Glossary

Key terms for preparing submissions to a health technology assessment (HTA) advisory committee for funding of a medicine, medical service or prosthesis

(Version 1)

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Pharmaceutical Benefits Advisory Committee
Medical Services Advisory Committee
Prostheses List Advisory Committee

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Record of updates

Introduction

This glossary defines key terms used by the documents and processes that inform health technology assessment (HTA) of a proposed health technology (medicine, medical service or prosthesis), and consequent consideration and recommendation by an HTA advisory committee about listing in the Australian Government funding arrangements — the Pharmaceutical Benefits Scheme (PBS), the Medicare Benefits Schedule (MBS) and the Prostheses List. There are three HTA advisory committees:

- Pharmaceutical Benefits Advisory Committee (PBAC)
- Medical Services Advisory Committee (MSAC)
- Prostheses List Advisory Committee (PLAC).

This glossary should be read in conjunction with guidelines for preparing submissions to HTA advisory committees. It is intended to help those who prepare submissions to understand the terminology as it is used by each HTA advisory committee and its advisers. Some terms in the glossary will not be found in every guideline; however, they have been included to make the glossary a more substantial resource for applicants to more than one HTA advisory committee.

The glossary has benefited during its preparation by input from the officers of the Pharmaceutical Benefits Division and Medical Benefits Division of the Australian Government Department of Health and Ageing. As is usual with any document prepared with such broad input, it is not possible to achieve complete agreement by all contributors on every detail; nevertheless, the updated document should continue to help ensure that all people involved in preparing, evaluating and using submissions to HTA advisory committees are using a common language.

Feedback on this glossary is welcome and should be forwarded to hta@health.gov.au.

Principles for using this glossary

The starting point for each definition was a review of the standard texts acknowledged in the references. For some terms, a preferred definition has been chosen for its inclusion in the glossary when several definitions could apply (such as trial or economic evaluation). This is to promote consistency in the use of such terms. For other terms, the standard definition has been customised to reflect its application to one of the three HTA advisory committees (such as cost-effective or cost-minimisation analysis). Considerable effort has been expended to ensure that the definitions in the glossary are consistent with their use in each context. **Readers of this glossary should be cautioned that such definitions may not necessarily apply in other contexts.**

Definitions are presented using the following conventions:

Terms are in bold type and arranged alphabetically. You can move around the glossary to any initial letter by pressing 'Control+mouse click'(MS Word document) or 'mouse click' (PDF file) on the letter you require. To return to this principles list, Control+click/click on 'Principles'. To return to the start of the glossary section, Control+click/click on 'Top'.

All terms defined in this glossary are hyperlinked to their definition at their first use in another entry. To return to your previous location in the document after following a hyperlink, press 'Alt+Left arrow'.

For ease of searching and comparing terms, where the key word in a term is not the first word, it is presented as 'generic term, descriptor' (such as 'cost, financial'), as well as being entered separately in its normal order ('financial cost').

Cross-references in the form 'see … ', 'see also … ' and 'compare with … ' are provided as described below. Cross-referenced terms are hyperlinked. When the cross-reference refers to more than one term, the different terms are separated by semicolons:

- **'see … '** directs readers to a synonym or different form of the head word, where the definition is provided — for example, '**Primary outcome** (see outcome, primary)'
- **'see also … '** is used to expand understanding of a term, where there is a relationship between two or more terms — for example, 'Study (see also trial)'
- **'compare with … '** is used to highlight differences between similar terms or to indicate a term with the opposite meaning — for example, 'Analysis, primary (compare with analysis, secondary)'.

If a term is used in a different way by different HTA processes, or only relates to one or two of the HTA processes, the relevant HTA advisory committee is contained after the term in square brackets and not bolded — for example, 'Submission [PBAC]'.

Acronyms and abbreviations (such as MSAC, TGA, QALY) are entered in alphabetical order with the term in full. The term itself is also entered under its full name (in alphabetical order) with an expanded definition.

Glossary

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Abandoned (see obsolete)

Absolute risk (see risk, absolute)

Absolute risk difference (see risk difference)

Accuracy (see also validity, trial or study)
The degree to which a measurement, or an #estimate based on measurements, represents the true value of the variable being measured.

ACMD
Advisory Committee on Medical Devices

ACPM
Advisory Committee on Prescription Medicines

ACSMD
Advisory Committee on the Safety of Medical Devices

ACSOM
Advisory Committee on the Safety of Medicines

Acquisition cost (see cost, acquisition)

Admitted patient (see patient, admitted)

Adverse outcome (see outcome, adverse)

Adverse reaction (see reaction, adverse)

Advisory Committee on Medical Devices (ACMD)
A committee of the TGA that primarily advises and makes recommendations to the TGA about including particular medical devices on the Australian Register of Therapeutic Goods (ARTG).

Advisory Committee on Prescription Medicines (ACPM)
A committee of the TGA that primarily advises and makes recommendations to the TGA about including particular prescription medicines on the Australian Register of Therapeutic Goods (ARTG).

Advisory Committee on the Safety of Medical Devices (ACSMD)
A committee of the TGA that primarily advises the TGA on the safety of medical devices.

Advisory Committee on the Safety of Medicines (ACSOM)
A committee of the TGA that primarily advises the TGA on the safety of medicines.

Aggregated
Statistics based on groups of related variables, such as all the relevant costs and benefits (regardless of who incurs them).

AHMAC
Australian Health Ministers' Advisory Council

Analysis, cohort-expected value (see analysis, deterministic)

Analysis, conjoint (see also discrete choice experiment)
A survey method of data collection and analysis based on the premises that any health state, good or service can be described by its characteristics or attributes, and that the extent to which an individual values the health state, good or service depends on appropriate aggregation of the levels of these characteristics. Conjoint analysis tends to use ranking and rating methods.

Analysis, decision (see also clinical management algorithm)
A technique that formally identifies the options in a decision-making process, quantifies the probable outcomes (and costs) of each, determines the option that best meets the objectives of the decision maker, and assesses the robustness of this conclusion.

Analysis, deterministic
A decision analysis that always returns the same result for a specified set of inputs.

Analysis, economic (see also economic evaluation; analysis, financial)
An umbrella term covering both economic evaluation and financial analysis.

Analysis, financial (see also cost, financial)
A procedure for comparing only the financial costs and cost offsets of competing health technologies, rather than comparing their clinical and economic cost and benefit. Also called a budgetary analysis.

Analysis, incremental
A measure of how much extra a proposed health technology costs to produce an extra unit of outcome compared with an available health technology (or no clinical management) for a specified indication. It is calculated by dividing the difference in the net costs for the two health technologies by the difference in their net outcomes.

Analysis, joint
A measure of the extent to which a proposed health technology shares, rather than substitutes for, existing health technologies, such as the partial cost changes when the proposed health technology is likely to change current patterns of resource provision to an incomplete extent.

Analysis, marginal
An analytical technique that examines the extra costs and outcomes caused by producing and providing one extra unit of a resource.

Analysis, primary (compare with analysis, secondary)
The analysis of the primary outcome that is used in the prespecified sample size calculation (or power).

Analysis, probabilistic sensitivity
A means of representing parameter and stochastic uncertainty in the results of an economic

evaluation. In a decision analytic model, probability distributions are assigned to the uncertain parameters and are repeatedly evaluated (such as using a Monte Carlo simulation).

Analysis, regression
Given data on a dependent variable *y*, and one or more independent variables *x*1, *x*2 and so on, regression analysis involves finding the 'best' mathematical model (within some restricted class of models) to describe *y* as a function of the *x*'s. The most common form is a linear model; in epidemiology, the logistic and proportional hazard (Cox) models are also common.

Analysis, scenario
An extended form of multiway sensitivity analyses, involving the simultaneous substitution of parameter values and assumptions associated with the base case to apply the model to other circumstances of use.

Analysis, secondary (compare with analysis, primary)
Other analyses of the primary outcome; any analysis of a secondary outcome.

Analysis, sensitivity (see also robustness)
An analytical process by which the results and conclusions of an economic analysis are assessed for robustness.

Analysis, subgroup (see also subgroup)
An analysis in which the effect of a health technology is evaluated in a subgroup of a study or trial, including the analysis of its complementary subgroup. Subgroup analyses can be prespecified, in which case they are easier to interpret. If not prespecified, they are difficult to interpret because they tend to uncover false positive results.

Analysis, supplementary
The results of an economic evaluation, including a cost-benefit analysis, which takes into account a broader array of consequences in terms of costs and outcomes than the base-case analysis.

Analysis, truncated time-to-event
Time-to-event data where the trial follow-up is insufficient to record all events.

Analysis, utility
A method of measuring outcomes in terms of the preferences or utilities that individuals express for specific health statuses or health outcomes; it provides a common unit that can be used to compare different types of outcomes under conditions of uncertainty.

Analytical plan, focused (see also translation/translated)
A plan for the conduct of a premodelling study to address a translation issue that focuses on the objective and presentation of the study, including details about data sources, methods and analyses.

Anatomical Therapeutic Chemical (ATC) Classification System
An international system, controlled by the World Health Organization Collaborating Centre for Drug Statistics Methodology, that categorises all medicines into one of fourteen anatomical groups, each of which is divided into therapeutic uses and further subdivided into chemical subgroups.

Applicability/applied (see also translation/translated; validity, trial or study; validity, external)
An assessment of the extent to which participants and circumstances of use in a trial or study are similar to the proposed population for the health technology (including the baseline risk of participants and their circumstances of use), and thus the extent to which the results of the trial or study can be applied to the context of the requested PBS restriction or MBS item descriptor.

Application [PLAC] (compare with submission [PBAC]; assessment, submission-based [MSAC])
The dossier provided by an applicant in support of a request to have a prosthesis listed in the Prostheses List.

Appraisal (HTA) (see also assessment; evidence)
The deliberation of the HTA advisory committee, comprising a consideration of the assessment of the evidence relating to the proposed health technology, and taking into account the assumptions, uncertainties and other relevant factors to its decision making.

AR-DRG
Australian Refined Diagnosis Related Groups

ARTG
Australian Register of Therapeutic Goods

Assessment (see also appraisal)
The compilation, analysis, presentation and scientific critique of the best evidence available for consideration by the HTA advisory committee to address the question of public funding for a proposed health technology.

Assessment, clinical [PLAC]
An evaluation by a clinical expert of evidence provided in an application.

Assessment, contracted [MSAC]
The dossier prepared by a group contracted by the Australian Government Department of Health and Ageing in support of a request to have a medical service considered by MSAC or for MSAC to consider varying an existing medical service on the MBS.

Assessment, health technology (HTA)
A range of processes and mechanisms based on scientific evidence to assess the comparative quality, safety, efficacy, effectiveness and cost-effectiveness of health technologies.

Assessment, submission-based [MSAC] (compare with assessment, contracted; application [PLAC]; submission [PBAC])
The dossier provided by an applicant in support of their request to have a medical service considered by MSAC or for MSAC to consider varying an existing medical service.

Assessment group (see group, assessment)

Association (see also causality)
A statistical dependence between two or more events, characteristics or variables. An association exists when the value of one predicts the value of the other(s) more often than what would occur by chance. An association does not necessarily mean that one event,

characteristic or variable causes the other (which requires a number of additional criteria to be satisfied, including a dose-response relationship and a plausible mechanism).

ATAGI
Australian Technical Advisory Group on Immunisation

ATC classification
Anatomical Therapeutic Chemical classification

Attributable risk or attributable fraction (see risk, attributable)

AUST L number
Australian Listing number

AUST R number
Australian Registration number

Australian Health Ministers' Advisory Council (AHMAC)
A subcommittee of the Standing Council on Health (SCoH) that primarily advises SCoH about strategic issues relating to the coordination of health services across Australia and, as applicable, with New Zealand.

Australian Listing (AUST L) number
A unique identification number assigned to a listed therapeutic good that is entered in the Australian Register of Therapeutic Goods (ARTG) according to the criteria for listing described in the *Therapeutic Goods Act 1989* and its regulations.

Australian Refined Diagnosis Related Groups (AR-DRG)
The Australian diagnosis-related group (DRG) classification system, developed by the Australian Government and updated every two years.

Australian Register of Therapeutic Goods (ARTG)
The register of therapeutic goods for human use that may be imported to, supplied in or exported from Australia.

Australian Registration (AUST R) number
A unique identification number assigned to a registered therapeutic good that is entered in the Australian Register of Therapeutic Goods (ARTG) according to the criteria for registration described in the *Therapeutic Goods Act 1989* and its regulations.

Australian Technical Advisory Group on Immunisation (ATAGI)
An immunisation advisory body of the Australian Government that primarily provides technical advice on the medical administration of vaccines available in Australia, including those on the National Immunisation Program.

Authority-required benefit (see benefit, authority-required)

Authority-required benefit (streamlined) (see benefit, authority-required (streamlined))

Base case
The results of an economic evaluation using the projected most likely values against which the results of sensitivity analyses are compared.

Baseline
The initial set of measurements taken at the beginning of a trial or study (and after a run-in period, if applicable).

Baseline risk (see risk, baseline)

Before-and-after study (see study, before-and-after)

Benchmark (see frame of reference)

Benefit (compare with outcome, health)
An advantage or improvement caused by a health technology, or the desired outcome of using a health technology.

Benefit, authority-required [PBAC]
A medicine (or proposed prescription in relation to a medicine) listed in the PBS, that is restricted and requires prior approval from the Australian Government Department of Human Services (or the Australian Government Department of Veterans' Affairs) before prescribing. In some cases, the application for prior approval must be made in writing.

Benefit, authority-required (streamlined) [PBAC] (see also benefit, authority-required)
A medicine listed in the PBS that is restricted and requires a four-digit authority code to be written on the authority prescription.

Benefit, group [PLAC]
The amount that a private health insurer is required to provide for a prosthesis on the Prostheses List to a privately insured patient with appropriate cover as part of hospital treatment or hospital-substitute treatment. This same amount applies to all prostheses listed in the same group or subgroup, and with the same suffix.

Benefit, incremental
The absolute difference between the benefits of alternative health technologies of the same medical condition, disease or disorder.

Benefit, marginal
The extra benefit caused by providing one extra unit of a resource.

Benefit, Medicare (see also service, clinically relevant)
The payment of a rebate for a professional service listed in the MBS. Medicare benefits are claimable only for clinically relevant services rendered by an appropriate health practitioner. When a service is not clinically relevant, the fee and payment arrangements are a private matter between the practitioner and the patient. There are currently three levels of Medicare benefit payable: 75%, 85% or 100% of the Schedule Fee.

Benefit, net
In a cost-benefit analysis, the total benefit (valued in monetary units) minus the total cost.

Benefit, pharmaceutical
A medicine listed in the PBS for subsidy by the Australian Government, which may further be defined in terms of its form, manner of administration or brand.

Benefit, restricted [PBAC] (compare with benefit, unrestricted)
A medicine listed in the PBS that can only be prescribed for specific therapeutic uses as defined in the PBS.

Benefit, single [PLAC] (see benefit, group)

Benefit, unrestricted [PBAC] (compare with benefit, restricted)
A medicine listed in the PBS that has no restrictions on its therapeutic use.

Bias (see variation, systematic)

Bias, observer
The error due to systematic differences between the true value and that actually recorded by the observer.

Bias, selection
The error due to systematic differences in characteristics between those who are selected for a trial or study (or for each group in a trial or study) and those who are not.

Billing code [PLAC]
A reference code allocated to a listed prosthesis.

Blind/blinding
The procedure or process of keeping participants, and/or those responsible for the care of participants, and/or observers responsible for measuring the trial or study outcomes ignorant of the health technology group to which the participants have been allocated. In a diagnostic accuracy study, blinding also involves being ignorant of the participant's disease status.

Brand (compare with generic)
The proprietary or trade name by which a medicine or medical device is identified.

Budgetary analysis (see analysis, financial)

Budget impact analysis (see analysis, financial)

CAG [PLAC]
Clinical Advisory Group

Cardinal data (see data, cardinal)

Case-control study (see study, case-control)

Casemix
An information tool involving the use of scientific methods to build and make use of classifications of patient care episodes. Casemix helps to describe the relationship between a

hospital's activity and costs, and makes use of data about classifications that are clinically meaningful and explain variation in resource use.

Case series
A study where the use of a health technology has been assessed in a series of cases (which may or may not be consecutive patients) and the results reported. There is no separate control group for comparison.

Case series with historical controls
A quasi-experimental study in which the outcomes measured in a group of participants (with a specified indication) who are managed with a proposed health technology are compared with outcomes measured in a similar group of participants (usually seen previously in the same setting) who are managed with an existing health technology.

Catch-up vaccination program (see vaccination program, catch-up)

Categorical data (see data, categorical)

Causality (see also association)
The process of relating factors to the effects they produce. Bradford Hill (a clinical epidemiologist) proposed the following elements to consider when judging whether an association between a factor and an outcome is causal: strength of association; consistency; specificity; dose-response relationship; temporal relationship (i.e. exposure to the factor always precedes the outcome; this is the only essential criterion); biological plausibility; coherence; evidence; and analogy.

CBA
Cost-benefit analysis

CC
Complication and/or comorbidity codes

CEA
Cost-effectiveness analysis

Chance (see variation, random)

Charge (see also fee charged)
The market price associated with a good or service; does not necessarily reflect the economic cost or opportunity cost.

Chi-square test
A test based on comparison of a statistic to a chi-square distribution. Often used for detecting whether two or more population distributions differ from one another.

CI
Confidence interval

Circumstances of use
A description of the circumstances surrounding the use of a health technology in a population, which are expected to affect its overall effectiveness.

Class, therapeutic [PBAC]
A group of medicines with the same or similar pharmaceutical mechanism of action. These medicines may or may not have the same basic chemical structure. However, there may be differences between medicines within a class — for example, their side-effect profiles.

Clinical Advisory Group (CAG)
A subcommittee of the Prosthesis List Advisory Committee (PLAC) that primarily advises PLAC on applications to list prostheses and their clinical effectiveness on the Prostheses List.

Clinical assessment [PLAC] (see assessment, clinical)

Clinical effectiveness (see effectiveness, clinical)

Clinical heterogeneity (see heterogeneity, clinical)

Clinical management algorithm (see also analysis, decision)
A description of the health care resources provided over time (including how frequent and when) to a population of individuals under the circumstances defined for the health technology and conditioned by the proportion of individuals managed through each clinical pathway.

Clinical management algorithm, current
The set of clinical pathways that define the stream of health care resources currently provided over time to manage a patient population, which is conditioned by the probabilities of different events being experienced by those patients or different information being gathered about those patients during the period captured by the algorithm.

The current clinical management algorithm describes:

- the eligible patient population and their current clinical management up to the point where the proposed health technology would be appropriate
- how these patients are currently managed without the proposed health technology from this point onwards, noting that there may be more than one possible clinical pathway.

Clinical management algorithm, proposed
The set of clinical pathways that define the stream of health care resources that would be provided over time to manage a patient population if the proposed health technology was publicly funded. This is also conditioned by the probabilities of different events being experienced by those patients or different information being gathered about those patients during the period captured by the algorithm.

The proposed clinical management algorithm describes:

- the eligible patient population and their current clinical management up to the point where the proposed health technology would be appropriate
- how these patients would be managed with the proposed health technology from this point onwards, noting that there may be more than one possible clinical pathway.

There will be one proposed clinical management algorithm for each decision option.

Clinical pathway
A description of the health care resources provided over time (including how frequent and when) to an individual under the circumstances defined for the health technology.

Clinically equivalent [PLAC]
A proposed prosthesis is substantially clinically equivalent if, in comparison with one or more listed prostheses, it:

- has the same intended use as the existing prostheses
- has the same or very similar technological characteristics as the existing prostheses
- does not raise new questions of safety and effectiveness
- has demonstrated in clinical studies that it is safe and effective during a time period commensurate with its intended use, risk and likelihood of failure
- is not a high-risk prosthesis (such as load-bearing, articulating, a mobile implant)
- is not new or novel in design.

Clinically important (compare with statistically significant)
The extent to which a treatment effect or other outcome provides an improvement in symptoms, or quality or quantity of life that is relevant and worthwhile for patients.

Clinically relevant service (see service, clinically relevant)

CMA
Cost-minimisation analysis

Co-administered intervention (see intervention, co-administered)

Cochran *Q* statistic (see also I^2 statistic)
A measure of statistical heterogeneity in a meta-analysis. It is the sum of the squared deviations of the estimates of each trial from the overall meta-analytical estimate, weighting each trial's contribution in the same manner as in the meta-analysis.

Co-dependent health technologies
Health technologies that are dependent on each other such that their use needs to be combined (either sequentially or simultaneously) to achieve or improve the intended effect on health outcomes of either health technology.

Cohort-expected value analysis (see analysis, deterministic)

Cohort study (see study, cohort)

Commentary [PBAC] (see also critique [MSAC])
A written analysis of a submission to evaluate the validity of the assessment provided to support the claims for comparative safety, clinical effectiveness and cost-effectiveness, and identify clinical and economic issues for consideration by PBAC and its subcommittees.

Common reference
A health technology (including placebo or watchful waiting for no health technology) against which the proposed health technology and its main comparator have been compared in separate direct randomised trials.

Comorbidity
A concomitant but unrelated pathologic or disease process in a patient. The term is usually used in epidemiology to indicate the coexistence of two or more medical conditions.

Comparative cost (see cost, comparative)

Comparative safety (see safety, comparative)

Comparator, main (see also indication, main)
The existing health technology (or other current clinical management) that most health care practitioners will replace in practice should the proposed health technology be implemented as proposed.

Complex restriction [PBAC]
A restriction involving several elements, which need to be linked in a logical way.

Complication
A morbid process or event occurring during a disease that is not an essential part of the disease, although it may result from it or from independent causes.

Complication and/or comorbidity (CC) codes
When applying diagnostic-related groups, diagnoses that are likely to result in significantly greater resource consumption.

Composite outcome (see outcome, composite)

Condition, medical
The health state of a person that might require therapy.

Conditional listing [PLAC]
A listing (for selected prostheses) that requires additional circumstances or conditions to be satisfied before a private health insurance benefit is payable.

Confidence interval (CI)
The calculated interval with a specified probability (by convention, 95%) that the true value of a variable — such as the mean, proportion or rate — is contained within that interval.

Confounding
The distortion of a measure of an exposure's effect (such as to a therapeutic health technology) on the risk of an outcome of interest brought about by the association of the exposure with one or more other factors that can influence the outcome.

Conjoint analysis (see analysis, conjoint)

Consensus report
A statement or practice based on general or majority agreement within a group.

Consequence (see outcome)

Conservative
Generally, a resistance to change. A behavioural response to uncertainty involving harm, costs and benefits where the expected rate of harm or costs is given a greater weight than the expected rate of benefits. In practice, this means that where alternative assumptions, estimates or values are available for a modelled economic evaluation, the conservative assumption, estimate or value is the one that is less likely to result in the requested outcome for the proposed health technology. Adopting a conservative assumption, estimate or value has the advantage of addressing the uncertainty if it does result in the requested outcome.

Conservative management and/or conservative treatment
An approach to medical care that offers less intensive or invasive options for the management of a particular medical condition.

Consumption of resources (see resources, consumption)

Contingent valuation (CV) (see valuation, contingent)

Continuation criteria
The specific intention of a restriction containing continuation criteria is to identify, from all individuals who were eligible to initiate use of the proposed health technology, those individuals who would be eligible to continue subsidised access to the proposed health technology.

Continuous data (see data, continuous)

Contracted assessment [MSAC] (see assessment, contracted)

Control group (see group, control)

Co-payment [MSAC] (see cost, gap; cost, out-of-pocket; gap, patient)

Co-payment [PBAC]
A payment made by the user at the time of dispensing as part of the total payment for that pharmaceutical benefit.

Correlation (see association)

Cost, acquisition
The purchase cost of a good or service to an institution, agency or individual.

Cost, comparative
How much one health technology costs compared to an alternative health technology.

Cost, direct
The value of all health care resources that are provided with a health technology or in dealing with adverse outcomes, or other current and future consequences linked to the health technology.

Cost, economic or opportunity
The value of the best alternative use of a resource that is foregone as a result of its current use.

Cost, financial (see also analysis, financial)
The monetary value of providing a resource accounted for in the budget of the provider, or of funding the resource accounted for in the budget of the funding arrangement.

Cost, gap (compare with cost, out-of-pocket; gap, patient)
The gap cost in relation to the Original Medicare Safety Net refers to the difference between the Medicare Benefit (85%) and the Schedule Fee for out-of-hospital services.

Cost, health care resource
The monetary value of a resource provided to deliver health care services as part of the clinical management of a medical condition, disease or disorder.

Cost, incremental
The absolute difference between the costs of alternative health technologies for the same medical condition, disease or disorder.

Cost, marginal
The extra cost of producing one extra unit of a resource.

Cost, net
In an incremental analysis, the monetary value of any increase in resource provision minus any cost offsets — for example, those resulting from an improvement in outcome.

Cost, out-of-pocket (see also cost, gap)
A cost, in relation to the Extended Medicare Safety Net, that refers to the difference between the Medicare Benefit, including any benefits paid through the Original Medicare Safety Net and the fee charged by the practitioner for out-of-hospital services.

Cost analysis
A partial economic evaluation that only compares the costs in monetary units of clinical management involving the proposed health technology with clinical management involving its main comparator(s).

Cost-benefit analysis (CBA)
An economic evaluation that compares health technologies in which both costs and benefits are measured in monetary terms to calculate a net monetary gain/loss or benefit gain/loss.

Cost-consequence analysis (see also natural unit; compare with cost-effectiveness analysis)
An economic evaluation that compares health technologies as an array of all material costs and outcomes measured in their natural units rather than a single representative outcome as presented in a cost-effectiveness analysis.

Cost-effective [MSAC] (compare with value for money)
MSAC considers a proposed medical service to be cost-effective if it considers that, for a specified main indication, the incremental benefits of clinical management involving the proposed medical service over clinical management involving its main comparator(s) justify its incremental costs and harms.

Cost-effective [PBAC] (compare with value for money)
PBAC considers a proposed medicine to be cost-effective if it considers that, for a specified main indication, the incremental benefits of therapy involving the proposed medicine over therapy involving its main comparator(s) justify its incremental costs and harms.

Cost-effective [PLAC] (compare with value for money)
PLAC considers a proposed prosthesis to be cost-effective if it considers that, for a specified indication and comparator, the value of incremental net health benefits (that is, incremental health benefits less harms) are greater than the incremental costs.

Cost-effectiveness acceptability curves
A graph that summarises the results of a cost-effectiveness analysis by plotting a range of

possible cost-effectiveness thresholds on the horizontal axis against the probability that the proposed health technology will be cost-effective on the vertical axis.

Cost-effectiveness analysis (CEA) (see also natural units; compare with cost-consequence analysis)
An economic evaluation that compares health technologies that have a common health outcome in which costs are measured in monetary terms and the outcome is measured in natural units.

Cost-efficacy analysis (see also economic evaluation, stepped; economic evaluation, trial-based)
A cost-effectiveness analysis using the most internally valid data available (that is, from adequate randomised trials). If a more externally valid modelled economic evaluation is required, it is a first step to show the implications of incorporating translations and assumptions.

Cost-minimisation analysis (CMA)
An economic evaluation that identifies the least costly health technology after the proposed health technology has been demonstrated to be no worse than its main comparator(s) in terms of effectiveness and toxicity.

Cost neutral
The result of a financial analysis that concludes that implementing the proposed health technology would neither increase nor decrease costs to the government.

Cost-utility analysis (CUA)
An economic evaluation that compares health technologies in which costs are measured in monetary terms, and outcomes are measured in terms of extension of life and the utility value of that extension (such as quality-adjusted life-years or healthy-year equivalents).

Critique [MSAC] (see also commentary [PBAC])
A written analysis of either a contracted assessment or submission-based assessment against the decision analytic protocol to evaluate the validity of the assessment provided to support the claims for comparative safety, clinical effectiveness and cost-effectiveness, and identify clinical and economic issues for consideration by MSAC and its Evaluation Sub-committee.

Cross-over (see also trial, randomised cross-over; compare with group, parallel)
A method of comparing two alternative health technologies. Upon completion of one health technology, participants are switched to the other health technology.

Cross-sectional study (see study, cross-sectional)

CUA
Cost-utility analysis

CV
Contingent valuation

DAP
Decision analytic protocol

Data (see also evidence; opinion)
Measurements of variables of interest.

Data, cardinal (see also utility)
Ordinal data in which the difference between two equidistant estimates on the ranked scale has the same value irrespective of where the estimates lie on the scale (such as 0.9 – 0.8 = 0.2 – 0.1).

Data, categorical
Data in which the variables can only have discrete values.

Data, continuous (see also data, dichotomous)
Data with a potentially infinite number of possible values along a continuum (such as age, height).

Data, dichotomous (see also data, continuous)
Data that are classified into either one of two mutually exclusive values — for example, 'yes' and 'no', or 'cured' and 'not cured'.

Data, nominal
Data that have been classified into unordered qualitative categories.

Data, ordinal
Data that are classified into ordered (that is, one category is higher or lower than another), qualitative (that is, the numerical distance between their possible values is undefined or unknown), mutually exclusive categories.

Data, prospective (see also data, retrospective)
Data collected about events that occur after a study has started.

Data, retrospective (see also data, prospective)
Data collected about events that occurred before a study was started.

Data, time-to-event (see also data)
Data that incorporate a measure of the time lapse before an event occurs — for example, time to relapse, time to death or time-to-treatment cessation.

Decision analysis (see analysis, decision)

Decision analytic protocol (DAP) [MSAC]
The set of materials developed by the Protocol Advisory Sub-committee (PASC) of MSAC. The DAP defines a limited set of decision options which, for each option, compares the current clinical management algorithm to the proposed clinical management algorithm in a decision analysis.

Decision tree
A flow diagram depicting the probable consequences of the various decision options in a decision analysis.

DerSimonian–Laird random effects model (see model, random effects)

Description [PLAC]
The details specific to a product, which could include:

- model number
- descriptors for the product or product components — for example, a spinal system that consists of screws, a threaded rod, hex nuts, a washer and an endplate
- composition
- any special features.

Deterministic analysis (see analysis, deterministic)

Device, included medical [PLAC]
A medical device to which Chapter 4 of the *Therapeutic Goods Act 1989* and its regulations applies, which has been included on the Australian Register of Therapeutic Goods (ARTG), and which has been issued with a unique identification number.

Device, medical (see also product; prosthesis)
A medical device is (from the *Therapeutic Goods Act 1989*):

1. Any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap

iii. investigation, replacement or modification of the anatomy or of a physiological process

iv. control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

2. An accessory to such an instrument, apparatus, appliance, material or other article.

PLAC uses the terms product and prosthesis interchangeably with medical device.

DHS
Australian Government Department of Human Services

Diagnosis
The identification of a medical condition by investigation.

Diagnosis, differential
The process of considering the possible causes of a patient's complaint before making a diagnosis.

Diagnosis-related group (DRG)
A patient classification scheme that provides a clinically meaningful way of relating the types of patients treated in a hospital to the resources required by the hospital.

Diagnosis-related group (DRG) cost weight
A measure of the relative cost of a DRG. Usually, the average cost across all DRGs is chosen as the reference value, and is given a weight of 1.

Diagnostic accuracy study (see study, diagnostic accuracy)

Dichotomous data (see data, dichotomous)

Differential diagnosis (see diagnosis, differential)

Direct cost (see cost, direct)

Direct description of quality of life (see quality of life, direct description of)

Direct elicitation of utility (see utility, direct elicitation of)

Direct randomised trial (see trial, direct randomised)

Disaggregated
Statistics that are based on individual (that is, ungrouped) variables — for example, separating the relevant costs and benefits according to who incurs them.

Discounting
The process by which the streams of future costs and/or benefits (beyond 12 months) are converted to equivalent present values.

Discount rate (see rate, discount)

Discrete choice experiment (see also analysis, conjoint)
A survey method of data collection and analysis based on the premises that any health state, good or service can be described by its characteristics or attributes, and that the extent to which an individual values the health state, good or service depends on appropriate aggregation of the levels of these characteristics. Discrete choice experiments tend to use choice or trade-off decisions.

Dispensed price [PBAC] (see price, dispensed)

Dispensed price for maximum quantity (DPMQ) [PBAC] (see price, dispensed for maximum quantity)

DoHA
Australian Government Department of Health and Ageing

Dominance
When clinical management involving one health technology has greater overall clinical

effectiveness and lower overall costs than clinical management involving a different health technology, it is said to have dominance.

Double-blind
A trial or study design in which both the participants and observers responsible for measuring the outcomes are kept ignorant of the group to which participants are assigned.

Double-counting
Counting the same component variable (such as a study, an outcome or a cost) more than once when constructing or deconstructing a composite variable.

Downstream (see also upstream)
Occurring (in time) after the initial provision of the health technology to an individual.

DPMQ
Dispensed price for maximum quantity

DRG
Diagnosis-related group

Drop-out (compare with withdrawal)
When a participant leaves before the end of a study and is therefore not included in all the follow-up measurements.

Drug Utilisation Sub-Committee (DUSC)
A subcommittee of PBAC that primarily advises PBAC on the utilisation and financial analyses in submissions.

DUSC
Drug Utilisation Sub-Committee

DVA
Australian Government Department of Veterans' Affairs

Dynamic model (see model, dynamic)

Economic analysis (see analysis, economic)

Economic cost (see cost, economic or opportunity)

Economic evaluation
A comparative analysis of the costs and outcomes of health technologies. An umbrella term covering cost-benefit analysis, cost-effectiveness analysis, cost-consequence analysis, cost-minimisation analysis and cost-utility analysis. The analysis involves identification, measurement and valuation of the differences in costs and outcomes caused by substituting health technologies.

Economic evaluation, modelled (see also economic evaluation, stepped)
An economic evaluation based on inputs and outcomes obtained from sources other than, or in addition to, one or more direct randomised trials.

Economic evaluation, stepped (see also economic evaluation, modelled)
An economic evaluation that is presented in at least three sequential steps, derived from inputs and outcomes translated from direct randomised trials and other sources:

1. The first step is a trial-based economic evaluation that is derived from the unmodified trial-based estimate of treatment effect on the incremental provision of health care resources and incremental health outcomes. Steps 2 and 3 should be presented if the trial-based economic evaluation is not sufficient to provide the base case.

2. The second step examines the effects of applying the treatment effects on health care resources and outcomes to the intended population and the circumstances of use identified by the requested restriction, using a modelled economic evaluation.

3. The third step examines the additional effects on the modified economic evaluation of extrapolating the provision of health care resources and health outcomes to the time horizon of the economic evaluation and/or any transformation of health outcomes. This final step generates the base case of the modelled economic evaluation.

Economic evaluation, trial-based
An economic evaluation based only on inputs and outcomes reported in one or more direct randomised trials.

Economics Sub-Committee (ESC) [PBAC]
A subcommittee of PBAC that primarily advises PBAC on the cost-effectiveness aspects in submissions.

Effectiveness, clinical
The extent to which a health technology produces its intended outcome(s) in a defined population in uncontrolled or routine circumstances.

Efficacy
The extent to which a health technology produces its intended outcome(s) in a defined population in controlled or ideal circumstances.

Efficiency (see also efficiency, allocative; efficiency, technical)
The extent to which the maximum possible benefit is achieved out of the available resources.

Efficiency, allocative (see also efficiency; efficiency, technical)
An allocation of the mix of resources for maximum benefit (that is, such that there is no change in spending priorities that would further improve overall welfare).

Efficiency, technical (see also efficiency; efficiency, allocative)
The production of the greatest amount or quality of outcomes for any specified level of resources.

EMBASE
An electronic database of journal citations that contains more entries from European journals than Medline does.

EMSN
Extended Medicare Safety Net

Episode of care
A period of health care with a defined start and end.

Equity
The recourse to the principles of fairness to inform decision making — for example, from a general policy viewpoint, the funding arrangements promote fairness by promoting affordable access to cost-effective health technologies.

Equivalence (see also noninferiority)
Assessed by whether there is sufficient evidence to conclude that two alternative health technologies are noninferior compared with each other.

Error, random (see variation, random)

Error, systematic (see variation, systematic)

ESC [MSAC]
Evaluation Sub-committee

ESC [PBAC]
Economics Sub-Committee

Established service (see service, clinically relevant)

Estimate
The value of a quantity that is known, believed or suspected of incorporating some amount of error.

Etiologic fraction (see risk, attributable)

Evaluation group [PBAC] (see group, evaluation)

Evaluation Sub-committee (ESC) [MSAC]
A subcommittee of MSAC that primarily advises MSAC on the issues and uncertainties arising from the evidence presented in an assessment report.

Evidence (see also data; opinion)
An umbrella term covering data and opinion.

Evidence, quality of
The degree to which bias has been prevented through the design and conduct of research from which data-based evidence is derived.

Evidence, strength of
The magnitude, precision and reproducibility of the effect of the health technology (includes magnitude of the effect size, confidence interval width, *P*-value and the exclusion of clinically unimportant effects). In the case of nonrandomised studies, additional factors such as biological plausibility, biological gradient and temporality of associations may be considered.

Ex-manufacturer price [PBAC] (see price, ex-manufacturer)

Exposed group (see group, exposed)

Extended Medicare Safety Net (EMSN) (see Safety Net, Extended Medicare)

Extended Medicare Safety Net (EMSN) benefit cap (see also Safety Net, Extended Medicare)
The EMSN benefit cap is an upper limit on the EMSN benefit that can be paid through the EMSN for an MBS item. The EMSN benefit cap does not limit the out-of-pocket costs that accumulate towards the EMSN threshold. Where an item has an EMSN benefit cap, EMSN benefits are calculated in the same way — that is, 80% of the patient's out-of-pocket costs for Medicare-eligible out-of-hospital services. However, where an EMSN benefit cap applies, the EMSN benefit payable must not exceed the EMSN benefit cap amount. Under law, the EMSN benefit cap must be an amount greater than zero dollars. The EMSN benefit caps are set out in a Determination made by the health minister and must be approved by both Houses of Parliament before an MBS item can be capped. EMSN benefit caps can be set as a fixed dollar amount or expressed as a percentage of the Schedule Fee.

External validity (see validity, external)

Extrapolation/extrapolated (see also translation/translated)
An assessment of the extent to which the outcomes reported within the trial or study continue beyond the duration of the follow-up and, thus, the extent to which the results of the trial or study can be extended beyond this duration.

False negative rate (see rate, false negative)

False positive rate (see rate, false positive)

Fee, Schedule (compare with fee charged; benefit, Medicare)
A Schedule Fee is determined by the government for each medical service listed in the MBS. It is determined on the basis of being reasonable, on average, for that service, having regard to usual and reasonable variations in the time involved in performing the service on different occasions, and to reasonable ranges of complexity and technical difficulty encountered. As a general rule, Schedule Fees are adjusted annually, usually in November. The Medicare benefit for a service is calculated from the Schedule Fee.

Fee charged (compare with benefit, Medicare; cost, out-of-pocket; Fee, Schedule)
The fee charged to the patient by the provider of a professional service listed in the MBS.

Final outcome (see outcome, final)

Financial analysis (see analysis, financial)

Financial cost (see cost, financial)

Financial implications (see analysis, financial)

First-line treatment (see treatment, first-line)

Fit-for-purpose
Structuring the size and type of a review or evaluation to fit the type, complexity and cost of the item(s) involved.

Fixed combination product [PBAC]
A product comprising a fixed combination of active component medicines in either a single dosage form or individual dosage forms in a composite packaging.

Fixed-effect model (see model, fixed-effect)

Focused analytical plan (see analytical plan, focused)

Follow-up
The observation, during a specified time period, of trial or study participants to measure changes in outcomes of interest.

Force of infection
The probability per unit of time that a susceptible person acquires infection.

Forest plot
A graphical display of the results of a meta-analysis depicting the point estimates and confidence intervals for each trial with or without the statistically combined overall point estimate and its confidence interval.

Frame of reference
A basis for examining the consistencies of decision making in terms of maximising value for money by comparing the results of incremental cost-effectiveness ratios that report comparable outcomes in the denominator.

Friction method (see method, friction)

Funding arrangement
An arrangement that helps to fund services or products for people eligible to receive the funding (such as under the PBS, MBS and Prostheses List).

Funnel plot
A graphical display of some measure of the precision of a trial plotted against the treatment effect size to examine whether there is a link between precision and treatment effect (and hence identify possible heterogeneity among the trials).

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Gap, Greatest Permissible (GPG)

Section 10(3) of the *Health Insurance Act 1973* requires that the difference between the Schedule Fee for an item and the 85% benefit must not exceed the amount of the GPG. Therefore the GPG works to increase the Medicare rebate payable for high-cost services that attract the 85% benefit. The GPG does not apply to services where the 75% benefit is paid. The GPG is increased by the consumer price index on 1 November each year.

Gap, patient (compare with cost, gap; cost, out-of-pocket)
Private health insurers can cover the 'patient gap' (that is, the difference between the Medicare rebate and the Schedule Fee) for services attracting benefits at the 75% level that can be covered by private health insurers. The benefits are those paid for professional services rendered to a patient as part of an episode of hospital treatment or for professional services rendered as part of an episode of hospital-substitute treatment.

Gap cost (see cost, gap)

Generalisability (see applicability)

Generic (name)
The accepted or official nonproprietary name (not a chemical formula or a brand) by which a medicine or medical device is identified.

Gold standard (see standard, gold)

Grandfathering provision [PBAC]
The provision of a PBS subsidy to a patient who was receiving therapy involving the proposed medicine before its listing in the PBS and for which a restriction involving prior authorisation is required by the PBS.

Greatest Permissible Gap (GPG) (see Gap, Greatest Permissible)

Group, assessment [MSAC] (see also group, evaluation [PBAC])
An external organisation contracted by the Australian Government Department of Health and Ageing primarily to draft a decision analytic protocol, or to prepare a contracted assessment or to critique a submission-based assessment.

Group, control (see also group, exposed)
A group of participants who are observed but who do not receive clinical management involving the proposed health technology. They may receive alternative clinical management, no clinical management or a placebo. They provide data on the streams of outcomes (clinical and economic) for comparison with the streams of outcomes observed for the exposed group.

Group, evaluation [PBAC] (see also group, assessment [MSAC])
An external organisation contracted by the Australian Government Department of Health and Ageing primarily to prepare a commentary.

Group, exposed (see also group, control)
A group of participants who receive clinical management involving the proposed health technology. They provide data on the streams of outcomes (clinical and economic) for comparison with the streams of outcomes observed for the control group.

Group, parallel (compare with cross-over)
An experimental design where each group in a comparative trial receives only one health technology and does not cross over to the other health technology.

Group/subgroup [PLAC]
Prostheses that have comparable features or functions, and are grouped together on the Prostheses List.

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Hazard ratio (see ratio, hazard)

Head-to-head randomised trial (see trial, direct randomised)

Health care resource
A resource provided as part of the clinical management of a medical condition, disease or disorder — for example, a medicine, medical service, hospital service, diagnostic service, investigational service or community-based service.

Health care resource cost (see cost, health care resource)

Health care system viewpoint (see viewpoint, health care system)

Health Expert Standing Panel (HESP)
A panel appointed by MSAC, from which a member is assigned to provide expert advice to MSAC or its subcommittees about the application of the proposed health technology in the Australian setting.

Health outcome (see outcome, health)

HealthPACT
Health Policy Advisory Committee on Technology

Health Policy Advisory Committee on Technology (HealthPACT)
A subcommittee of the Hospital Principal Committee that primarily undertakes horizon scanning of new and emerging technologies.

Health-related quality of life
The physical, social and mental aspects that are relevant and important to the health aspects of an individual's overall wellbeing.

Health status (compare with quality of life)
A measure of the extent to which an individual is able to function physically, mentally and socially.

Health technology (see also health technology, therapeutic; health technology, investigative)
A technology used in a health care system — for example, therapeutic services (such as medicines and procedures), medical devices, investigative medical services (such as diagnostic tests and imaging services), equipment and supplies, and organisational and managerial systems. For the purposes of some definitions of this glossary, particularly in relation to existing health technologies, this usual definition is extended to include any medical service, placebo or watchful waiting instead of an active health technology.

Health technology, investigative (compare with health technology, therapeutic)
A type of health technology that is expected to, or claimed to be able to, generate clinically relevant information about the individual to whom the service is rendered. To achieve an improvement in health outcomes, this information must result in a change in the clinical management of an intermediate intervention. In this sense, investigative procedures can only indirectly improve health outcomes.

Health technology, therapeutic (compare with health technology, investigative)
A type of health technology that is expected to, or claimed to be able to, directly improve health outcomes. Nothing else needs to be rendered to achieve the improvement in health outcomes.

Health technology assessment (HTA) (see assessment, health technology)

Healthy-year equivalent (HYE) (compare with life-year, quality-adjusted)
The hypothetical number of years spent in perfect health that could be considered equivalent to the actual number of years spent in a defined imperfect state of health. It differs from a quality-adjusted life-year (QALY) because not only is it based on an individual's preference for a specific level of health status, but also on the individual's preference for the duration of their life.

Herd immunity
The resistance of a group to the invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group.

HESP
Health Expert Standing Panel

Heterogeneity, clinical
The variation in, or diversity of, participants, health technologies and measurements of outcomes across a set of trials, or the variation in the internal validity of those trials. That is, clinical heterogeneity refers to differences in methods across trials being compared, implying that it might not be sensible to combine them in a meta-analysis.

Heterogeneity, statistical
The variation in the effect of therapy involving a therapeutic health technology on an outcome across a set of measurements. This depends on what scale the effect is measured on, because statistical heterogeneity can occur for one scale of measurement (such as the risk difference on the absolute or additive scale), but not for others (such as the relative risk or odds ratio on the multiplicative scale). Statistical heterogeneity on the absolute scale — that is, for an additive measure of effect (such as the risk difference) — is common. The risk difference has often been shown to vary by the baseline characteristics of participants. Statistical heterogeneity on the multiplicative scale — that is, for a relative measure of effect (such as the odds ratio or relative risk) — is less common.

Highly specialised drug (HSD)
A medicine that is listed in the PBS to treat chronic conditions but to which only public and private hospitals with appropriate specialist facilities are allowed access because of its clinical use or other specialised features. Funding is provided under the HSD Program within s. 100 of the *National Health Act 1953*.

Hospital Principal Committee (HPC)
A principal committee of the Australian Health Ministers' Advisory Council (AHMAC) that, among other things, advises AHMAC on the appropriateness, likely impact, policy implications, effectiveness and safety of clinical and technical developments, particularly in relation to hospital care.

Hospital-substitute treatment [PLAC] (see treatment, hospital-substitute)

Hospital treatment (see treatment, hospital)

HPC
Hospital Principal Committee

HSD
Highly specialised drug

HTA
Health technology assessment

HTA advisory committee
Expert HTA advisory committees, appointed by the health minister, provide advice to the Australian Government about which proposed health technologies should be considered for listing on the PBS, MBS and the Prostheses List, and what the recommended benefit or subsidy should be. Current HTA advisory committees are PBAC, MSAC and PLAC.

Human capital method (see method, human capital)

Hybrid health technology
A health technology that combines the characteristics of more than one type of health technology (such as a medicine and a medical device) into a single entity.

HYE
Healthy-year equivalent

Hypothetical cohort (see analysis, deterministic)

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***I*^{2} statistic**
A variable used to measure the percentage of the variability in effect estimates across trials or subgroups that is due to statistical heterogeneity rather than sampling error (chance). A naive categorisation of values for I^2 would not be appropriate for all circumstances, although adjectives of low, moderate and high have been tentatively assigned to I^2 values of 25%, 50% and 75%, respectively.

ICER
Incremental cost-effectiveness ratio

Immunogenicity outcome (see outcome, immunogenicity)

Implicit price deflator
A parameter used to update a unit cost to account for inflation in prices since the unit cost was determined.

Incidence (compare with prevalence)
The number of individuals manifesting with a new attribute or new disease within a specified time period in a defined population, divided by the number of people in that population.

Included medical device (see device, included medical)

Incremental analysis (see analysis, incremental)

Incremental benefit (see benefit, incremental)

Incremental cost (see cost, incremental)

Incremental cost-effectiveness ratio (ICER) (see ratio, incremental cost-effectiveness)

Incremental safety (see safety, incremental)

Indication
The medical condition, disease or disorder that is the reason for starting clinical management.

Indication, main (see also comparator, main)
The indication likely to account for the largest proportion of patients treated with the proposed health technology.

Indirect comparison (compare with trial, direct randomised; see also trial)
An analysis that indirectly compares the proposed health technology to its main comparator by comparing one set of trials, in which participants were randomised to receive the proposed health technology or a common reference, with another set of trials, in which participants were randomised to receive the main comparator or the common reference.

Inpatient (see patient, admitted)

Input
A resource provided as part of managing a medical condition, disease or disorder. A variable that is included in an analysis or a model.

Instrument
A tool used to measure a variable, including any defined administrative procedures in its use and scoring instructions in its interpretation.

Intangible outcome (see outcome, intangible)

Intention to treat (ITT)
A principle of analysis that includes data from all participants allocated to a specified clinical management group as representing that group irrespective of whether they received or completed the prescribed regimen, or whether they were followed for the full duration of the trial or study. This involves following up participants to contribute data and/or prespecifying procedures to deal with missing data.

Intermediate outcome (see outcome, intermediate)

Internal validity (see validity, internal)

Interval data (see data, cardinal)

Intervention (see also therapy; compare with investigation)
Clinical management with a therapeutic health technology that has a direct effect on health outcomes (such as a medicine or a surgical procedure).

Intervention, co-administered
An intervention that is given at the same time as the main intervention of interest.

Investigation (see also diagnosis; compare with intervention)
Clinical management with an investigative health technology (such as a diagnostic test or an imaging service).

ITT
Intention to treat

JBC
Jurisdictional Blood Committee

Joint analysis (see analysis, joint)

Jurisdictional Blood Committee (JBC)
A subcommittee of the Hospital Principal Committee (HPC) that primarily provides national policy leadership on matters relating to the national blood supply.

Kaplan–Meier curve
A graphical display of the results of a nonparametric method of compiling time-to-event tables. The method combines calculated probabilities of the event occurring, with estimates to allow for censored observations (which are assumed to occur randomly). The resulting intervals are defined as ending each time an event (such as death or withdrawal) occurs, and are therefore unequal.

League table (see frame of reference)

Leakage
Using a health technology beyond its approved funding conditions.

Length of stay (LOS)
The LOS of a patient is measured in patient days. A same-day patient should be allocated a LOS of one patient day. The LOS of an overnight-stay patient is calculated by subtracting the date the patient is admitted from the date of separation and deducting total leave days. Total contracted patient days are included in the LOS.

Life-year
An outcome measure calculated by multiplying the number of affected individuals by the number of years each individual is expected to live.

Life-year, quality-adjusted (QALY) (compare with healthy-year equivalent)
An outcome measure calculated by weighting the number of life-years by utility values of the quality of life experienced during those life-years.

Likelihood ratio (see ratio, likelihood)

Likert scale
An ordinal scale of responses to a question or statement ordered in a hierarchical sequence.

LOS
Length of stay

Main comparator (see comparator, main)

Main indication (see indication, main)

Managed entry [PBAC]
The memorandum of understanding (agreed to on 5 May 2010 between Medicines Australia and the Australian Government) refers to managed entry schemes that provide for PBAC to recommend PBS coverage at a price justified by the existing evidence, pending submission of more conclusive evidence of cost-effectiveness to support listing of the medicine at a higher price.

Manufacturing quality [PLAC]
Manufacturing quality is assessed in the context of the quality management system implemented by the medical device manufacturer. Those systems are assessed against Australian/International Standard *AS ISO 13485 — Medical devices — quality management systems — requirements for regulatory purposes*.

Mapping (compare with matching)
In relation to utility analyses, a general term to describe approaches to transform generic or disease-specific quality-of-life measures into utility weights.

Marginal analysis (see analysis, marginal)

Marginal benefit (see benefit, marginal)

Marginal cost (see cost, marginal)

Marginal utility (see utility, marginal)

Marginal value (see value, marginal)

Market share
The extent of use of a health technology in relation to the overall use of all health technologies for a market defined by one or more indications.

Markov model (see model, Markov)

Mask/masking (see blind/blinding)

Matching (compare with mapping)
In relation to utility analyses, a general term to describe approaches to align utility weights from one set of respondents to a particular health status or health outcome of interest by showing that the respondents are experiencing a similar health status or outcome.

MAUI
Multi-attribute utility instrument

MBS
Medicare Benefits Schedule

MBS fee (see fee, MBS)

MBS item
The description of an existing health technology or other medical service included in the MBS.

MBS review
An evidence-based review of one or more existing MBS services with regard to safety, effectiveness and cost effectiveness. The review will ensure that MBS services align with contemporary clinical practice, represent value for money and provide health outcomes for patients. Stakeholder consultation is central to the MBS Reviews process and there will be multiple opportunities for stakeholders to provide feedback throughout the review process.

MBSMC
Medicare Benefits Schedule Management Committee

MCID
Minimal clinically important difference

Mean
A measure of central tendency. The arithmetic average that is calculated by adding all the individual values in the group and dividing by the number of values in the group.

Measurement
The procedure of applying a standard scale to a variable or a set of values.

Median
A measure of central tendency. The exact midpoint of a distribution of data that is ordered from the highest to the lowest value.

Medical condition (see condition, medical)

Medical device (see device, medical)

Medical Services Advisory Committee (MSAC)
An independent HTA advisory committee of the Australian Government that primarily advises the health minister on whether it supports the public funding of proposed health technologies and other medical services.

Medicare, Extended Safety Net (see Safety Net, Extended Medicare)

Medicare, Original Safety Net (see Safety Net, Original Medicare)

Medicare benefit (see benefit, Medicare)

Medicare Benefits Schedule (MBS)
Under the authority of the *Health Insurance Act 1973*, a listing and description of the professional services for which a Medicare benefit is payable by the Australian Government, the amount of a patient's cost that is met through a government rebate, and any conditions applying to the use of that service.

Medicare Benefits Schedule Management Committee (MBSMC)
A committee of the Australian Government Department of Health and Ageing that primarily provides advice, direction and recommendations on any matters relating to the MBS.

Meta-analysis (see also meta-regression; compare with systematic overview; systematic review)
A statistical combination of results from independent randomised trials.

Meta-regression (see also meta-analysis)
A regression-based technique used in a meta-analysis of multiple trials to explore the relationship between a particular trial characteristic and trial results.

Method, friction (see also method, human capital)
A method of estimating the production change associated with illness to the economy by measuring only the production lost during the friction period in which organisations restore their initial production level — for example, the time taken to replace a sick worker.

Method, human capital (see also method, friction)
A method of estimating the production change associated with illness based on the sum of the remaining lifetime earnings of each healthy individual of particular ages valued at labour market rates (such as average salaries).

Minimal clinically important difference (MCID)
The smallest difference in a score that is considered worthwhile or clinically important when considering overall benefits and harms to health.

Model, Cox proportional hazards
A statistical model in survival analysis asserting that the effect of the trial or study factors on the hazard rate in the study population is multiplicative and does not change over time.

Model, decision analytic
A model that informs a decision analysis.

Model, dynamic (compare with model, static)
A model applied in the context of vaccination, and usually structured as a decision analytic model (such as a Markov model) in which the force of infection depends on the number of infectious individuals in the population at each time point, and this number would be expected to change following immunisation.

Model, fixed effect (compare with model, random effects)
The model used in a meta-analysis based on the assumption that all trials are estimating the same treatment effect and that the difference in effect observed across trials is only due to chance.

Model, Markov
An iterative decision analytic model that represents the changes in the proportions of individuals who are in different discrete health states based on probabilities of remaining in each state or transiting to another state at the end of each successive time period.

Model, random effects (compare with model, fixed effect)
The model used in a meta-analysis based on the assumption that the treatment effect truly differs across trials and that the goal is to determine the average of the different effects.

Model, state transition
A model involving more than one time period.

Model, static (compare with model, dynamic)
A model applied in the context of vaccination, and usually structured as a decision analytic model (such as a Markov model) in which the force of infection is constant over time.

Modelled economic evaluation (see economic evaluation, modelled)

Monte Carlo simulation
Computer experiments of complex relationships that simulate and repeatedly evaluate sequences of events in a model using random numbers controlled by one or more specified distribution functions.

MSAC
Medical Services Advisory Committee

Multi-attribute utility instrument (MAUI)
An instrument that has the following three elements:

- a descriptive system comprising a generic health-related quality-of-life questionnaire containing a set of items or statements with multiple response categories
- a scaling technique used to derive preference-based rankings in a sample of the health states covered by the descriptive system
- a scoring algorithm that is used to extrapolate data from the sample to generate cardinal weights for all health states covered by the descriptive system.

Multiple comparisons
A simultaneous comparison of more than two sets of results from one trial or study. The statistical analysis should be adjusted to account for the increasing chance that a result will have a *P*-value of less than 0.05.

Multiple Operation Rule (MOR) (see Rule, Multiple Operation)

National Immunisation Program (NIP)
Under the authority of the *National Health Act 1953*, a listing and description of the vaccines that are subsidised by the Australian Government and any conditions applying to the use of that vaccine.

National Products Price List (NPPL)
Under the authority of the National Blood Agreement, a listing and description of blood products and blood-related products that are funded by Australian governments.

Natural unit (see also cost-consequence analysis; cost-effectiveness analysis)
The unit by which a health outcome or health care resource is measured and reported (such as life-years gained, cases not detected, mmHg for blood pressure, prescription packs for medicines, admissions for hospital care).

Negative predictive value (NPV) (see value, negative predictive)

Net benefit (see benefit, net)

Net cost (see cost, net)

NIP
National Immunisation Program

NNH
Number needed to harm

NNT
Number needed to treat

Nominal data (see data, nominal)

Nonadmitted patient (see patient, nonadmitted)

Nonhealth care resource
A resource required as a result of the medical condition, disease or disorder under clinical management, but not provided as part of the clinical management of the medical condition, disease or disorder — for example, home help, day care or meals on wheels.

Noninferiority (see also equivalence)
The proposed health technology is no worse (primarily in terms of effectiveness) than its main comparator.

Noninferiority threshold (see minimal clinically important difference)

NPPL
National Products Price List

NPV
Negative predictive value

Number needed to harm (NNH)
The number of patients with a specified indication who receive the specified health technology such that one patient experiences an adverse outcome in a specified time period. The reciprocal of risk difference if the specified health technology is less effective or more harmful.

Number needed to treat (NNT)
The number of patients with a specified indication who must be provided with the specified health technology to achieve the desired outcome or to prevent the adverse outcome in one patient in a specified time period. The reciprocal of the risk difference if the specified health technology is more effective.

Observational study (see study, observational)

Observer bias (see bias, observer)

Obsolete
Superseded by other technologies, or demonstrated to be ineffective or harmful.

Odds ratio (see ratio, odds)

OMSN
Original Medicare Safety Net

Opinion (see also evidence; data)
The view of one or more individuals that does not present direct measurement.

Opportunity cost (see cost, economic or opportunity)

Ordinal data (see data, ordinal)

Original Medicare Safety Net (OMSN) (see Safety Net, Original Medicare)

Orphan drug
A medicine that is used to treat a rare disease or disorder, and is registered under special arrangements by the TGA.

Outcome
An effect produced by, or as a result of, clinical management or other factor(s), which may include a subsequent change in the provision of resources following the start of clinical management.

Outcome, adverse (see also reaction, adverse)
An unwanted event measured in a trial or study of a health technology, or for which no judgment has been made of its cause (such as whether it was caused by clinical management involving the proposed health technology).

Outcome, composite
A prespecified outcome of a trial or study that is made up of multiple components, and is recorded as occurring for a participant when any one of the components is experienced.

Outcome, final
The ultimate outcome of clinical management or disease in terms of overall effect on both quality of life and life expectancy.

Outcome, health (compare with benefit)
A change (or lack of change) in health status caused by clinical management or factor when compared with a previously documented health status using disease-specific measures, general quality-of-life measures or utility measures.

Outcome, immunogenicity
A surrogate outcome that measures the effect of a vaccine on the immune system of the vaccinated individual.

Outcome, intangible
Any outcome due to clinical management involving the proposed health technology that is difficult to measure and value (such as changes in the provision of resources or production changes). Intangible outcomes may include concepts such as suffering and disability, which may be implicitly valued by PBAC or MSAC (only if presented as a demonstrated outcome), or explicitly valued in a utility analysis or in a willingness-to-pay analysis.

Outcome, intermediate (see also surrogate outcome)
A variable that occurs in a causal pathway from a clinical management or factor to the final outcome.

Outcome, patient-relevant
An umbrella term covering any health outcome that is perceptible to the patient (the more meaningful to the patient, the greater the patient relevance); any resource provided as part of ongoing clinical management of the patient's medical condition, disease or disorder; any working time changes; or any intangible outcome. Common examples of patient-relevant outcomes include primary outcomes, quality-of-life or utility measures, and economic outcomes.

Outcome, primary
The outcome that is prespecified, before the trial is conducted and before data are analysed, to be the main outcome that will be used to assess the comparative clinical effectiveness of the proposed health technology and the control. It is the outcome that is used in the primary analysis.

Outcome, secondary (see also outcome; outcome, primary)
An outcome used to evaluate additional effects of the proposed health technology prespecified to be less important than the primary outcome.

Outcome, surrogate (see also outcome, intermediate)
A variable that is suspected, but not necessarily demonstrated, to occur on the causal pathway from a clinical management or factor to the clinically relevant final outcome (such as intraocular pressure as a surrogate for glaucoma).

Outmoded (see obsolete)

Out-of-pocket cost (see cost, out-of-pocket)

Outpatient (see nonadmitted patient)

Panel of Clinical Experts (PoCE)
A subcommittee of PLAC that primarily provides expert clinical advice to PLAC about prostheses.

Parallel group (see group, parallel)

Parameter
In epidemiology, a measurable characteristic of a population. In economics, a constant in a model or formula (such as health outcome, utility and provision of resources).

PASC
Protocol Advisory Sub-committee

Pathology Services Table (PST)
Lists the pathology tests for which Medicare benefits are available, their Schedule Fees and conditions for use.

Pathology Services Table Committee (PSTC)
A committee of the Australian Government Department of Health and Ageing that primarily reviews the Pathology Services Table to ensure that the MBS services, fees and conditions

(or uses) are appropriate, and consults with professional and other expert groups on these issues.

Patient, admitted (compare with patient, nonadmitted)
A patient who receives hospital services and undergoes a hospital's formal admission process, and is thus accepted by a hospital for inpatient care. This includes hospital-in-the-home care.

Patient, nonadmitted (compare with patient, admitted)
A patient who receives hospital services, but does not undergo a hospital's formal admission process.

Patient co-payment [PBAC]
The amount that a patient pays for a PBS medicine when it is dispensed.

Patient gap (see gap, patient)

Patient-relevant outcome (see outcome, patient-relevant)

PB11 [PBAC]
The application form to accompany a submission to PBAC for the listing of a medicine in the PBS.

PBAC
Pharmaceutical Benefits Advisory Committee

PBS
Pharmaceutical Benefits Scheme

Perspective
The viewpoint from which an economic analysis is conducted (such as society, health care system, government, individual), which defines the costs and outcomes to be examined.

PHA
Private Healthcare Australia (formerly AHIA — Australian Health Insurance Association)

Pharmaceutical benefit (see benefit, pharmaceutical)

Pharmaceutical Benefits Advisory Committee (PBAC)
An independent HTA advisory committee of the Australian Government that primarily makes recommendations to the health minister on the listing of medicines in the PBS.

Pharmaceutical Benefits Scheme (PBS)
Under the authority of the *National Health Act 1953*, a listing and description of the medicines that are subsidised by the Australian Government, the amount of that subsidy and any conditions applying to the use of that medicine.

Pharmacovigilance (see also post-market surveillance; vigilance)
Coordinated activities encompassing surveillance to identify and evaluate previously unconfirmed undesirable effects of medicines, and measures taken in response to reduce the risk of these effects.

PLAC
Prostheses List Advisory Committee

PMS
Post-market surveillance

PoCE
Panel of Clinical Experts

Point estimate
An estimate of the parameter of interest.

Positive predictive value (PPV) (see value, positive predictive)

Post-market surveillance (PMS) (see also vigilance)
The activity of monitoring the performance of a health technology post-approval.

Power
The ability of a randomised trial to detect a difference of a prespecified magnitude.

PPV
Positive predictive value

Precision (compare with variance)
A measure of the variability or random variation in a set of data. The inverse of variance.

Preference (see also value; utility)
In economics, an umbrella term covering both value and utility.

Premodelling study
An analysis used to provide inputs for a stepped or modelled economic evaluation, including by translating evidence from the clinical evaluation.

Present value (see value, present)

Prevalence (compare with incidence)
The number individuals with an attribute or disease at a specified point in time in a defined population, divided by the number of people in that population.

Prevention, primary
Activities aimed to reduce the instances of a disease occurring in a population.

Prevention, secondary
Activities aimed to reduce progression of a disease or disorder.

Price
The exchange value of a good or service, most commonly expressed as the amount of money an individual or organisation is prepared to pay to buy a unit of that good or service. The price of a medicine in the PBS illustrates why the purchaser may need to be identified, as the following could all apply: dispensed price; list price or price to chemist; price to wholesaler or ex-manufacturer price.

Price, dispensed [PBAC]
The price of a medicine, including wholesaler and pharmacist mark-ups, and pharmacist dispensing fees.

Price, ex-manufacturer [PBAC]
The price of a medicine direct from the manufacturer to the wholesaler or pharmacist.

Price advantage
The larger requested or listed price of a health technology compared to its main comparator(s).

Price for maximum quantity, dispensed (DPMQ) [PBAC]
The price of a medicine published in the PBS, including mark-ups and pharmacist dispensing fees to be applied to the specified maximum quantity for the purpose of an economic evaluation (being the price applicable to a particular quantity of the medicine when it is dispensed).

Primary analysis (see analysis, primary)

Primary outcome (see outcome, primary)

Primary prevention (see prevention, primary)

Primary vaccination program (see vaccination program, primary)

Prior approval [PBAC] (see also benefit, authority-required)
A medicine listed in the PBS that is restricted and requires prior authorisation from the Australian Government Department of Human Services.

Probabilistic sensitivity analysis (see analysis, probabilistic sensitivity)

Probability
An expression of the degree of certainty that an event will occur, on a scale from zero (certainty that the event will not occur) to one (certainty that the event will occur).

Probability distribution (or probability density function)
A numerical or mathematical representation of the relative likelihood of each possible value that a parameter may have.

Product [PLAC] (see device, medical; prosthesis)

Product information
Information approved by the TGA relating to the safe and effective use of a therapeutic good, including information regarding the usefulness and limitations of that good.

Production change
The value, estimated in monetary units, of the potential working time gained, lost or impaired, measured in units of time (days, weeks, years, etc), which is realised as changes in productive activity and/or changes in productive performance.

Professional service (see service, professional)

Prospective data (see data, prospective)

Prostheses List (PL)
Under the authority of the *Private Health Insurance Act 2007*, a listing of the prostheses that private health insurers must fund and the benefits payable for them.

Prostheses List Advisory Committee (PLAC)
An independent HTA advisory committee of the Australian Government that primarily makes recommendations to the health minister on appropriate listing of, and benefits for, prostheses in the Prostheses List.

Prostheses List category (see group)

Prosthesis (see also device, medical)
Refer to the Prostheses List Guide, found at Prostheses List Guide.

Protocol Advisory Sub-committee (PASC)
A subcommittee of MSAC that primarily determines the decision analytic protocols (DAPs).

Provision of resources (see resources, provision of)

PSD
Public summary document

PST
Pathology Services Table

PSTC
Pathology Services Table Committee

Public summary document (PSD)
Information available to the public about recommendations from PBAC or MSAC, so that stakeholders (such as doctors, health professionals and patients) are aware of the rationale for specific health technology assessment recommendations, and gain an improved understanding of the overall PBS or MBS listing process.

***P*-value** (see also confidence interval; statistically significant)
The probability (obtained from a statistical test) that the null hypothesis (that there is no association between the factor and the outcome) is incorrectly rejected. The *P*-value obtained from a statistical test corresponds to the probability of claiming that there is an association when in fact there is none.

Q-TWiST
Quality-adjusted time without symptoms and toxicity

QALY
Quality-adjusted life-year

Quality-adjusted life-year (QALY) (see life-year, quality-adjusted)

Quality-adjusted time without symptoms and toxicity (Q-TWiST)
Developed originally for cancer care, a method of estimating quality-adjusted life-years that

divides life expectancy into time with toxicity from chemotherapy, followed by the time free of symptoms of disease or chemotherapy toxicity and followed by the time with disease symptoms. Each of these time periods is adjusted by the respective utility weight.

Quality of evidence (see evidence, quality of)

Quality of life (see also health status)
The extent to which an individual perceives themself to be able to function physically, mentally and socially.

Quality of life, direct description of (see also utility, direct elicitation of)
A description of the impact of a particular health status, or a health outcome or quality of life obtained from the individual who is experiencing it.

Quality use of medicines (QUM)
The judicious selection of management options, the appropriate choice of medicines (where a medicine is considered necessary), and the safe and effective use of medicines.

Quasi-experimental study (see study, quasi-experimental)

QUM
Quality use of medicines

Random effects model (see model, random effects)

Random error (see variation, random)

Random variation (see variation, random).

Randomisation
The process by which participants are allocated to one of two or more health technology groups by chance, to thus minimise selection bias. Other than random variation, the resulting groups are also likely to be similar to one another at the start of the trial. Randomisation involves using a prespecified plan to ensure that chance alone determines allocation to health technology groups.

Randomised cross-over trial (see trial, randomised cross-over)

Rate, discount
The specified percentage used in a formula to convert future costs and/or benefits into equivalent present values.

Rate, false negative
The complement of test sensitivity.

Rate, false positive
The complement of test specificity.

Ratio, hazard
A measure of effect produced by a time-to-event survival analysis. It represents the increased

instantaneous rate with which one group is likely to experience the outcome of interest relative to another group.

Ratio, incremental cost-effectiveness (ICER)
A comparison of two alternative health technologies calculated by dividing the incremental costs from substituting the proposed health technology for its main comparator by the incremental health outcomes from this substitution.

Ratio, likelihood
A comparison of the proportion of positive or negative test results in those with the disease to the proportion in those without the disease. The likelihood ratio for a positive test result is sensitivity/(1 minus specificity). The likelihood ratio of a negative test result is (1 minus sensitivity)/specificity.

Ratio, odds (compare with risk, relative)
The ratio of two odds. Usually, this is the ratio of the odds in favour of exposure (such as to the proposed health technology) among the people with the disease or outcome of interest to the odds in favour of exposure among those without the disease or outcome of interest.

Reaction, adverse (see also outcome, adverse)
An unwanted event reported in the approved product information, or for which some judgment has been made of its cause (such as whether it was caused by clinical management involving the proposed health technology); an adverse effect.

Receiver operating characteristic (ROC) curve
A graphic means for assessing the ability of a test to discriminate between healthy and diseased persons. It plots sensitivity of the test on the vertical axis against (1 minus specificity) of the test on the horizontal axis, as the threshold value for labelling the test positive is varied.

Reference standard (see standard, reference)

Regression analysis (see analysis, regression)

Rehabilitation
Restoration, maintenance or improvement of a physically or mentally disabled person's function and wellbeing (such as an exercise program for patients who have had a stroke).

Relative risk (see risk, relative)

Relative risk reduction (see risk reduction, relative)

Relative value [MSAC] (see value, relative)

Relevance (of outcomes)
A measure of whether trial or study results assess direct improvements in health outcomes, such as quality of life and survival.

Reliability
The extent to which the results obtained by a measurement procedure or instrument can be replicated under identical conditions.

Repatriation Pharmaceutical Benefits Scheme (RPBS)
Subsidises medicines for the treatment of eligible veterans, war widows and widowers, and their dependants. Those who are eligible can receive all medicines listed in the RPBS in addition to all PBS medicines.

Reproducibility (see reliability)

Resource
A factor of production, an input or a produced good.

Resources, consumption of (compare with resources, provision of)
The process step where a resource is consumed by a recipient. A less preferred basis for estimating costs because not all provided resources are consumed.

Resources, provision of (compare with resources, consumption of)
The process step where a resource is provided to a recipient — for example, by the health care system. A preferred basis of estimating costs (as opposed to the consumption of resources).

Responsiveness
The ability of an instrument to measure differences in health states between individuals. It is also the ability to measure changes in health states over time experienced by any individual.

Restricted benefit (see benefit, restricted)

Restricted time-to-event analysis (see analysis, truncated time-to-event)

Restriction [PBAC]
The general intention of a restriction is to identify the population of individuals who would be eligible for PBS-subsidised use of the proposed medicine, usually by reference to certain diagnostic criteria of a medical condition, disease or disorder.

Retrospective data (see data, retrospective)

Risk (see also risk, absolute; risk, baseline)
The probability that an event will occur in a defined population within a specified time period or by a certain age.

Risk, absolute (see also risk, baseline; compare with risk, relative)
The observed or calculated risk of an event.

Risk, baseline (see also risk, absolute)
At the time when a participant is enrolled in a study or when a patient starts a therapy, the risk of future events of interest in the absence of the therapy.

Risk, relative (compare with risk, absolute; ratio, odds; risk difference)
Within the same time period, the ratio of the risk of an outcome in the exposed group (such as to clinical management involving the proposed health technology) to the risk of the same outcome in the control group.

Risk difference (compare with ; risk reduction, relative)
Within a specified time period, the difference of the risk of an outcome in the exposed group

(such as those with clinical management involving the proposed health technology) in a trial or study, and the risk of the same outcome in the control group.

Risk reduction, relative (compare with risk, relative; risk difference)
One minus the relative risk. The relative risk reduction can be calculated only when the proposed health technology is more effective than its main comparator.

Risk-sharing arrangement (RSA) [PBAC]
An arrangement agreed between the supplier of a PBS-listed medicine and the Australian Government that adequately monitors identified risks (or undesired events such as cost-ineffective use or greater-than-expected use) and manages them by appropriate mechanisms for sharing the impact of these risks between the supplier and the government should they arise.

Robustness (see also analysis, sensitivity)
The extent to which the conclusion of an economic analysis is likely to remain unchanged, even if estimates of key variables, assumptions or a model's structure are changed in the analysis to reflect remaining uncertainties.

ROC curve
Receiver operating characteristic curve

RPBS
Repatriation Pharmaceutical Benefits Scheme

RSA
Risk-sharing arrangement

Rule, Multiple Operation (MOR)
The MOR is set out under s. 15 of the *Health Insurance Act 1973* and requires that Medicare benefits are paid in accordance with a reduction in the Schedule Fee for operations that are performed by the same practitioner on the one occasion. The MOR is automatically applied to all services in group T.8 'surgical operations' of the MBS. The Schedule Fee for a service subject to the MOR is calculated as 100% for the item with the highest Schedule Fee, 50% of the Schedule Fee for the item with the next highest Schedule Fee and 25% of the Schedule Fee for any subsequent items. The MOR exists as it recognises that there are efficiencies gained from performing more than one operation on the one occasion. The MOR applies to both in-hospital and out-of-hospital services. There are no exemptions from the MOR.

Rule of rescue
Four factors, which apply in exceptional circumstances, are particularly influential in favour of listing. When all four factors apply concurrently, this is called the 'rule of rescue.'

1. No alternative health technology exists in Australia to treat patients with the medical condition meeting the criteria of the requested restriction.

2. The medical condition defined by the requested restriction is severe, progressive and expected to lead to premature death.

3. The medical condition defined by the requested restriction applies to only a very small number of patients.

4. The proposed health technology provides a worthwhile clinical improvement to qualify as rescue from the medical condition.

Safety (compare with toxicity)
The reverse of toxicity.

Safety, comparative
The safety of one health technology compared to an alternative health technology.

Safety, incremental
The absolute difference between the safety profiles of alternate health technologies for the same medical condition, disease or disorder.

Safety Net, Extended Medicare (EMSN) (see also Safety Net, Original Medicare; Extended Medicare Safety Net benefit cap)
Once a Medicare-eligible family or single reaches the relevant annual threshold in out-of-pocket costs for Medicare-eligible out-of-hospital services, the EMSN pays 80% of the family's or single's out-of-pocket costs for out-of-hospital services for the remainder of the calendar year, except for a small number of services where an upper limit or 'EMSN benefit cap' applies. The EMSN applies automatically to all out-of-hospital Medicare services and the only EMSN-exempt services are those where benefits are only paid at 75% of the Schedule Fee. EMSN benefits are not payable for services where a patient receives a benefit through their private health insurer — a patient may receive either EMSN benefits or private health insurer benefits, not both. Out-of-hospital services for the purposes of the EMSN and Original Medicare Safety Net include all Medicare-eligible services where the 85% or 100% benefit is paid.

Safety Net, Original Medicare (OMSN) (see also Safety Net, Extended Medicare)
The OMSN provides singles and families with an increase in their MBS rebate to 100% of the Schedule Fee once gap costs have reached an annual threshold. Gap costs are measured as the difference between the Schedule Fee and the rebate. Patients generally only qualify once they have had a significant number of services and most benefits are paid for specialist attendances, particularly psychiatry, and radiation oncology. The OMSN applies automatically to services where the 85% benefit is paid. Services that attract the 75% benefit or 100% benefit (general practitioner services) do not apply to the OMSN.

Same-day admission
An admission where a patient is admitted to hospital and separated from hospital on the same date.

Sample size calculation
Relies on a formula that calculates the sample size of a study, based on the minimal clinically important difference (MCID), power and the risk of a Type I error.

Scenario analysis (see analysis, scenario)

Scenario-based valuation (see valuation, scenario-based)

Schedule Fee (see Fee, Schedule)

SCoH
Standing Council on Health

Screening
Detection of a disease, abnormality or associated risk factors in asymptomatic people (such as using Pap smears or mammography).

Search strategy
One or more series of commands defined by a researcher that directs the identification of relevant citations in one or more citation databases using combinations of indexing terms. An effective search strategy retrieves as many relevant citations as possible without retrieving an unmanageably large number of irrelevant citations. Choosing appropriate databases to search is also a critical element.

Secondary analysis (see analysis, secondary)

Secondary outcome (see outcome, secondary)

Secondary prevention (see prevention, secondary)

Second-line treatment (see treatment, second-line)

Section 100
Section 100 of the *National Health Act 1953* empowers the health minister to make special arrangements to ensure that an adequate supply of medicines will be available to a specified population.

Selection bias (see bias, selection)

Sensitivity (see also specificity)
The proportion of individuals classified as positive by the gold (or reference) standard who are correctly identified by the investigative health technology (also called the true positive rate).

Sensitivity analysis (see analysis, sensitivity)

Separation
The process by which an admitted patient completes an episode of care in hospital.

Service, clinically relevant
A service that is generally accepted by the relevant profession as necessary for the appropriate clinical management of the patient. Medicare benefits are claimable only for clinically relevant services rendered by an appropriate health practitioner.

Service, professional
Professional services that attract Medicare benefits include existing health technologies and other medical services rendered by or ‘on behalf of’ a medical practitioner. The latter includes services where a part of the health technology is performed by a technician employed by a medical practitioner or, in accordance with accepted medical practice, acting under the supervision of the medical practitioner.

SG
Standard gamble

Side effect (see reaction, adverse)

Significant (see statistically significant)

Single-arm study (see study, single-arm)

Size [PLAC]
May be expressed as length, diameter, width, height, holes, degrees, dioptres, volume or other specification of the product or its components as detailed in the product information or technical documentation.

Societal viewpoint (see viewpoint, societal)

Specificity (see also sensitivity)
The proportion of individuals classified as negative by the gold (or reference) standard who are correctly identified by the investigative health technology (also called the true negative rate).

Sponsor [PLAC]
Manufacturer, supplier or importer responsible for:

- supplying products, prostheses or medical devices in Australia
- submitting manufacturer's evidence of conformity to the TGA
- applying for an entry for the product in the Australian Register of Therapeutic Goods (ARTG).

Standard, gold (see also standard, reference)
The gold standard is a method, procedure or measurement that is widely accepted to be the best available.

Standard, reference (see also standard, gold)
An independently applied test that is compared with the proposed diagnostic test to ascertain the accuracy of the proposed diagnostic test. Required for the verification of true negatives and true positives.

Standard gamble (SG)
A method of eliciting the utility for a particular health status or health outcome where the respondent is offered a choice between two alternatives. Alternative 1 is clinical management with two possible outcomes: either the respondent returns to full health and lives for a fixed number of additional years (probability *P*) or the respondent dies immediately (probability 1–*P*). Alternative 2 has a certain outcome of remaining in the health status for the fixed number of additional years. The probability *P* is varied until the respondent is indifferent between the two alternatives.

Standing Council on Health (SCoH)
The committee of health ministers from governments in Australia and New Zealand.

State transition model (see model, state transition)

Static model (see model, static)

Statistic
A measurement of a variable of interest that is subject to random variation.

Statistical heterogeneity (see heterogeneity, statistical)

Statistical interaction (see heterogeneity, statistical)

Statistically significant
The probability that the association between the factor and the outcome is due to chance is less than a specified level (by convention, $P < 0.05$).

Stepped economic evaluation (see economic evaluation, stepped)

Strength of evidence (see evidence, strength of)

Study (see also trial)
An investigation of the health and/or economic consequences of one or more health technologies in people, which may or may not involve a randomisation step. If a randomisation step is involved, the preferred term is trial.

Study, before-and-after
A quasi-experimental study in which participants are observed before and after a health technology is started.

Study, case-control
An observational study in which the past history of exposure to a suspected risk factor (such as clinical management involving the proposed health technology) is compared between cases (who have the outcome or disease) and controls (who come from the same population as the cases but do not have the outcome or disease).

Study, cohort
An observational study where a cohort of people (for example, people born in certain year; people admitted to hospital for a certain condition) are followed over time to compare the incidence of the outcome(s) in people who are exposed and not exposed at the start of the study. Cohort studies can be prospective (where cohorts are identified at a current point in time and followed forward in time to collect health records) or retrospective (where cohorts are defined at a point of time in the past and information is collected on subsequent outcomes).

Study, cross-sectional
A study in which resource provision and/or health status is measured across a defined population at the same time.

Study, diagnostic accuracy
A study that compares the accuracy of a proposed investigative health technology with a gold standard test.

Study, observational
A nonrandomised study that observes the characteristics and outcomes over time of participants who do and do not use a particular health technology. An umbrella term covering cohort and case-control studies.

Study, quasi-experimental
A nonrandomised study in which the investigator lacks full control over the allocation and/or the timing of the clinical management, but otherwise conducts the study as a randomised trial. An umbrella term for before-and-after study, case series with historical controls and a comparison of the results of single-arm studies.

Study, single-arm
A group of participants with a specified indication and managed with a specified clinical management (such as involving the proposed health technology) are systematically observed to measure outcomes of interest. A quasi-experimental study can be generated by comparing the results of one or more single-arm studies of clinical management involving the proposed health technology with the results of one or more similar studies (usually by different investigators in different settings) of clinical management involving its main comparator(s).

Study population and setting (see also target population and setting)
The population and setting used in one or more studies, used to underpin effectiveness or a cost-effectiveness analysis.

Subgroup
A defined set of individuals in a population group or of participants in a trial or study, such as subgroups defined by sex or age.

Subgroup analysis (see analysis, subgroup)

Submission [PBAC] (compare with application [PLAC]; assessment, submission-based [MSAC])
The dossier provided by an applicant in support of its request to have a medicine listed in the PBS or to vary an existing listing of a medicine.

Submission-based assessment [MSAC] (see assessment, submission-based)

Substantial clinical equivalence [PLAC]
When a proposed prosthesis demonstrates essentially the same function and design characteristics of a prosthesis with proven clinical outcomes that is already listed in the Prostheses List.

Suffix [PLAC]
An identifier that denotes a prosthesis is similar in design and function to other prostheses in the same group or subgroup, but has additional features that deliver different clinical outcomes.

Summary statistic
Quantitative estimate of the overall effect of a particular health technology on a particular outcome obtained from a meta-analysis of all available trials.

Supplementary analysis (see analysis, supplementary)

Surrogate outcome (see outcome, surrogate)

Survival data (see data, time-to-event)

System [PLAC]
A product comprising two or more components.

Systematic error (see variation, systematic)

Systematic overview
The systematic, organised and structured evaluation of a problem of interest using information from all relevant independent randomised trials. It includes a qualitative component (assessment of trial quality and comparability) and a quantitative component (meta-analysis).

Systematic review
Research that summarises the evidence on a clearly formulated question according to a predefined protocol. Systematic and explicit methods are used to identify, select and critically appraise relevant studies, and to extract, collate and report their findings. Statistical meta-analysis may or may not be used.

Systematic variation (see variation, systematic)

Target population and setting (see also study population and setting)
The intended population and setting of the health technology under consideration.

Technology
The application of scientific or other organised knowledge — including any tool, technique, product, process, method, organisation or system — to practical tasks.

TGA
Therapeutic Goods Administration

TGA clinical evaluator's report
The report summarising and reviewing the clinical evidence (Module 4) of the application to the TGA seeking marketing approval for a proposed medicine.

TGA delegate's overview
The TGA delegate's summary of the application to the TGA for a proposed medicine, a proposed action for registration and a request for advice from the Advisory Committee on Prescription Medicines.

Therapeutic class (see class, therapeutic)

Therapeutic good
Health technologies regulated by the TGA, including medicines, medical devices, human cells and tissues, and blood.

Therapeutic Goods Administration (TGA)
A division of the Australian Government Department of Health and Ageing that regulates the quality, safety and efficacy of therapeutic goods available within Australia.

Therapy (see also intervention; compare with investigation)
Clinical management of an individual for the purpose of improving health outcomes by combating (such as preventing, curing, ameliorating) a medical condition, disease or disorder; all resources provided in this management or care.

Time series
A set of measurements taken during a specified time period. An interrupted time series is generated when a set of measurements is taken before the introduction of a proposed health technology, or some other change in the system, followed by another set of measurements taken during a specified time period after the change.

Time-to-event data (see data, time-to-event)

Time trade-off (TTO)
A method of eliciting the utility for a particular health status or health outcome where the respondent is offered a choice between two alternatives. Alternative 1 is living for a fixed time period (t) in a particular health status. Alternative 2 is living for a shorter time period (x) in full health. The duration in full health is altered until the respondent is indifferent between the two alternatives.

Tornado diagram
A graphical display of the result of a set of one-way sensitivity analyses. The horizontal axis presents the results of the economic evaluation. The vertical axis presents each sensitivity analysis ranked from the variable with the greatest effect on the result of the economic evaluation to the variable with the least effect.

Toxicity
The harm to health caused by a health technology considering the entire profile of adverse reactions and adverse outcomes.

Trace
A graphical display of a variable over time, with time reported on the horizontal axis and a measure of the variable on the vertical axis.

Transformation/transformed (see also translation/translated)
An assessment of the extent to which the outcomes reported in a trial relate to and/or predict outcomes of greater patient relevance or outcomes valued in utility terms, and thus the extent to which the results of the trial can be transformed to be more relevant to an economic evaluation.

Transition probability
The probability that individuals in a particular health state might transfer into another particular health state during the course of a cycle in a state transition model.

Translation/translated (see also analytical plan, focused; transportability)
An umbrella term covering applicability, extrapolation and transformation, which together convert the systematic overview of the results of the direct randomised trial evidence to the listing requested, and thus to the framework of a modelled economic evaluation.

Transportability (see also translation)
The ability of a trial, study or model to produce unbiased inferences to another specified health care system (such as from overseas to Australia).

Treatment (see therapy)

Treatment, first-line (compare with treatment, second-line)
The preferred initial treatment of a patient at a particular stage of their medical condition.

Treatment, hospital [PLAC]
As defined under s. 121-5 of the *Private Health Insurance Act 2007* (including the provision of goods and services), hospital treatment:

(a) is intended to manage a disease, injury or condition; and

(b) is provided to a person:

  (i) by a person who is authorised by a hospital to provide the treatment; or

  (ii) under the management or control of such a person; and

(c) either:

  (i) is provided at a hospital; or

  (ii) is provided, or arranged, with the direct involvement of a hospital.

Treatment, hospital-substitute [PLAC]
As defined under s. 69-10 of the *Private Health Insurance Act 2007*, hospital-substitute treatment is clinical management that:

(a) substitutes for an episode of hospital treatment; and

(b) is any of, or any combination of, nursing, medical, surgical, podiatric surgical, diagnostic, therapeutic, prosthetic, pharmacological, pathology or other services or goods intended to manage a disease, injury or condition; and

(c) is not specified in the Private Health Insurance (Complying Product) Rules as a treatment that is excluded from this definition.

Treatment, second-line (compare with treatment, first-line)
The next preferred treatment of a patient at a particular stage of their medical condition after the first-line treatment cannot be used.

Treatment effect (see also validity, internal)
After starting a therapy or not (or after starting two different therapies), the difference in outcomes that remains after excluding random and systematic variation as alternative explanations. It is therefore best measured in a direct randomised trial.

Treatment effect variation (see variation, treatment effect)

Trial (see also trial, direct randomised; cross-over; randomisation; compare with study)
An investigation of the health and/or economic effect of one or more therapies in humans that involves a randomisation step.

Trial, direct randomised (see also indirect comparison; randomisation; trial)
A trial in which participants are randomly allocated to groups that receive either the proposed health technology or its main comparator.

Trial, randomised cross-over (see also cross-over)
Participants are measured before and after randomly allocated (and usually blinded) exposure to different health technologies administered over two or more consecutive periods.

Trial-based economic evaluation (see economic evaluation, trial-based)

Triangulation
The use of multiple sources of data or multiple approaches to determine the consistency or otherwise of the conclusions from those sources or approaches.

Truncated time-to-event analysis (see analysis, truncated time-to-event)

TTO
Time trade-off

Type I error
The risk of a false positive result from a study. In a superiority trial, it is the probability of detecting a 'statistically significant difference' when its treatments are actually equally effective.

Type II error
The risk of a false negative result from a study. In a superiority trial, it is the probability of not detecting a 'statistically significant difference' when there is actually a difference of a prespecified magnitude.

Uncertainty
Any reduction of confidence in a conclusion. Statistical uncertainty arises from chance (or random variation), when a variable includes a range of estimates within which the true value of the variable is likely to be found. Inferential uncertainty arises from bias (or systematic variation) when there are alternative explanations for a measured difference or arises when translations are made from an estimate. Clinical uncertainty arises when the proposed health technology has both clinical advantages and disadvantages compared with its main comparator(s). Structural uncertainty arises in a model when all the relationships between the various components are not fully demonstrated. Uncertainty also arises when assumptions need to be made in the absence of relevant data.

Uncertainty interval
The calculated interval with a specified probability (by convention, 95%) that the true I^2 statistic is contained within the interval.

Unrestricted benefit (see benefit, unrestricted)

Upstream (see also downstream)
Occurring before the health technology is initially provided to an individual.

Utilisation
The number of uses of a health technology in a specified time period.

Utility (see also preference)
The numerical value assigned by an individual to a preference for, or a desirability of, a specific level of health status or a specific health outcome. The process of eliciting a utility involves a trade-off between quality and quantity of life. By convention, utility is measured on a cardinal scale, with 0 = death and 1 = full health.

Utility, direct elicitation of (see also quality of life, direct description of)
A utility for a particular health status or a health outcome obtained from a respondent who is experiencing it using a standard gamble or time trade-off technique.

Utility, marginal
The extra utility caused by providing one extra unit of a resource.

Utility analysis (see analysis, utility)

Vaccination program, catch-up
Provides coverage of individuals who could benefit from vaccination at the introduction of a new vaccination program, but who are older than the age range specified for efficient delivery of the ongoing primary vaccination program.

Vaccination program, primary (see also vaccination program, catch-up)
Provides coverage of individuals in the age range specified for the most efficient delivery of a vaccine.

Vaccine
A suspension of attenuated or killed microorganisms administered for the prevention, amelioration or treatment of infectious diseases.

Validity, external (see also applicability; treatment effect; validity, trial or study)
A trial or study has external validity if it is free of confounding and can produce unbiased inferences regarding a specified target population beyond the participants in the trial or study.

Validity, internal (see also applicability; treatment effect; validity, trial or study)
A trial or study has internal validity if, apart from possible sampling error, the measured difference in outcomes can be attributed only to the different therapies assigned.

Validity, measurement
The extent to which a method or instrument accurately records the intended measurement.

Validity, trial or study (see also applicability; validity, internal; validity, external)
The extent to which an inference drawn from a trial or study is justifiable when the following are taken into account:

- the methods of the trial or study
- the representativeness of the sample investigated
- the nature of the population from which the sample is drawn.

Valuation
The process of quantifying the desirability of an outcome in utility or monetary terms, or of quantifying the cost of a resource or individual's productivity in monetary terms.

Valuation, contingent (CV)
Using survey methods to present respondents with scenario-based questions involving descriptions of the health states, goods or services to be valued according to the respondents' maximum willingness to pay.

Valuation, scenario-based
Valuation of one or more health states, each based on a description presented in a scenario format.

Value (see also preference)
In economics, a quantitative measure of the desirability of an outcome. This may be measured in monetary terms — for example, the maximum amount that an individual is willing to pay for a good or a service, a defined benefit, or to avoid a defined harm. In science, the magnitude of a measurement.

Value, marginal
The maximum amount that an individual is willing to pay for one extra unit of a resource or for the extra outcome(s) resulting from its provision.

Value, negative predictive (NPV) (see also value, positive predictive)
The probability that the condition of interest is false if the result is negative — for example, the probability that the disease is absent given a negative test result.

Value, positive predictive (PPV) (see also value, negative predictive)
The probability that the condition of interest is true if the result is positive — for example, the probability that the disease is present given a positive test result.

Value, present
The equivalent value today of a future cost or benefit after adjusting for time preferences by discounting.

Value, relative [MSAC]
The consideration of the professional remuneration for one service in relation to another.

Value for money (compare with cost-effective)
A proposed health technology is considered to represent value for money by an HTA advisory committee if it considers that, for a specified main indication, the incremental benefits of the proposed health technology are valued higher than the opportunity costs of obtaining those benefits.

Variable
Any attribute, phenomenon or event that can have different values.

Variance (compare with precision)
A measure of the variability or random variation in a dataset calculated as the sum of the squares of deviations from the mean, divided by the number of degrees of freedom in the dataset.

Variation, random
An explanation of the distribution of variables as being due to chance. An alternative explanation for an apparent treatment effect, or for an apparent result of an investigative health technology or medical service.

Variation, systematic
The deviation of results or inferences from the truth, or processes leading to such deviation (whether intended or not). An error due to systematic differences. An alternative explanation for an apparent treatment effect, or for an apparent result of an investigative health technology or medical service.

Variation, treatment effect (see also heterogeneity, statistical)
A measure of the extent to which the effect of a treatment varies across populations (such as across trials or subgroups). It depends on the effect measure used.

VAS
Visual analogue scale

Viewpoint, health care system
The viewpoint for an economic evaluation that considers all material incremental changes in the provision of health care resources and all material incremental changes in health outcomes.

Viewpoint, societal
The viewpoint for an economic evaluation that considers all material incremental changes in costs and consequences without considering to whom they accrue.

Vigilance (see also post-market surveillance)
Proactive monitoring of the marketplace in which a health technology is supplied to detect any problems with the health technology.

Visual analogue scale (VAS)
A line on a page, often 10 cm in length, which:

- has clearly defined extreme end points and may have other marks along the line
- is used as a method of measuring the extent of a participant's response to a question.

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Willingness to pay (WTP)
The maximum amount of money that an individual is prepared to give up to ensure that a proposed beneficial change occurs. A beneficial change could include an improved health outcome or ensuring that the proposed health technology is substituted for its main comparator based on valuing the resulting difference(s) in outcomes.

Withdrawal (compare with drop-out)
Arises when a participant actively chooses to be removed from a trial or study (removal of consent).

Within-trial analysis (see economic evaluation, trial-based)

WTP
Willingness to pay

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Y | A B C D E F G H I J K L M N O P Q R S T U V W X Y Z | Principles | Top

Z | A B C D E F G H I J K L M N O P Q R S T U V W X Y Z | Principles | Top