



Australian Government

Department of Health, Disability and Ageing

Expert Clinical Advisory Groups Member Guidelines

The Prescribed List of Medical Devices and Human Tissue Products

June 2023



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1. Introduction

The Prescribed List of Medical Devices and Human Tissue Products (PL) Expert Clinical Advisory Groups (known here after as the ECAGs, established on 1 July 2023, are sub-committees of the Medical Devices and Human Tissue Advisory Group (MDHTAC)). These Guidelines need to be read together with the ECAGs Terms of Reference.

The Department of Health, Disability and Ageing (the department) works with and provides support to the ECAGs.

2. Role of ECAGs

The primary role of the ECAGs is to assess the comparative clinical effectiveness of medical devices and human tissue products (the products) in context of their functionality, design characteristics, specifications, and intended use, indications and patient populations, being considered for listing or listed on the PL. Assessments by an ECAG inform advice to the MDHTAC, the department, and the Minister for Health and Ageing (the Minister), on the suitability of the products for listing on the PL, or for amending the details of the existing billing codes (for the products already listed on the PL), or for any post-listing activities as required.

3. Terms of Reference

ECAGs assess the comparative clinical effectiveness of the products for the purposes of establishing their eligibility and appropriateness for listing on the PL under the Private Health Insurance Act 2007.

The ECAG Terms of Reference is attached at [Attachment A](#).

4. Composition of the ECAGs

Each ECAG is composed of a ministerially-appointed Chair (who also resides on the MDHTAC) and departmentally-appointed clinical expert members (individuals with contemporary subject matter expertise). Members are appointed by the department.

The size and composition of each ECAG will be determined by the department, in consultation with the MDHTAC Chair, and is expected to be reflective of clinical expertise required to assess the types of products listed on the PL and presented in applications for assessments.

The department may seek nominations from medical colleges for suitably qualified and experienced clinical professionals, when and where required. Further, the ECAGs Chairs or the department may occasionally invite additional clinicians to attend some of the ECAGs' meetings when specific expertise or speciality are required.

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 department.

ECAGs member appointments will be initially for two years from 1 July 2023.

Members may resign from the ECAGs 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 department will consider appointments to vacancies, as appropriate.

The department retains the discretion to terminate a member's appointment to the ECAGs at any time and for whatever reason. As the Chair of each ECAG is also a member of the MDHTAC and appointed by the Minister, termination of the appointment of an ECAG Chair must be approved by the Minister.

6. Proxies

Where an ECAG member is unable to attend a meeting, proxies will **not** be allowed to attend the meeting due to the technical nature of the ECAGs.

Where an ECAG Chair cannot be present at an ECAG or MDHTAC meeting, they must nominate a proxy who is an ECAG member who is a clinical expert. The proxy will then be approved by the department and the MDHTAC Chair (for attendance the MDHTAC).

7. Confidentiality

ECAG members may, on occasion, be provided with confidential material. Members are not to disclose this material to anyone outside the ECAGs 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 an ECAGs member, partner or close family friend has a direct financial or other interest in matters under consideration or proposed matters for consideration by the ECAGs. 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's / 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 ECAGs, the member must not be involved in any related discussion or decision-making process.

An ECAG member is not to participate in ECAGs business until the Confidentiality, Conflict of Interest, Privacy and Secrecy Deed Poll form has been completed and reviewed by the department.

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

An ECAG member will be deemed to be undertaking official ECAG's business:

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

Note: Formal speeches and papers to be delivered by a member on behalf of the ECAG need to be cleared with the Chair and the department prior to presentation. A copy is to be provided to the HTAsupportunit@health.gov.au.

11. Insurance

The department's insurance coverage for legal liabilities extends to ECAGs 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 ECAGs

The work of the ECAGs 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 ECAGs
- providing policy advice to the ECAGs
- developing, in consultation with the Chair, agendas for ECAGs meetings and other business involving the department and the ECAGs
- distributing of agenda and associated material
- ensuring all members are kept informed of issues and information relevant to the work of the ECAGs
- 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 ECAGs.

13. Operation of the ECAGs

The Chair is ultimately responsible to the department for the operation of the ECAGs. The Chair will preside at all meetings at which they are present. If the Chair cannot attend the meeting, the Chair or the department will nominate a proxy (one of the ECAG clinicians members) who will preside.

The ECAGs normally hold 3 meetings each year, and members may also undertake additional work on specific projects the department asked and ECAG agreed to lead or participate in.

Each ECAG Chair in discussion with members may agree on the minimum number of members required for the meetings 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. The Chair (or their proxy) must be present and will have the deciding vote.

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 ECAGs members no later than 2 weeks before the meeting, ensuring that members have enough time to prepare for the meeting.

The minutes of the meeting are drafted by the department and cleared by the relevant ECAG Chair. They 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 ECAGs, 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

Below lists the current remuneration rates for the committee:

Office	Annual Fees Rate (\$)	Daily Fees Rate (\$)
Member	Not applicable	*\$901

* In addition, ECAG clinical expert members and the Chair receive (non-meeting day) preparation fees when they assess an application.

Non Statutory Committee – Remuneration Tribunal

Remuneration for the ECAG Chair is in accordance with the principles and rates set by the Remuneration Tribunal Determinations.

Below lists the current remuneration rates for the ECAGs:

Office	Annual Fees Rate (\$)	Daily Fees Rate (\$)
Chairperson	\$35,600	Not applicable

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 or Territory government.

16. Taxation Arrangements

ECAG 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 according 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.servicesaustralia.gov.au/individuals/online-help/mygov>

17. Salary Packaging

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

18. Superannuation

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

The ECAG 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 an ECAG 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 ECAGs 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

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

Where the ECAGs 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.

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

ECAGs 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 ECAG business related flights will be booked by the department through the department's approved travel management company. ECAG 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, ECAG 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 ECAGs related business.

The department will not pay any additional costs incurred by ECAG 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:

- once the meeting has been acquitted, with the payment made in the next pay run (fortnightly)
- by electronic funds transfer into a financial institution account of the member's choice.

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

Remuneration Information

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

Remuneration will be paid to members once the department has confirmed that members have attended the ECAG meeting or other meeting as requested by the department. The duration of the ECAG meeting is to be specified.

The amount of the daily fee to be paid is calculated in accordance with Remuneration Tribunal guidelines which are summarised as follows:

- if a formal meeting is 3 hours or more – full daily fee is paid
- if a formal meeting, or formal meeting and business of the ECAG on the day of a formal meeting, is two hours or more but less than three hours – an amount equal to 60% of the daily fee is paid or
- if a ECAG meeting is less than two hours – an amount equal to 40% of the daily fee is paid.

The daily fee for a formal meeting includes a component to cover normal preparation time, but where the department considers the period of preparation time involved is so unusual as to warrant further remuneration recognition that period may be included as business of the ECAG.

The Assessment of Applications

The daily fee for a formal meeting includes a component to cover normal preparation time.

Any ECAG Chair or clinical member also receives (non-meeting) day preparation fees when they assess applications.

Eligibility for each payment must be certified by the department.

Business between meetings

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

The Chair may write, 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 travel allowance received by committee members.

Members may claim additional expenses such as taxi fares, parking fees and ECAG 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 ECAG 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 ECAG 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

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

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

Attachment A: Terms of Reference

Purpose:

The Prescribed List (PL) of Benefits for Medical Devices and Human Tissue Products Expert Clinical Advisory Groups (ECAGs) are sub-committees of the Medical Devices and Human Tissue Advisory Committee (MDHTAC).

The primary role of the ECAGs is to assess the comparative clinical effectiveness of medical devices and human tissue products (products) in the context of their functionality, design characteristics, specifications, and intended use, indications and patient populations, being considered for listing or listed on the PL. Assessments by an ECAG inform advice to the MDHTAC, the Department of Health, Disability and Ageing (the department), and the Minister for Health and Ageing (the Minister), on the suitability of the products for listing on the PL, or for amending the details of the existing billing codes (on the PL), or for any post-listing activities as required.

ECAG specialty:

There are currently six ECAGs:

- Specialist Orthopaedic (including: shoulder, ankle, foot, upper limb and skeletal reconstruction)
- Hip and Knee
- Ophthalmic
- Spinal and Neurosurgical
- Cardiovascular (including: cardiac, cardiothoracic and vascular)
- General Surgery (including: ear, nose and throat (ENT), plastic and reconstructive surgery, urogenital and all other general surgery devices).

Roles and function:

The role of the ECAGs is to assess the products for the purposes of establishing their eligibility and appropriateness for listing on the PL under the *Private Health Insurance Act 2007* and the correctness of the listing details. This includes assessments:

- of the comparative clinical effectiveness of the products in context of their functionality, characteristics, specifications and intended use, indications and patient population and available comparators (either listed on the PL or other treatments)
- whether there are valid Medical Benefits Schedule items describing the Medicare services relevant to the use of the medical device
- whether the category, sub-category, group, sub-group stated in the application or the billing code is listed in (for the medical device and products already listed on the PL) is correct
- whether all products identified by the catalogue numbers stated in the application or recorded for the billing code, are sufficiently similar (in all their design characteristics, specifications, intended indications, use, etc) to be eligible for listing under the same billing code
- of any other matters relevant to listing of the products on the PL.

The ECAGs are required to provide advice, including any anomalies identified and the rationale for any recommendations, on the matters related to their assessments. During the meetings / discussions, the department records discussions, reasons, and outcomes of ECAGs to ensure correctness of the records.

The advice is provided to the MDHTAC or, where required, to the department.

The MDHTAC and the department may seek any additional advice from an ECAG related to their expertise on matters pertaining to the PL.

The ECAGs are part of the Commonwealth Health Technology Assessment (HTA) system. Commonwealth HTA processes should be:

- sustainable
- transparent, accountable and independent
- consultative and reflective of Australian community values
- administratively efficient
- flexible and fit for purpose
- informed by robust and relevant evidence.

Membership and composition:

Each ECAG is composed of a ministerially-appointed Chair (who also resides on the MDHTAC) and departmentally-appointed clinical members. Members are appointed by the department.

The size and composition of each ECAG will be determined by the department, in consultation with the MDHTAC Chair, and is expected to be reflective of clinical expertise required to assess the types of products listed on the PL and presented in applications for assessments.

The department may seek nominations from medical colleges for suitably qualified and experienced clinical professionals, when and where required.

Current membership of each ECAG can be found on the department's website. Further, the ECAGs Chairs or the department may occasionally invite additional clinicians to attend some of the ECAGs' meetings when specific expertise or specialty are required.

Chairs

The Chair of each ECAG is also a member of the MDHTAC and thus is appointed by the Minister. Respectively, termination of the appointment of an ECAG Chair must be approved by the Minister. Initial appointments will be for two years from 1 July 2023.

ECAG Chairs must participate in all relevant ECAG and all MDHTAC meetings (convened at least three times a year) and any other meetings concerning the PL as required.

Where a Chair cannot be present at an ECAG or MDHTAC meeting, the ECAG Chair must nominate a proxy and advise the department or the MDHTAC Chair (respectively).

Members

ECAG members include clinical experts (individuals with contemporary subject matter expertise).

The department formally appoints an endorsed nominee to a membership position. Initial appointments will be for two years from 1 July 2023.

The department, in consultation with the ECAG Chairs and MDHTAC Chair as required, can terminate an ECAG member's appointment at any time, at its discretion.

Conflicts of Interest

ECAG Chairs and members must advise the department of any potential conflicts of interest that may arise and complete appropriate paperwork as provided by the department.

Should any member have a conflict of interest, they will be excluded from assessments of the respective applications and from the relevant discussions during the meetings.

Quorum:

Each ECAG may agree on the minimum number of members required for the meetings 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. The Chair (or their proxy) must be present and will have the deciding vote.

Votes:

Most matters are expected to be decided by consensus.

Where members cannot arrive at a consensus position, a vote will be taken and the matter or issue decided by a simple majority. Where a vote is equal, the Chair will have the deciding vote.

Meeting schedule:

Each ECAG meets at least three times per year either face-to-face or via videoconference. Business may also be conducted out-of-session, via email or videoconference as required.

Reporting

The ECAGs report to the department and the MDHTAC.

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>)