Australian Government
Department of Health

Consultation Paper

Proposal for a cost recovered pathway for Medical Services Advisory Committee (MSAC) applications

4 January 2022

WE WOULD LIKE YOUR FEEDBACK

We invite you to lodge a submission on this paper by no later than **5pm on Friday 18 February 2022** through the Consultation Hub.

Please note that feedback received after this date may not receive consideration.

The Department of Health (the Department) is seeking feedback on any issues that respondents consider relevant to the proposal.

Consultation submissions may range from a brief comment or short letter outlining your views on a particular topic to a more substantial document covering a range of issues.

Respondents should support their submission with evidence.

Each submission and comment, except where supplied in confidence, will be considered for publication on the Department's website, and if published, remain indefinitely as a public document.

If respondents would like their feedback to remain confidential, please mark it as such, or indicate which sections should be confidential, and which are appropriate for publication. It is important to be aware that confidential feedback may still be subject to access under Freedom of Information laws. The Freedom of Information process usually includes consultation with the respondents prior to a decision about the release of information.

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INTRODUCTION

This paper seeks your feedback on a proposed cost recovered Health Technology Assessment (HTA) pathway for applications to the Medical Services Advisory Committee (MSAC).

This proposal seeks to address one of the key recommendations (recommendation 31) from the House of Representatives 'Inquiry into approval processes for new drugs and novel medical technologies in Australia' titled The New Frontier – Delivering better health for all Australians that was tabled on 25 November 2021. This recommendation includes that the Department should, in consultation with relevant stakeholders, introduce fees for MSAC applications on a cost recovery basis as a means to increase the speed and efficacy of MSAC assessments. This proposal subsequently provides a mechanism to allow for shortened processing timeframes for MSAC applications through the implementation of fees.

The introduction of cost recovery arrangements will offer benefits to applicants in terms of greater clarity, transparency, and certainty of timeframes for MSAC processes. Currently the existing MSAC processes do not have formalised definitive timeframes. The proposed cost recovered pathway will have definitive timeframes for applicants lodging an application with complete information in accordance with MSAC requirements. Standardised redaction criteria for the application form and the Public Summary Documents (PSD) will also be developed to expedite this process and ensure consistency for stakeholders responding to consultations.

The MSAC timeframes will be standardised with:

- 6 weeks for triage and suitability;
- 4 months for PICO Advisory Sub-committee (PASC) consideration;
- 24 weeks from receipt of complete application to MSAC consideration; and
- 8 weeks for release of MSAC minutes to the applicant.

MSAC provides advice to the Australian Government (Government) on whether medical services, health technologies and health programs should be publicly funded (and if so, in what circumstances) based on an assessment of the best available evidence of its comparative safety, clinical effectiveness, cost-effectiveness and total cost.

MSAC was originally established to provide advice on funding for services through the Medicare Benefits Schedule (MBS). Due to its broad remit and wide range of expertise, MSAC's role has expanded to undertake assessment of codependent technologies, and health technologies and services funded by other (non-MBS) mechanisms.

The expansion of MSAC's role has led to the evolution of MSAC processes and diversion of MSAC resources to assess a broader range of applications seeking funding from non-MBS sources. Stakeholder feedback shows that applicants desire greater clarity, transparency, and certainty of timeframes for MSAC processes.

This paper is intended to inform advice to Government on a proposal to introduce cost recovery to align the MSAC program with the whole of Government cost recovery policy in line with the Australian Government Charging Framework.

HOW WILL WE USE YOUR FEEDBACK?

The Department will consider feedback from this consultation alongside recommendations from the final report on *House of Representatives 'Inquiry into approval processes for new drugs and novel medical technologies in Australia'* titled The New Frontier – Delivering better health for all Australians.

Implementation of the proposal including changes to process will be subject to Government consideration and agreement and will require passage of legislation to enable charging.

Consultation feedback will also assist in planning the implementation approach and identifying any unintended consequences for introduction of cost recovered HTA pathway for MSAC. If the proposal is agreed by Government, further consultation would occur through the development of a Cost Recovery Implementation Statement (CRIS) to ensure stakeholder concerns and regulatory impacts are addressed, prior to the commencement of charging.

Guidance and education material including cost recovery administrative guidelines, updates to the MSAC process framework, process maps and timelines will be developed to ensure smooth transition and successful implementation of the cost recovered pathway.

HEALTH TECHNOLOGY ASSESSMENT IN AUSTRALIA

The Government conducts HTA for a wide range of health technologies to determine if they are clinically relevant and whether public funds should be spent to subsidise access for Australians. Different HTA bodies undertake these assessments:

- The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent expert body appointed by the Government. Members include doctors, health professionals, health economists and consumer representatives. PBAC makes recommendations about new medicines for listing on the Pharmaceutical Benefits Schedule (PBS).

- The Life Saving Drugs Program (LSDP) Expert Panel is an independent expert body appointed by the Government. The LSDP Expert Panel advises the Chief Medical Officer about the listing of medicines for rare diseases on the LSDP. This process relies on HTA undertaken by the PBAC, as applications for listing must first go to PBAC. If the PBAC finds that the medicine is clinically effective but not cost effective, the sponsor can seek LSDP listing. The LSDP Expert Panel assesses whether the medicine meets the LSDP's eligibility requirements, drawing on the HTA undertaken by the PBAC.

- MSAC is an independent non-statutory committee comprised of a broad range of medical, surgical, and other health experts including general practitioners, oncologists, epidemiologists, cardiologists, pathologists, surgeons, health economists and consumer representatives.

Applications considered by the Medical Services Advisory Committee

MSAC is responsible for the HTA of applications seeking an MBS listing. Its role has also expanded to include advising on a range of other medical services, health technologies and health programs.

This includes:

- Codependent applications - A codependent application occurs when MSAC is asked to assess a medical service that relies on another technology to achieve its intended purpose or enhance its effect. Codependent applications are those seeking subsidy under different schemes. For example, when PBAC assesses a medicine that requires a diagnostic test to determine whether the PBS listed drug can be prescribed. The PBAC would evaluate the medicine, while MSAC will assess the diagnostic test.

- Blood products - New, innovative, high-cost treatments are rapidly emerging in the blood sector. Under the National Blood Agreement, a product change proposal must first be registered with the Therapeutic Goods Administration (TGA) and provided to

the National Blood Authority (NBA)[1] for assessment. It will then be considered by the Jurisdictional Blood Committee (JBC) which may refer the product for MSAC evaluation of the comparative clinical and cost effectiveness of the technology. If MSAC supports funding a product, the NBA will then seek JBC's agreement to supply before a funding decision is made by all Health Ministers to include the product on the National Product Price List (NPPL).

- Prostheses products - Technologies that are first-in-class or other breakthrough technologies that are likely to have a significant financial impact on the health system are referred to MSAC. MSAC provides advice to PLAC on the suitability of the medical device for listing on the PL and may also provide advice to Government on the listing of an associated service on the MBS. Sponsors may make applications to list devices on the PL at the same time as the associated service is considered by MSAC. Devices will not be listed on the PL until an item for the associated service is included on the MBS.

- High cost, highly specialised therapies (HSTs)[2] - These therapies are defined as being administered to public hospital in-patients and cost over $200,000 as per the 2020-25 National Health Reform Agreement (NHRA), with funding determined by the Independent Hospitals Pricing Authority. Technology suppliers submit applications directly to the Department seeking a HTA of the therapy by MSAC.

- Other health technologies seeking public funding from established non-MBS sources, such as the National Diabetes Services Scheme (NDSS) and pharmacy programs.

MSAC is supported by two sub-committees, the PICO[3] Advisory Sub-committee (PASC) and the Evaluation Sub-committee (ESC). Information relating to the current MSAC Terms of Reference, each sub-committee and the current processes are outlined at **Attachment A**.

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[1] *The role of NBA is to ensure an adequate, safe, secure, and affordable supply of blood products, and blood-related products and services in Australia.*

[2] '*Means TGA approved medicines and biologicals delivered in public hospitals where the therapy and its conditions of use are recommended by MSAC or PBAC; and the average annual treatment cost at the commencement of funding exceeds $200,000 per patient (including ancillary services) as determined by the MSAC or PBAC with input from the IHPA; and where the therapy is not otherwise funded through a Commonwealth program or the costs of the therapy would be appropriately funded through a component of an existing pricing classification.' Addendum to the National Health Reform Agreement 2020-25, p.90.*

[3] *PICO – Population Intervention Comparator and Outcomes*

WHY MAKE CHANGES?

The Department is seeking to align MSAC funding arrangements with the Australian Government Charging Framework, which outlines the Government's policy on cost recovery:

"Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for it unless the government has decided to fund that activity. Where it is appropriate for the Australian Government to participate in an activity, it should fully utilise and maintain public resources, through appropriate charging. The application of charging should not, however, adversely impact disadvantaged Australians."

Charging for government activities can:

- promote equality, whereby the recipients who create the need for a government activity, rather than the public, bear its costs;
- influence demand for government activities;
- improve the efficiency, productivity and responsiveness of government activities and accountability for those activities; and
- increase cost consciousness for all stakeholders by raising awareness of how much a government activity costs.

The services for listing on the PBS and the PL, including costs associated with Government HTA committees (PBAC and PLAC), are cost recovered.

Pharmaceutical Benefits Scheme Listing Cost Recovery

The PBS cost recovery arrangements include fees for various submission categories based on an activity-based costing model that reflects the efficient costs of providing PBS and National Immunisation Program (NIP) evaluation and listing services to industry. Refer to the *Cost Recovery Implementation Statement for listing of medicines on PBS and designated vaccines on NIP* for additional information.

Prostheses List Administration Cost Recovery

The Prostheses List Advisory Committee (PLAC) is a committee composed of an independent Chair and individuals with expertise in HTA, specialist surgery/interventional work, health economics and consumer issues, and representatives of stakeholders in private health insurance. PLAC makes recommendations about the listing of medical devices on the Prostheses List (PL).

The cost recovery arrangements for PL listing consists of three fee categories – an application fee, initial listing fee and ongoing listing fee. These arrangements have not been adjusted since 2008. Refer to the *Cost Recovery Implementation Statement for PL administration* for additional information.

In the 2021-22 Budget, the Government committed $22 million over four years to improve and modernise the PL and its arrangements. Building on the previous reform activities, the Government has agreed to maintain the PL, with some improvements including an update to the existing cost recovery arrangements to align with the Australian Government Charging Framework.

Consistent with the announcement from the 2021-22 Budget, the Department's Prostheses List Reform Taskforce will be considering improvements to the listing process. This includes developing fit-for-purpose application and assessment pathways. Each pathway will have varying levels of complexity and administration.

One of the pathways will be using MSAC services for new and novel devices or incremental change to existing devices that require HTA and the outcome of which is Prostheses listing. This includes Prostheses applications with and without an associated MBS service (i.e. codependent technologies). The pathway that utilises MSAC processes will be subject to the fee categories applicable under the proposed cost recovered MSAC pathway, pending decision by the Government. A separate consultation process will be undertaken on proposed criteria and changes to PL listing processes and cost recovery arrangements.

Approach to MSAC Cost Recovery

The MSAC assesses approximately 45 applications each year which includes applications seeking HTA for MBS listing, codependent applications with the PBS and PL, and shared funding arrangements such as blood products and NHRA. These applications are received from a mix of commercial and non-commercial entities.

The MSAC process comprises:

- An application form
- A PICO confirmation for a medical service, health technology or health program
- An Assessment Report[4] that is either:
    - An Applicant Developed Assessment Report (ADAR) – applicants can decide to prepare their own Assessment Report; or
    - A Department Contracted Assessment Report (DCAR) – if agreed with the applicant, the Department can contract a HTA Group to prepare an Assessment Report.

[4] An Assessment Report is a document that captures the technical details relevant to the assessment of a technology for consideration by MSAC.

- A commentary on an ADAR – the purpose of the commentary is to critically appraise the approach taken in the ADAR and identify strengths and weaknesses in the evidence used. The Commentary is prepared by the HTA Group.

MSAC's broad scope and range of expertise has made it the most appropriate committee to continue to assess medical services, health technologies and health programs seeking funding from MBS, non-MBS sources and other national funding programs. Data from 2017-19 indicates that for MBS, non-MBS (i.e. health technologies seeking funding from sources other than MBS such as NHRA and NPPL) and codependent applications:

- the volume has increased over the years, with this trend expected to continue; and

- the majority (60%) of these applications are sponsored by commercial entities. For the purpose of this proposal, a commercial entity is defined as those that are established to make a profit but not including peak representative bodies, professional medical colleges, universities, and research organisations.

Recent advancements in technology has resulted in increasingly complex and resource intensive MSAC assessments that require significant, additional MSAC resources and effort, in part due to the need to coordinate parallel HTA processes.

The Department proposes to introduce cost recovery arrangements for all MSAC applications from commercial entities seeking reimbursement decisions. It is reasonable to cost recover for these applications as the majority (60%) of these applications are generated by commercial entities that likely receive a direct financial benefit if MSAC makes a recommendation that the subject of their application receive public funding.

The introduction of cost recovery arrangements will offer benefits to applicants in terms of greater clarity, transparency, and certainty of timeframes for MSAC processes. This will address some of the stakeholder feedback received through submissions to the *House of Representatives 'Inquiry into approval processes for new drugs and novel medical technologies in Australia'*.

Departmental data from 2017-2019 indicates that 40% of applications seeking funding only through the MBS and non-MBS sources are generated by non-commercial entities, such as representative groups, medical colleges, specialist colleges or individuals. These applications would continue to be funded by Government, through the existing non-cost recovered MSAC process.

The Department may consider whether eligibility criteria is required for non-cost recovered applications to ensure that Government funded services continue to only be utilised by non-commercial entities without the capacity to pay. This would ensure Australians continue to enjoy affordable access to health care services funded under the MBS, a major source of subsidy for non-pharmaceutical healthcare services.

COST RECOVERY PROPOSAL

This proposal is for a separate cost recovered applicant driven HTA pathway for applications to MSAC. Applicants in this pathway must lodge an ADAR application (where the applicant is required to produce their own Assessment Report).

Scope and Eligibility Criteria

The following application types received by commercial entities will be subject to the cost-recovered pathway:

- Codependent technologies - medical services and health technologies that are subsidised under the MBS and another subsidy program, such as the PBS or the PL
- Health technologies (new or amended) seeking funding from MBS
- High-cost, highly specialised therapies funded under NHRA for delivery in state and territory public hospitals
- Blood products to be included on the NPPL
- Medical devices considered by MSAC for inclusion on the PL
- New or amended MBS items as a result of changes to items on the PL
- Health technologies funded under other established non-MBS programs such as the NDSS.

Examples of MSAC applications that may be subject to cost recovery include:

- An application from Australian Medicines Company Pty Ltd requesting public funding of diagnostic testing under the MBS for non-small cell lung cancer to determine eligibility for a specific drug under the PBS.
- An application from Medical Devices Company Pty Ltd requesting a new MBS listing of nerve stimulation for depressive episodes with prosthesis listing of the pulse generator device.
- An application from Pathology Company requesting a new MBS listing for a genomic test to inform breast cancer treatment.

The following application types will **not** be subject to cost recovery:

- An application from a non-commercial entity such as a professional medical college or representative group, seeking funding from MBS or any other national subsidy programs.

Examples of MSAC applications that would NOT be subject to cost recovery are:

- An application from the Gastroenterological Society of Australia requesting MBS listing of endoscopic mucosal resection for patients with large colorectal polyps.

- An application from the College of Radiologists requesting MBS listing of obstetric MRI.

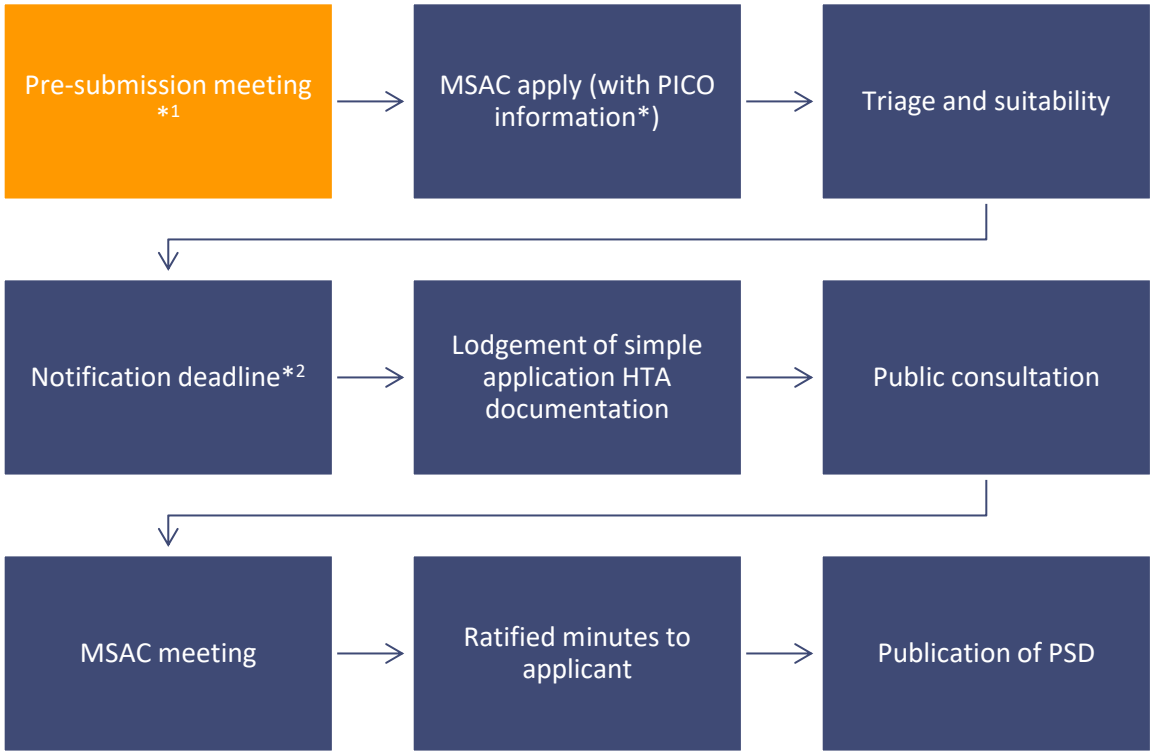
Application Categories

The proposed pathway for cost recovered applications has two application categories to reflect the complexity and the assessment effort required:

- Simple application category (see Figure 1 below) - applies to applications in which a clinical claim is not necessary to be assessed by MSAC and no economic modelling is required. In this instance, only an abbreviated application would be required, including utilisation and financial analysis. Such applications would require consideration by MSAC only. This would include applications such as streamlined codependent submissions and resubmissions with a clearly defined scope.

- Complex application category (see Figure 2 below) - applies to applications with a superior or non-inferior clinical claim, where an application asserts a superior or similar health benefit relative to a comparator and would require cost effectiveness or cost minimisation analysis. Such applications would require consideration by PASC, ESC and MSAC, unless the applicant decides to opt out of PASC.

Figure 1: Simple Applications – High Level Process Map[5]



Note:

** Invoicing point*

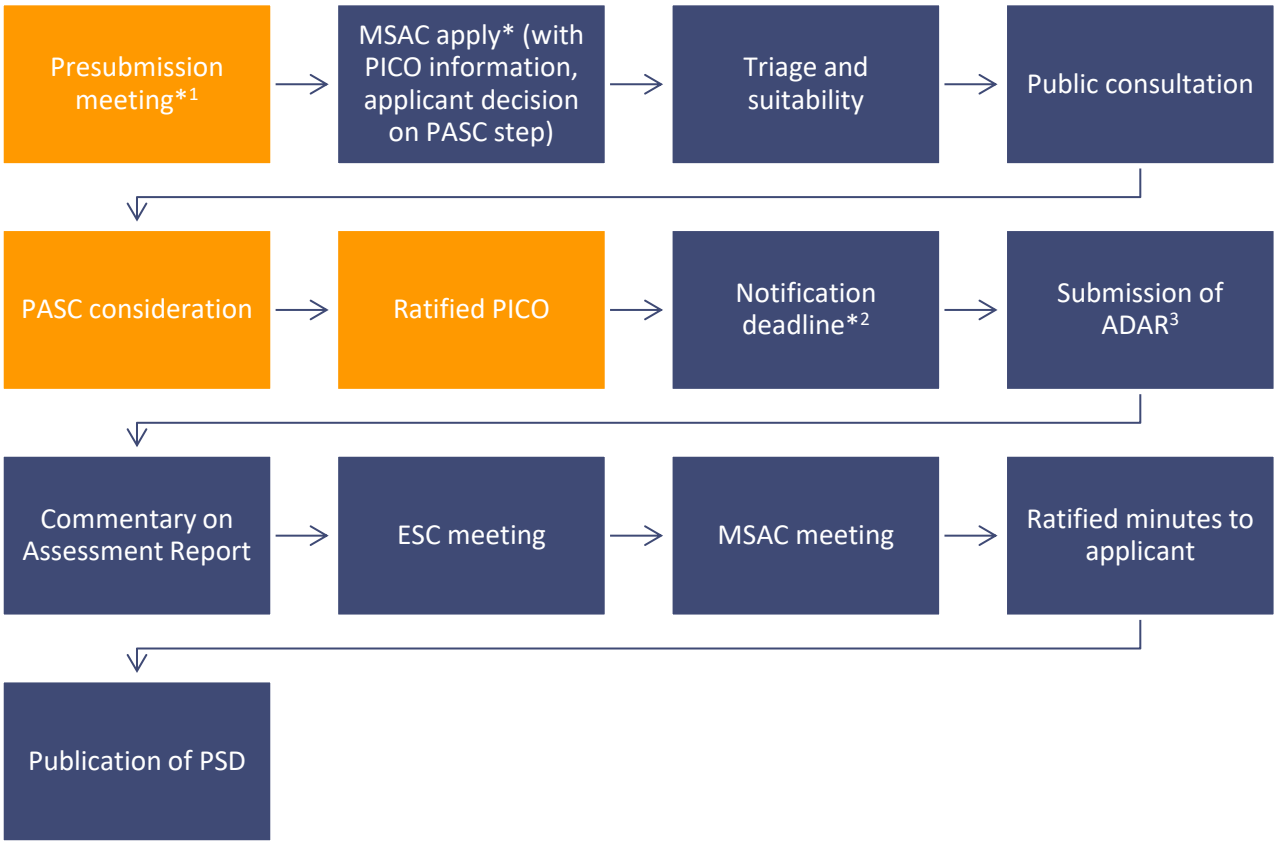
1 - Pre-submission meeting will be available any time before lodgement of HTA documentation but not during the suitability assessment.

2 -The deadline by which the applicant must agree to the assessment pathway and notify the Department to proceed.

Orange: optional step

[5] MSAC only required

Figure 2: Complex Applications – High Level Process Map[6]



Note:

** Invoicing point*

1 - Pre-submission meeting will be any time before lodgement of ADAR but will not be available during suitability assessment and when the draft PICO is under consideration by PASC.

2 -The deadline by which the applicant must agree to the assessment pathway and notify the Department to proceed.

3- ADAR – Applicant Developed Assessment Report

Orange: Optional steps

[6] ESC and MSAC required (with optional PASC)

OVERVIEW OF KEY STEPS UNDER THE PROPOSED PATHWAY

Formal Pre-submission Meeting

Applicants would have access to a formal pre-submission meeting with the Department to discuss their application prior to lodgement. A pre-submission meeting can occur before or after development of the PICO but is not intended to replace PASC advice.

The pre-submission step will assist in providing guidance to applicants to develop their applications in accordance with the MSAC guidelines and relevant previous recommendations made by MSAC and identify any other issues that may arise during MSAC's consideration of the application.

The Department could advise the potential applicant on the:

- MSAC process and timeframes specific to their application
- Completion of the application form
- Development of HTA documentation

This step would be optional and would attract a fee for services where the application meets the eligibility criteria for the cost-recovered pathway. It is assumed that applicants new to the MSAC process would choose to make use of a pre-submission meeting. Experience from PBAC processes suggests that applicants familiar with the MSAC process would, in many cases, be likely to seek pre-submission meetings for more complex applications.

The Department may also facilitate joint pre-submission meetings with the PBAC secretariat, PLAC secretariat and other stakeholders as appropriate and the fee will only be charged once. Accordingly, MSAC representatives would also be able to attend meetings in other HTA processes such as the PBAC.

MSAC Apply

The application form referred to as *MSAC apply* will need to be completed by the applicant with all of the relevant information when lodging an application to MSAC. 'Applicant' refers to the entity seeking the MSAC HTA. Applicants must nominate the funding pathway, the relevant application category, and the decision to skip PASC upfront in their application.

Triage and Suitability

This step involves the Department verifying whether an application is suitable for consideration by MSAC, the availability of evidence for assessment and whether the applicant has nominated the appropriate application category. Following acceptance of the application, targeted and public consultation will be undertaken on the redacted application form. It is proposed that

standardised redaction criteria for the application form will be developed to expedite this process and ensure consistency for stakeholders responding to consultations.

For applications that have been referred by other committees for MSAC HTA, the Triage and Suitability step will involve the Department verifying the nominated application category and the availability of evidence for assessment. For example: Prostheses applications referred by PLAC for the MSAC assessment.

The Department will seek input from relevant internal areas and funding bodies to inform the suitability assessment. The applicant will be notified of the outcome within six weeks or will otherwise be advised within this timeframe that further consideration is required to confirm the designated funding pathway.

PASC Consideration

PASC was initially introduced to ensure that an MSAC application accurately captures current clinical practice and reasonably reflects the likely future practice with the proposed new medical service. The Department contracts an external HTA group to prepare a 'PICO Confirmation Document' based on information in the application form. PASC considers the developed PICO and commonly suggests amendments. The PICO informs the structure of the Assessment Report provided to ESC and MSAC.

Under the cost recovered pathway, when an organisation applies to MSAC for assessment of a codependent technology, MBS, or non-MBS technology, they would be able to choose to bypass the PASC step. Choosing to bypass PASC would shorten the MSAC process timeframes by approximately four months. For commercial entities, earlier consideration by MSAC may potentially provide a financial benefit, following a positive outcome and subsequent reimbursement decision by the relevant funding body.

While applicants have previously been able to bypass PASC following consideration by the MSAC Executive, there has not been a formalised process where the applicant takes responsibility to opt out of PASC consideration.

Applicants should note the risk associated with bypassing PASC. If the PICO criteria are not developed and applied correctly, there is an increased risk that MSAC may find the application to have an incorrect PICO and reject suitability for public funding or defer their decision while awaiting further information. This outcome would result in additional activity, which would be subject to cost recovery.

Assessment

The best available evidence will inform the development of an Assessment Report which outlines the safety, effectiveness, cost effectiveness and cost of the medical therapy in question. This is referred to as the ADAR, if developed by the applicant, and is the main basis for funding advice by MSAC.

Applicants would be solely responsible for developing the Assessment Report and other assessment material in line with guidelines produced by MSAC. Applications eligible for the cost recovered pathway would not be able to request for a DCAR. In practice, applicants for non-MBS and codependent technologies already opt to lodge ADARs.

In preparing or commissioning their own Assessment Report, applicants have control over the contents and delivery timeframes. The assessment carried out by the applicant would still be subject to the same quality requirements as those contracted by the Department.

The Department will contract an external HTA group to review the applicant's Assessment Report and provide a Commentary to ESC and MSAC.

ESC and MSAC Consideration and Outcomes

ESC reviews the ADAR to ensure it appropriately summarises the available evidence and issues arising, in a manner which will appropriately inform MSAC's deliberations. ESC provides a report to MSAC.

The MSAC agenda will be published on the website prior to the meeting. MSAC considers the Commentary and the ESC report to determine whether to recommend the service and/or health technology in question for public funding, and if so under what conditions. MSAC's decision is recorded by the Department and later forwarded to the Minister for Health and any other relevant authority for a funding decision.

The outcomes of MSAC's deliberation of an application are summarised and agreed with the applicant. It is proposed that standardised redaction criteria will be developed for the ratified Public Summary Document (PSD), like the PBAC criteria and process. This would assist with releasing minutes to the applicant within definitive timeframes of 8 weeks and ensure consistency of redactions across MSAC and PBAC PSDs for codependent applications.

Indicative Cost Recovery Fees

In line with the Australian Government Charging Framework, the costs estimated in Table 1 below are calculated using an activity-based costing model. The model identifies discrete activities involved for each application category and assigns the cost of all products and services required to complete the activities. This includes:

- Direct costs – These costs include the staff salaries (including on-costs for superannuation and leave) for those directly included in the activity, committee costs and supplier costs (e.g. HTA evaluators and consultants).

- Indirect costs – These costs include overheads for staff directly involved in the activities using the Department of Finance's approved costing methodology. Indirect costs include staff training and development, workers compensation premium, human resources support, organisational services, desktop ICT services and property operating expenses.

Table 1: Estimated fees

Fee category	Activity	Indicative fees
Pre-submission meeting with the Department (optional)	This step is optional and can be chosen by the applicant. The following activities are included: - Department assessment of the pre-submission meeting request and briefing material to determine the scope and eligibility - Facilitating pre-submission meeting with the Medical Officers and representatives from MSAC and other HTA /policy areas where appropriate. - Facilitating joint pre-submission meetings for codependent submissions with the MBD secretariat, PBAC secretariat, PLAC secretariat and other stakeholders as appropriate.	$7,620
PASC consideration (optional)	This step is optional and can be chosen by the applicant. The following activities are included: - Department contracts external HTA group to prepare 'PICO Confirmation Document" and decision analytic framework - PASC meeting to review PICO (provision of commentary to guide ADAR) - Publication of PICO	$62,050
Application category: Simple (without PASC)	Category status is nominated by the applicant and validated by the Department. Applies to applications that do not require MSAC assessment of a clinical claim and where no economic modelling is required such as: - streamlined codependent submissions. - certain resubmissions (such as those with a clearly defined scope).	$19,230, *including a non-refundable deposit fee of $4,190**.

Fee category	Activity	Indicative fees
	The following activities with definitive timeframes are included: - Triage and suitability - Public consultation - Receipt and assessment of simple application HTA documentation (including utilisation and financial analysis) - MSAC consideration - Release of minutes to applicants	
Application category: Complex (without PASC)	Category status is nominated by the applicant and validated by the Department. Applies to applications with a superior or non-inferior clinical claim relative to a comparator and that require cost effectiveness or cost minimisation analysis such as: - Integrated codependent submissions - Complex technologies seeking funding under the MBS, NHRA and other funding programs. The following activities with definitive timeframes are included: - Triage and suitability - Public consultation - Receipt of ADAR - Commentary by external evaluators on the ADAR - ESC consideration - MSAC consideration - Release of minutes to applicants	$140,710, *including a non-refundable deposit of $4,190**.

**The non-refundable deposit is for the triage and suitability step, regardless of whether the application continues to assessment.*

Digitisation of MSAC Applications

In the 2021-22 Budget, the Government announced that it will provide $36.0 million over four years (and $1.6 million per year ongoing) to expand the Health Products Portal (HPP).This forms part of the *Commonwealth's deregulation agenda to reduce unnecessary regulatory burden and support Australia's economic recovery by making it easier for businesses to get people into jobs and interact with government.*

The HPP aligns with the Government's Digital Service Standard and is being developed in consultation with industry groups and end users (through user research and beta testing activities) as part of a user-centred approach.

The Department launched the HPP in October 2019 focusing on the pharmaceutical industry and management of items on the PBS. The Department is in the process of expanding the HPP user base to enable applications to the MSAC, via the HPP.

The HPP is a single, secure, and easy to use platform through which industry can interact with Government to apply, track, pay for and manage listings for regulated and subsidised health-related products and services.

The HPP will provide significant regulatory savings to industry, across a range of HTA categories which build on each other over time to realise cumulative benefits. Once the project is fully implemented, the estimated savings to the pharmaceutical and medical device industry will be around $157 million annually. This estimate is based on digitisation of approximately 8,000 interactions per year between industry and government.

Cost recovery fees for MSAC applications will need to consider the ongoing maintenance and depreciation costs, once HPP functionality is available for these applications. The indicative fees are likely to increase to reflect the additional costs.

Waiver of Cost Recovery Fees

Under the proposal, an applicant would be able to seek a waiver of cost recovery fees that would otherwise be payable, if they meet the criteria which are listed in Table 2. These criteria are based on that currently used to waive PBS cost recovery fees.

Under this model, an applicant may apply to the delegate of the Secretary of the Department to waive the fees if:

- the application involves a public interest component; and
- where payment of the fee would make proceeding with the application financially unviable.

The applicant will be required to support their application for a waiver of fees with evidence. The types of supporting documentation that applicants may use is described in Table 2.

Table 2: Waiver Criterion

Public interest criterion information that may be considered by the Department upon application for waiver of cost recovery fees:
1. How the application involves the public interest, which may include but are not limited to applications where the medical service and/or health technology: a) is suitable for a patient population that is not large enough to make the application financially viable; or b) is to be used for palliative care, paediatric care or for medical treatment of Aboriginal and/or Torres Strait Islander peoples; or c) addresses differences in access to care in rural and remote areas, or an area(s) of unmet clinical need. d) Applicants should provide supporting evidence of estimated utilisation - summarise size of population (and any relevant subgroups), incidence and prevalence of disease or condition in Australia, characteristics of the patient population such as their age, sex, comorbidities and disease- or condition-related characteristics. 2. What the service and/or health technology seeks to do and its benefit, for example: a) If the MSAC or one of the Department's health working groups has encouraged the applicant to sponsor the HTA of the medical service and/or technology, the supporting documentation should include this information. b) Provide sufficient justification to satisfy the delegate of how the medical service and/or technology offers a benefit over existing publicly funded comparators.
Financial unviability criterion information that may be considered by the Department upon application for waiver of cost recovery fees:
3. A brief outline of the anticipated financial viability of the application: a) The applicant should provide evidence of how payment of the fee would make the application financially unviable. b) The extent to which the fee that has been requested to be waived would be returned through expected revenue from future listing on MBS, PBS and/or PL. c) Costs directly attributable to the medical service and/or technology should be included, and while other costs not included in the production of the medical service and/or technology may be included, this would need to be made clear and detailed. 4. If other costs are included (i.e. overhead costs), this must be able to be justified with additional supporting documentation, such as through a further breakdown to show

Public interest criterion information that may be considered by the Department upon application for waiver of cost recovery fees:					
the category split such as head office costs, storage and transportation costs or sales costs. 5. An example of how financial unviability could be presented is shown below:					
	Year 1 $	Year 2 $	Year 3 $	Year 4 $	Year 5 $
Revenue for the product (Price x est. sales volume)					
Less Cost of goods sold					
Less Overhead costs*					
= Net Profit					

**While not required, if included, overhead costs would need to be justified, and a further breakdown showing the split between categories required*

SERVICES FOR COST RECOVERED APPLICATIONS

Applicants that are eligible to be cost recovered will be provided with an agreed process from the receipt of application as well as improved certainty of timeframes for MSAC processes.

Certainty of Timeframes

Currently the existing MSAC processes do not have formalised definitive timeframes. The proposed cost recovered pathway will have guaranteed timeframes for applicants lodging an application with complete information in accordance with MSAC requirements.

The timeframes will be standardised with:

- 6 weeks for triage and suitability
- 4 months for PASC consideration
- 24 weeks from receipt of HTA documentation/ADAR to MSAC consideration
- 8 weeks for release of MSAC minutes to the applicant

The 24-week MSAC cycle process is the equivalent of the 17-week PBAC cycle i.e. from receipt of a submission to PBAC consideration. Refer to **Attachment B** for high level comparison of MSAC and PBAC pathways.

Certainty of timeframes within this pathway benefits commercial applicants because they will be able to more accurately predict when they will be informed of MSAC funding advice. This could have important positive flow on effects for businesses, such as improved financial planning and reporting.

Increased Transparency

The Department will develop a set of standardised redactions for application forms, the PICO Confirmation Document and the PSD. This will streamline current processes. Codependent application PSDs for PBAC decisions already have standardised redaction criteria, so expanding this initiative will ensure consistency in the information published by the Department. It will enable the Department to provide applicants with information on the outcome of MSAC meetings (MSAC minutes) within a definitive timeframe of 8 weeks and ensure that the PSD is published as soon as possible.

A separate consultation process will be undertaken on the introduction of standardised redaction criteria before implementation.

Improved Clarity

MSAC process framework will be updated to provide improved clarity on the MSAC cost recovered pathway, including the process steps and the relevant timeframes.

There will also be guidance documentation developed that will provide information on the cost recovery administrative matters and the waiver mechanism to ensure the applicants with non-financial incentive are not discouraged.

Additional guidance and education material including procedure guidance and process maps will also be available to ensure smooth transition and successful implementation of the cost recovered pathway.

IMPACT ON NON-COST RECOVERED APPLICATIONS

Applications from non-commercial entities that are not subject to cost recovery will have assessment timeframes that are guided by availability of resources.

Attachment A: MSAC Terms of Reference, pathway, and processes

MSAC Terms of Reference

The MSAC will:

- Advise the Minister for Health on whether a medical service, health technology or health program should be publicly funded, and what circumstances, if any, should apply to such funding based on an assessment of the comparative safety, clinical effectiveness, cost effectiveness and total cost using the best available evidence;

- Have due regard to the advice of states and territories where it is relevant to comparative safety, clinical effectiveness and/or 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 around access to medical services, health technologies and health programs that Australians need, at a cost individuals and the community can afford;

- Collaborate, where appropriate, with international health technology agencies to share information and technical expertise to ensure the MSAC has access to, and is using the best available information and methodology in undertaking its assessments; and,

- Provide advice to the Minister for Health and/or Department (the Department) on the evaluation of a medical service, health technology or health program for public funding that has been referred by other relevant bodies or committees.

The MSAC may also establish sub-committees to assist the MSAC to effectively undertake its roles and functions. The MSAC may delegate some of its functions to the MSAC Executive.

The PICO Advisory Sub-committee

The PASC, formerly known as the Protocol Advisory Sub-committee, is a standing sub-committee of MSAC with membership that may include, but is not limited to, consumer representatives and experts in epidemiology, nuclear medicine, health policy and clinical expertise. The PASC oversees the development of a PICO Confirmation that uses the widely accepted PICO approach that is intended to:

- capture current clinical practice and reasonably reflect likely future practice with the proposed new service;

- identify all potentially impacted healthcare resources; and

- present and justify the framework for evidence collection during the assessment phase of the MSAC process.

The Evaluation Sub-committee

The ESC is a standing sub-committee of the MSAC with membership that may include, but is not limited to, consumer representation and expertise in health economics, epidemiology, public health and clinical expertise.

The purpose of the ESC is to consider the clinical evidence and economic assessment presented in an Assessment Report in detail, provide advice on the quality, validity and relevance of the assessment, and identify any issues that MSAC will consider, such as where evidence may be weak.

MSAC and its sub-committees are further supported by clinical experts and HTA Groups who provide a range of assessment, review and research support services to the Department.

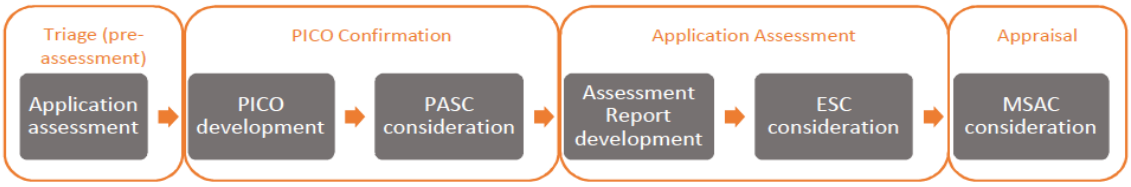
MSAC Application Process

An applicant seeking public funding for a medical service or an amendment to an existing service listed on the MBS submits preliminary information and a comprehensive application form to the medical services HTA Team in the Department.

The Department then assesses the application to determine its suitability to proceed through the MSAC process. The suitability assessment considers two broad components – the appropriateness of consideration by the MSAC, and the necessity and feasibility for the application to be assessed using a HTA Framework. Informal public consultation will occur after suitability is determined and continue throughout the application's MSAC process. The Department, in consultation with the applicant and the MSAC Executive as needed, will decide on the most appropriate pathway for each application to progress through the MSAC process.

Figure 1 provides a high-level representation of the overall MSAC process, including the stages and committee/sub-committee involvement. Note that the passage of each application through this end-to-end MSAC process may be varied due to some applications not requiring a full assessment.

Figure 1: High-level MSAC process



Codependent application process

The HTA assessment process for codependent technologies has focused on supporting an integrated approach to reduce duplication of effort across the respective committees, and to minimise potential barriers for patients to have to pay for one health technology when the other is subsidised.

This is demonstrated through the PBAC - MSAC (MSAC) codependent submission process, which includes an integrated approach for a subsidy submission for a medicine and co-dependent test by an applicant. A feature of the integrated codependent approach includes the preparation of a single evaluation document for use by MSAC and the PBAC. This evaluation

document is then considered by the economic subcommittees of PBAC and MSAC at a joint meeting, and a joint Economic Subcommittee (ESC) Advice document prepared for the PBAC and MSAC. PBAC then meets three weeks before MSAC, which gives enough time for PBAC to raise any questions if needed for MSAC consideration, for the applicant to comment on the questions and for MSAC to consider its advice.

MSAC assessment pathways

MSAC Applicants have the choice of two different assessment pathways for producing an Assessment Report for MSAC's consideration:

- Departmental Contracted Assessment Report (DCAR) –the Department organises, coordinates, and covers the costs associated with developing and preparing the necessary MSAC documents for consideration. This includes the Department directly liaising with the HTA group regarding the requirements and timeframes. The Department also facilitates the HTA group engaging with the applicant to resolve minor issues.

- Applicant developed Assessment Report (ADAR) - the applicant is responsible for organising, coordinating, and covering the costs associated with developing and preparing the necessary MSAC documents for consideration. In doing so, they must consider the necessary requirements and timeframes.

Majority of the applications using the DCAR and ADAR pathway go through the three committees – the PASC (PICO[7] Advisory Sub-Committee), Evaluation Sub-committee (ESC) and MSAC.

Table 3: MSAC Stages

Stage	**Description**
Triage (Pre-assessment)	The purpose of this stage is to ensure the applicant is aware of the process, likely pathway, and evidence expectations. This stage involves the Department verifying the availability of evidence for assessment, consideration of whether the application is suitable for consideration by MSAC and consideration of what would be the most efficient pathway through which the application will be progressed. Targeted public consultation on the completed application form will also be undertaken. The major stakeholders in this stage are the applicant, PASC Secretariat, and relevant medical professional.
PICO confirmation	The purpose of this stage is to develop the PICO Confirmation and determine the relevant clinical algorithms to progress an assessment. At the end of this stage, the applicant, Department and PASC aim to have an agreed PICO to undertake a systematic review of the evidence and generate an economic evaluation/model. The Department will engage a HTA group to develop the PICO Confirmation which will clearly articulate the following aspects of the assessment:

[7] PICO – Population, Intervention, Comparator and Outcomes

Stage	Description
	Patients/Population – specification of the characteristics of the patients for whom the intervention is to be considered for use. Intervention – specification of the proposed intervention and how it is delivered. Comparator – specification of the service (if there is a service)/usual standard of care most likely to be rendered in the population under consideration in the absence of the proposed intervention being available in the Australian health care system. Outcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention. This stage also informs the development of a decision analytic framework that will underpin the economic evaluation within the Assessment Report in the application assessment phase. Following production of the PICO Confirmation, it will be reviewed by PASC. PASC provides commentary on the PICO confirmation and guidance for the Assessment Report to be completed in the next stage of the HTA process. In a small number of cases, PASC may advise a PICO is insufficient and require it to be redrafted or amended. The final PICO Confirmation will be made available on the MSAC website for public consultation at any time in the MSAC process. This provides an opportunity for all interested parties to comment on the proposed assessment approach. The major stakeholders in this stage are PASC, the PASC Secretariat, the applicant, clinical experts, MSAC Executive, HTA groups and consumers/patients.
Application assessment by ESC	The purpose of this stage is for ESC to review the Assessment Report to identify the gaps and levels of uncertainty in the evidence. ESC will provide advice on the quality, validity, and relevance of internal and external assessments for applications being considered by MSAC. The major stakeholders in this stage are ESC, ESC Secretariat, clinical expert(s), MSAC Executive, HTA groups and consumers/patients.
Appraisal by MSAC	MSAC considers a wide range of information, including the Assessment Report assessing the evidence; the independent critique of the report, feedback from the applicant, the ESC Report on the evidence; any feedback on the ESC Report provided by the applicant and/or other relevant parties; and the individual expertise of MSAC members. MSAC's advice to the Minister is made public in the form of by a PSD that explains the rationale for MSAC's advice and is made available on the MSAC website. The major stakeholders in this stage are MSAC, MSAC Secretariat and MSAC Executive.

Attachment B: Comparison of MSAC and PBAC pathways

Process step	MSAC (current process)	MSAC (proposed cost recovered process)	PBAC (current process)
Pre-submission services	Non-formal	Formal with established processes	Formal with established processes
Lodgement of application form	Application form	MSAC apply – Online form through the Health Products Portal (HPP)	PBAC Intent to apply –online form through HPP
Pre-assessment	Triage and Suitability	Triage and Suitability (6-week timeframe) [8]	Not applicable
Application accepted and applicant notified	Applicable	Applicable	Applicable
Stakeholder consultation	Applicable (all relevant stakeholders)	Applicable (all relevant stakeholders)	Applicable[9]
PASC considers PICO	Mandatory[10]	Optional to opt-out of PSAC, resulting in shortened process timeframes by 4 months	Not applicable
Applicant provides ADAR/HTA documentation based on application category	No fixed deadline for lodgement	Notification deadline for lodgement	PBAC submission through HPP (Submission deadline for category submission)

[8] *Application receipt to decision on acceptance of the application for MSAC consideration.*
[9] *Consumers can provide their views about medicines or vaccines on each PBAC agenda via a web interface. Generally, there are eight weeks for consumer input in relation to PBAC submissions.*
[10] *Mandatory, unless agreed by MSAC Executive*

Process step	MSAC (current process)	MSAC (proposed cost recovered process)	PBAC (current process)
Assessment	No formal definitive timeline	24-week – Receipt of applicant developed Assessment Report to MSAC consideration	17-week – Receipt of submission to PBAC consideration
Validation of application category	Not applicable	Applicable	Applicable
Department contracts HTA evaluators for Commentary on assessment documentation	Applicable	Applicable	Applicable
Committee agenda published	Target timeframe	Definitive timeframe	Week 8 of the cycle
ESC consideration	Applicable	Applicable	Applicable[11]
Committee meeting	MSAC meeting	MSAC meeting	PBAC meeting
High-level outcomes communicated to applicant	Applicable	Applicable	Applicable
Ratified minutes provided to applicant	Target timeframe	Definitive timeframe	Definitive timeframe

Note: Text in orange are new steps for cost recovered pathway compared to existing MSAC pathway processes

[11] *Note: The PBAC has two subcommittees – ESC and the Drug Utilisation Sub Committee (DUSC). DUSC considers as subset of PBAC submissions and advises the PBAC and the applicant on important matters relating to use and cost, and reviews utilisation of currently listed PBS medicines.*