



Australian Government

Department of Health

Health Economics Sub-Committee (HESC)

Operational Guidelines



May 2017

Disclaimer

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

Table of Contents

1. Purpose.....	3
2. Role.....	3
3. Membership	3
4. Secretariat.....	3
5. Quorum	3
6. Votes.....	3
7. Undertaking Assessments	4
8. Meeting Arrangements.....	4
9. Conflict Of Interest	5
10. Disclosure of Information	7
11. Contact with Stakeholders	8
12. Attendance at PLAC meetings	8
13. Key Performance Indicators.....	8
Attachment A - Nominee and Member Risk Assessment Matrix	9

1. Purpose

The purpose of this document is to set out the arrangements under which the Health Economics Sub-Committee (HESC) will operate to deliver on its Terms of Reference. This document is supported by and should be read in parallel with the HESC Member Guidelines and HESC Terms of Reference.

2. Role

The primary role of the HESC is to undertake health economic assessments that assess if a product's cost is relative to its comparative clinical effectiveness. The assessments inform the HESC's advice to the PLAC on appropriate Prostheses List Minimum Benefits.

3. Membership

The HESC is a sub-committee of the Prostheses List Advisory Committee (PLAC). Membership of the HESC will include the Chair being a current PLAC Member. Other members of HESC may or may not be members of PLAC. Members may serve on the HESC and the PLAC including any of PLAC's sub-committees.

3.1. Chair

The Chair of HESC should be a member of PLAC. The Chair has the role of facilitating discussion and overseeing the general progress and administration of HESC, in consultation with the Secretariat.

Should the Chair be unable to attend a meeting, the Chair will nominate another Member to chair the meeting (in preference to deferring the meeting). The Chair will, however, be given the opportunity to provide input into the HESC meeting outcomes before they are provided to PLAC.

3.2. Proxies and observers

Proxies are not permitted to attend HESC meetings. Observers must complete the 'Deed of Confidentiality' and 'Conflict of Interest Declarations' and will not have voting/decision making rights.

4. Secretariat

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

5. Quorum

To enable a HESC meeting to proceed, a quorum will constitute half the number of members plus one. The Chair (or their alternative) must also be present. Similarly, a HESC decision either in or out of session requires a majority vote in favour of a resolution. In the event of a tied vote, the Chair has casting vote.

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

HESC provides advice and makes recommendations to PLAC regarding the setting of benefit levels on prostheses. 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.

In undertaking this work, HESC may consider factors including:

- evidence and advice on the comparative clinical effectiveness of the product when compared with other listed products;
- the minimum insurance benefits payable for, and the cost of, clinical comparators suggested or nominated by clinicians;
- relativities to other groups (the proportion of additional benefit payable in respect of a suffix for products in other groups within the assessment body or category);
- benefits proposed by the sponsor;
- benefits for alternative products;
- public sector pricing of products in Australia;
- international pricing; and
- utilisation data if and where appropriate.

7.1. Scope of HESC

HESC may:

- review evidence, expert opinion and assumptions integrated in clinical assessments and financial analyses of each prosthesis in order to provide a proposed benefit; and/or
- request additional information from sponsors and other parties if necessary to support the determination of an appropriate benefit.

7.2. Assessment of applications

HESC members are to assess applications and propose benefits and complete documentation and templates provided by the Secretariat.

7.3. Documenting advice to PLAC

HESC is to provide considered and documented advice on proposed benefits prior to PLAC meetings, as per PLAC Secretariat timeframes. HESC members are required to endorse their advice to PLAC and Minutes of meetings to which they have attended.

8. Meeting Arrangements

HESC will meet on the following basis.

Meetings will be held as required, (including for the discussion of matters such as setting of HESC operating guidelines and processes), as determined by the HESC Chair and/or Secretariat.

Meetings may be held face-to-face:

- in Canberra

- directly prior to PLAC meetings; or
- they may be held by teleconference.

Business may also be conducted out of session, via email or teleconference. Teleconferences should not normally exceed three hours in duration. Out-of-session meetings will be conditional on approval from the Secretariat.

The meeting venue or teleconference will be arranged by the Secretariat at the discretion of the Chair.

8.1. 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. Where practical the Secretariat will circulate papers to Members one week prior to a HESC meeting. This timeframe will allow the HESC Secretariat to compile applications and consider any further information required before applications are forwarded to HESC. Should additional information (including from the sponsor) be requested by either the Secretariat or HESC, consideration of benefit proposals will be delayed until the information is provided. This may mean benefits are not set within the one Prostheses List cycle.

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.

Outcomes of meetings will be kept and submitted to HESC members for ratification at the next HESC meeting.

9. Conflict Of Interest

The HESC 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 Members of the HESC and its Chair.

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 HESC are required to submit completed Conflict of Interest Declarations to the HESC secretariat (prostheses@health.gov.au) **three business days prior** to the next HESC 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 HESC is Committee-in-Confidence.

Documents assessed by HESC Members are to be treated with the utmost care and discretion, in accordance with terms of their deed of confidentiality. Members must not disseminate or discuss such documents with others outside the HESC membership or the PLAC.

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.

The HESC Secretariat is responsible for organising secure transportation and disposal of HESC related documentation to and from HESC members.

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 HESC Members directly regarding the business of the HESC. Contact may only be facilitated through the Secretariat.

12. Attendance at PLAC meetings

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

13. Key Performance Indicators

There are three (3) Key Performance Indicators (KPI's) for the HESC.

1. HESC members are to assess applications and propose benefits and complete documentation and templates provided by the Secretariat.
2. Members must attend 75% of all scheduled HESC meetings within a 12 month period. Attendance must be for the entirety of the Committee meeting.
3. HESC is to provide considered and documented advice on proposed benefits prior to PLAC meetings, as per PLAC Secretariat timeframes.

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	<p>Assess risk in context of Committee work</p> <p>Develop risk management plan</p>	Nominee or Member invited to choose between high risk interest or Committee membership