



Australian Government

Department of Health

Clinical Advisory Group

Operational Guidelines



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Disclaimer

Please note that the content of this document is intended as a guide only and may be subject to change without prior notice.

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1. Purpose

The purpose of this document is to set out the arrangements under which the Clinical Advisory Groups (CAGs) will operate to deliver on their Terms of Reference. This document is supported by and should be read in parallel with the CAG Member Guidelines and CAG Terms of Reference.

2. Role

The primary role of the CAGs is to undertake health technology assessments that consider the comparative clinical function and effectiveness of medical devices being considered for listing on the Prostheses List. The assessments inform the CAGs advice to the PLAC and the Department of Health on the suitability to list on the Prostheses List.

3. Membership

The CAGs are sub-committees of the Prostheses List Advisory Committee (PLAC). The sub-committees are composed of a Chair and individuals with contemporary subject matter clinical expertise or technical profession, and may include a consumer representative.

3.1. Members

The number of clinician Members will depend on the specialities and sub-specialities covered by the CAG. There should be sufficient clinical Members to ensure that there are at least two clinicians with appropriate expertise available to assess applications.

If deemed necessary by the Chair, reserve clinician Members may be appointed. A reserve clinician Member is not required to attend meetings or assess applications regularly, but may attend meetings and assess applications as needed. A reserve Member should be a former Member of the CAG who is not affected by a high risk conflict of interest declarable matter.

The clinician Membership should reflect a broad cross-section of contemporary clinical practice across Australia.

3.2. Proxies

Due to the technical nature of the CAGs proxy Members are not permitted.

4. Secretariat

The Department of Health will provide secretariat services and policy advice to the CAGs.

5. Quorum

To enable a CAG meeting to occur there must be at least three Members including the Chair in attendance (either in person or by teleconference or videoconference). The Members present will have expertise in the speciality and/or sub-speciality of the items (including applications) on the agenda for discussion.

If unable to attend a meeting, the appointed Chair will nominate another clinician Member to take the Chair for the meeting.

If a regular clinician Member cannot attend a meeting, a reserve clinician Member can attend instead.

6. Votes

Most matters will be decided by consensus.

Where a matter cannot be decided by consensus, Members will vote. The outcome of a vote will be decided by a simple majority. Where a vote is equal, the Chair will have the deciding vote.

7. Undertaking Assessments

Transparency of decisions is essential to maintaining the integrity of the listing process. Particular care is required in documenting and advising the PLAC on assessment decisions.

It is essential that for each assessment, assessors review applications to ensure that evidence, expert opinion and assumptions provided support the listing of the item.

In undertaking assessment of applications, the assessor will have reference to:

- The Guide (Prostheses List – Guide to listing and setting benefits for prostheses)
- the Clinical Evaluation Form
- CAG Terms of Reference
- CAG Operational Guidelines (this document)

8. Meeting Arrangements

8.1. Frequency

The CAGs usually meet approximately four times per year, either face to face or by teleconference or videoconference. Other meetings may be convened as required.

The Chair may cancel a meeting if the business for discussion is considered to be insufficient in volume or importance to conduct a meeting.

8.2. Agenda, meeting papers and record of meeting

The Secretariat will develop meeting agendas in consultation with the Chair.

The Secretariat will circulate meeting papers to Members as required by the Chair, but as a general rule no later than five working days before the meeting, ensuring that Members receive papers with at least one weekend to read them before the meeting.

The record of meeting will record outcomes from the meeting especially the recommendations made by the CAG on applications to list new items and requests to amend current listings.

The Secretariat will provide the draft minutes of the meeting to the Chair for clearance or amendment no later than five working days after the meeting.

9. Conflict Of Interest

The CAGS will comply with the *Department of Health advisory committee guidelines on conflict of interest for members and nominees*. The Guidelines are an internal departmental document which provides the department, the Prostheses List Advisory Committee and its sub-committees with guidance relating to:

- declaration of interest requirements;
- the management by committees of members' interests in relation to matters coming before the committee; and
- members' obligations of confidentiality.

The integrity of the PLAC's decision and recommendation making process should be supported through appropriate management of

9.1. What is a conflict of interest?

The Department of Health defines conflict of interest as any instance where a staff member, contractor, partner/family member or close family friend has a direct financial or other interest that influences, or may appear to influence, proper consideration or decision making on a matter or proposed matter.

It is important to note that the **appearance** of a conflict of interest is as important as any actual conflict of interest. Perception alone can call in to question the impartiality of a person in discharging their duties. This is particularly relevant in cases where a person is required to fulfil multiple roles, as is the case for most CAG Chairs and Members.

9.2. Failure to disclose conflict of interest

Under the *Public Service Act 1999*, APS employees who breach the requirement to disclose and avoid conflicts of interest may be subject to numerous sanctions, including termination of employment. In the case of the PLAC, this would translate to removal of Members from the committee.

If the private interest compromises the proper performance of the official's public duties then the conduct moves beyond a conflict of interest and may constitute corrupt conduct as defined in the *Independent Commission Against Corruption Act 1988*.

9.3. Managing conflict of interest

PLAC has adopted a risk-based approach to managing conflicts of interest for its sub-committees. For each Nominee, Member or Assessor's declared matters, an assessment is to be made based on the range and nature of interests which are such that, the performance of a Committee Member could be affected by those interests.

Risks are assessed as low, medium and high. A table of example declarable matters is provided at [Attachment A](#).

9.4. Chair and Member Conflict of Interest Review Process

The Department reviews nominations received and prepares a summary of potential Chairs and Members including any and all matters of actual or perceived conflicts of interest.

1. Chair and Member nominees with a risk rating of Low are progressed to formal consideration.
2. Chair nominees with a risk rating of either Medium or High require consultation between the Department and the PLAC Chair to discuss and agree on the risk rating and risk management approach to be taken for that Nominee. The approach could be either of two options:
 - i. develop a risk management plan that provides guidance on managing the risk in the context of Committee work; or
 - ii. invite the Nominee to choose between declared matter or Committee membership.
3. Member nominees with a risk rating of either Medium or High require the PLAC's discussion and agreement on the risk rating and risk management approach to be taken for that Nominee prior to progressing to formal consideration.

9.5. Ongoing management of conflict of interest

Chairs and Members must provide an annual declaration of interests when requested by the Secretariat.

Members must also provide a signed declaration of interests to the Secretariat before each meeting, ensuring that they declare any interest that may bring them into conflict in discussing or providing advice on any matter on the agenda for that meeting.

Members of a CAG are required to submit completed Conflict of Interest Declarations to the CAG secretariat (CAG@health.gov.au) **three business days prior** to the next CAG meeting.

These Conflict of Interest Declarations will be forwarded to the Chair for consideration, so that they may determine the 'materiality' of the interest, and decide whether to:

- Allow the Member to participate fully in the deliberation by the committee and in any decision about making recommendations; or,
- Allow the Member to participate in discussion but not in making a decision about a recommendation; or,
- Allow the Member to be present to answer questions or provide specific advice on particular matters or of a technical nature, but not to participate in discussion or in making a decision about a recommendation; or,
- Exclude the Member wholly from consideration of the matter.

Ad hoc declarations can be submitted to the Chair or the Secretariat on the day of the meeting for consideration and Members will be advised if it is necessary for them to excuse themselves for the relevant part or all of the meeting.

The Chair, in consultation with the Department, will consider the declared matter and advise how the conflict will be dealt with at the commencement of the meeting.

Information provided to the Chair and Secretariat will be treated in-confidence.

If a Member does not want the particular details of a declarable matter to be disclosed to others in the CAG, the Chair will make a general statement about the Member having a potential conflict and how it will be managed in the context of the business of that particular Group.

All members' Meeting Disclosure of Interest Declarations (including declarations of no conflict) must be recorded in each CAG record of meeting.

10. Disclosure of Information

The business of the CAGs is Committee-in-Confidence.

Documents such as briefs, minutes and spreadsheets are circulated to Members for the purposes of performing their roles and functions. Members must not disseminate or discuss such documents with others outside the Committee Membership.

Discussions in meetings are also confidential, and Members must not discuss issues raised outside the Committee membership.

10.1. Deed of Undertaking

Prior to commencement of their official duties, committee members are asked to read and sign a Deed of Undertaking in Relation to Confidential Information and Conflict of Interest. In signing this Deed Poll, members have agreed to the outlined definitions of Conflict of Interest, as well as to adhere to the confidentiality requirements for the information being handled by the committee.

In particular members are obliged to keep secret and confidential all Confidential Information and ensure that they do not directly or indirectly disclose Committee-in-Confidence information to any person outside the Committee.

In signing the Deed Poll, members have understood and acknowledged that any unauthorised use or disclosure of Confidential Information may make him or her liable for prosecution under the laws of the Commonwealth.

11. Contact with Stakeholders

Stakeholders, such as medical device sponsors, private health insurers and private hospitals, are not permitted to contact CAG Members directly regarding the business of the CAGs. Contact may only be facilitated through the Secretariat.

12. Attendance at PLAC meetings

The PLAC Chair will invite the Chair of each CAG to attend a meeting from time to time to observe the PLAC at work.

The PLAC Chair may invite the CAG Chair or another Member to attend a meeting if there is a matter on the agenda relating to the work of the CAG, and the PLAC's consideration would benefit from discussion with a CAG Member.

13. Key Performance Indicators

There are two (2) Key Performance Indicators (KPI's) for a CAG.

1. Assessments must be fully completed and returned to the CAG Secretariat within the requested timeframe.
2. Members must attend 75% of all scheduled CAG meetings within a 12 month period. Attendance must be for the entirety of the Committee meeting.

Attachment A - Nominee and Member Risk Assessment Matrix

Assessment to be made based on the range and nature of interests which are such that, the performance of a Committee Member could be affected by those interests.

N.B. The examples provided below do not provide an exhaustive list.

REFERENCE	Low Risk	Medium Risk	High Risk
<p>Pecuniary interests</p> <p>Important to consider that the context of the Members relationships may moderate the Risk ratings, eg. single sponsor –v– multiple sponsors</p>	<ul style="list-style-type: none"> • Shareholdings low value • Fellowships low value • Research grants low value • Education grants low value • Travel grants • Conference fees • Other hospitality from a company involved in relevant industry • Paid speaker 	<ul style="list-style-type: none"> • Directorships • Board memberships • Employment • Consultancy • Commission fee-paid work • Paid expert adviser • Shareholdings moderate value • Investments • Trusts • Partnerships • Known future advantage or benefit from a company • Fellowships moderate value • Research grants moderate value • Education grants moderate value • Paid clinical trials • Paid product development 	<ul style="list-style-type: none"> • Investments significant value • Trusts significant value • Partnerships directly related to organisation involved in the development, manufacturer or marketing and distribution of a relevant product. • Significant association with a single organisation involved in the development, manufacturer or marketing and distribution of a relevant product.
Indirect pecuniary interests	<ul style="list-style-type: none"> • Family member with a medical condition relevant to the consideration of the Committee • Participation as a researcher 	<ul style="list-style-type: none"> • Participation in clinical trials • Participation in product development 	<ul style="list-style-type: none"> • Significant relationship with a person associated with the development, manufacturer or marketing and distribution of a relevant product.
Personal interests	<ul style="list-style-type: none"> • Membership of a professional organisation 	<ul style="list-style-type: none"> • Significant personal belief that may impact the Members capacity to participate in the work of the Committee 	<ul style="list-style-type: none"> • Significant relationship with a person associated with the development, manufacturer or marketing and distribution of a relevant product.
MANAGEMENT STRATEGY	Record disclosure and monitor	Assess risk in context of Committee work Develop risk management plan	Nominee or Member invited to choose between high risk interest or Committee membership