



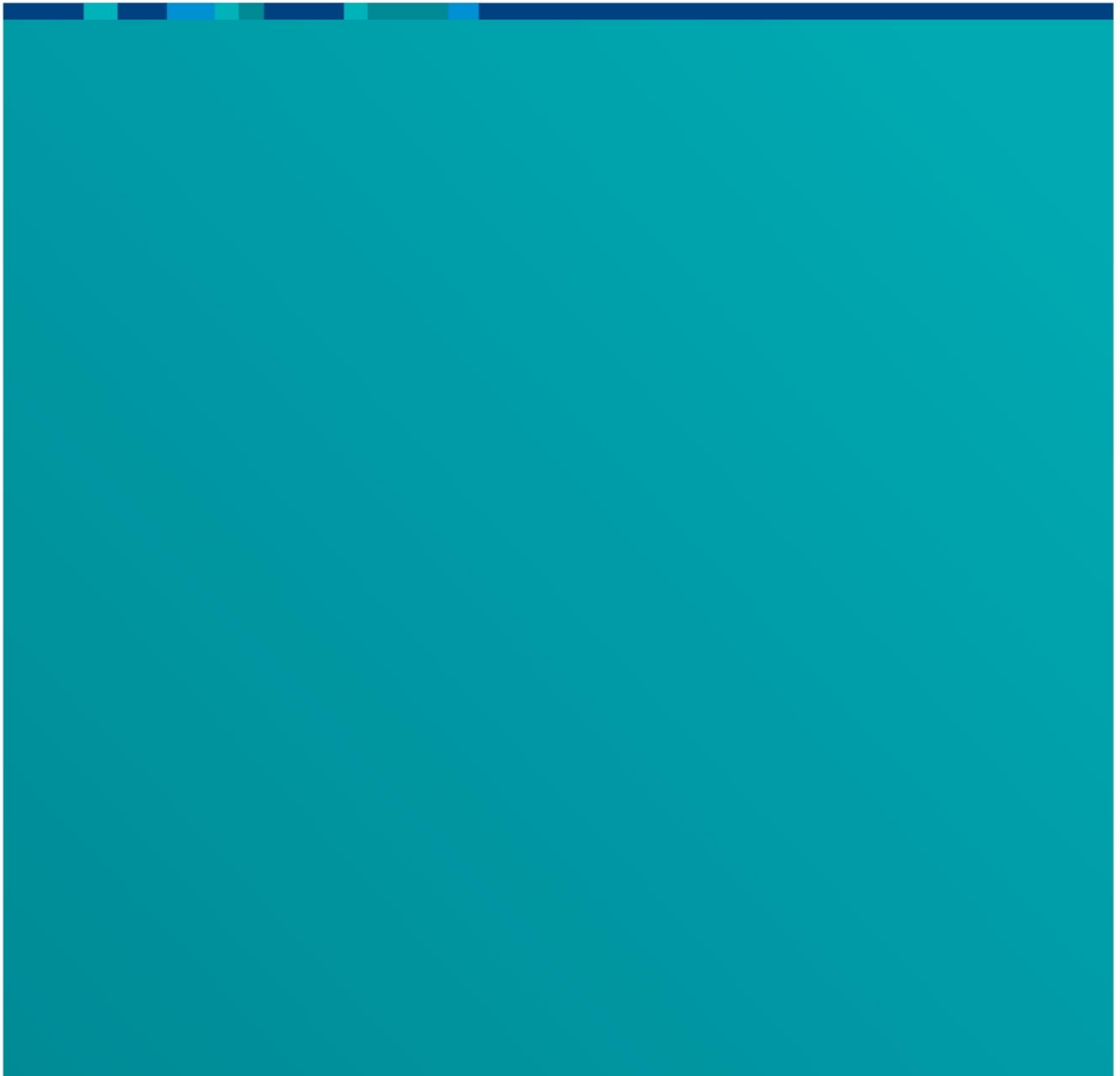
**Australian Government**

**Department of Health**

# Frequently Asked Questions

A Guide to Accompany the Consultation Paper on a Proposal for a Cost Recovered Pathway for Medical Services Advisory Committee (MSAC) applications

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## 1. Which applications are covered by the cost recovery proposal?

The following application types from commercial entities (i.e. entities that are established to make a profit, but not including peak representative bodies, professional medical colleges, universities, and research organisations) seeking MSAC services for reimbursement decisions will be subject to cost recovery:

- Codependent technologies - medical services and health technologies that are subsidised both under the Medicare Benefits Schedule (MBS) and an additional subsidy program, such as the Pharmaceutical Benefits Scheme (PBS) or the Prostheses List (PL).
- High-cost, highly specialised therapies funded under National Health Reform Agreement (NHRA) for delivery in state and territory public hospitals.
- Blood products to be included on the National Products Price List (NPPL).
- Medical devices considered by Medical Services Advisory Committee (MSAC) for inclusion on the PL.
- New or amended MBS items as a result of changes to items on the PL.
- New or amended health technologies seeking subsidy under the Medicare Benefits Schedule (MBS).
- Health technologies funded under other established non-MBS programs such as the National Diabetes Services Scheme (NDSS) and Pharmacy programs.

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

- Applications from non-commercial entities such as professional medical colleges, representative groups, universities, and research organisations will not be cost recovered.

## 2. Why are we introducing cost recovery for certain applications to the MSAC?

The Department is seeking to align the MSAC Health Technology Assessment (HTA) program 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 MSAC was initially established and funded to undertake assessments for listings on the MBS. The role of the MSAC has since expanded to assess applications for suitability for public funding of codependent technologies and technologies seeking funding from other non-MBS sources such as the NHRA and the NPPL (for the subsidised supply of blood products).

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.

This cost recovery proposal also presents an opportunity to provide definitive timeframes for MSAC processes. This includes an option to opt out of the PICO<sup>1</sup> Advisory Sub-committee (PASC) consideration. This has the potential to reduce processing timeframes by up to 4 months. This option requires the applicant to have the requisite HTA capability to prepare their Assessment Report without PASC advice.

### 3. How does cost recovery benefit the applicant?

Under this proposal, applications subject to cost recovery will receive:

- Certainty of timeframes. At present timeframes associated with the MSAC processes vary greatly. This proposal guarantees the MSAC timeframes for the eligible applicants with known funding destination of:
  - 6 weeks for the triage and suitability phase.
  - 4 months for the PASC consideration.
  - 24 weeks from receipt of HTA documentation/ADAR to the MSAC consideration.
  - 8 weeks for release of MSAC minutes to the applicant.
- Formal optional pre-submission meeting services.
- Reduced processing times by up to 4 months where the applicant chooses to opt-out of the PASC consideration.

### 4. Will co-dependent applications be required to pay cost recovery fees for the use of multiple HTA pathways?

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 two or more different schemes. For example, when

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<sup>1</sup> Population, Intervention, Comparator and Outcome

the Pharmaceutical Benefits Advisory Committee (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 component, while MSAC will assess the diagnostic test component of the application. The Department will therefore seek to recover the costs of both the PBAC and the MSAC component services of the HTA delivered, in line with the [Australian Government's Charging policy](#).

## 5. What if an applicant cannot afford to pay?

This proposal includes the ability to seek a waiver of the applicable cost recovery fees. The proposed model is based on that is currently used to waive PBAC cost recovery fees.

Under this model, an applicant may apply to the delegate of the Secretary of the Department to waive the relevant 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 relevant evidence.

Stakeholder education material providing guidance on process for requesting a waiver and the required documentation will be developed as part of the cost recovery.

## 6. How are the proposed cost recovery fees derived?

In line with the [Australian Government Charging Framework](#), the costs estimated are calculated using the 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 approving costing methodology. Indirect costs include staff training and development, workers compensation premiums, human resources support, organisational services, desktop ICT services and property operating expenses.

More information about the activities that contribute to the cost recovery fees for the various charging categories is available in the public consultation paper.

## 7. What if my application needs to be considered by PASC or ESC and/or MSAC twice (or more), do I need to pay again?

In line with the [Australian Government Charging Framework](#), the costs paid by the applicant is for the effort and resources of the Department to complete the applicant requested service. If the service is requested twice, the fees will need to be paid accordingly.

## 8. I have an MSAC application for a novel MBS service associated with a new prostheses listing. How will this application be cost recovered?

The applicant will be required to pay a separate fee for their application to list the prostheses on the PL (under existing PLAC cost recovery arrangements) and a fee for the MSAC application (under this proposal) based on the category reflecting the amount of assessment required. The Department will undertake assessment and the applicant will be notified of the PL outcome and the MSAC outcome within the definitive timeframes proposed under the cost recovery proposal.

The Department is currently implementing reforms to modernise the PL listing process and cost recovery arrangements. There is a separate consultation planned on the [PL reform](#) (HTA) pathways that will be the subject of a further consultation process.

## 9. Will the revised timeframes for release of minutes to applicants also be applied to non-cost recovered applications?

Applications from non-commercial entities seeking listing under MBS or any other funding program are not subject to cost recovery and will be dependent on the availability of resources to assess and consider the application. The timeframes may be the same, but may differ depending on workload of the Department, contracted assessment groups and the MSAC.