Australian Government
Department of Health and Aged Care

Expert Clinical Advisory Groups Terms of Reference

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

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 and Aged Care (the department), and the Minister for Health and Aged Care (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 are 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.