



Medical Devices and Human Tissue Advisory Committee - Member Guidelines

The Prescribed List (PL) of Benefits for
Medical Devices and Human Tissue Products

May 2023

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1. Introduction

The Medical Devices and Human Tissues Advisory Committee (MDHTAC) (known here after as the Committee), established on 1 July 2023, makes recommendations to the Minister for Health and Aged Care (Minister) and advises the Department of Health and Aged Care (Department) on issues relating to medical devices and human tissue products being considered for listing or listed on the Prescribed List (PL) of Benefits for Medical Devices and Human Tissue Products.

The Department works with and provides support to the Committee.

2. Role of the Committee

MDHTAC's primary role is to make recommendations to the Minister and advise the department about the suitability of medical devices and human tissues products (the products) for listing on the PL and their associated benefits, or on amending the details of the existing billing codes (for the products already listed on the PL), or on any other post-listing activities as required. The PL identifies the minimum amount payable by private health insurers for medical devices and products.

Recommendations and advice are based on an assessment of comparative clinical effectiveness and cost-effectiveness of products using the best available evidence compared with other similar products already listed on the PL or alternative treatments. It is one of the eligibility requirements that there is evidence available that the product is no less clinically effective than the comparator [either listed on the PL or, if there are no appropriate comparators listed on the PL, the alternative treatments]. This process ensures that privately insured Australians have access to a range of products that are clinically effective and represent value for money.

3. Terms of Reference

MDHTAC assess the products for the purposes of establishing their eligibility and suitability for listing on the PL under the *Private Health Insurance Act 2007*.

The MDHTAC Terms of Reference is at **Attachment A**.

4. Composition of the Committee

The MDHTAC is comprised of an independent Chair, Chairs of each Expert Clinical Advisory Group (ECAG), a consumer representative, and up to two clinical / health technology assessments experts who do not reside on ECAGs, all of whom are appointed by the Minister in consultation with the department.

The size and composition of the MDHTAC is determined in consultation with the Minister, and may change from time-to-time to address the changes in the matters required to be discussed and advised on.

5. Terms of Appointment

Each member is appointed on the basis of their individual skills, knowledge and expertise and holds their appointment at the discretion of the Minister.

Committee member appointments will be for a two-year term, from 1 July 2023, unless specified otherwise by the Minister.

Members may resign from the Committee at any time by advising about their intention to resign to the department (by sending email to HTAsupportunit@health.gov.au and copied to the Chair).

The Minister, in consultation with the department, will consider appointments to vacancies, as appropriate. The department may seek nominations from medical colleges and / or societies for suitably qualified and experienced professionals, when and where required.

The Minister, in consultation with the department retains the discretion to terminate a member's appointment to the Committee at any time and for whatever reason.

6. Proxies

Where the Chair cannot be present at an MDHTAC meeting, the Deputy Chair must fulfill the Chair role who is an MDHTAC member and has expertise in health economics / health technology assessment. The proxy will then be approved by the department.

Where any of the ECAG Chairs cannot be present at an MDHTAC meeting, they must nominate a proxy who is an ECAG member and is a clinical expert from their respective ECAG. The proxy will then be approved by the department and the MDHTAC Chair.

Proxies external to this **will not** be allowed to attend the meeting due to the technical nature of the MDHTAC.

7. Confidentiality

Committee members may, on occasion, be provided with confidential material. Members are not to disclose this material to anyone outside the Committee and are to treat this material with the utmost care and discretion and in accordance with terms of their confidentiality agreement.

8. Conflict of Interest

Conflict of interest is defined as any instance where a committee member, partner or close family friend has a direct financial or other interest in matters under consideration or proposed matters for consideration by the Committee. A member must disclose to the Chair any situation that may give rise to a conflict of interest or a potential conflict of interest, and seek the department / Chair's agreement to retain the position giving rise to the conflict of interest. Where a member gains agreement to retain their position on the Committee, the member must not be involved in any related discussion or decision-making process.

A committee member is not to participate in committee business until the Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll form has been completed.

Proxies may only attend a meeting when they have signed a Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll form, which is undertaken prior to a member joining a committee.

Further guidance on Conflict of Interest is at **Attachment B**.

9. What conflicts should be declared?

Actual conflicts of interest, where an individual has an interest (whether financial or non-financial) or an affiliation that **affects or will affect** their ability to perform work under the Appointment fairly and independently. Examples include where the individual providing the declaration:

- directly benefits from the Commonwealth accepting the person's advice
- directly receives funding from the department under another agreement or
- is advising on an arrangement or assisting formulating policy relating to an industry or business, in which they have a financial interest or on which they sit on a board.

Potential conflicts of interest, where an individual has an interest (whether financial or non-financial) or an affiliation that **may affect** their ability to perform work under the Appointment fairly and independently. Examples include where the individual providing the declaration:

- is appointed as an ECAG member but is also an industry representative of a relevant industry
- conducts work for other organisations who work for the department.

Perceived conflicts of interest, where an individual has an interest (whether financial or non-financial) or an affiliation that **could be perceived to affect** their ability to perform work under the Appointment fairly and independently. Examples include where the individual providing the declaration:

- partakes in recreational activities which could be perceived to be at odds with the department's agenda or objectives under the Appointment or
- has a reasonably close friendship with a sitting member of the Parliament of Australia and they are regularly seen in public together.

A Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll form **MUST** be completed by all Members on an annual basis, however, this can be updated at any time as required.

10. Official Business

A committee member will be deemed to be undertaking official committee business:

- during travel to and from and while attending meetings of the Committee
- while undertaking a task at the request of the Chair, including representing the Committee on other committees, sub-committees or forums approved by the Chair.

Note: Formal speeches and papers to be delivered by a member on behalf of the Committee should be cleared with the Chair and the Department prior to presentation. A copy is to be sent to the HTAsupportunit@health.gov.au.

11. Insurance

The department's insurance coverage for legal liabilities extends to committee members who act in an official capacity on behalf of the department.

The department's insurance does not extend to cover the member's private travel arrangements for example private motor vehicle or passengers.

12. Support for the Committee

The work of the Committee is supported by the Department's staff who have knowledge of the Prescribed List of Benefits for Medical Devices and Human Tissue Products and the Department's processes for appointments and other HTA committee related functions.

The Department is responsible for:

- providing support to the Committee
- providing policy advice to the Committee
- developing, in consultation with the Chair, agendas for Committee meetings and other business involving the department and the Committee
- distributing of agenda and associated material
- ensuring all members are kept informed of issues and information relevant to the work of the Committee
- arranging venues and catering for meetings, if required
- arranging appropriate travel and accommodation, if required
- verifying reimbursement of eligible expenses
- carrying out annual conflict of interest checks.

The department will not provide a fax, computer or other equipment to a member to undertake business of the Committee.

13. Operation of the Committee

The Chair is ultimately responsible to the department for the operations of the Committee. The Chair will preside at all meetings at which they are present. If the Chair cannot attend the meeting, the Deputy Chair will preside.

The Committee normally holds 3 meetings each year. Members may also undertake additional work on specific projects the Department asked and MDHTAC agreed to lead or participate in.

It is expected that a quorum of half the members plus the Chair (or their proxy) be present at each meeting, however in the rare unforeseen circumstance that this is not possible, the Chair in consultation with members and the department may agree on the minimum number of members required for a meeting to proceed. Such decisions should be made based on the numbers of applications and other items to be discussed and decided, and the variety of expertise and specialty required / present. The Chair (or their proxy) must always be present.

A draft agenda is prepared by the Department and may be discussed with the Chair prior to the meeting if required. The agenda will always include the applications to be discussed and other PL related matters as required.

The agenda papers are made available to MDHTAC members no later than 2 weeks before the meeting, ensuring that members have enough time for preparing to the meeting.

The minutes of the meeting are drafted by the Department and cleared by the MDHTAC Chair. The Department may seek clarification and input from the ECAG Chairs where required when preparing the Minutes. The Minutes will provide the record of the discussions with sufficient statements of reason to justify the recommendations. The Minutes will also contain a concise description of any action items. Minutes will be made available to members usually together with the next meeting agenda papers.

14. Business between Meetings

The Chair may write, sign letters and conduct business between meetings on behalf of the Committee, working with the department. Any correspondence must be copied to: HTAsupportunit@health.gov.au.

Members are expected to advise the Chair and HTAsupportunit@health.gov.au when they have completed any action items assigned to them from previous meetings.

Any material requiring members and/or Chair attention or action between the meetings will be circulated by email.

15. Remuneration

Non Statutory Committee – Remuneration Tribunal

Remuneration for the committee members is in accordance with the principles and rates set by the Remuneration Tribunal Determinations.

Below lists the current remuneration rates for the Committee:

Office	Annual Fees Rate (\$)	Daily Fees Rate (\$)
Chairperson	\$154,130	Not applicable
*Member	\$35,600	Not applicable

*In addition, ECAG Chairs receive (non-meeting day) preparation fees when they assess an application.

Commonwealth and State/Territory Employees

Where a person is employed full-time by the Commonwealth (or a business owned by the Commonwealth) or in the administration of a Territory and is appointed to a part-time public office, section 7(11) of the [Remuneration Tribunal Act 1973](#) prevents that employee from being paid for that part-time public office, even though the Remuneration Tribunal may have set fees for that public office.

Whether a State public servant can receive payment for holding a part-time public office (for example on a Federal Government board) is a matter for the relevant State government.

16. Taxation Arrangements

Committee members who are receiving annual fees or daily fees are to notify their Tax File Number Declaration (TFD). The member must complete Tax File Declaration form.

Taxation instalment deductions will be calculated accordingly to the Australian Taxation Office (ATO) requirements. If the member does not provide a Tax File Number Declaration (TFD), a withholding tax will be withheld at the rate of 47% of the remuneration fee.

The department no longer provides payment summaries. End of financial year income tax statements can be access through the member's MyGov account. If the member does not have a MyGov account, they should visit the following to create one:

<https://www.servicessaustralia.gov.au/individuals/online-help/mygov>.

17. Salary Packaging

Salary packaging is **not** allowable for MDHTAC members.

18. Superannuation

The department will make an employer superannuation contribution for committee members.

The committee member may choose the superannuation fund or retirement savings account to which the department will make future superannuation guarantee contributions (10.5%). If the ECAG member does not make a choice, the department's 'employer contributions' will be paid into the preferred fund of the department.

19. Personal Information

The personal information a committee member provides is required to enable the department to contact the member and to undertake any necessary financial and administrative transactions.

The general information retained by the department may include:

- members' names
- contact phone numbers
- address
- places of employment
- curricula vitae
- cultural background
- correspondence to members or
- details of submissions from the department.

Sensitive information retained by the department may include:

- tax file numbers

- financial information
- culturally sensitive issues
- conflict of interest details.

Staff members have access to this information on a "needs to know" basis. Access is restricted to management, staff responsible for the matters related to the PL and staff processing the payments and organising the MDHTAC meetings.

Generally, the records are retained as per the [Administrative Functions Disposal Authority](#).

Members may contact the Freedom of Information Unit on (02) 6289 1666 or by calling the toll-free number 1800 020 103 (extension 1666) to obtain advice regarding access to their personal information.

20. Travel Arrangements

Travel Allowance Rates

Committee members travelling on official committee business are regarded as being on official government business and may receive travel allowance and reimbursement for additional expenses.

Where the committee member receives travel allowance or reimbursement of travelling expenses from any other source for the same travel, the department will not make a payment of travel allowance or expenses to the member.

Where travel on official business does not require an overnight absence, the department will not make a payment of travel allowance.

Committee members attending an event where meals are provided will not receive the component of the travel allowance in respect of those meals.

Committee members will be paid travel allowance in accordance with the [Remuneration Tribunal \(Official Travel\) Determination 2022](#) (date of effect 28 Aug 2022).

The level of travel allowance is at the Tier 1 rate.

Accommodation

Accommodation may be:

- booked and paid by the department through:
 - the accommodation reservation service provider, The Hotel Network or
 - other accommodation providers.

Air Travel

All committee business related flights will be booked by the department through the department's approved travel management company. Committee members are not to book their own flights and seek reimbursement from the department.

When booking travel, the department is to comply with the Government's 'Best Fare of the Day' policy. The Best Fare of the Day is "the cheapest fare which suits official requirements".

Members for this Committee are entitled to fly business class. In line with the department's commitment to delivering efficiencies, cost savings and appropriate use of public monies, the department encourages members to consider economy class travel where possible.

Where practicable, committee members should travel on the day of the meeting. Confirmation of reservation will be forwarded to members.

The preferred method of air travel ticketing is an E-ticket. A boarding pass will be provided to member prior to departure on proof of identity at the outgoing airport terminal.

Members are responsible for contacting HTAsupportunit@health.gov.au if they would like their flights changed. The department will ensure members are made aware of their revised air travel arrangements.

The department does not belong to a frequent flyer scheme and members will not accrue frequent flyer points for air travel undertaken in conjunction with committee related business.

The department will not pay any additional costs incurred by MDHTAC members when they conduct their private business and will not pay airline lounge membership.

Use of Private Vehicle

While air travel is the preferred means of transport, alternative means of travel may be approved when it is considered to be in the best interests of the department.

Members may claim motor vehicle allowance if they travel by their own vehicle to/from a meeting. Motor vehicle allowance is paid according to the [Remuneration Tribunal \(Official Travel\) Determination 2022](#) (date of effect 28 Aug 2022) at a flat rate of 78 cents per kilometer.

Prior to travel the Expenditure Approver has a duty of care to sight a copy of the member's driver licence, insurance and registration documentation.

The member will receive the lesser of the calculated motor vehicle allowance or the amount the department would have to pay for the flights (where an airline service is not in operation the motor vehicle allowance is payable).

Any traffic or parking infringements sustained by the member will be the responsibility of the member.

21. Payment Arrangements

General Information

Payment of members' remuneration, travel allowance and additional expenses will be made:

- within one week following the month in which the expenditure is acquitted
- by electronic funds transfer into a financial institution account of the member's choice.

No committee payments will be made until a completed Committee Member Onboarding form has been provided by the member to the HTAsupportunit@health.gov.au.

Remuneration Information

[Remuneration Tribunal \(Remuneration and Allowances for Holders of Part-time Public Office\) Determination 2022](#)

Remuneration to members of the Committee is paid via an annual salary, pro-rata in monthly instalments. This remuneration is for attending meetings and for conducting the business of the Committee.

Business between meetings

Where MDHTAC members participate in seminars, working parties or other representations not related to the ECAG membership, members cannot claim any expenses from the Department for such participation.

The Chair may write and sign letters and conduct business between meetings on behalf of the committee. The correspondence must be copied to HTAsupportunit@health.gov.au.

Additional costs incurred by the member

An incidental component is included in the domestic and overseas travel allowance received by committee members.

Members may claim additional expenses such as taxi fares, parking fees and committee related phone calls. Reimbursement for expenses valued at \$82.50 (GST incl) and above, must be accompanied by a tax invoice and all other expenditure should be evidenced by an original invoice or receipt.

Where the committee member has lost an invoice valued below \$82.50, it is at the discretion of the Department's Expenditure Approver to approve the reimbursement of the unreceipted expenditure. However, in accordance with the Taxation legislation the department must have the Tax Invoice for goods and services valued \$82.50 (GST incl) and over to claim the input tax credit.

22. Media Contact

All contact with the media will require consultation with the department and the MDHTAC Chair. Any information to be released to the media will need to be cleared through the department's area responsible for communication.

23. Forms to be Completed

Committee members will need to complete and return the following forms to HTAsupportunit@health.gov.au:

- Instrument of Appointment and Acceptance of Appointment Form
- Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll (External Committee Members)
- Committee Member Onboarding Form
- Tax File Number Declaration Form
- Superannuation Choice Form

Attachment A: Medical Devices and Human Tissue Committee (MDHTAC) Terms of Reference

Purpose:

The Medical Devices and Human Tissues Advisory Committee (MDHTAC) is a ministerially appointed committee composed of an independent Chair and members with expertise in health technology assessment, specialist surgery/interventional work, health economics and/or consumer issues.

MDHTAC's primary role is to make recommendations to the Minister for Health and Aged Care (Minister) and advise the Department of Health and Aged Care (Department) about the suitability of medical devices and human tissues products (products) for listing on the Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List or PL) and their associated benefits, or on amending the details of the existing billing codes (for the products already listed on the PL), or on any other post-listing activities as required. The Prescribed List identifies the minimum amount payable by private health insurers for medical devices and products.

The MDHTAC's recommendations and advice are based on an assessment of comparative clinical effectiveness and cost-effectiveness of products using the best available evidence compared with other similar products already listed on the PL or alternative treatments. It is one of the eligibility requirements that there is evidence available that the product is no less clinically effective than the comparator [either listed on the PL or, if there are no appropriate comparators listed on the PL, the alternative treatments]. This process ensures that privately insured Australians have access to a range of products that are clinically effective and represent value for money.

Roles and function:

The role of the MDHTAC is to make recommendations and provide advice to enable the Minister to exercise his or her powers under the Private Health Insurance Act 2007 and the Department to administer the PL. This includes:

- making recommendations on whether the applicants provided sufficient evidence demonstrating suitability of the products for listing on the PL and whether any conditions of listing may need to be placed on the billing code;
- advising about the benefits for products to be listed on the Prescribed List if required;
- advising on the applications seeking to amend the existing billing codes on the Prescribed List;
- reviewing and advising on the listed products and/or benefits as appropriate;
- advising on any other matters pertaining to the medical device and human tissue products listing arrangements.

The MDHTAC may refer the products to the Medical Services Advisory Committee (MSAC) either via the Evaluation Sub Committee of MSAC or directly to MSAC.

The MDHTAC will refer any concerns about safety of products that arise during assessment of applications to list products to the Therapeutic Goods Administration (TGA) for investigation and appropriate action.

The MDHTAC should liaise with the Pharmaceutical Benefits Advisory Committee (PBAC) and/or its subcommittees for advice on comparative clinical effectiveness and cost effectiveness of a new product incorporating a medicine.

The MDHTAC should liaise with the MSAC, the TGA and PBAC to develop assessment processes that maximise the use of the clinical and technical expertise of each body and reduce duplication of assessment.

The MDHTAC may establish subcommittees, comprising members or co-opted individuals with appropriate expertise, to assist the MDHTAC to perform its role under these Terms of Reference. Each subcommittee will operate according to terms of reference approved by the MDHTAC and the Department.

The MDHTAC is not bound to accept the advice of its subcommittees in making recommendations to the Minister.

Composition:

The MDHTAC's size and composition is determined in consultation with the Minister.

The MDHTAC will include an independent Chair and members appointed by the Minister.

Six members of the MDHTAC will also be appointed as Chairs of six Expert Clinical Advisory Groups (ECAGs) (one Chair per ECAG). Members who are appointed as a Chair of an ECAG will act as the expert discussant on the matters covered by their ECAG. The members of the MDHTAC who Chair an ECAG will be appointed as such by the Minister.

The MDHTAC will also be comprised of up to three additional members, one, a consumer representative and up to two clinical / health technology assessments experts (who do not reside on ECAG), all of whom will be appointed as members by the Minister.

Members must sign Deeds of Confidentiality and Conflict of Interest Declarations upon appointment, and are required to declare potential, perceived or actual conflicts for each meeting / issue being considered. The Chair, in collaboration with the Department, will determine if and how a perceived, actual or potential conflict of interest will be managed.

Membership and Chair appointments are for a two-year term, from 1 July 2023, unless specified otherwise by the Minister. The Minister, in consultation with the Department, can terminate any MDHTAC appointment at any time at its discretion.

The MDHTAC's composition may be changed from time-to-time to address the changes in the matters required to be discussed and advised on.

Quorum:

It is expected that a quorum of half the members plus the Chair (or their proxy if allowed) be present at each meeting, however in the rare unforeseen circumstance that this is not possible, the Chair in consultation with members and the Department may agree on the minimum number of members required for a meeting to proceed. Such decisions should be made based on the numbers of applications and other items to be discussed and decided, and the variety of expertise and speciality required/present. The Chair (or their proxy) must always be present.

Only members who are the Chair of the MDHTAC, or a Chair of an ECAG, are allowed to have a proxy.

The Chair of the MDHTAC, if unavailable, may send a proxy to attend on their behalf.

Members who are a Chair of an ECAG, if unavailable, may send a proxy to attend on their behalf. The proxy must be a member from the same ECAG.

Where members cannot arrive at a consensus position, a vote will be taken, and the matter or issue decided by a simple majority. Members only will vote on matters relating to listing of products or amending the existing billing codes. In the event of a tied vote, the Chair will cast the deciding vote.

Meeting schedule:

MDHTAC meets no less than three times per year either face-to-face or via videoconference. Sub-committees and working groups may also meet separately. Business that does not require the whole committee may also be conducted out of session, via email or videoconference.

Reporting

The MDHTAC reports to the Minister for Health and Aged Care or the Minister's delegate.

Attachment B: Health technology assessment committees – conflicts of interest process guide

Please refer the department's website for the Guide

(<https://www.health.gov.au/resources/publications/health-technology-assessment-committees-conflicts-of-interest-process-guide>)