Australian Government

Department of Health

MSAC Application Form Instructions

(Previously known as MSAC Application Form Guidelines)

For New and Amended Requests for Public Funding

Version 1 of *'Instructions'* – April 2021

(Noting these replace the previous 'Application Form *Guidelines')*

These instructions correspond to the current Application Form Template for new and amended requests for public funding. This includes funding through the Medicare Benefits Schedule (MBS) or alternative funding programs/arrangements. These instructions contain 'process-related' information for completing an MSAC Application Form**.** The separate MSAC Guidelines should be used to guide health technology assessment (HTA) content of the Application Form.

This document will continue to evolve, to reflect changes to the Medical Services Advisory Committee (MSAC) process, and feedback from stakeholders.

Suitability - These instructions describe detailed information the Department needs to determine if the proposed service/technology is suitable for MSAC assessment (including identifying the pathway and resource effort needed to progress the application through the MSAC process).

Targeted Consultation - Once suitability of an application has been determined, the Department will provide a completed and redacted version of the Application Form to relevant professional bodies/organisations. These include (but are not limited to): colleges/societies representing health professionals who would provide the service/technology; colleges/societies representing those who would request the service/technology *(in the case of investigative services only);* and organisations representing **consumers** (patients, carers, families and others).

If you need further assistance, Departmental staff are available in the Health Technology Assessment (HTA) Team, via the email address below.

Email: hta@health.gov.au
Website: www.msac.gov.au

1. INTRODUCTION

1.1 Purpose and role of the Medical Services Advisory Committee

The Medical Services Advisory Committee (MSAC) is an independent, non-statutory committee, established in 1998. It is comprised of individuals with expertise in clinical medicine, health economics and consumer matters.

MSAC appraises new medical services, health technologies and health programs for public funding, through an assessment of their comparative safety, clinical effectiveness, cost effectiveness and total cost, using best available evidence. This includes amendments and reviews of existing services on the Medicare Benefits Schedule (MBS), as well as new or amended services funded through alternative (**non**-MBS) programs (e.g. blood products, health screening programs, or other public services where funding is shared between the Commonwealth and States/Territories).

MSAC's published *Terms of Reference* require it to:

- Advise the Minister for Health on whether a medical service, health technology or health program should be publicly funded, based on evidence; and the circumstances (if any) that should apply to such funding;
- Have due regard to advice from States and Territories, where it is relevant to comparative safety, clinical effectiveness, cost effectiveness and total cost of a high cost therapy *(that is expected to be delivered in a public hospital setting, as set out in Appendix B-(B1) of the National Health Reform Agreement – Addendum 2020-2025);*
- Publish its advice and/or assessments to improve awareness on access to medical services, health technologies and health programs that Australians need, at a cost that individuals and the community can afford;
- Collaborate, where appropriate, with international health technology agencies, to share information and technical expertise so MSAC has access to (and is using) best available information and methodology in undertaking its assessments; and
- Provide advice to the Minister for Health and/or Department of Health (the Department) on evaluation of a medical service, health technology or health program for public funding that has been referred by other relevant bodies or committees.

MSAC may also establish sub-committees, so it can effectively undertake its role and functions. MSAC may delegate some functions to the MSAC Executive.

There is no obligation on Government to accept or implement the advice that 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 for clinically-relevant professional services provided by allied health, general practice and specialist medical practitioners. The key objective of Medicare is to ensure quality, accessible and affordable health care services.

1.3 Medicare Benefits Schedule (MBS)

The Medicare Benefits Schedule (MBS) provides publicly-funded rebates to patients for private medical (professional) services/technologies that are provided to private patients on a fee-for-service basis. The MBS facilitates universal access to certain allied health, general practice and specialist medical services. Public hospital and public clinic/day-surgery services *(including public out-patient services)* are not funded through the MBS.

The MBS lists and describes professional services where a Medicare benefit/rebate is payable, including the amount of that benefit/rebate, and any conditions applying to use of that service. The MBS changes from time-to-time, to reflect (for example) the availability of new medical services, changing medical practices, 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 MSAC does not evaluate specific devices, but evaluates the proposed medical service during which the device may be used to deliver the service, in the context of an MBS listing.

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

While most applicants to MSAC are seeking reimbursement under the MBS, MSAC is not restricted to providing advice around MBS funding. MSAC also provides advice in regards to non MBS funding where relevant. An Application Form should be lodged for all requests for public funding, regardless if funding is being sought under the MBS or an alternative funding program/arrangement.

1.4 MBS Reviews

In April 2015, the Australian Minister for Health announced formation of the Medicare Benefits Schedule (MBS) Review Taskforce. The Taskforce provided expert guidance to Government on reshaping the MBS to better support the quality of Australians' health care, and sustainability of Medicare.

The Taskforce has completed its review of the MBS, considering all individual MBS items, as well as rules and legislation governing their use.

The Department assesses how these reviews fit within the MSAC process, as well as considering potential impacts from MBS changes.

New MSAC applications received *(that are linked to MBS items reviewed by the MBS Review Taskforce)* will be aligned with advice and outcomes from those MBS reviews. The MBS Reviews Taskforce has referred its recommendations on new and novel services to MSAC, for consideration. This may eventuate in a request to a stakeholder that they lodge a new MSAC application. In these cases, potential MSAC applicants should always liaise with the HTA team (via hta@health.gov.au), prior to commencing the detailed process of populating and lodging an MSAC Application Form. Applicants should mention the link with MBS Review outcomes.

2. APPLICANT MATERIAL / DOCUMENTS

2.1 Commercial-in-Confidence material

Documents in possession of the Department of Health are subject to requirements of the *Freedom of Information Act 1982*. This means 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 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 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 made. Information on relevant Government policies is available at Australian Government Solicitor - 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

A redacted version of the Application Form will be provided to professional bodies/organisations and consumer organisations that have been identified in Part 5 of the Application Form. It will also be provided to any additional groups the Department deems appropriate/relevant for consultation. This will occur after 'suitability' of the proposed medical service has been determined.

The redacted Application Form will also be published on the application's individual webpage on the MSAC website (so interested stakeholders can provide comments by two cut-off dates prior: (1) to the first sub-committee stage of the MSAC process; and (2) to the second sub-committee stage of the MSAC process. This occurs after 'MSAC suitability' has been determined by the Department. The webpage is publicly available, and can be viewed by all interested stakeholders (in Australia and internationally).

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 the proposed service is suitable for MSAC's consideration.

- Would the proposed medical service be regarded (by the relevant profession) as being 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 in many circumstances, screening services.
- Would the proposed medical service be likely to meet the Government's current policy parameters for funding professional services under Medicare?
- If not seeking funding through the MBS, can you identify an alternative, existing public funding program/arrangement that may apply for the medical service, health technologies and health program?

If you are uncertain if a proposed service is suitable for consideration of public funding, please contact the HTA Team (in the Department of Health), via hta@health.gov.au. Alternatively, you could seek guidance from the relevant medical/health **college or 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 change to an existing service). Please note that the MSAC process is for evidence-based **health technology assessment (HTA)** of a new or amended medical service, health technology or health program.

MSAC is not the process for seeking information on billing or reimbursement/rebates for a service that has been provided to a patient, and billed by their practitioner.

3.3 When to lodge an application to MSAC

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

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

The HTA Team processes applications after the MSAC application lodgement cut-off date. These can be found on the MSAC website, under the PASC Calendar Key dates: (http://www.msac.gov.au/internet/msac/publishing.nsf/Content/pasc-calendar-key-dates)

The time taken for an application to be determined 'suitable' will depend on completeness of Application Form, quality of evidence, complexity of service, and complexities of policy considerations.

To assist Applicants in tracking progress of their applications, an Application Manager will be assigned to each application. An Application Manager will support Applicants through the process, and work with them to assist decision-making about the application. As major documents are ratified (e.g. PICO Confirmation and Public Summary Documents), those documents are usually uploaded to MSAC website (on the application's individual webpage).

4. APPLICANT WITHDRAWAL FROM THE PROCESS

An Applicant may request their MSAC application be withdrawn at any time.

Applicants should note the following (if MSAC has completed its consideration of an application, and the Applicant then seeks withdrawal of 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) MSAC's advice about that application may still be provided to Government.

5. REGULATORY REQUIREMENTS

All therapeutic goods used in 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, as long as the Applicant has evidence the relevant sponsor/manufacturer has commenced the TGA process. Confirmation of inclusion of a product on the ARTG is required before MSAC can finalise its own appraisal of the corresponding medical service/technology.

Further information on how therapeutic goods are defined can be found at www.tga.gov.au.

6. ADVICE TO THE MINISTER

After MSAC's consideration (of an MBS-related service), the Department of Health is required to consider final financial impact to Government, consult further with relevant stakeholders (if necessary), seek agreement from Cabinet, and draft and implement legislative change(s) to amend or add an item to the MBS. It should be noted there is no obligation on Government to accept or implement MSAC's advice.

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

This must be the main applicant 'organisation or individual' (**not a consultant or lobbyist** acting for the applicant). *Information on lobbyists and consultants is sought in Question 2 below.*

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

Where the Applicant is a professional medical/health organisation, please ensure the person nominated as the primary *(and secondary)* contact can assist with Departmental enquiries about the application.

These details will be used by the Department to contact the Applicant about status of their application.

The Department should be notified about any changes to these details (as soon as they occur), as the Department will **not** communicate with a person who is not the primary (or secondary) contact.

If the primary contact is not available, the Department will only communicate with an alternative contact (if provided by the Applicant).

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 for the Applicant?

If yes, please provide details about the applicant organisation.

In 2008, the Australian Government introduced a Lobbying Code of Conduct and established a Register of Lobbyists. This ensures 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 purpose of lobbying Government representatives) must be registered on the Register of Lobbyists, and must comply with 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 Prime Minister and Cabinet. Further information is available at: http://lobbyists.pmc.gov.au/.

(c) Have you engaged a consultant to act on your behalf?

If 'yes', you must provide the name and contact details of that consultant. Any correspondence from the Department will be sent to the **primary applicant contact *(and secondary contact if one is provided),* as well as the consultant**. If the consultant's role finishes, you must inform the Department as soon as possible (so the Department can remove that consultant from its email distribution list for that application).

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, population, and specific indications (where applicable).

While there have been a small number of exceptions in the past, **no trade names** should be included in the title **(i.e. the title should be brand-agnostic).** If specific technology components/parameters of technology function/performance forms part of MSAC's advice, these would be included in the eventual listing/funding description (if necessary). Examples of application titles can be found on individual application 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/finesse wording, but will consult with the Applicant about this. The Department retains the right to refuse to publish information provided by the Applicant, if the Department considers the information to be inaccurate, misleading or advertorial in nature.

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

Please limit the description to 150 words. **Ensure it is clear to a person without a scientific or clinical background.** Examples of descriptions of medical conditions can be found on individual application webpages on the MSAC website.

Once MSAC '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/finesse wording provided, but will consult with the Applicant about this. The Department retains the right to refuse to publish information provided by the Applicant, if the Department considers the information to be inaccurate, misleading or advertorial in nature.

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

Please limit the description to 150 words. **Ensure it is clear to a person without a scientific or clinical background.** Claims of therapeutic or diagnostic performance, cost effectiveness or strength of evidence **should not be included** in this description. Examples of succinct descriptions of medical services can be found on individual application webpages on the MSAC website.

Once 'MSAC 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/finesse wording provided, but will consult with the Applicant about this. The Department retains the right to refuse to publish information provided by the Applicant, if the Department considers the information to be inaccurate, misleading or advertorial in nature.

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 that is listed on the MBS. A medical service is clinically relevant if it is generally accepted by the medical profession as being necessary for appropriate treatment of the patient.

Please state if this is a request for MBS funding. If the proposed service is seeking public funding from other *(non-MBS)* sources of public funding, please state this at Question 6(f).

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

Please state if this proposal is to amend an existing MBS item/s – i.e. any change to an existing MBS item. Further information on an amendment to an existing MBS item/s is requested in Questions 6(c) and 6(d).

Please state if a new MBS item number/s is being sought. Further information is requested in Questions 6(e) and (f).

(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/technology:

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

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

Sub-questions in Part 7 help determine the nature of the amendment, and how they will be classified to determine the most appropriate MSAC pathway. They also provide guidance on alternative options if MSAC is not appropriate.

Depending on *degree* of the amendment, some will not require a full health technology assessment (HTA). If suitable, they may even need an alternative (non-HTA) pathway. The nature of the amendment also influences intensity of the process (i.e. is PASC required), if an HTA is to be conducted.

i. An amendment to the way the service/technology is clinically delivered under existing item(s)/funding, where intended use of an existing item/funding would be expanded to include a new medical condition (that is completely different to the medical condition currently eligible under existing item(s)/funding).

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

iii. An amendment to the MBS fee for an existing MBS item, where there is nothing to compare clinically (because the clinical service essentially remains the same).

iv. An amendment to the time and complexity of an existing item(s)/service, where there is nothing to compare clinically (because the clinical service essentially remains the same) – e.g. time-tiered initial and subsequent-attendance MBS items.

v. Access to an existing item(s)/service 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 MBS 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 wording in an existing item descriptor, without altering its intended use, or changing a service description that corrects terminology that is not technically correct or is ambiguous;
- a change that addresses a typographical error, or align an item descriptor with regulations (e.g. inclusion of a missing word, to correct an error); and
- a change that proposes removal of a reference to brand names in an existing item descriptor, therefore making wording of the descriptor brand and device agnostic.

vii. An amendment to an existing 'consultation' item, where a single model of care is proposed to be the only clinical encounter covered by that service (e.g. one type of clinical encounter is included in the item descriptor).

viii. An amendment to an existing 'global' (broadly-based) consultation item (which are professional attendance items on the MBS that accommodate a range of clinical encounters under one MBS item) – e.g. 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 MBS item(s) is being requested, what is the nature of the change to the MBS?

Question 6(e) helps determine the nature of the new item being sought, and how they will be classified to determine the most appropriate MSAC pathway. It also provides guidance on alternative options if MSAC is not appropriate. Depending on the request for a new item(s), some will not require an HTA, and may require an alternative, non-HTA pathway. The nature of the new service also influences intensity of the process (i.e. is PASC required), if an HTA is to be conducted.

i. A new item(s) which 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).

ii. A new item that proposes a new way of clinically delivering a service on 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 (broad-based) consultation attendance items that cover multiple clinical encounters;
- codependent applications to subsidise an investigative and therapeutic medical service, where one depends on the other; and
- codependent applications to cover time and complexity of administering delivery of a drug.

iii. A new item that proposes a specific/single consultation item (where a single model of care would be the only clinical encounter covered by the service) – i.e. one issue is included in the item descriptor.

vi. A new item that proposes a global (broadly-based) consultation item, where a range of clinical encounters are proposed (e.g. a health practitioner group requesting new 'general' professional attendance items).

(f) Is the proposed service seeking public funding other than the MBS (i.e. alternative funding program/arrangement)?

Please state if the proposed service is seeking public funding outside the MBS (i.e. no MBS item is intended). This can include blood products, screening programs (where the MBS may not be relevant/appropriate), or shared Commonwealth and State/Territory funding, such as that provided through the National Health Reform Agreement [NHRA]).

Advice provided by MSAC on blood products will be considered as defined under Schedule 4 of the *National Blood Agreement*.

It should be noted that, unless the Minister provides direction, Medicare benefits/rebates are generally not payable for health screening services.

However, the Minister has directed that Medicare benefits/rebates be paid for some categories of health screening. These include medical examinations or tests on asymptomatic patients in the course of normal medical practice. This ensures patients receive medical advice or treatment that is necessary to maintain their health. Benefits/rebates would be payable for the consultation 'attendance' and associated tests which are considered reasonably necessary (based on a patient's individual circumstances).

(g) If yes, please advise

Please provide further information if you are seeking public funding through an alternative funding program/arrangement (i.e. not the MBS).

8. What is the type of medical service/technology?

Please identify the type of service/technology you are seeking funding for.

A ***therapeutic medical service*** is a service that impacts on health outcomes *directly* (i.e. no other intermediate medical service needs to be provided to achieve improvement in health outcomes). Examples include novel surgical techniques, 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 evidence that needs to be presented to MSAC. This is expanded on in Section 2A – Assessment of therapeutic technologies, in the MSAC Guidelines.

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 would usually result in a change in 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 evidence that needs to be presented to MSAC. This is expanded on in Section 2B – Assessment of investigative technologies, in the MSAC Guidelines.

Consultation medical services are services that tend to combine an investigative component (e.g. clinical history, examination, and requesting investigations) and a therapeutic component (e.g. execution of a

management plan) for the patient. Taking a history and examining a patient is essential for a medical consultation, with information *(that is clarified by this clinical assessment)* assisting the health practitioner to determine what should happen next (in terms of investigations and patient management/treatment).

- A ***single consultation medical service*** is where the service explained in the item descriptor is a specific 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 MSAC.

An ***allied health service*** is a service not undertaken by an eligible medical, nursing, midwifery or dental health professional (i.e. it is undertaken by an eligible audiology, physiotherapy, podiatry, psychology, etc. professional)

A ***codependent technology*** occurs where use of one health technology (to directly improve health outcomes) – e.g. a medicine, medical device or procedure - is improved by use of another health technology - e.g. a pathology or imaging technology - and where both technologies require consideration for public funding. Additional guidance on codependent technologies can be found in Technical Guidance (TG) 2 – PICO, TG 15.6 – Codependent technologies, and in Appendix 8 – Codependent technologies of the MSAC Guidelines.

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

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

If you are seeking an investigative service, please state 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 genetic variations 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 genetic variation, 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 on in Section 2B – Assessment of investigative technologies, in the MSAC Guidelines. For tests on heritable genetic variations, see TG 2.1 – Genetic testing, and the subsequent sections referenced.

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

Please state if the proposed medical service relies on a pharmaceutical/biological product, 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 tissue (such as human heart valves, corneas, bones [part and whole] and muscle tissue). Further information on the definition of a prosthesis (and a detailed explanation of whether a device associated with a proposed service is relevant to the Prostheses List) can be found on the Department's website: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm

Further explanations 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 state 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 state 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 state the PBAC submission number.

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

Please state the trade and generic names of the pharmaceutical.

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

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

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

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

If the proposed service/technology is dependent on use of a prosthesis, please state the Prostheses List billing code(s), trade and clinical names of the prosthesis, and any other device components 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 state the PLAC application number.

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

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

Please state if there are other sponsor(s) and/or manufacturers that have a similar prosthesis or implantable device, relevant to your application.

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

If Question 11(d) is relevant to your application, please provide 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.

MBS items generally describe the professional service, without specifying a particular brand of device delivered as part of the service. This is so other 'equivalent' devices may not necessarily need separate MSAC assessment or MBS listing. However, MSAC reserves the right to restrict funding of a medical service so that it accommodates use of a particular brand or device and not others (because of safety, clinical effectiveness, cost-effectiveness or total cost impacts).

On a case-by-case basis, MSAC would provide a rationale for this.

When an application is subjected to a broader assessment across multiple device options, MSAC observes procedural fairness and commercial-in-confidence issues.

After receipt of an MSAC Application Form, Departmental HTA and medical advisers (together with the PLAC Secretariat) assesses the broader clinical landscape. This ensures other relevant sponsor(s) and/or manufacturer(s) with a similar prosthesis or implantable device have been identified in the Australian market.

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

Please list any single and/or multi-use consumables used as part of the proposed service (e.g. catheters, electrodes, syringes and needles, bandages and dressings etc.). Medical consumables tend to be non-durable and/or disposable in nature, and are often restricted to single use per patient. In some circumstances, these consumables can be expensive.

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

14. (a) If the proposed medical service involves 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 answers you have provided under other questions, but we need that information briefly summarised here. This summary will enable the Department to identify if the TGA needs to be contacted (to confirm regulatory status of a particular therapeutic good(s) associated with the MSAC application).

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

(b) Has it been listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? If the therapeutic good has been listed on the ARTG, please state the ARTG identification numbers, TGA-approved indication(s), and TGA-approved purpose(s).

If applicable, please state the ARTG ID, TGA approved indication(s) and TGA approved purposes(s).

(c) If a medical device is involved, has the medical device been classified by TGA as a Class III OR Active Implantable Medical Device (AIMD) under 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 is not in the process of being listed/registered/included by the TGA, an application will not be eligible for MSAC's consideration.

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

For more information on these classifications, please see the TGA website:
https://www.tga.gov.au/sites/default/files/devices-argmd-p1-01.pdf

(d) Is the therapeutic good classified by TGA for Research Use Only (RUO)?

Indicate whether the therapeutic good classified is for Research Use Only (i.e., where there is no reporting of patient/client results).

15. (a) If not listed on the ARTG, is the therapeutic good exempt from regulatory requirements under the *Therapeutic Goods Act 1989*?

Approval may be based on a full evaluation (where an Australian Registration [Aust R] number is provided) or a detailed evaluation of efficacy (with no safety having been reviewed), with an Australian Listing [Aust L] being provided.

If there is an exemption, please provide supporting documentation as an attachment to your Application Form.

(b) If the therapeutic good is not ARTG listed, is the therapeutic good in the process of being considered by TGA?

If the therapeutic good is in the process of being considered by TGA, please state the date of submission to TGA, estimated date of approval, TGA Application ID, anticipated TGA indication(s), and anticipated TGA purpose(s).

(c) If the therapeutic good is NOT in the process of being considered by TGA, is an application to TGA being prepared?

Please state if an application is being prepared, together with estimated date of submission, proposed indication(s), and proposed purpose(s).

For all answers provided above, please note the Department will confirm this information with TGA.

PART 4 – SUMMARY OF EVIDENCE

16. Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. *At 'Application Form lodgement', please do not attach full text articles; just provide a summary.*

Provide a summary of key journal articles/research projects most likely to be relevant to MSAC's assessment of the merits of the proposed service/technology.

Providing this summary enables the Applicant to signal the likely evidence base for the subsequent Assessment Report (as long as this evidence remains relevant, following finalisation of the Ratified PICO).

Two of the most frequently-used databases to undertake a search are Medline and Embase.

Please state the specific type of study design, title of the study, short summary of the study, website link to the study, and date the study was published. A table has been provided in the Application Form to capture this information.

The provision of information on evidence is simply to provide a snapshot of the evidentiary landscape. This will enable Departmental HTA and medical advisers to assess broad availability (and status) of the body of evidence/trials. This has implications for timing of the assessment through MSAC.

At Application Form lodgement, Applicants are not expected to provide a detailed analysis of the body of evidence (i.e. what it is saying or likely to say).

17. 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.

If published studies are unavailable, the Application Form should contain sufficient information about 'yet-to-be-published' articles or research (that may provide future results to MSAC). MSAC needs to be confident there are no current trials or studies underway (that are likely to influence their advice).

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

For Questions 17 and 18, the Department's HTA and Medical Advisers will verify (via a general search of key clinical trial databases and registries, such as www.clinicaltrials.gov) when results are likely to available for key studies.

Applicants are welcome to submit unpublished evidence relevant to MSAC's consideration, as part of the subsequent Assessment Report *(as long as this evidence has been accepted for peer review publication, and the proposed publication date falls relatively close to the date of the MSAC meeting).*

In this section, Applicants should **also** flag if they are aware of 'grey literature' (e.g. individual patient data), that may be pertinent to their application.

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

18. List all appropriate professional bodies/organisations representing the health professionals who provide the service. For MBS-related applications ONLY, please attach a brief 'Statement of Clinical Relevance' from the most relevant college/society.

List all appropriate professional bodies/organisations representing the health professionals that provide the proposed service.

For MBS-related applications, please obtain a 'Statement of Clinical Relevance' from the most relevant professional medical college/society, where they succinctly state their 'in-principle' support for the proposed service.

- The Statement of Clinical Relevance can be in the form of a simple email, from an authorised officer in the most relevant professional college/society. The email should succinctly state they support commencement of a process towards MSAC/Government consideration of a particular application. *Specifically, is the proposed service regarded as being 'clinically relevant' by that sector of the Australian medical profession (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.* **This is a key requirement for MBS listing.**

The Applicant should also provide a complete list of appropriate professional bodies/organisations, who will be targeted (i.e. contacted) at a later date, by the Department. The Department will provide a redacted version of the Application Form to identified stakeholders (so they can provide their feedback), along with others that may not have been identified by the Applicant.

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

Identify any impact on different/other professional groups, as well as the MBS items (or alternatively-funded programs/products) that those other groups provide services under.

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

20. List the consumer organisations relevant to the proposed medical service (noting there is NO NEED to attach a support letter at the 'Application Lodgement' stage of the MSAC process):

Identify consumer organisations relevant to the proposed medical service. Although MSAC's assessment is based on clinical trial evidence, MSAC and the Department place high importance on considering the views of consumers (and their experiences with the proposed service).

The Department will contact these groups, during the 'Targeted Consultation' stage of the MSAC process.

21. List relevant sponsor(s) and/or manufacturer(s) that produce <u>similar</u> products/technologies to the one used/delivered under the proposed service:

Identify relevant sponsor(s) and/or manufacturer(s) that produce similar products/technologies to the one that will be delivered during the proposed service.

22. Nominate two experts that can be contacted about the proposed medical service, and current clinical management of the condition

Please provide contact details for two clinical experts that can be contacted by: the Department; HTA Groups contracted by the Department; and/or MSAC and its sub-committees. These experts must have the capacity to spend some time providing clinical advice during MSAC's assessment (usually by email).

Also, given Applicants are invited to attend the PICO Advisory Sub-Committee Meeting (where their PICO Confirmation will be discussed), Applicants are encouraged to have appropriate experts attend with them.

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

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

<u>PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION</u>

<u>Additional guidance on this section can be found in TG 2 – PICO, of the MSAC Guidelines.</u>

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

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

24. Specify the characteristics of patients with (or suspected of having) the medical condition, who would be eligible for the proposed medical service/technology (including details on how a patient would be investigated, managed and referred within the Australian health care system, in the lead up to being eligible for the service):

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

Please also specify <u>other patients</u> who may need to access the service/technology (who may form part of MSAC's evaluation).

<u>PART 6b – INFORMATION ABOUT THE INTERVENTION</u>

25. Describe key components and clinical steps involved in delivering the proposed medical service/technology:

Explain the central components pertinent to delivering the service/technology.

26. 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.

27. 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.

28. If applicable, are there any limitations on provision of the proposed 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.

29. 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 (pharmaceuticals, diagnostics and investigative 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.

30. If applicable, state 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.

31. If applicable, state 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.

32. 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.

33. If applicable, state 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.

34. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

Please indicate all relevant setting(s) in which the proposed 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 service can be performed in more than one setting, describe the rationale for each setting (e.g. some services can be delivered in consulting rooms, while some services should only be delivered in a hospital building [or day clinic, either within or separate from hospital grounds]. Please indicate if the patient should be an admitted patient (i.e. in-hospital status), or could be either admitted (in-patient) or non-admitted (out-patient).

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

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

PART 6c – INFORMATION ABOUT COMPARATOR(S)

36. Nominate the appropriate comparator(s) to the proposed service/technology (i.e. how is the proposed population currently managed in the absence of the proposed medical service in the Australian health care system). This includes identifying health care resources that need to be delivered at the same time as the comparator service.

Outline the comparator (alternative intervention) currently used to manage the patient population proposed in Part 6a. Identify any healthcare resources (pharmaceuticals, diagnostics and investigative services, etc.) currently performed in association with the comparator.

For an investigative medical service, please make the distinction between the comparator versus the reference standard. Please refer to Section 1, TG 2.3 – Comparator, in the MSAC Guidelines for further guidance.

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

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

38. (a) Will the proposed service/technology be used in addition to, or instead of, the nominated comparator(s)?

Will the proposed service/technology replace or supplement the current service/comparator?

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

If the proposed service/technology will replace the current medical service/comparator, describe how it will differ from what is currently available (and its potential advantage).

PART 6c CONTINUED – INFORMATION ABOUT ALGORITHMS (CLINICAL MANAGEMENT PATHWAYS)

39. Define and summarise the CURRENT clinical management pathway (algorithm) that patients follow when they receive the COMPARATOR service (i.e. the landscape before the proposed service is introduced). An easy-to-follow flowchart is preferred, depicting the current clinical management pathway), but dot-points would be acceptable. Please include health care resources used in the current landscape (e.g. pharmaceuticals, diagnostics and investigative services, etc.).

Also explain the differences (if any) in pathways if alternative (other) comparators have been identified.

40. Define and summarise the PROPOSED clinical management pathway (algorithm) that patients would follow after the proposed service/technology is introduced, including variation in health care resources.

As above, please provide a flowchart/diagram (or dot-points if this is not possible), demonstrating how the clinical management pathway/algorithm would change after the proposed service/technology was introduced.

Please include health care resources that would change (e.g. pharmaceuticals, diagnostics and investigative services, etc.).

PART 6d – INFORMATION ABOUT CLINICAL OUTCOMES

41. Summarise the clinical claim for the proposed service/technology, against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Briefly outline specific clinical claim in this section, whether the proposed service/technology is 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 conducted during the 'evaluation' stage of the MSAC process. Please refer to TG 1.2 – Defining clinical claim in the MSAC Guidelines.

42. Please state what the overall clinical claim is:

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

Briefly outline in this section whether the application will put forward an 'overall' claim that the proposed medical service is either non-inferior (no worse than main comparator) or superior to its main comparator, depending on combined effect of claims. This has implications on the nature of evidence that needs to be presented to MSAC. This is expanded on in TG 1.2 – Defining clinical claim in the MSAC Guidelines.

43. 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):

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 in an MSAC application.

Once a list of relevant outcomes has been compiled, Applicants should prioritise 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 analysed, if the application identifies relevant studies. Conclusions about **effects of the intervention/s** will be largely based on these outcomes.

In general, there should 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 listed as minor outcomes. In addition, **minor outcomes may include a limited number of additional outcomes the application intends to address.** These may only be specific to some applications (e.g. laboratory tests and other surrogate measures may not be considered main outcomes, as they are less important than **clinical endpoints** in informing decisions).

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

44. Estimate the prevalence and/or incidence of the condition in the proposed population:

Briefly outline key epidemiological facts about prevalence and/or incidence of the condition. Please communicate this in terms of prevalence in the broader Australian population, as well as **number of patients (percentage) with the condition who would use the proposed service/technology**?

45. **Estimate the number of times the proposed medical service/technology would be delivered to an individual patient per year:**

    e.g. once, twice, only once per lifetime, etc.?

46. **How many years would the proposed medical service/technology be required for the patient?**

    If more than once per lifetime, indicate **how many years the proposed service would be required for the patient?** Take into account the need to repeat the proposed service, and state when and why the service would need repeating (e.g. does a pathology test need to be repeated for monitoring purposes or to determine success of treatment)? If so, what is the time interval between repeated services, and is this fixed or variable per patient?

47. **Estimate the expected number of patients who would utilise the proposed service/technology in the first full year.**

    What is the expected number of patients who would utilise the proposed service in the first full year of provision?

48. **Estimate the anticipated uptake of the proposed medical service/technology over the next three years, factoring in any constraints in the health system in meeting needs of the proposed population (such as supply and demand factors), as well as commentary on risk of 'leakage' to populations not intended for the service.**

    What is the anticipated uptake of the proposed medical service over the next three years? Please identify potential barriers that may affect the rate of uptake.

    Please identify risk of usage that extends beyond the proposed patient population, including likely impact the proposed medical service may have on existing MBS items or other (non-MBS) services.

PART 8 – COST INFORMATION

49. **Indicate the likely cost of providing the proposed service/technology. Where possible, please provide overall cost and breakdown:**

    Please provide an indicative fee/price for providing the proposed service. Please identify equipment and consumable costs **separately from the 'professional service' component of the fee/price**.

50. **Specify how long the proposed medical service/technology typically takes to perform:**

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

51. **If public funding is sought through the <u>MBS</u>, please draft a proposed MBS item descriptor to define the population and usage characteristics that defines eligibility for the medical service/technology.**

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

52. **If public funding is sought through an <u>alternative (non-MBS) funding arrangement</u>, please draft a service description to define the population and usage characteristics that defines eligibility for the service/technology.**

    For each proposed listing, please provide details in the table (removing any MBS references)