered trademark component, please explain what characteristics distinguish it from others, and will the use of a non-branded term in an item descriptor inadvertently enable other products to be claimed.

30 If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

If the proposed medical service has a prosthesis or device component to it, please advise if it involves a new approach towards managing particular sub-groups of patients with specific medical conditions.

Please refer to answers in Questions 9 through to 11.

31 If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency).

If applicable, indicate any limitations of delivering the proposed medical service to the patient, for example, whether it is a once-off or a lifetime intervention, etc.

32 If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service.

If applicable, identify any healthcare resources (pharmaceutics, diagnostic and investigational services, etc) that are generally performed in association with the proposed medical service. Please provide MBS item numbers (if appropriate) including estimating the frequency and location as part of delivering the proposed medical service.

33 If applicable, advise which health professionals will primarily deliver the proposed service.

If applicable, identify the health professionals who will perform the proposed service. Please consider allied health practitioners, nurses, general practitioners, specialists or sub-specialists.

For diagnostic tests, please describe which health professionals will order the test, interpret the test and use the test results.

34 If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery.

If applicable, specify whether the proposed service should only be rebated by the health professional billing the service or by the health professional performing the service on behalf of another health professional.

Further, please specify whether the proposed medical service could be delegated to be performed by another health professional, for example, a nurse, sonographer, etc.

35 If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it.

Identify whether the proposed service should be restricted and limited to specific specialities or practitioners who have the appropriate training, credentialing or accreditation in performing the service. Please also include if there are referral limitations.

36 If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery.

If applicable, describe the training requirements that would be needed to acquire any proposed accreditation, the duration and costs of training, whether training would be one off or ongoing and if credentialing or accreditation is a requirement.

37 (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings)

Please indicate all relevant proposed setting(s) in which the proposed medical service will be performed.

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each.

Where the proposed medical service can be performed in more than setting, please describe the rationale surrounding each setting. For example, some services can be delivered in consulting rooms, however, in some cases the service may be delivered in the hospital setting.

38 Is the proposed medical service intended to be entirely rendered in Australia?

Please advise if the proposed medical service is intended to be entirely rendered in Australia, including if a component of the service is provided outside of Australia. For example, the collection and a preparation of a sample may be performed in Australia, however the sample is shipped overseas for testing.

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

39 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service).

Outline the comparator (intervention) that is currently used to manage the patient population proposed in Part 6a and identify any healthcare resources (pharmaceutics, diagnostic and investigational services, etc.) that are currently performed in association with the current comparator.

For an investigative medical service, please make the distinction between what is the comparator versus the reference standard. Please refer to the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee* for further details.

40 Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

If the comparator(s) nominated is covered by an existing MBS item number, please provide the relevant item number(s).

41 Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources).

Explain the current clinical management pathway (algorithm) after the point(s) where the proposed intervention has been introduced.

Explain the differences in pathways if any alternative options have been identified in response to Question 25.

42 (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

Will the proposed medical service replace or supplement the current medical service?

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted.

If the proposed medical service is to replace the current medical service, describe how it will differ from what is currently available and its potential advantage.

43 Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline).

Referring to question 39, please summarise how the current clinical management pathways are expected to change as a consequence of introducing the proposed medical service. Please advise of any variation in health care resources (pharmaceutics, diagnostic and investigational services, etc).

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

44 Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms).

Briefly outline specific clinical claims in this section, whether the proposed medical service is either non-inferior (no worse than) or superior to its main comparator in terms of relative safety and clinical effectiveness. This will inform the type of economic evaluation that is subsequently conducted in the 'evaluation' stage of the MSAC process. Please refer to the *Technical Guidelines for preparing assessment reports* on how to submit an assessment report.

45 Please advise if the overall clinical claim is for.

Is the application claiming superiority over the comparator or non-inferiority (equivalence / no worse that the main comparator) in terms of effectiveness?

Briefly outline in this section whether the application is going to put forward an 'overall' claim that the proposed medical service is either non-inferior (no worse than the main comparator) or superior to its main comparator depending on the combined effect of the claims listed in Question 42. This has implications on the nature of the evidence that needs to be presented to the committee for consideration. This is expanded upon in the *Technical Guidelines for preparing assessment reports.*

46 List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator.

Outcomes may include survival (mortality), clinical events (e.g. strokes or myocardial infarction), patient-reported outcomes (e.g. symptoms, quality of life), adverse events, burdens (e.g. demands on caregivers, frequency of tests, restrictions on lifestyle) and economic outcomes (e.g. cost and resource use). It is critical that outcomes used to assess adverse effects as well as outcomes used to assess beneficial effects are among those addressed by an application to MSAC.

Once a list of relevant outcomes has been compiled for the application, Applicants should prioritize the outcomes and select the main outcomes of likely relevance to the application. Applicants should broadly state which outcomes will be primary outcomes and which will be secondary outcomes . Primary outcomes are the main outcomes that would be expected to be analysed should the application identify relevant studies, and conclusions about the effects of the interventions under review will be based largely on these outcomes. There should in general be no more than three primary outcomes and they should include at least one desirable and at least one undesirable outcome (to assess beneficial and adverse effects respectively). Outcomes not selected as major outcomes would be expected to be listed as minor outcomes. In addition, minor outcomes may include a limited number of additional outcomes the application intends to address. These may be specific to only some applications. For example, laboratory

tests and other surrogate measures may not be considered as main outcomes as they are less important than clinical endpoints in informing decisions.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

47 Estimate the prevalence and/or incidence of the proposed population.

Briefly outline in this section key epidemiological facts in relation to prevalence and/or incidence of the condition in the current population?

48 Estimate the number of times the proposed medical service(s) would be delivered to a patient per year.

Indicate how many services of the proposed intervention would be provided to an individual patient each year (if applicable)?

49 How many years would the proposed medical service(s) be required for the patient?

Indicate how many years the proposed medical service would be required for the patient, for example, is it a lifetime intervention? Please take into account any need to repeat the proposed medical service in particular circumstances, for example, does a pathology test need to be repeated overtime for monitoring purposes? If so, what is the time interval between repeat services and is this fixed or variable or a combination of both?

50 Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year.

What is the projected number of patients who will utilise the proposed medical service for the first full year of provision?

51 Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service.

What is the anticipated uptake of the proposed medical service over the next three years, including identifying any potential barriers that may affect the uptake rate.

Please identify any risk of usage that extends beyond the patient population that has been proposed, including any likely impact that the proposed medical service may have on existing MBS items.

PART 8 – COST INFORMATION

52 Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown.

Please provide an indicative fee of providing the proposed service. Please identify any equipment and consumable costs separately.

53 Specify how long the proposed medical service typically takes to perform.

Please provide information on the time taken to perform the proposed medical service. It is useful to the Department to separate and explain the time to prepare for the service (pre-service time), the time taken to perform the 'actual' service (intra-service) and the time taken post service (after care).

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

For each proposed MBS listing, please provide details in the outlined table.